

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q**

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended **March 31, 2024**

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: **001-34705**

Codexis, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

200 Penobscot Drive, Redwood City, California

(Address of principal executive offices)

71-0872999

(I.R.S. Employer Identification No.)

94063

(Zip Code)

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

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: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of April 29, 2024, there were 70,557,577 shares of the registrant's Common Stock, par value \$0.0001 per share, outstanding.

Codexis, Inc.
Quarterly Report on Form 10-Q
For the Quarter Ended March 31, 2024

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PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

Codexis, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In Thousands, Except Per Share Amounts)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 58,046	\$ 65,116
Restricted cash, current	518	519
Short-term investments	27,469	—
Financial assets:		
Accounts receivable	6,240	10,036
Contract assets	2,571	815
Unbilled receivables	5,459	9,142
Total financial assets	14,270	19,993
Less: allowances	(65)	(65)
Total financial assets, net	14,205	19,928
Inventories	2,441	2,685
Prepaid expenses and other current assets	5,269	5,218
Total current assets	107,948	93,466
Restricted cash	1,062	1,062
Investment in non-marketable equity securities	9,700	9,700
Right-of-use assets - Operating leases, net	12,364	13,137
Property and equipment, net	14,668	15,487
Goodwill	2,463	2,463
Other non-current assets	1,354	1,246
Total assets	<u>\$ 149,559</u>	<u>\$ 136,561</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,465	\$ 5,947
Accrued compensation	6,502	11,246
Other accrued liabilities	5,374	4,735
Current portion of lease obligations - Operating leases	3,879	3,781
Deferred revenue	9,860	10,121
Total current liabilities	29,080	35,830
Deferred revenue, net of current portion	630	640
Long-term lease obligations - Operating leases	11,232	12,243
Long-term debt	28,102	—
Other long-term liabilities	1,248	1,233
Total liabilities	70,292	49,946
Commitments and Contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, \$ 0.0001 par value per share; 5,000 shares authorized, none issued and outstanding	—	—
Common stock, \$ 0.0001 par value per share; 200,000 shares authorized; 70,554 shares and 69,905 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	7	7
Additional paid-in capital	588,311	584,138
Accumulated other comprehensive loss	(16)	—
Accumulated deficit	(509,035)	(497,530)
Total stockholders' equity	79,267	86,615
Total liabilities and stockholders' equity	<u>\$ 149,559</u>	<u>\$ 136,561</u>

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2024	2023
Revenues:		
Product revenue	\$ 9,551	\$ 8,364
Research and development revenue	7,522	4,618
Total revenues	<u>17,073</u>	<u>12,982</u>
Costs and operating expenses:		
Cost of product revenue	4,855	4,521
Research and development	11,246	16,655
Selling, general and administrative	12,860	15,399
Restructuring charges	—	72
Total costs and operating expenses	<u>28,961</u>	<u>36,647</u>
Loss from operations	(11,888)	(23,665)
Interest income	909	1,089
Other expense, net	(516)	(25)
Loss before income taxes	(11,495)	(22,601)
Provision for income taxes	10	16
Net loss	<u>\$ (11,505)</u>	<u>\$ (22,617)</u>
Net loss per share, basic and diluted	\$ (0.16)	\$ (0.34)
Weighted average common stock shares used in computing net loss per share, basic and diluted	69,854	65,931

See accompanying notes to the unaudited condensed consolidated financial statements.

Codexis, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)
(In Thousands)

	Three Months Ended March 31,	
	2024	2023
Net loss	\$ (11,505)	\$ (22,617)
Other comprehensive loss:		
Unrealized loss on available-for-sale short-term investments, net of tax	(16)	—
Comprehensive loss	<u>\$ (11,521)</u>	<u>\$ (22,617)</u>

See accompanying notes to the unaudited condensed consolidated financial statements.

Codexis, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(In Thousands)

Three Months Ended March 31, 2024	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of January 1, 2024	69,905	\$ 7	\$ 584,138	\$ —	\$ (497,530)	\$ 86,615
Exercise of stock options	73	—	143	—	—	143
Release of stock awards	576	—	—	—	—	—
Stock-based compensation	—	—	3,171	—	—	3,171
Issuance of common stock warrants	—	—	859	—	—	859
Net loss	—	—	—	—	(11,505)	(11,505)
Other comprehensive loss	—	—	—	(16)	—	(16)
Balance as of March 31, 2024	<u>70,554</u>	<u>\$ 7</u>	<u>\$ 588,311</u>	<u>\$ (16)</u>	<u>\$ (509,035)</u>	<u>\$ 79,267</u>

Three Months Ended March 31, 2023	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of January 1, 2023	65,811	\$ 6	\$ 566,081	\$ —	\$ (421,290)	\$ 144,797
Exercise of stock options	143	—	281	—	—	281
Release of stock awards	479	—	—	—	—	—
Stock-based compensation	—	—	2,809	—	—	2,809
Issuance of common stock, net of issuance costs of \$390	328	—	1,150	—	—	1,150
Taxes paid related to net share settlement of equity awards	(65)	—	(404)	—	—	(404)
Net loss	—	—	—	—	(22,617)	(22,617)
Balance as of March 31, 2023	<u>66,696</u>	<u>\$ 6</u>	<u>\$ 569,917</u>	<u>\$ —</u>	<u>\$ (443,907)</u>	<u>\$ 126,016</u>

See accompanying notes to the unaudited condensed consolidated financial statements.

Codexis, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In Thousands)

	Three Months Ended March 31,	
	2024	2023
Operating activities:		
Net loss	\$ (11,505)	\$ (22,617)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,252	1,466
Reduction in the carrying amount of right-of-use assets	773	1,249
Stock-based compensation	3,171	2,809
Equity securities earned from research and development activities	—	(50)
Non-cash interest expense	82	—
Amortization of discount on short-term investments	(41)	—
Other non-cash items	(10)	(5)
Changes in operating assets and liabilities:		
Financial assets	5,571	20,856
Inventories	244	33
Prepaid expenses and other assets	(146)	586
Accounts payable	(2,038)	694
Accrued compensation and other accrued liabilities	(3,875)	(11,091)
Other long-term liabilities	(996)	(1,415)
Deferred revenue	(271)	(1,727)
Net cash used in operating activities	<u>(7,789)</u>	<u>(9,212)</u>
Investing activities:		
Purchase of property and equipment	(1,130)	(2,539)
Proceeds from sale of property and equipment	11	5
Investment in short-term investments	(27,444)	—
Investment in non-marketable securities	—	(750)
Net cash used in investing activities	<u>(28,563)</u>	<u>(3,284)</u>
Financing activities:		
Proceeds from exercises of stock options	281	281
Proceeds from issuance of common stock in connection with public offering	—	1,540
Costs incurred in connection with issuance of common stock at public offering	(60)	(65)
Proceeds from long-term debt	29,521	—
Payment of debt issuance costs	(461)	—
Taxes paid related to net share settlement of equity awards	—	(404)
Net cash provided by financing activities	<u>29,281</u>	<u>1,352</u>
Net decrease in cash, cash equivalents and restricted cash	(7,071)	(11,144)
Cash, cash equivalents and restricted cash at the beginning of the period	66,697	116,026
Cash, cash equivalents and restricted cash at the end of the period	<u>\$ 59,626</u>	<u>\$ 104,882</u>
Supplemental disclosure of cash flow information:		
Interest paid	\$ 147	\$ 7
Income taxes paid	\$ 17	\$ 193
Supplemental non-cash investing and financing activities:		
Capital expenditures incurred but not yet paid	\$ 371	\$ 819

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the unaudited condensed consolidated balance sheets as of March 31, 2024 and 2023 to the total of the same such amounts shown above in the unaudited condensed consolidated statements of cash flows:

	March 31,	
	2024	2023
Cash and cash equivalents	\$ 58,046	\$ 102,831
Restricted cash, current and non-current	1,580	2,051
Total cash, cash equivalents and restricted cash	<u>\$ 59,626</u>	<u>\$ 104,882</u>

See accompanying notes to the unaudited condensed consolidated financial statements.

Codexis Inc.

**Notes to Condensed Consolidated Financial Statements
(Unaudited)**

Note 1. Description of Business

In these notes to the unaudited condensed consolidated financial statements, the “Company,” “we,” “us,” and “our” refers to Codexis, Inc. and its subsidiaries on a consolidated basis.

