

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): May 4, 2023

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)

Registrant's telephone number, including area code (650) 421-8100

Not Applicable

(Former name or former address, if changed since last report)

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 (see General Instruction A.2. below):

- 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 Symbols(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 2.02 Results of Operations and Financial Condition.

On May 4, 2023, Codexis, Inc. (the “Company”) announced its financial results for the quarter ended March 31, 2023. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 2.02 of this Current Report (including Exhibit 99.1 attached hereto) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statement and Exhibits.

(d) Exhibits.

Exhibit No.	Exhibit Description
99.1	Press release dated May 4, 2023 relating to the financial results for the quarter ended March 31, 2023
104	Cover Page Interactive Data File (the cover page XBRL tags are 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: May 4, 2023

CODEXIS, INC.

By:

/s/ Sriram Ryali

Name:

Sriram Ryali

Title:

Chief Financial Officer

Codexis Reports First Quarter 2023 Financial Results

CDX-7108 Clinical Development Program Remains on Track

Estimated Cash Runway Through End of 2024 Funds Important Upcoming Milestones

Company Reiterates 2023 Total Revenue Guidance with Adjustments to Product vs. R&D Revenue Mix and Range on Gross Margin

REDWOOD CITY, Calif., May 4, 2023-- Codexis, Inc. (NASDAQ: CDXS), a leading enzyme engineering company, today announced financial results for the first quarter ended March 31, 2023, and provided a business update.

“We had a productive first quarter as we continued to execute our strategy, building upon the strong foundation of our Pharmaceutical Manufacturing business and identifying and focusing on the highest value opportunities in Life Sciences and Biotherapeutics. This includes encouraging interim Phase 1 clinical data for CDX-7108 for patients with exocrine pancreatic insufficiency and the pre-commercial availability of our newly engineered DNA ligase for next-generation sequencing, where we are seeing high inbound customer interest in the ongoing sampling and testing,” said Stephen Dilly, MBBS, PhD, President and Chief Executive Officer of Codexis. “Our top priorities for this year are preparing for the Phase 2 clinical trial initiation of CDX-7108 with our partner, Nestlé Health Science, and the continued planned build-out of our RNAi synthesis platform. On that front, we are on track with our development work to support siRNA manufacturing and are excited to highlight our progress at the TIDES USA annual meeting next week. The enzymatic solution we are refining has the potential to lower costs and increase efficiencies throughout the manufacturing scale-up for pharmaceutical companies. With more than 300 RNAi therapeutics currently in development, we see this as a significant opportunity and plan to share more detail on our growing capabilities in the space throughout the year.”

First Quarter and Recent Business Highlights

- Codexis announced interim results from the Phase 1 clinical trial of CDX-7108, which is being co-developed with Nestlé Health Science S.A., for the treatment of exocrine pancreatic insufficiency (EPI). Data from five subjects with EPI in the proof-of-concept arm indicated improved lipid absorption when patients are administered CDX-7108 versus placebo. Importantly, no safety issues were noted in the 48 healthy subjects that participated in the single ascending dose and multiple ascending dose portion of the study. Based on these encouraging data, Codexis and Nestlé expect to file an Investigational New Drug (IND) application for CDX-7108 by the end of 2023, with the Phase 2 clinical trial initiation anticipated in the first half of 2024.
- In February 2023, at the Advances in Genome Biology and Technology (AGBT) General Meeting, Codexis announced the pre-commercial availability of its newly engineered DNA ligase for next-generation sequencing, or NGS. This DNA ligase was specifically engineered to improve ligation efficiency, potentially allowing for increased sensitivity and more accurate detection in disease indications where samples are small and signals are weak. The Company continues to see high levels of engagement and pre-commercial interest from customers who are currently sampling and testing the enzyme. For additional details, please see the white paper available at <https://www.codexis.com/resources/detail/11503/a-ligase-with-superior-ligation-efficiency>.
- In April 2023, Codexis announced a pre-conference workshop at the 2023 [TIDES USA annual meeting](#) to highlight the role of an enzymatic approach to support nucleic acid-based therapeutics manufacturing. The workshop will be held live and virtually on Sunday, May 7, 2023, from 12:30 pm – 1:30 pm PT.

