

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 19, 2020

Codexis, Inc.

(Exact name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-34705
(Commission
File Number)

71-0872999
(I.R.S. Employer
Identification No.)

200 Penobscot Drive
Redwood City, CA 94063
(Address of Principal Executive Offices) (Zip Code)

(650) 421-8100
(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 communication 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	CDXS	The Nasdaq Global Select 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 1.01. Entry into a Material Definitive Agreement.

Strategic Collaboration and License Agreement

On March 19, 2020, Codexis, Inc. (the “Company”) entered into a Strategic Collaboration and License Agreement (the “Takeda Agreement”) with Shire Human Genetic Therapies, Inc., a subsidiary of Takeda Pharmaceutical Co. Ltd. (“Takeda”), effective as of March 23, 2020 (“Effective Date”).

Pursuant to the Takeda Agreement, the Company and Takeda will collaborate to research and develop protein sequences for use in gene therapy products for certain disease indications (each, a “Field”) in accordance with each applicable program plan (each, a “Program Plan”) agreed by the parties.

The Company is primarily responsible for the research and development of protein sequences under the Program Plans (the “Protein Sequences”) and Takeda will reimburse the Company’s internal and external expenses incurred under the Program Plans in accordance with a budget agreed by the parties under the Program Plan. Subject to the terms of the Takeda Agreement, Takeda has the sole right, but not the obligation, to develop, manufacture and commercialize gene therapy products that include nucleic acid sequences that encode the Protein Sequences (“Products”) at Takeda’s sole cost and expense.

Promptly after the Effective Date, the parties will initiate activities under three Program Plans for Fabry Disease, Pompe Disease, and an unnamed blood factor deficiency respectively (the “Initial Programs”). Under the terms of the Takeda Agreement, Takeda has an exclusive right to a certain number of additional disease indications (“Reserved Target Indications”) for a limited period, as provided under the Takeda Agreement (the “Exclusivity Period”). During the Exclusivity Period, and subject to the terms of the Takeda Agreement, Takeda may elect to initiate a Program Plan for one or more Reserved Target Indications (“Additional/Option Program,” with Initial Programs, the “Programs”), provided, (a) if Takeda elects to initiate an Additional/Option Program while the parties are collaborating on three other Programs at the time of such election, or (b) if Takeda elects to initiate an Additional/Option Program using the last remaining Reserved Target Indication, then Takeda must pay an option exercise fee to the Company to initiate such Additional/Option Program.

The Company will own all rights to the Protein Sequences and corresponding nucleic acid sequences and any and all intellectual property rights therein. Subject to the foregoing, Takeda will own all rights to the Products and any and all intellectual property rights therein. Under the terms of the Takeda Agreement, the Company granted to Takeda, under certain of the Company’s know how and patent rights, an exclusive, worldwide, royalty-bearing, sublicensable license to use the Protein Sequences and their corresponding nucleic acid sequences to develop, manufacture and commercialize the applicable Products in the applicable Field. The Company also granted to Takeda a limited non-exclusive, worldwide, sublicensable license under certain of the Company’s know-how and patent rights (a) to research the Protein Sequences within or outside the applicable Fields and (b) to research the Products outside of the applicable Fields, which such rights excluding Takeda’s ability to perform any Investigational New Drug-enabling activities, and the licenses to research the Protein Sequences expire after a pre-determined period of time.

Each party is obligated to use diligent efforts to perform the activities assigned to it under each Program Plan. Subject to the terms of the Takeda Agreement, Takeda is obligated to use commercially reasonable efforts to develop, manufacture and commercialize the Protein Sequences, the corresponding nucleic acid sequences and the Products in the applicable Field.

Under the Takeda Agreement, Takeda will make a one time, non-refundable cash payment to the Company of \$8,500,000, and subject to the terms of the Takeda Agreement, the Company is eligible to receive up to \$22,300,000 as reimbursement of research and development fees and pre-clinical milestone payments for the Initial Programs, in the aggregate. In addition, the Company is eligible to receive certain development and commercialization milestone payments to the Company in the aggregate of up to \$100,000,000 per target gene, the modulation of which would lead to the treatment of the disease indications by the applicable Product. Takeda is also required to pay to the Company tiered royalties on net sales of the Products sold by Takeda, its affiliates and its sublicensees on a Product-by-Product and country-by-country basis at a rate in the mid to low single digit range, subject to certain reductions and offsets in accordance with the terms of the Takeda Agreement. Takeda’s obligation to pay royalties to the Company continues, on a Product-by-Product and country-by-country basis, from the date of the first commercial sale of a Product in a country until the latest of (i) expiration of all valid claims of a patent exclusively licensed to Takeda by the Company under the Takeda Agreement, (ii) expiration of exclusivity granted by a regulatory authority for such Product in such country, and (iii) ten years from the date of such first commercial sale.

The term of the Takeda Agreement begins on the Effective Date and continues on a Product-by-Product and country-by-country basis, until the expiration of Takeda’s obligation to pay royalties to the Company with respect to that Product in that country.