We discover, develop, enhance, and commercialize novel, high performance enzymes and other classes of proteins leveraging our proprietary CodeEvolve® directed evolution technology platform.

We previously managed our business as two business segments, Performance Enzymes and Novel Biotherapeutics. During the third and fourth quarters of 2023, we made changes to the structure of our organization in connection with the restructuring of our business that we announced in July 2023, including the discontinuation of investment in certain development programs, primarily in our biotherapeutics business, consolidation of operations to our Redwood City, California headquarters, and headcount reduction. In connection with these organizational structure changes, corresponding changes were made to how our business is managed, how results are reported internally and how our Chief Executive Officer (“CEO”), our chief operating decision maker, assesses performance and allocates resources. As a result of these changes, our previous Performance Enzymes and Novel Biotherapeutics operating segments were combined into a single reportable segment. Effective October 1, 2023, the Company's operations are managed and reported to the CEO on a consolidated basis. The CEO assesses performance and allocates resources based on the consolidated results of operations. We believe that these changes better align internal resources to create a more efficient and effective organizational structure. Under this new organizational and reporting structure, we managed our business as one reportable segment as of December 31, 2023. Comparative prior period disclosures that reflected the previous two segments' information have been revised to conform to this change in our reportable segment.

Note 2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (“GAAP”) and the applicable rules and regulations of the Securities and Exchange Commission (“SEC”) for interim financial information but does not include all the information and notes required by GAAP for complete financial statements. These interim unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2023. The condensed consolidated balance sheet at December 31, 2023 has been derived from the audited consolidated financial statements at that date, but does not include all disclosures, including notes, required by GAAP for complete financial statements. The significant accounting policies used in preparation of the unaudited condensed consolidated financial statements for the three months ended March 31, 2024 and 2023, are consistent with those discussed in Note 2 to the audited consolidated financial statements in the Company's 2023 Annual Report on Form 10-K and are updated below as necessary. There have been no significant changes in our significant accounting policies or critical accounting estimates since December 31, 2023.

The unaudited condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and, in the opinion of management, reflect all adjustments of a normal recurring nature considered necessary to present fairly our financial position as of March 31, 2024 and results of operations for the interim periods presented. The interim results are not necessarily indicative of the results for any future interim period or for the entire year.

The unaudited condensed consolidated financial statements include the accounts of Codexis, Inc. and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of our unaudited condensed consolidated financial statements in conformity with GAAP requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses and related disclosure of contingent assets and liabilities. We regularly assess these estimates which primarily affect revenue recognition, deferred revenue, inventories, valuation of equity investments, goodwill arising out of business acquisitions, accrued liabilities, stock awards, and the valuation allowances associated with deferred tax assets. Actual results could differ from those estimates and such differences may be material to the condensed consolidated financial statements.

Short-term Investments

We classify all marketable debt securities that have effective maturities of three months or less from the date of purchase as cash equivalents and those with effective maturities of greater than three months as short-term investments securities in the condensed consolidated balance sheets. We determine the appropriate classification of our short-term investments at the time of purchase and reevaluate such designation at each balance sheet date. We have classified and accounted for our short-term investments as available-for-sale. After consideration of our risk versus reward objectives, as well as our liquidity requirements, we may sell these debt securities prior to their effective maturities.

We carry these short-term investments at fair value, and report the unrealized gains and losses, net of taxes, as a component of stockholders' equity, except for the changes in allowance for expected credit losses, which are included in "Other expense, net" in the unaudited condensed consolidated statements of operations. We determine any realized gains or losses on the sale of short-term investments on a specific identification method, and we record such gains and losses as a component of other income and expenses.

Short-term investments are reviewed periodically for allowances for credit losses and impairment. When evaluating the investments, the Company reviews factors such as the extent to which the fair value of the security is less than the amortized cost basis, adverse conditions specifically related to the security, the financial condition of the issuer, the Company's intent to sell, and whether it would be more likely than not that the Company would be required to sell the investments before the recovery of the amortized cost basis.

Accounting Pronouncements

Recently adopted accounting pronouncements

Aside from those recently issued accounting pronouncements not yet adopted and described below, there were no recent accounting pronouncements or changes in accounting pronouncements during the three months ended March 31, 2024, that are of significance or potential significance to us.

Recently issued accounting pronouncements not yet adopted

In March 2024, the Financial Accounting Standards Board ("FASB") issued ASU No. 2024-02 *Codification Improvements*. The amendments in this ASU amends the Codification to remove references to various concepts statements and impacts a variety of topics in the Codification. This ASU is effective for public companies with annual periods beginning after December 15, 2024, with early adoption permitted. We are currently evaluating the effects of the standard on our consolidated financial statements and related disclosures.

In December 2023, FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. The amendments in the ASU, which requires public companies, on an annual basis, to provide disclosures of specific categories in the rate reconciliation, as well as disclosure of income taxes paid disaggregated by jurisdiction. This ASU is effective for public companies with annual periods beginning after December 15, 2024, with early adoption permitted. We are currently evaluating the effects of the standard on our consolidated financial statements and related disclosures.

In November 2023, FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. The amendments in the ASU are intended to improve reportable segment disclosure requirements primarily through enhanced disclosures about significant segment expenses. The standard is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The standard should be applied retrospectively to all prior periods presented in the financial statements. We are currently evaluating the effects of the standard on our consolidated financial statements and related disclosures.

In October 2023, FASB issued ASU No. 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*. The amendments in the ASU are intended to amend certain disclosure and presentation requirements for a variety of topics within the Accounting Standards Codification ("ASC"). These amendments align the requirements in the ASC to the removal of certain disclosure requirements set out in Regulation S-X and Regulation S-K, as announced by the SEC. The effective date for each amended topic in the ASC is either the date on which the SEC's removal of the related disclosure requirement from Regulation S-X or Regulation S-K becomes effective, or on June 30, 2027, if the SEC has not removed the requirements by that date. Early adoption is prohibited. We are currently evaluating the effects of the standard on our consolidated financial statements and related disclosures.

Note 3. Revenue Recognition

Disaggregation of Revenue

The following table provides information about disaggregated revenue from contracts with customers by geographic regions. The geographic regions that are tracked are the Americas (United States, Canada, and Latin America), EMEA (Europe, Middle East, and Africa), and APAC (Australia, New Zealand, Southeast Asia, and China).

Disaggregated information is as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
Primary geographical markets:		
APAC	\$ 7,257	\$ 7,309
Americas	7,244	2,584
EMEA	2,572	3,089
Total revenues	\$ 17,073	\$ 12,982

Contract Balances

The following table presents balances of contract assets, unbilled receivables, contract costs, and contract liabilities (in thousands):

	March 31, 2024	December 31, 2023
Contract assets	\$ 2,571	\$ 815
Unbilled receivables	6,372	9,904
Contract liabilities: deferred revenue	\$ 10,490	\$ 10,761

We had no asset impairment charges related to financial assets in the three months ended March 31, 2024 and 2023.

The increase in contract assets was primarily due to increases in product revenue from contracts subject to over time revenue recognition. The decrease in unbilled receivables was primarily due to the timing of billings. The decrease in deferred revenue was primarily due to the timing of recognition of revenue.

As of March 31, 2024, we have \$5.5 million of short-term unbilled receivables presented as unbilled receivables within current assets and \$0.9 million of long-term unbilled receivables that is included within the other non-current assets line item in the condensed consolidated balance sheets. As of December 31, 2023, we had \$9.1 million of short-term unbilled receivables presented as unbilled receivables within current assets and \$0.8 million of long-term unbilled receivables that is included within the other non-current assets line item in the condensed consolidated balance sheets.

We recognized the following revenues (in thousands):

Revenue recognized in the period for:	Three Months Ended March 31,	
	2024	2023
Amounts included in contract liabilities at the beginning of the period:		
Performance obligations satisfied	\$ 371	\$ 1,602
Changes in the period:		
Changes in the estimated transaction price allocated to performance obligations satisfied in prior periods	189	(216)
Performance obligations satisfied from new activities in the period - contract revenue	16,513	11,596
Total revenues	\$ 17,073	\$ 12,982

Performance Obligations

The following table includes estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied or partially unsatisfied at the end of the reporting periods. The estimated revenue does not include contracts with original durations of one year or less, amounts of variable consideration attributable to royalties, or contract renewals that are unexercised as of March 31, 2024.