First Quarter 2023 Financial Highlights

- Total revenues for first quarter 2023 were \$13.0 million compared to \$14.0 million in the prior year, excluding enzyme sales related to PAXLOVID™ of \$0 and \$21.3 million in each period, respectively. This represents an 8% decrease compared to first quarter 2022. Including these enzyme sales, first quarter 2023 total revenues were down 63% compared to \$35.3 million in the prior year. On a segment basis, \$9.5 million in revenue was from the Performance Enzymes segment and \$3.5 million was from Biotherapeutics in first quarter 2023.
- Product revenues for first quarter 2023 were \$8.4 million compared to \$9.4 million in the prior year, excluding first quarter 2022 enzyme sales related to PAXLOVID™ and representing a decrease of 11%. Including these enzyme sales, product revenues were down 73% from \$30.7 million in first quarter 2022.
- R&D revenues for first quarter 2023 were \$4.6 million compared to \$4.7 million in first quarter 2022; R&D revenues were flat, primarily due to higher revenue from Nestlé, offset by lower research and development fees from existing collaboration agreements.
- Product gross margin for first quarter 2023 was 46% compared to 72% in first quarter 2022; the decrease was largely driven by variability in the product mix and reflects the volume of lower margin products sold during first quarter 2023.
- R&D expenses for first quarter 2023 were \$16.7 million compared to \$19.5 million in first quarter 2022; the decrease was primarily driven by reduced costs associated with lower headcount, decreases in outside services related to Chemistry, Manufacturing and Controls (“CMC”) and regulatory expenses, lower stock-based compensation costs and lower lab supply costs.
- Selling, General & Administrative expenses for first quarter 2023 were \$15.4 million compared to \$15.7 million in first quarter 2022; the decrease was primarily due to lower legal fees and lower stock-based compensation costs, partially offset by higher payroll-based expenses and higher outside and temporary services.
- The net loss for first quarter 2023 was \$22.6 million, or \$0.34 per share, compared to a net loss of \$8.4 million, or \$0.13 per share, for first quarter 2022. Excluding enzyme sales related to PAXLOVID™, net loss for first quarter 2022 was \$25.3 million, or \$0.39 per share.
- As of March 31, 2023, the Company had \$102.8 million in cash and cash equivalents.

2023 Financial Guidance

Codexis provided an update to its 2023 financial guidance issued on February 23, 2023.

- The Company reiterated its 2023 total revenue guidance range of \$63 million to \$68 million, excluding enzyme sales related to PAXLOVID™, with adjustments to the mix of product revenues versus R&D revenues.
 - Product revenues are now expected to be in the range of \$30 million to \$35 million, excluding enzyme sales related to PAXLOVID™, compared to previous guidance of \$35 million to \$40 million. The change reflects variability in timing of orders of enzyme from a large customer that previously built pre-launch inventory of a recently approved pharmaceutical product.
 - R&D revenues are now expected to be in the range of \$28 million to \$33 million, compared to previous guidance of \$25 million to \$30 million. The change is related to Pfizer applying a portion of its existing retainer fee toward a license to develop future new product candidates unrelated to PAXLOVID™. As a result, the Company expects to recognize \$5.0 million as non-cash R&D revenue in the second quarter 2023.
- Codexis updated its 2023 guidance for gross margin on product revenue, which is now expected to be in the range of 55% to 65%, excluding enzyme sales related to PAXLOVID™. This shift is driven by variability in the product mix, including an increased volume of lower margin products sold during the first quarter of this year.
- Finally, Codexis expects that its existing cash and cash equivalents will be sufficient to fund its planned operations through the end of 2024.

For an updated corporate presentation as of May 4, 2023, visit the Codexis Investor Relations website www.codexis.com/investors.

About Codexis

Codexis is a leading enzyme engineering company leveraging its proprietary CodeEvolver® technology platform to discover, develop and enhance novel, high-performance enzymes and other classes of proteins. Codexis enzymes solve for real-world challenges associated with small molecule pharmaceuticals manufacturing, nucleic acid synthesis and genomic sequencing, and – as biotherapeutic candidates – they have the potential to treat challenging diseases. Codexis' unique enzymes can drive improvements such as higher yields, reduced energy usage and waste generation, improved efficiency in manufacturing, greater sensitivity in genomic and diagnostic applications and potentially more efficacious therapeutics. For more information, visit www.codexis.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “positioned,” “potential,” “predict,” “seek,” “should,” “suggest,” “target,” “on track,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. To the extent that statements contained in this press release are not descriptions of historical facts, they are forward-looking statements reflecting the current beliefs and expectations of management, including but not limited to statements regarding anticipated milestones such as timing of data from clinical trials being publicly released, as well as timing of initiating clinical trials and potential interactions with regulators; the potential of Codexis' enzymatic solutions to lower costs and increase efficiencies, and whether such solutions will represent a significant opportunity for Codexis; Codexis' expectations regarding 2023 total revenues, product revenues and gross margin on product revenue, as well as its ability to fund planned operations through the end of 2024. 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' biotherapeutic programs being early stage, highly regulated and expensive; if any of its collaborators terminate their development programs under their respective license agreements with Codexis; Codexis may need additional capital in the future in order to expand its business; Codexis may be unable to obtain regulatory approval for its product candidates given the lengthy, time consuming and inherently unpredictable nature of such approval processes; clinical trials are difficult to design and implement, expensive, time-consuming and involve an uncertain outcome; results of preclinical studies, early clinical trials of product candidates and interim results from ongoing clinical trials may not be predictive of results of later studies or trials; Codexis may not be able to maintain orphan drug designations for certain of our product candidates, and may be unable to maintain the benefits associated with orphan drug designation; even if Codexis obtains regulatory approval for any products that it develop alone or with collaborators, such products will remain subject to ongoing regulatory requirements; 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; and market and economic conditions may negatively impact Codexis business, financial condition and share price. 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 27, 2023 and in Codexis' Quarterly Report on Form 10-Q filed with the SEC on or about the date hereof, 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. Codexis' results for the quarter March 31, 2023 are not necessarily indicative of our operating results for any future periods.

