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)
June 29, 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 8.01 - Other Events

On June 29, 2022, Codiak BioSciences, Inc. (the “Company”) issued a press release announcing the initiation of patient dosing in its Phase 1 clinical trial of exoASO-STAT6, an engineered exosome precision medicine candidate designed to selectively deliver antisense oligonucleotides to disrupt STAT6 signaling in tumor associated macrophages and induce an anti-tumor immune response. 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.

Item 9.01 - Financial Statements and Exhibits

(d) Exhibits

Exhibit Number	Description
99.1	Press release, dated June 29, 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: June 29, 2022

Codiak BioSciences, Inc.

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

Codiak Initiates Patient Dosing in Phase 1 Clinical Trial of exoASO™-STAT6 in Patients with Advanced Hepatocellular Carcinoma, Liver Metastases from Primary Gastric Cancer and Colorectal Cancer

– exoASO-STAT6 is the third engineered exosome candidate generated from Codiak's engEx™ Platform to enter clinical development –

CAMBRIDGE, Mass., June 29, 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 announced the initiation of patient dosing in its Phase 1 clinical trial of exoASO-STAT6, an engineered exosome precision medicine candidate designed to selectively deliver antisense oligonucleotides to disrupt STAT6 signaling in tumor associated macrophages (TAMs) and induce an anti-tumor immune response. exoASO-STAT6 is Codiak's third clinical program and the first to evaluate a systemically administered exosome-based drug candidate.

"Targeting macrophages is the next great frontier in cancer immunotherapy and we are encouraged by the monotherapy anti-tumor activity exhibited by exoASO-STAT6 in preclinical models, which has not been observed among other approaches to date. We believe this may indicate the potential to bring transformative treatments to patients facing intractable forms of cancer," said Douglas E. Williams, Ph.D., CEO, Codiak. "The initiation of this trial is also a significant milestone for our company, as the advancement of exoASO-STAT6 into the clinic highlights the versatility of our engineering platform. This candidate is the first of our programs to target macrophages, the first to carry a nucleic acid and the first to be administered intravenously."

The Phase 1 clinical trial will evaluate the safety, tolerability, biomarkers and preliminary anti-tumor activity of exoASO-STAT6 in patients with advanced hepatocellular carcinoma (HCC), patients with liver metastases from primary gastric cancer and colorectal cancer (CRC). The study is anticipated to enroll patients across four cohorts at sequentially escalating dose levels, with subjects in the initial cohorts receiving biweekly exoASO-STAT6 administered intravenously over the course of 28 days. Ultimately the trial may enroll up to 30 patients. Initial Phase 1 data are expected in the first half of 2023.

TAMs promote tumor growth by exhibiting an immune suppressive M2 phenotype. Reprogramming TAMs toward a pro-inflammatory M1 phenotype may be a compelling approach to induce anti-tumor immunity. The M2 phenotype is controlled by key transcription factors such as STAT6, which have proven difficult to drug selectively in TAMs using prior approaches. Codiak plans to initially develop exoASO-STAT6 for primary cancers of the liver, where STAT6 expression has been correlated with poor survival.

In multiple *in vivo* preclinical studies, exoASO-STAT6 demonstrated potent single agent activity, including >90% tumor growth inhibition and 50-80% complete responses. In HCC models, exoASO-STAT6 induced significant knockdown of STAT6 mRNA, attenuated tumor growth and induced complete remission of tumor lesions in 50% of mice. This anti-tumor activity was enhanced (75% complete remissions) when exoASO-STAT6 was administered with anti-PD1 antibodies. The monotherapy activity was accompanied by remodeling of the tumor microenvironment including significant expansion of M1-like macrophages and induction of an adaptive anti-tumor immune response, enabling tumor elimination.

About the engEx™ Platform

Codiak's proprietary engEx Platform is designed to enable the development of engineered exosome therapeutics for a wide spectrum of diseases and to manufacture them reproducibly and at scale to pharmaceutical standards. By leveraging the inherent biology, function and tolerability profile of exosomes, Codiak is developing engEx exosomes designed to carry and protect potent drug molecules, provide selective delivery and elicit the desired pharmacology at the desired tissue and cellular sites. Through its engEx Platform, Codiak seeks to direct tropism and distribution by engineering exosomes to carry on their surface specific targeting drug moieties, such as proteins, antibodies/fragments, and peptides, individually or in combination. Codiak scientists have identified two exosomal proteins that serve as surface and luminal scaffolds. By engineering the exosome surface or lumen and optimizing the route of administration, Codiak aims to deliver engEx exosomes to the desired cell and tissue to more selectively engage the drug target, potentially enhancing the therapeutic index by improving potency and reducing toxicity.

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 diseases, spanning oncology, neuro-oncology, infectious disease and rare disease. For more information, visit http://www.codiakbio.com and follow @CodiakBio.

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 timing of release of data, 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, 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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