The balances in the table below are partially based on judgments involved in estimating future orders from customers subject to the exercise of material rights pursuant to respective contracts as of March 31, 2024 (in thousands):

	Remainder of 2024	2025	2026	2027 and Thereafter	Total
Product revenue	\$ 9,850	\$ 140	\$ 140	\$ 360	\$ 10,490

Note 4. Net Loss per Share

Basic net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock outstanding, less restricted stock awards ("RSAs") subject to forfeiture. Diluted net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock shares outstanding, less RSAs subject to forfeiture, plus all additional common shares that would have been outstanding, assuming dilutive potential common stock shares had been issued for other dilutive securities. For all periods presented, diluted and basic net loss per share are identical since potential common stock shares are excluded from the calculation, as their effect was anti-dilutive.

Anti-Dilutive Securities

In periods of net loss, the weighted average number of shares outstanding, prior to the application of the treasury stock method, excludes potentially dilutive securities from the computation of diluted net loss per common share because including such shares would have an anti-dilutive effect.

The following shares were not considered in the computation of diluted net loss per share because their effect was anti-dilutive (in thousands):

	Three Months Ended March 31,	
	2024	2023
Shares issuable under the Equity Incentive Plan and ESPP	13,105	9,397
Warrants ⁽¹⁾	424	—
Total potentially dilutive securities	13,529	9,397

⁽¹⁾ Pertains to the warrants issued in connection with the Innovatus Loan. For additional information, see Note 11, "Debt."

Note 5. Investments in Non-Marketable Securities

Non-Marketable Equity Securities

Our non-marketable equity securities are investments in privately held companies without readily determinable market value and primarily relate to our investments in Molecular Assemblies, Inc. ("MAI"), seqWell Inc. ("seqWell"), and Arzeda Corp. ("Arzeda"). These investments are accounted for under the measurement alternative and are measured at cost minus impairment, if any, plus or minus changes resulting from observable price changes for identical or similar securities of the same issuer. Non-marketable equity securities are measured at fair value on a non-recurring basis and classified within Level 2 in the fair value hierarchy when we estimate the fair value of these investments using the observable transaction price paid by third party investors for the same or similar security of the same issuers. The fair value of non-marketable equity securities are classified within Level 3 when we estimate fair value using unobservable inputs such as when we remeasure due to impairment and we use discount rates, market data of comparable companies, and rights and obligations of the securities the Company holds, among others. We adjust the carrying value of non-marketable equity securities which have been remeasured during the period and recognize resulting gains or losses as a component of other expense, net in the unaudited condensed consolidated statements of operations.

There was no remeasurement event for our investments in MAI, seqWell, Arzeda, and other non-marketable equity securities that occurred during the three months ended March 31, 2024 and 2023. We recognized no realized gains or losses during the three months ended March 31, 2024 and 2023.

The following table presents the carrying value of our non-marketable equity securities (in thousands):

	March 31, 2024	December 31, 2023
MAI	\$ 6,693	\$ 6,693
seqWell	2,625	2,625
Arzeda	82	82
Other investments in non-marketable equity securities	300	300
Total non-marketable equity securities	\$ 9,700	\$ 9,700

Note 6. Fair Value Measurements

The following tables show the Company's cash, cash equivalents, and short-term investments by significant investment category as of March 31, 2024 and December 31, 2023 (in thousands):

March 31, 2024						
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Short-term Investments
Cash	\$ 11,350	\$ —	\$ —	\$ 11,350	\$ 11,350	\$ —
Level 1:						
Money market funds	22,849	—	—	22,849	22,849	—
Level 2 ⁽¹⁾ :						
Commercial paper	28,713	—	(17)	28,696	18,878	9,818
Corporate debt	980	—	—	980	—	980
U.S. treasury securities	21,639	2	(1)	21,640	4,969	16,671
Subtotal	51,332	2	(18)	51,316	23,847	27,469
Total	<u>\$ 85,531</u>	<u>\$ 2</u>	<u>\$ (18)</u>	<u>\$ 85,515</u>	<u>\$ 58,046</u>	<u>\$ 27,469</u>

⁽¹⁾ The valuation techniques used to measure the fair values of the Company's Level 2 financial instruments uses inputs that are either directly or indirectly observable for the asset through correlation with market data at the measurement date and for the duration of the instrument's anticipated life.

December 31, 2023						
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Short-term Investments
Cash	\$ 8,742	\$ —	\$ —	\$ 8,742	\$ 8,742	\$ —
Level 1:						
Money market funds	56,374	—	—	56,374	56,374	—
Total	<u>\$ 65,116</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 65,116</u>	<u>\$ 65,116</u>	<u>\$ —</u>

We limit the credit risk associated with our cash equivalents and short-term investments by placing them with banks and institutions we believe are highly credit-worthy and investing in highly-rated investments. As of March 31, 2024, and December 31, 2023, the contractual maturity of all investments held was less than one year.

During the three months ended March 31, 2024 and 2023, we did not recognize any significant credit losses nor other-than-temporary impairment losses on our short-term investments.

Note 7. Balance Sheets Details

Inventories

Inventories consisted of the following (in thousands):

	March 31, 2024	December 31, 2023
Raw materials	\$ 108	\$ 108
Work in process	37	7
Finished goods	2,296	2,570
Total Inventories	\$ 2,441	\$ 2,685

Prepaid expenses and other current assets

As of March 31, 2024, prepaid expenses and other current assets consisted of prepaid expenses of \$4.7 million and other current assets of \$0.5 million. As of December 31, 2023, prepaid expenses and other current assets consisted of prepaid expenses of \$4.6 million and other current assets of \$0.6 million.

Property and Equipment, net

Property and equipment, net consisted of the following (in thousands):

	March 31, 2024	December 31, 2023
Laboratory equipment	\$ 37,744	\$ 37,216
Leasehold improvements	11,901	11,912
Computer equipment and software	2,642	2,565
Office equipment and furniture	1,116	1,469
Construction in progress	1,169	1,636
Property and equipment	54,572	54,798
Less: accumulated depreciation and amortization	(39,904)	(39,311)
Property and equipment, net	\$ 14,668	\$ 15,487

Depreciation expense included in both research and development expenses and selling, general and administrative expenses in the unaudited condensed consolidated statements of operations was as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
Research and development	\$ 1,032	\$ 1,243
Selling, general and administrative	220	223
Total depreciation expense	\$ 1,252	\$ 1,466

Other Accrued Liabilities

Other accrued liabilities consisted of the following (in thousands):

	March 31, 2024	December 31, 2023
Accrued professional and outside service fees	\$ 2,482	\$ 2,330
Accrued purchases	2,418	1,402
Other	474	1,003
Total other accrued liabilities	\$ 5,374	\$ 4,735

Note 8. Stock-based Compensation

Employee Stock Purchase Plan

In April 2023, the Board approved an employee stock purchase plan (the "ESPP") which became effective upon approval at the Annual Meeting in June 2023. The ESPP allows eligible employees of the Company to purchase shares of our common stock through payroll deductions over 24-month offering periods. The per share purchase price will be the lower of 85% of the closing trading price per share of our common stock on the first trading date of an offering period in which a participant is enrolled or 85% of the closing trading price per share on the purchase date. Participant purchases are limited to a maximum of \$25,000 of fair value of our stock per calendar year. The Company is authorized to grant up to 2,000,000 shares of common stock under the ESPP. The first offering period of the ESPP commenced in December 2023 and as of March 31, 2024, the Company had not issued any shares of common stock under the ESPP. We recognized \$0.1 million of stock-based compensation expenses related to the ESPP in the three months ended March 31, 2024.

Stock Options

Stock options granted to employees generally have a maximum term of ten years and vest over four years from the date of grant, of which 25% vest at the end of one year, and 75% vest monthly over the remaining three years. In January 2024, the Board approved the grants of stock options with a vesting term over three years from the date of grant, of which 33% vest at the end of one year, and 67% vest monthly over the remaining two years.