For More Information

Investor Contact

Carrie McKim

(336) 608-9706
ir@codexis.com

Media Contact
Media Contact
Lauren Musto (781) 572-1147
media@codexis.com

Codexis, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(In Thousands, Except Per Share Amounts)

	Three Months Ended March 31,	
	2023	2022
Revenues:		
Product revenue	\$ 8,364	\$ 30,690
Research and development revenue	4,618	4,650
Total revenues	12,982	35,340
Costs and operating expenses:		
Cost of product revenue	4,521	8,521
Research and development	16,655	19,500
Selling, general and administrative	15,399	15,705
Restructuring charges	72	—
Total costs and operating expenses	36,647	43,726
Loss from operations	(23,665)	(8,386)
Interest income	1,089	42
Other expense, net	(25)	(3)
Loss before income taxes	(22,601)	(8,347)
Provision for income taxes	16	9
Net loss	\$ (22,617)	\$ (8,356)
Net loss per share, basic and diluted	\$ (0.34)	\$ (0.13)
Weighted average common stock shares used in computing net loss per share, basic and diluted	65,931	65,096

Codexis, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In Thousands)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 102,831	\$ 113,984
Restricted cash, current	525	521
Financial assets:		
Accounts receivable	9,934	31,904
Contract assets	2,449	2,116
Unbilled receivables	7,797	7,016
Total financial assets	20,180	41,036
Less: allowances	(163)	(163)
Total financial assets, net	20,017	40,873
Inventories	1,996	2,029
Prepaid expenses and other current assets	4,585	5,487
Total current assets	129,954	162,894
Restricted cash	1,526	1,521
Investment in non-marketable equity securities	21,310	20,510
Right-of-use assets - Operating leases, net	38,013	39,263
Property and equipment, net	23,609	22,614
Goodwill	3,241	3,241
Other non-current assets	415	350
Total assets	\$ 218,068	\$ 250,393
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 4,494	\$ 3,246
Accrued compensation	6,611	11,453
Other accrued liabilities	8,340	15,279
Current portion of lease obligations - Operating leases	5,492	5,360
Deferred revenue	13,374	13,728
Total current liabilities	38,311	49,066
Deferred revenue, net of current portion	15,508	16,881
Long-term lease obligations - Operating leases	36,845	38,278
Other long-term liabilities	1,388	1,371
Total liabilities	92,052	105,596
Stockholders' equity:		
Common stock	6	6
Additional paid-in capital	569,917	566,081
Accumulated deficit	(443,907)	(421,290)
Total stockholders' equity	126,016	144,797
Total liabilities and stockholders' equity	\$ 218,068	\$ 250,393

Codexis, Inc.
Segmented Information
(Unaudited)
(In Thousands)

	Three Months Ended March 31, 2023			Three Months Ended March 31, 2022		
	Performance Enzymes	Novel Biotherapeutics	Total	Performance Enzymes	Novel Biotherapeutics	Total
Revenues:						
Product revenue	\$ 8,364	\$ —	\$ 8,364	\$ 30,690	\$ —	\$ 30,690
Research and development revenue	1,122	3,496	4,618	2,409	2,241	4,650
Total revenues	9,486	3,496	12,982	33,099	2,241	35,340
Costs and operating expenses:						
Cost of product revenue	4,521	—	4,521	8,521	—	8,521
Research and development ⁽¹⁾	8,099	7,312	15,411	6,122	12,346	18,468
Selling, general and administrative ⁽¹⁾	2,798	951	3,749	3,541	720	4,261
Restructuring charges	—	72	72	—	—	—
Total segment costs and operating expenses	15,418	8,335	23,753	18,184	13,066	31,250
Income (loss) from operations	<u>\$ (5,932)</u>	<u>\$ (4,839)</u>	<u>(10,771)</u>	<u>\$ 14,915</u>	<u>\$ (10,825)</u>	<u>4,090</u>
Corporate costs ⁽²⁾			(10,364)			(11,205)
Unallocated depreciation and amortization			(1,466)			(1,232)
Loss before income taxes			<u>\$ (22,601)</u>			<u>\$ (8,347)</u>

⁽¹⁾ Research and development expenses and selling, general and administrative expenses exclude depreciation and amortization of finance leases .

⁽²⁾ Corporate costs include unallocated selling, general and administrative expense, interest income, and other expense, net.