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): December 30, 2020

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 December 30, 2020, Codiak BioSciences, Inc. (the "Company") issued a press release announcing results from the initial part of its Phase 1 clinical trial of exoIL-12. 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 December 30, 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: December 30, 2020

Codiak BioSciences, Inc.

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

Codiak Reports Positive Initial Phase 1 Results for exoIL-12™ Demonstrating Tolerability and Absence of Systemic IL-12 Exposure in Healthy Volunteers

– exoIL-12 resulted in no local or systemic treatment-related adverse events –

– Local administration of exoIL-12 demonstrated no systemic exposure to IL-12 –

– Dose selection data and advancement into multi-dose study in cutaneous T cell lymphoma patients anticipated in Q1 2021 –

CAMBRIDGE, Mass., December 30, 2020 — 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 primary objectives were met in the initial part of its Phase 1 trial, which evaluated a single ascending dose of exoIL-12 in healthy volunteers. In this randomized, placebo controlled, double-blind study, exoIL-12 demonstrated a favorable safety and tolerability profile, with no local or systemic treatment-related adverse events and no detectable systemic exposure of IL-12.

“This is an important milestone, as these results show that exoIL-12 acts in humans as we had expected, based on our preclinical evaluations. The safety and tolerability profile observed here support the target profile that we are hoping to achieve with this candidate,” said Benny Sorensen, M.D., Ph.D., Senior Vice President and Head of Clinical Development, Codiak. “We’re looking forward to advancing exoIL-12 into the multi-dose part of the study in cutaneous T cell lymphoma patients and presenting the detailed results from the healthy volunteer part of this study at an upcoming medical conference.”

exoIL-12 is the first engineered exosome therapeutic candidate to be evaluated in humans and one of two Codiak programs currently in clinical development. exoIL-12 was engineered using the company’s proprietary engEx™ Platform and designed to display functional IL-12 on the exosome surface using the exosomal protein, PTGFRN, as a scaffold, the capability of which was identified by Codiak scientists.

IL-12 is a potent anti-tumor cytokine, but prior clinical development conducted by others[1] of recombinant IL-12 (rIL-12)-based therapies has generally been hindered by significant safety and tolerability concerns. To overcome these limitations, exoIL-12 was designed to facilitate dose control of IL-12 and limit systemic exposure and associated toxicity by localizing IL-12 in the tumor microenvironment (TME) in order to potentially expand the therapeutic index.

Initial Data from Healthy Volunteers

A total of five cohorts each with five subjects, randomized 3:2 active drug to placebo, were enrolled and dosed in the first part of the Phase 1 study. Each cohort received a subcutaneously administered single ascending dose of exoIL-12: 0.3 µg, 1.0 µg, 3.0 µg, 6.0 µg or 12.0 µg, respectively.

No treatment-related adverse events were observed throughout 10 days of follow-up. In particular, no chills, fever, fatigue, dizziness, myalgia, headache or back pain were reported. These symptoms have been observed in previous clinical studies of subcutaneously administered rIL-12 at comparable doses (ranging from 2 to 12 µg)[1] to those used in Codiak’s study of exoIL-12.

Plasma pharmacokinetic (PK) measurements of subjects that received exoIL-12 showed no systemic exposure with levels of IL-12 below the limit of quantification. In contrast, previous rIL-12 clinical studies showed dose-dependent systemic exposure with dosages of 5 and 12 µg resulting in Cmax plasma levels of approximately 15 to 45 pg/ml within 6 to 12 hours after dosing.[1]

Codiak's analyses of pharmacodynamic (PD) data from the healthy volunteer portion of the exoIL-12 trial, including skin IL-12 levels and IL-12 signaling from skin punch biopsies collected before and at 24 hours, Day 8 and Day 15 after subcutaneous administration around the injection site, are ongoing and are expected to be available in early Q1 2021. The company intends to use these results to identify an optimal pharmacological dose to carry forward into the second part of the trial, which is on track to begin in Q1 2021 and will evaluate repeat dosing of exoIL-12 in patients with early-stage cutaneous T cell lymphoma (CTCL).

exoIL-12 Development and Ongoing Phase 1 Clinical Trial

Codiak is initially focusing development of exoIL-12 on tumors that have previously shown clinical responses to IL-12 used as a monotherapy, such as CTCL. While the biological rationale for IL-12 as a cancer treatment has been validated in previous human clinical studies, its utility has been severely limited due to serious adverse events caused by systemic exposure.

Codiak has engineered exoIL-12 to display fully active IL-12 on the surface of the exosome, which is designed to facilitate potent local pharmacology at the tumor injection site with precisely quantified doses. Exosomal delivery has demonstrated limited systemic exposure to IL-12 in preclinical models and resulted in significant and prolonged PD activity and both local and systemic anti-tumor immune responses.

The Phase 1 clinical trial is designed in two parts to evaluate safety, tolerability, PK and PD of exoIL-12 after single, ascending, subcutaneous doses in healthy volunteers, followed by repeat dose exoIL-12 into the lesions of stage IA-IIB CTCL patients. Patients with CTCL will be monitored for safety, PK, and PD effects through analysis of blood and tumor biopsies, and for local and systemic anti-tumor efficacy using validated CTCL assessment criteria. Safety, biomarker and preliminary anti-tumor efficacy results from CTCL patients are anticipated in mid-2021.

About exoIL-12™

exoIL-12 is Codiak's exosome therapeutic candidate engineered to display fully active IL-12 on the surface of the exosome, using the exosomal protein, PTGFRN, as a scaffold, and designed to facilitate potent local pharmacology at the injection site with precisely quantified doses. By limiting systemic exposure of IL-12 and associated toxicity, Codiak hopes to enhance the therapeutic index with exoIL-12, delivering a more robust tumor response, dose control and an improved safety profile.

Codiak intends to focus development of exoIL-12 on tumors that have, in previous clinical testing, shown clinical responses to IL-12 used as a monotherapy. This includes cutaneous T cell lymphoma (CTCL), melanoma, Merkel cell carcinoma, Kaposi sarcoma, glioblastoma multiforme and triple negative breast cancer.

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 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 diseases, spanning oncology, neuro-oncology, neurology, neuromuscular disease and infectious 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 exoIL-12, including expected design of clinical trials and 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 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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1 Gokhale MS, Vainstein V, Tom J, et al. Single low-dose rHuIL-12 safely triggers multilineage hematopoietic and immune-mediated effects. *Exp Hematol Oncol*. 2014;3(1):11. Published 2014 Apr 11. doi:10.1186/2162-3619-3-11