Stock-Based Compensation Expense

Stock-based compensation expense is included in the unaudited condensed consolidated statements of operations as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
Cost of product revenue	\$ 115	\$ 129
Research and development	820	722
Selling, general and administrative	2,236	1,958
Total	\$ 3,171	\$ 2,809

The following table presents total stock-based compensation expense by security type included in the unaudited condensed consolidated statements of operations (in thousands):

	Three Months Ended March 31,	
	2024	2023
Stock options	\$ 1,514	\$ 922
RSUs and RSAs	1,317	1,126
PSUs	247	837
PBOs	16	(76)
ESPP	77	—
Total	\$ 3,171	\$ 2,809

As of March 31, 2024, unrecognized stock-based compensation expense, net of expected forfeitures, was \$13.3 million related to unvested stock options and \$6.5 million related to unvested RSUs and RSAs. Stock-based compensation expense for these awards will be recognized through 2028.

Note 9. Capital Stock

Exercise of Options

For the three months ended March 31, 2024 and March 31, 2023, we issued 72,856 and 142,856 shares, respectively, upon option exercises at a weighted-average exercise price of \$1.97 and \$1.97 per share, respectively, with net cash proceeds of \$0.1 million and \$0.3 million, respectively.

Sales Agreements

In May 2021, we filed a Registration Statement on Form S-3 with the SEC (the “2021 Registration Statement”), that automatically became effective upon its filing, under which we may sell common stock, preferred stock, debt securities, warrants, purchase contracts, and units from time to time in one or more offerings. On February 27, 2023, we filed a post-effective amendment to the 2021 Registration Statement. Pursuant to that post-effective amendment, we registered an aggregate \$200.0 million of securities. In May 2021, we entered into an Equity Distribution Agreement (“EDA”) with Piper Sandler & Co (“PSC”), under which PSC, as our exclusive agent, at our discretion and at such times that we may determine from time to time, may sell over a three-year period from the execution of the EDA up to a maximum of \$50.0 million of shares of our common stock. Under the terms of the EDA, PSC may sell the shares at market prices by any method that is deemed to be an “at the market offering” as defined in Rule 415 under the Securities Act of 1933, as amended (the “Securities Act”).

We are not required to sell any shares at any time during the term of the EDA. The EDA will terminate upon the earlier of: (i) the issuance and sale of all shares through PSC on the terms and conditions of the EDA, or (ii) the termination of the EDA in accordance with its terms. Either party may terminate the EDA at any time upon written notification to the other party in accordance with the EDA, and upon such notification, the offering will terminate. Under no circumstances shall any shares be sold pursuant to the EDA after the date which is three years after the registration statement is first declared effective by the SEC. We agreed to pay PSC a commission of 3% of the gross sales price of any shares sold pursuant to the EDA. With the exception of certain expenses, we will pay PSC up to 8% of the gross sales price of the shares sold pursuant to the EDA for a combined amount of commission and reimbursement of PSC's expenses and fees.

During the three months ended March 31, 2024 and 2023, nil and 327,480 shares, respectively, of our common stock were issued and sold pursuant to the EDA. During the three months ended March 31, 2023, we received gross proceeds of \$1.5 million, or \$1.2 million in net proceeds after PSC's commissions and direct offering expenses of \$0.4 million. As of March 31, 2024, \$41.3 million worth of shares remained available for sale under the EDA. The 2021 Registration Statement is set to expire in May 2024. On April 24, 2024, we terminated the EDA.

On May 2, 2024, we entered into a Controlled Equity OfferingSM Sales Agreement (the “Cantor Sales Agreement”) with Cantor Fitzgerald & Co., as sales agent (“Cantor”), under which Cantor, at our discretion and at such times that we may determine from time to time, may sell up to a maximum of \$75.0 million of shares of our common stock. Under the terms of the Cantor Sales Agreement, Cantor may sell the shares at market prices by any method that is deemed to be an “at the market offering” as defined in Rule 415 under the Securities Act. We intend to file a registration statement on Form S-3 registering the offer and sale of these shares under the Securities Act. We will pay a commission of up to 3.0% of gross sales proceeds of any common stock sold under the Cantor Sales Agreement.

Note 10. Commitments and Contingencies

Lease and other information

The Company has entered into operating leases primarily for office and laboratory space. Lease costs amounts included in the measurement of lease obligations and other information related to non-cancellable operating leases were as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
Operating lease cost ⁽¹⁾	\$ 1,032	\$ 1,830

⁽¹⁾ The Company had no variable lease costs.

Other information:

	Operating Leases
Weighted-average remaining lease term (in years)	3.6 years
Weighted-average discount rate	6.6 %

Cash paid (in thousands):	Three Months Ended March 31,	
	2024	2023
Operating cash flows from operating leases	\$ 1,173	\$ 1,882

As of March 31, 2024, our maturity analysis of annual undiscounted cash flows of the non-cancellable operating leases are as follows (in thousands):

Years Ending December 31,	Operating Leases	
2024 (remaining 9 months)	\$	3,554
2025		4,868
2026		5,014
2027		2,533
2028		760
Thereafter		319
Total minimum lease payments		17,048
Less: imputed interest		1,937
Lease obligations	\$	15,111

Reconciliation of operating lease liabilities as shown within the unaudited condensed consolidated balance sheets:

Current portion of lease obligations - Operating leases	\$	3,879
Long-term lease obligations - Operating leases		11,232
Total operating lease liabilities	\$	15,111

Other Commitments

We enter into supply and service arrangements in the normal course of business. Supply arrangements are primarily for fixed-price manufacture and supply. Service agreements are primarily for the development of manufacturing processes. Commitments under service agreements are typically subject to cancellation at our discretion which may require payment of certain cancellation fees. The timing of completion of service arrangements is subject to variability in estimates of the time required to complete the work.

The following table provides quantitative data regarding our other commitments. Future minimum payments reflect amounts that we expect to pay including potential obligations under services agreements subject to risk of cancellation by us (in thousands):

	Payments Due by Period		
	Total	2024 (Remaining 9 Months)	2025 and Thereafter
Facility maintenance agreement	\$ 701	\$ 701	\$ —

Legal Proceedings

We may be involved in legal actions in the ordinary course of business, including inquiries and proceedings concerning business practices and intellectual property infringement, employee relations and other claims. We will recognize a loss contingency in the condensed consolidated financial statements when it is probable a liability has been incurred and the amount of the loss can be reasonably estimated. We will disclose any loss contingencies that do not meet both conditions if there is a reasonable possibility that a material loss may have been incurred. Gain contingencies are not recorded until they are realized.

Indemnifications

We are required to recognize a liability for the fair value of any obligations we assume upon the issuance of a guarantee. We have certain agreements with licensors, licensees and collaborators that contain indemnification provisions. In such provisions, we typically agree to indemnify the licensor, licensee and collaborator against certain types of third-party claims. The maximum amount of the indemnifications is not limited. We accrue for known indemnification issues when a loss is probable and can be reasonably estimated. There were no accruals for expenses related to indemnification issues for any periods presented.

Note 11. Debt

Innovatus Loan Agreement

On February 13, 2024 (the "Closing Date"), we entered into a 5-year term loan and security agreement (the "Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP ("Innovatus"), an affiliate of Innovatus Capital Partners, LLC, for an aggregate principal amount of up to \$40.0 million and with a maturity date of February 13, 2029 (the "Innovatus Loan"). The Innovatus Loan consists of two tranches, of which the first tranche of \$30.0 million was funded on February 13, 2024. We will be eligible to draw down the second tranche of \$10.0 million upon achievement of certain milestones including pre-specified revenue thresholds.

The floating per annum interest rate of the Innovatus Loan is equal to the sum of (a) the greater of (i) prime rate published in the Money Rates section of the Wall Street Journal and (ii) 7.50%, plus (b) 3.25%; provided that, at the election of the the Company, up to 2.0% of such rate shall be payable in-kind until the third anniversary of the closing date. The Company is required to make monthly interest-only payments through February 1, 2027, after which the Company is required to make monthly amortizing payments, with the remaining balance of the principal plus accrued and unpaid interest due at maturity. 2.0% of the interest is payable in-kind for the first three years of the term by increasing the principal balance. Prepayments of the loan, in whole or in part, will be subject to an early prepayment fee which ranges between 3% and 1% and declines each year until the third anniversary date of the Closing Date, after which no prepayment fee is required. The Company is also required to pay an exit fee upon any payment or prepayment equal to 3% of the aggregate principal amount of the tranches funded under the Innovatus Loan.