The Takeda Agreement expires in its entirety upon the expiration of Takeda's obligation to pay royalties to the Company with respect to the Products in all countries worldwide. Subject to the terms of the Takeda Agreement, and after the first anniversary of the Effective Date with respect to the Initial Programs or after the first anniversary of confirmation of the applicable Program Plan by the parties with respect to the Additional/Option Programs, Takeda may terminate a Program upon specified prior written notice to the Company. Subject to the terms of the Takeda Agreement, Takeda may terminate the Takeda Agreement, at-will, on a Product-by-Product basis upon specified prior written notice to the Company and the Takeda Agreement in its entirety upon specified prior written notice to the Company. Subject to the terms of the Takeda Agreement, Takeda may terminate the Takeda Agreement on a Product-by-Product basis for safety reasons upon specified prior written notice to the Company. Either party may terminate the Takeda Agreement for an uncured material breach by the other party, or the other party's insolvency or bankruptcy.

The foregoing is only a summary of the material terms of the Takeda Agreement, does not purport to be a complete description of the rights and obligations of the parties thereunder and is qualified in its entirety by reference to the Takeda Agreement that will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ending March 30, 2020.

Item 7.01. Regulation FD Disclosure

On March 23, 2020, the Company issued a press release announcing the Takeda Agreement. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein.

The information furnished pursuant to this Item 7.01 of this Report, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Exchange Act, regardless of any general incorporation language in any such filing, unless the Company expressly sets forth in such filing that such information is to be considered "filed" or incorporated by reference therein.

Item 9.01. Financial Statement and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated March 23, 2020
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 23, 2020

CODEXIS, INC.

By: /s/ Ross Taylor
Name: Ross Taylor
Title: Senior Vice President and Chief Financial Officer



Codexis Signs Strategic Collaboration and License Agreement with Takeda to Advance Novel Gene Therapies for Rare Genetic Disorders

Partnership to leverage Codexis' protein engineering platform for the discovery and development of novel transgenes for lysosomal storage disorders and blood factor deficiencies

REDWOOD CITY, Calif. (March 23, 2020) -- Codexis, Inc., a leading protein engineering company and developer of novel biotherapeutics, announces the signing of a strategic collaboration and license agreement with Takeda Pharmaceutical Company Limited (Takeda) for the research and development of novel gene therapies for certain disease indications, including the treatment of lysosomal storage disorders and blood factor deficiencies.

Under the terms of the agreement, Codexis will generate novel gene sequences encoding protein variants tailored to enhance efficacy as a result of increased activity, stability, and cellular uptake using its CodeEvolver[®] protein engineering platform. Takeda will combine these improved transgenes with its gene therapy capabilities to generate novel candidates for the treatment of rare genetic disorders.

“Our CodeEvolver[®] platform technology enables the rapid engineering of novel genetic sequences that encode more efficacious proteins. The prospects of these improved sequences for the development of differentiated gene therapies for patients with rare diseases therefore holds great promise,” stated John Nicols, Codexis’ President and CEO. “Takeda’s expertise in developing novel treatments for patients with rare genetic disorders, and its commitment to developing the best possible gene therapies, makes them an ideal partner for our growing Novel Biotherapeutics business unit.”

Gjalt Huisman, Codexis’ Senior Vice-President, and General Manager, Novel Biotherapeutics added, “We are looking forward to working with Takeda to advance our pre-clinical assets for lysosomal storage disorders, and to broaden our biotherapeutics pipeline to now include blood factor disorders.”

Terms of Agreement

Under the terms of the agreement, the parties will begin collaborative work on three initial programs. Codexis is responsible for the creation of novel enzyme sequences for advancement as gene therapies into pre-clinical development. Takeda is responsible for the pre-clinical and clinical development and commercialization of gene therapy products resulting from the collaboration programs. Under the terms of the agreement, in addition to the three initial programs, Takeda may initiate up to four additional programs for separate target indications. Subject to the terms of the agreement, Codexis is eligible to receive an upfront payment, reimbursement for research and development fees, development and commercial milestone payments, and low- to mid-single digit percentage royalties on sales of any commercial product developed through such initial programs and any other programs that Takeda may elect under the agreement. Back Bay Life Science Advisors served as strategic and financial advisors to Codexis.

About Codexis, Inc.

Codexis is a leading protein engineering company that applies its proprietary CodeEvolver[®] protein engineering technology to develop proteins for a variety of applications, including enzymes as biotherapeutics, as biocatalysts for the commercial manufacture of pharmaceuticals and fine chemicals, industrial enzymes, and for use in molecular diagnostics. For its Biotherapeutics pipeline, Codexis’

technology enables improvements in protein efficacy, through enhancement of activity, affinity, stability, as well as uptake by target cells. For more information, see www.codexis.com.

Forward-Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding Codexis, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including Codexis' expectations regarding the prospects for the development and future commercialization by Takeda of novel gene therapies for specified target indications. You should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties and other factors that are, in some cases, beyond Codexis' control and that could materially affect actual results. Factors that could materially affect actual results include, among others: Codexis' dependence on its licensees and collaborators; Codexis' dependence on a limited number of products and customers; and potential adverse effects to Codexis' business if its customers' products are not received well in the markets. Additional information about factors that could materially affect actual results can be found in Codexis' Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on February 28, 2020, including under the caption "Risk Factors" and in Codexis' other periodic reports filed with the SEC. Codexis expressly disclaims any intent or obligation to update these forward-looking statements, except as required by law.

Investor Contact:

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