The Innovatus Loan contains customary representations and warranties and covenants, subject to customary carve outs, and includes financial covenants related to liquidity and net product revenue, with the latter beginning with the period ending September 30, 2024. The Company believes it is in compliance with the terms included within the Innovatus Loan as of March 31, 2024. The Innovatus Loan is secured by perfected first priority liens on the Company's assets, including a commitment by the Company to not allow any liens to be placed upon the Company's intellectual property.

In connection with the issuance of the Innovatus Loan, we recorded a debt discount of \$1.3 million and capitalized debt issuance costs of \$0.6 million. The discount and issuance costs will be amortized over the life of the Innovatus Loan. Interest expense for the Innovatus Loan for the three months ended March 31, 2024 was \$0.5 million, and is inclusive of non-cash amortization of the debt discount, debt issuance costs, payable in-kind interest, and accretion of final payment. The carrying amount of the Innovatus Loan approximates fair value given its recent issuance. The effective interest rate for the Innovatus Loan was 14.0% as of March 31, 2024.

Additionally, in connection with entering into the Innovatus Loan, we entered into a Warrant Agreement with Innovatus on February 13, 2024 and issued to Innovatus a warrant to purchase an aggregate of 424,028 shares of the Company's common stock at an exercise price of \$2.83 per share. The warrants may be exercised on a cashless basis, and are immediately exercisable through the 10th anniversary of the issuance date. At the time of issuance, the Company determined the estimated fair value of the warrants of \$0.9 million using the Black-Scholes model. As the warrants represent a freestanding equity instrument, the Company recorded the fair value of the warrants in additional paid-in capital as of March 31, 2024.

The Company accounts for the amortization of the debt discount and issuance costs utilizing the effective interest method. Long-term debt consisted of the following at March 31, 2024 (in thousands):

	March 31, 2024
Face value of debt	\$ 30,000
Add: payment in-kind interest	28
Add: amortized exit fee	17
Less: unamortized debt discount	(1,313)
Less: unamortized debt issuance costs	(630)
Total long-term debt	<u>\$ 28,102</u>

The future principal payments under the Innovatus Loan are as follows (in thousands):

Years Ending December 31,	
2024	\$ —
2025	—
2026	—
2027	13,264
2028	15,917
2029	2,653
Total principal payments	31,834
Add: amortized exit fee	17
Less: uncapitalized payment in-kind interest	(1,806)
Less: unamortized debt issuance fee	(1,313)
Less: unamortized debt issuance costs	(630)
Total long-term debt	\$ 28,102

Note 12. Segment, Geographical and Other Revenue Information

Segment Information

We previously managed our business as two business segments, Performance Enzymes and Novel Biotherapeutics. During the third and fourth quarters of 2023, we made changes to the structure of our organization in connection with the restructuring of our business that we announced in July 2023, including the discontinuation of investment in certain development programs, primarily in our biotherapeutics business, consolidation of operations to our Redwood City, California headquarters, and headcount reduction. In connection with these organizational structure changes, corresponding changes were made to how our business is managed, how results are reported internally and how our CEO, our chief operating decision maker, assesses performance and allocates resources. As a result of these changes, our previous Performance Enzymes and Novel Biotherapeutics operating segments were combined into a single reportable segment.

Effective October 1, 2023, the Company's operations are managed and reported to the CEO on a consolidated basis. The CEO assesses performance and allocated resources based on the consolidated results of operations. We believe that these changes better align internal resources and external go to market activities in order to create a more efficient and effective organizational structure. Under this new organizational and reporting structure, we managed our business as one reportable segment as of December 31, 2023. Comparative prior period disclosures that reflected the previous two segments' information have been revised to conform to this change in our reportable segment.

Significant Customers

Customers that each accounted for 10% or more of our total revenues were as follows:

	Percentage of Total Revenues for the Three Months Ended March 31,			
	2024		2023	
Customer A	35	%		*
Customer B	15	%	23	%
Customer C	10	%		*
Customer D		*	14	%
Customer E		*	13	%
Customer F		*	10	%

* Percentage was less than 10%

Customers that each accounted for 10% or more of accounts receivable balances as of the periods presented as follows:

	Percentage of Accounts Receivables as of			
	March 31, 2024		December 31, 2023	
Customer B	23	%	12	%
Customer G	23	%	13	%
Customer H		*	21	%
Customer I		*	12	%

* Percentage was less than 10%

Identifiable long-lived assets by location was as follows (in thousands):

	March 31, 2024		December 31, 2023	
	United States	\$	27,032	\$

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following management's discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited condensed consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2023 included in our Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on February 28, 2024 (the "Annual Report"). This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements include, but are not limited to, expectations regarding our strategy, business plans, financial performance and developments relating to our industry. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," or "continue," and similar expressions or variations. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in Part II, Item 1A: "Risk Factors" of this Quarterly Report on Form 10-Q and Part I, Item 1A: "Risk Factors" of our Annual Report, as incorporated herein and referenced in Part II, Item 1A: "Risk Factors" of this Quarterly Report on Form 10-Q and elsewhere in this report. The forward-looking statements in this Quarterly Report on Form 10-Q represent our views as of the date of this Quarterly Report on Form 10-Q. We anticipate that subsequent events and developments may cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

Business Overview

We are a leading enzyme engineering company leveraging our proprietary CodeEvolver[®] directed evolution technology platform to discover, develop, enhance, and commercialize novel, high-performance enzymes and other classes of proteins. Enzymes are naturally occurring biological molecules critical to almost all biochemical reactions that sustain life. They can be precisely engineered and optimized for specific functions, and to have particular characteristics, such as an ability to survive environments in which natural enzymes cannot, or to perform (bio)chemical transformations different than those for which they naturally evolved. We focus on leveraging our capacity to enhance the properties and performance of enzymes to drive pivotal improvements across two key focus areas: our foundational, revenue-generating pharmaceutical manufacturing business and our Enzyme-Catalyzed Oligonucleotide (ECO) Synthesis[™] ("ECO Synthesis[™]") manufacturing platform, which is currently in development to enable the commercial scale manufacture of RNA interference ("RNAi") therapeutics. Our unique enzymes drive improvements such as higher yields, increased purity, reduced energy usage and waste generation, and improved efficiency in manufacturing. In July 2023, we announced that we discontinued investment in certain development programs, primarily in our novel biotherapeutics business segment and that we are actively exploring options to drive value by potentially monetizing non-core assets within our biotherapeutics and Life Science portfolios.

Within the pharmaceutical manufacturing business, we utilize our CodeEvolver[®] technology platform to develop optimized enzymes that are used by some of the world's largest pharmaceutical companies to reduce their costs and improve the efficiency and productivity of their manufacturing processes for small molecule therapeutics. We also use the CodeEvolver[®] technology platform to develop enzymes for the synthesis of nucleic acids such as DNA/RNA, including enzymes utilized in our ECO Synthesis[™] manufacturing platform. We demonstrated gram-scale synthesis with the ECO Synthesis[™] manufacturing platform in December 2023 and expect to begin pre-commercial customer testing in 2024. We anticipate that this will be followed by early commercial licenses to the ECO Synthesis[™] manufacturing platform in 2025 and a full commercial launch in 2026.

As of March 31, 2024, we manage our business as one business segment. For additional information, see Note 12, "Segment, Geographical and Other Revenue Information" in the Notes to Unaudited Condensed Consolidated Financial Statements included in this Quarterly Report.

Recent Developments

Entered into exclusive licensing agreement for newly engineered double-stranded DNA ligase with Roche

On February 26, 2024, we announced that we entered into an agreement with Roche Sequencing Solutions, Inc. ("Roche") for an exclusive, global license for the Company's newly engineered double-stranded DNA (dsDNA) ligase for next-generation sequencing (NGS) library preparation and the Company's EvoT4[™] DNA ligase. Under the terms of the deal, Codexis will receive upfront and technical milestone payments. This deal supersedes the prior exclusive license on the EvoT4[™] DNA ligase.

Secured \$40.0 million in strategic financing deal with Innovatus Capital Partners to further strengthen cash position ahead of key milestones

On February 13, 2024, we announced that we entered into a loan facility agreement with an affiliate of Innovatus Capital Partners, LLC (Innovatus) for up to \$40.0 million, including \$30.0 million upfront and access to an additional \$10.0 million upon achieving certain prespecified revenue thresholds.

Appointment of new members of our Strategic Advisory Board (“SAB”)

On February 20, 2024, we announced the appointment Masad Damha, PhD and Jim Lalonde, PhD to our SAB. On April 11, 2024, we announced the appointment of Carole Cobb, MBA to our SAB as well. Drs. Damha and Lalonde and Ms. Cobb join John Maraganore, PhD, the founder and former Chief Executive Officer of Alnylam Pharmaceuticals on our SAB, which is now comprised of experts across oligonucleotide synthesis and manufacturing and was established to help guide the Company’s strategic direction, providing critical insights to inform the continued development of Codexis’ ECO Synthesis™ manufacturing platform.

Significant Collaborative Arrangements Update

Acquisition Agreement

In December 2023, we entered into an acquisition agreement (the “Acquisition Agreement”) with Nestlé Health Science, pursuant to which we agreed to assign our interests in CDX-7108 (including associated agreements and intellectual property rights) to Nestlé Health Science. Under the terms of the Acquisition Agreement, Nestlé Health Science will be solely responsible for the continued development and commercialization of CDX-7108, including all associated costs, and Codexis will receive upfront payment, future potential milestone payments and net-sales based royalties. We recognized research and development revenue of \$5.0 million during the fourth quarter of 2023 related to the Acquisition Agreement and received the \$5.0 million upfront fee in January 2024.

Pfizer Enzyme Supply Agreement

We are a party to the Pfizer Supply Agreement, covering the manufacture, sale and purchase of CDX-616 for use by Pfizer in the manufacture of nirmatrelvir. Under the terms of the Pfizer Supply Agreement, Pfizer paid us a fee of \$25.9 million in August 2022 which was recorded as deferred revenue. Pursuant to the agreement, 90% of the fee (\$23.3 million) is creditable against (i) future orders of CDX-616 used to manufacture PAXLOVID™ with shipment dates prior to December 31, 2023, and (ii) fees associated with any new development and licensing agreements with Pfizer entered into prior to April 4, 2023. On March 31, 2023, we entered into a license agreement whereby Pfizer utilized a portion of the \$23.3 million credit towards a license to develop future product candidates, for which we recognized \$5.0 million as non-cash research and development revenue in the second quarter of 2023. Pfizer's ability to utilize the credit under item (i) above expired on December 31, 2023, and under item (ii) above expired on April 4, 2023. Up to 50% of any portion of the \$25.9 million which has not been credited under items (i) and (ii) is creditable against future orders of CDX-616 used to manufacture PAXLOVID™ with shipment dates in 2024.

No product revenue was recognized from the Pfizer Supply Agreement during the three months ended March 31, 2024 and 2023. As of March 31, 2024 and December 31, 2023, we had \$9.5 million in deferred revenue related to the \$25.9 million fee received from Pfizer.

Strategic Collaboration Agreement

In October 2017, we entered into the Nestlé Strategic Collaboration Agreement (“SCA”) pursuant to which we and Nestlé Health Science have collaborated to leverage the CodeEvolver® protein engineering technology platform to develop novel enzymes for Nestlé Health Science’s established Consumer Care and Medical Nutrition business areas. The term of the Nestlé SCA has expired in December 2023, as we opted out of a renewal period through December 2024.

In January 2020, we entered into a development agreement with Nestlé Health Science pursuant to which we and Nestlé Health Science have collaborated to advance a lead candidate discovered through our Nestlé SCA, CDX-7108, targeting exocrine pancreatic insufficiency, into preclinical and early clinical studies. We, together with Nestlé Health Science, initiated a Phase 1 clinical trial of CDX-7108 in the fourth quarter of 2021, and on February 23, 2023, we and Nestlé Health Science announced interim results. In July 2023, we announced plans to discontinue our development support of CDX-7108.

Under the Nestlé SCA and the development agreement, we recognized nil and \$1.8 million in research and development fees for the three months ended March 31, 2024 and 2023, respectively.

Results of Operations

The following table shows the amounts from our unaudited condensed consolidated statements of operations for the periods presented (in thousands, except percentages):

	Three Months Ended March 31,		Change	
	2024	2023	\$	%
Revenues:				
Product revenue	\$ 9,551	\$ 8,364	\$ 1,187	14%
Research and development revenue	7,522	4,618	2,904	63%
Total revenues	17,073	12,982	4,091	32%
Costs and operating expenses:				
Cost of product revenue	4,855	4,521	334	7%
Research and development	11,246	16,655	(5,409)	(32)%
Selling, general and administrative	12,860	15,399	(2,539)	(16)%
Restructuring charges	—	72	(72)	100%
Total costs and operating expenses	28,961	36,647	(7,686)	(21)%
Loss from operations	(11,888)	(23,665)	11,777	(50)%
Interest income	909	1,089	(180)	(17)%
Other expense, net	(516)	(25)	(491)	1,964%
Loss before income taxes	(11,495)	(22,601)	11,106	(49)%
Provision for income taxes	10	16	(6)	(38)%
Net loss	\$ (11,505)	\$ (22,617)	\$ 11,112	(49)%

Revenues

Our revenues consisted of product revenue, research and development revenue, and royalties and license revenue as follows:

- Product revenue consist of sales of biocatalysts, pharmaceutical intermediates, and Codex[®] biocatalyst panels and kits.
- Research and development revenue include license, technology access and exclusivity fees, research services fees, milestone payments, royalties, optimization and screening fees.

Revenues are as follows (in thousands, except percentages):

	Three Months Ended March 31,		Change	
	2024	2023	\$	%
Product revenue	\$ 9,551	\$ 8,364	\$ 1,187	14%
Research and development revenue	7,522	4,618	2,904	63%
Total revenues	\$ 17,073	\$ 12,982	\$ 4,091	32%

Revenues typically fluctuate on a quarterly basis due to the variability in our customers' manufacturing schedules and the timing of our customers' clinical trials. In addition, we have limited internal capacity to manufacture enzymes. As a result, we are dependent upon the performance and capacity of third-party manufacturers for the commercial scale manufacturing of the enzymes used in our pharmaceutical and fine chemicals business.

We accept purchase orders for deliveries covering periods from one day up to 14 months from the date on which the order is placed. However, some of our purchase orders can be revised or cancelled by the customer without penalty. Considering these industry practices and our experience, we do not believe the total of customer purchase orders outstanding (backlog) provides meaningful information that can be relied on to predict actual sales for future periods.

Total revenues increased by \$4.1 million to \$17.1 million in the three months ended March 31, 2024 compared to the same period in 2023, or 32%.

Product revenue increased by \$1.2 million to \$9.6 million in the three months ended March 31, 2024 compared to the same period in 2023 primarily due to higher sales of branded pharmaceutical products.

Research and development revenue increased by \$2.9 million to \$7.5 million in the three months ended March 31, 2024 compared to the same period in 2023, primarily due to \$6.0 million higher revenue from Roche licensing agreement entered into in February 2024. This was offset by \$1.8 million lower research and development fees from Nestlé Health Science under the Nestlé SCA and development agreement and \$1.7 million lower revenue from Takeda under the Strategic Collaboration and License Agreement we entered into with Shire Human Genetic Therapies, Inc., a wholly-owned subsidiary of Takeda, in March 2020.

Cost and Operating Expenses

The following table shows the amounts of our cost of product revenue, research and development expense, selling, general and administrative expense, and restructuring charges from our unaudited condensed consolidated statements of operations for the periods presented (in thousands, except percentages):

	Three Months Ended March 31,		Change	
	2024	2023	\$	%
Cost of product revenue	\$ 4,855	\$ 4,521	\$ 334	7%
Research and development	11,246	16,655	(5,409)	(32)%
Selling, general and administrative	12,860	15,399	(2,539)	(16)%
Restructuring charges	—	72	(72)	100%
Total costs and operating expenses	\$ 28,961	\$ 36,647	\$ (7,686)	(21)%

Cost of Product Revenue and Product Gross Margin

The following table shows the amounts of our product revenue, cost of product revenue, product gross profit and product gross margin from our unaudited condensed consolidated statements of operations for the periods presented (in thousands, except percentages):

	Three Months Ended March 31,		Change	
	2024	2023	\$	%
Product revenue	\$ 9,551	\$ 8,364	\$ 1,187	14%
Cost of product revenue ⁽¹⁾	4,855	4,521	334	7%
Product gross profit	\$ 4,696	\$ 3,843	\$ 853	22%
Product gross margin (%) ⁽²⁾	49 %	46 %		

⁽¹⁾ Cost of product revenue consists of both internal and third-party fixed and variable costs, including materials and supplies, labor, facilities and other overhead costs associated with our product revenue.

⁽²⁾ Product gross margin is used as a performance measure to provide additional information regarding our results of operations on a consolidated basis.

Cost of product revenue increased by \$0.3 million in the three months ended March 31, 2024 compared to the same period in 2023 primarily due to a higher volume of product sales as compared to the same period in prior year. The product gross margin increased to 49% in the three months ended March 31, 2024 compared to 46% in the three months ended March 31, 2023, primarily due to variability in the product mix.

Research and Development Expenses

Research and development expenses consist of costs incurred for internal projects as well as collaborative research and development activities. These costs primarily consist of (i) employee-related costs, which include salaries and other personnel-related expenses (including stock-based compensation), (ii) various allocable expenses, which include occupancy-related costs, supplies, depreciation of facilities and laboratory equipment, and (iii) external costs. Research and development expenses are expensed when incurred.

Research and development expenses were \$11.2 million in the first quarter of 2024, a decrease of \$5.4 million, or 32%, from \$16.7 million in the first quarter of 2023. This decrease was primarily due to \$2.4 million decrease in costs associated with lower headcount, \$1.2 million decrease in outside services related to Chemistry, Manufacturing and Controls and regulatory expenses, \$1.2 million decrease in lease costs due to the assignment of our San Carlos facility lease during the fourth quarter of 2023, and \$0.5 million lower lab supply costs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist of employee-related costs, which include salaries and other personnel-related expenses (including stock-based compensation), hiring and training costs, consulting and outside services expenses (including audit and legal counsel related costs), marketing costs, building lease costs, and depreciation expenses and amortization expenses.

Selling, general and administrative expenses were \$12.9 million in the first quarter of 2024, a decrease of \$2.5 million, or 16%, compared to \$15.4 million in the first quarter of 2023. This decrease was primarily due to \$1.6 million decrease in costs associated with lower headcount, \$0.7 million in lower consulting and outside services, and \$0.2 million of lower marketing and advertising costs. These were partially offset by a \$0.3 million higher stock based compensation expense.

Restructuring Charges

Restructuring charges consist of one-time employee severance and other termination benefits due to workforce reduction plans that were initiated in the prior years. There were no restructuring charges recognized in the three months ended March 31, 2024. Restructuring charges were \$0.1 million for the three months ended March 31, 2023.

Interest Income and Other Expense, net (in thousands, except percentages):

	Three Months Ended March 31,		Change	
	2024	2023	\$	%
Interest income	\$ 909	\$ 1,089	\$ (180)	(17)%
Other expense, net	(516)	(25)	(491)	1,964%
Total other income, net	\$ 393	\$ 1,064	\$ (671)	(63)%

Interest Income

Interest income decreased by \$0.2 million in the three months ended March 31, 2024 compared to the same period in 2023, primarily due to lower average cash balances.

Other Expense, net

Other expense, net increased by \$0.5 million in the three months ended March 31, 2024, compared to the same period in 2023, primarily due to interest related to long-term debt.

Provision for Income Taxes (in thousands, except percentages):

	Three Months Ended March 31,		Change	
	2024	2023	\$	%
Provision for income taxes	\$ 10	\$ 16	\$ (6)	(38)%

The provision for income taxes for the three months ended March 31, 2024 and 2023, was primarily due to the accrual of interest and penalties on historic uncertain tax positions.

Net Loss

Net loss for the three months ended March 31, 2024 was \$11.5 million, or a net loss per basic and diluted share of \$0.16. This compared to a net loss of \$22.6 million, or a net loss per basic and diluted share of \$0.34 for the three months ended March 31, 2023. The decrease in net loss is primarily related to higher product and research and development revenues and lower operating expenses.

LIQUIDITY AND CAPITAL RESOURCES

Liquidity is the measurement of our ability to meet working capital needs and to fund capital expenditures. We have historically funded our operations primarily through cash generated from operations, stock option exercises and public and private offerings of our common stock. In addition, pursuant to the Loan Agreement, we received \$30.0 million from Innovatus, as Lender, on February 13, 2024 and may become eligible to borrow up to an additional \$10.0 million upon the achievement of certain financial milestones. We actively manage our cash usage and investment of liquid cash to ensure the maintenance of sufficient funds to meet our working capital needs. Our cash and cash equivalents are held in U.S. banks.

Our primary uses of capital for the foreseeable future, including the next 12 months, are for compensation and related expenses, research and development expenses including manufacturing costs, laboratory and related supplies, legal and other regulatory expenses, and general overhead costs.

The following summarizes our cash and cash equivalents and short-term investments balances and working capital as of March 31, 2024 and December 31, 2023 (in thousands):

	March 31, 2024	December 31, 2023
Cash and cash equivalents	\$ 58,046	\$ 65,116
Short-term investments	\$ 27,469	\$ —
Working capital	\$ 78,868	\$ 57,636

Sources of Capital

In addition to our existing cash and cash equivalents and revenue generated through our existing operations, we are eligible to earn milestone and other contingent payments for the achievement of defined collaboration objectives under our collaboration agreements. Our ability to earn these milestone and contingent payments and the timing of achieving these milestones is primarily dependent upon the outcome of our collaborators' research and development activities and is uncertain at this time.

We have historically experienced negative cash flows from operations as we continue to invest in key technology development projects and improvements to our CodeEvolver® technology platform, develop and commercialize new and existing products including our ECO Synthesis™ manufacturing platform and expand our business development and collaboration with new customers. Our cash flows from operations will continue to be affected principally by product sales and product gross margins, sales from licensing our technology to major pharmaceutical companies, and collaborative research and development services provided to customers, as well as our headcount costs, primarily in research and development. Our primary source of cash flows from operating activities is cash receipts from our customers for purchases of products, collaborative research and development services, and licensing our technology to major pharmaceutical companies. Our largest uses of cash from operating activities are for employee-related expenditures, rent payments, inventory purchases to support our product sales and non-payroll research and development costs.

Loan Agreement and Term Loans

On February 13, 2024, we entered into the Loan Agreement with Innovatus consisting of two tranches, of which the first tranche of \$30.0 million was completed upon execution of the Loan Agreement. We will be eligible to draw on the second tranche of \$10.0 million upon achievement of certain milestones including certain pre-specified revenue thresholds. The Term Loan carries an interest-only period of 36 months and will bear an interest at a floating rate of the sum of (a) the greater of (i) prime rate and (ii) 7.50%, plus (b) 3.25%.

Sales Agreements

In May 2021, we entered into an Equity Distribution Agreement (“EDA”) with Piper Sandler & Co (“PSC”), under which PSC, as our exclusive agent, at our discretion and at such times that we may determine from time to time, may sell over a three-year period from the execution of the EDA up to a maximum of \$50.0 million of shares of our common stock. In 2023, 3,079,421 shares of our common stock were issued and sold pursuant to the EDA, all during the first half of 2023, and we received net proceeds of \$7.9 million. As of March 31, 2024, \$41.3 million of shares remained available for sale under the EDA. The registration statement registering the offer and sale of the shares pursuant to the EDA is set to expire on May 7, 2024. On April 24, 2024, we terminated the EDA.

On May 2, 2024, we entered into a Controlled Equity OfferingSM Sales Agreement (the “Cantor Sales Agreement”) with Cantor Fitzgerald & Co., as sales agent (“Cantor”), under which Cantor, at our discretion and at such times that we may determine from time to time, may sell up to a maximum of \$75.0 million of shares of our common stock. Under the terms of the Cantor Sales Agreement, Cantor may sell the shares at market prices by any method that is deemed to be an “at the market offering” as defined in Rule 415 under the Securities Act. We intend to file a registration statement on Form S-3 registering the offer and sale of these shares under the Securities Act. We will pay a commission of up to 3.0% of gross sales proceeds of any common stock sold under the Cantor Sales Agreement.

Sales of our common stock under these arrangements could be subject to business, economic or competitive uncertainties and contingencies, many of which may be beyond our control, and which could cause actual results from the sale of our common stock to differ materially from expectations.

Liquidity

We believe that our existing cash and cash equivalents, combined with our future expectations for product revenues, research and development revenue, and expense management will provide adequate funds for ongoing operations, planned capital expenditures and working capital requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our capital resources sooner than we expect.

However, we may need additional capital if our current plans and assumptions change. In addition, we may choose to seek other sources of capital even if we believe we have generated sufficient cash flows to support our operating needs. Our need for additional capital will depend on many factors, including the financial success of our business, the spending required to develop and commercialize new and existing products including our ECO Synthesis™ manufacturing platform, the effect of any acquisitions of other businesses, technologies or facilities that we may make or develop in the future, our spending on new market opportunities, and the potential costs for the filing, prosecution, enforcement and defense of patent claims, if necessary. If our capital resources are insufficient to meet our capital requirements, and we are unable to enter into or maintain collaborations with partners that are able or willing to fund our development efforts or commercialize any products that we develop or enable, we will have to raise additional funds to continue the development of our technology and products and complete the commercialization of products, if any, resulting from our technologies. If future financings involve the issuance of equity securities, our existing stockholders would suffer dilution. In addition, under the Loan Agreement, we are subject to restrictive covenants that limit our ability to conduct our business and could be subject to additional covenants to the extent we seek other debt financing in the future. We may not be able to raise sufficient additional funds on terms that are favorable to us, if at all. If we fail to raise sufficient funds and fail to generate sufficient revenues to achieve planned gross margins and to control operating costs, our ability to fund our operations, take advantage of strategic opportunities, develop products or technologies, or otherwise respond to competitive pressures could be significantly limited. If this happens, we may be forced to delay or terminate development of new products or services, such as our ECO Synthesis™ manufacturing platform, or the commercialization of products resulting from our technologies, curtail or cease operations or obtain funds through collaborative and licensing arrangements that may require us to relinquish commercial rights, or grant licenses on terms that are not favorable to us. If adequate funds are not available, we will not be able to successfully execute our business plan or continue our business.

Cash Flows

The following is a summary of cash flows for three months ended March 31, 2024 and 2023 (in thousands):

	Three Months Ended March 31,	
	2024	2023
Net cash used in operating activities	\$ (7,789)	\$ (9,212)
Net cash used in investing activities	(28,563)	(3,284)
Net cash provided by financing activities	29,281	1,352
Net decrease in cash, cash equivalents and restricted cash	\$ (7,071)	\$ (11,144)

Cash Flows from Operating Activities

The \$1.4 million decrease in net cash used in operations for the three months ended March 31, 2024 as compared to the same period in 2023 was primarily due to the net effect of decreases in cash paid for operating expenses, primarily driven by the restructuring of our business in 2023 which included the assignment of our San Carlos facility lease in the fourth quarter of 2023, and changes in operating assets and liabilities.

Cash Flows from Investing Activities

The \$25.3 million increase in net cash used in investing activities for the three months ended March 31, 2024 as compared to the same period in 2023, was primarily due to higher cash utilized for purchase of short-term investments.

Cash Flows from Financing Activities

The \$27.9 million increase in net cash provided by financing activities for the three months ended March 31, 2024 as compared to the same period in 2023 was primarily due to proceeds from the Innovatus Loan in February 2024.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make judgments, estimates and assumptions in the preparation of our consolidated financial statements and accompanying notes. Actual results could differ from those estimates. There have been no material changes to our critical accounting policies or estimates during the three months ended March 31, 2024 from those discussed in our Annual Report.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market Risk Management

Our cash flows and earnings are subject to fluctuations due to changes in foreign currency exchange rates, interest rates and other factors. These market risk exposures are disclosed in Part II, Item 7A of our Annual Report.

Interest Rate Sensitivity

Our unrestricted cash, cash equivalents, and short-term investments in marketable securities total \$85.5 million as of March 31, 2024. We primarily invest these amounts in money market funds and short-term debt which are held for working capital purposes. We do not enter into investments for trading or speculative purposes. As of March 31, 2024, the effect of a hypothetical 10% decrease in market interest rates would have a \$0.4 million impact on a potential loss in future interest income and cash flows.

We are also exposed to market risk from changes in interest rates as a result of our indebtedness under the Innovatus Loan. At March 31, 2024, we had \$30.0 million principal amount outstanding under the Innovatus Loan. The floating per annum interest rate of the Innovatus Loan is equal to the sum of (a) the greater of (i) prime rate published in the Money Rates section of the Wall Street Journal and (ii) 7.50%, plus (b) 3.25%; provided that, at the election of the Company, up to 2.00% of such rate shall be payable in-kind until the third anniversary of the closing date. An immediate 10% change in the prime interest rate would result in a \$0.3 million impact on our results of operations over the next twelve months from March 31, 2024.

Foreign Currency Risk

Our results of operations and cash flows are subject to fluctuations due to changes in foreign currency exchange rates. In periods when the United States dollar ("USD") declines in value as compared to the foreign currencies in which we incur expenses, our foreign-currency based expenses increase when translated into USD. Although substantially all of our sales are denominated in USD, future fluctuations in the value of the USD may affect the price competitiveness of our products outside the United States. Our most significant foreign currency exposure is due to non-functional currency denominated monetary assets, primarily currencies denominated in other than their functional currency. These non-functional currency denominated monetary assets are subject to re-measurement which may create fluctuations in other expense, net, a component in our consolidated statement of operations and in the fair value of the assets in the consolidated balance sheets. As of March 31, 2024, the effect of a hypothetical 10% unfavorable change in exchange rates on currencies denominated in other than their functional currency would result in a potential loss in future earnings in our consolidated statement of operations and a reduction in the fair value of the assets of approximately \$41 thousand.

Investment in Non-Marketable Equity Securities

We own investments in non-marketable equity securities without readily determinable fair values. We may value these equity securities based on significant recent arms-length equity transactions with sophisticated non-strategic unrelated investors, providing the terms of these security transactions are substantially similar to the security transactions terms between the investors and us. The impact of the difference in transaction terms on the market value of the portfolio company may be difficult or impossible to quantify.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures and internal controls that are designed to provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, under the supervision of our Chief Executive Officer and Chief Financial Officer and with the participation of our disclosure committee, evaluated the effectiveness of our disclosure controls and procedures as defined by Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Based on this review, our Chief Executive Officer and Chief Financial Officer concluded that these disclosure controls and procedures were effective as of March 31, 2024 at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rules 13a-15 or 15d-15 that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. There were no significant changes to our internal control over financial reporting due to the adoption of new standards.

Inherent Limitations on Effectiveness of Controls

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, even if determined effective and no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives to prevent or detect misstatements. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PART II. OTHER INFORMATION

LEGAL PROCEEDINGS

ITEM 1.

We are not currently a party to any material pending litigation or other material legal proceedings.

ITEM 1A.

RISK FACTORS

You should carefully consider the risks described below together with the other information set forth in this Quarterly Report, which could materially affect our business, financial condition or future results. The risks described below are not the only risks facing our company. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. Additional discussion of the material risks and uncertainties summarized in this risk factor summary, as well as certain other risks and uncertainties that we face, can be found in this section.

RISK FACTORS SUMMARY

The following is a summary of the principal factors that cause an investment in the Company to be speculative or risky:

- We have a history of net losses and we may not achieve or maintain profitability.
- Biotherapeutic programs are highly regulated and expensive.
- We are dependent on a limited number of customers.
- Our product supply agreements with customers have finite duration and may not be extended or renewed.
- The demand for our product depends in part on our customers' research and development and the clinical and market success of their products.
- With respect to customers purchasing our products for the manufacture of API, the termination or expiration of such patent protection may materially and adversely affect our revenues, financial condition or results of operations.
- We are dependent on a limited number of contract manufacturers for large scale production of substantially all of our enzymes.
- We are dependent on our collaborators, and our failure to successfully manage these relationships could prevent us from developing and commercializing many of our products.
- If we are unable to develop and commercialize new products for the target markets, our business and prospects will be harmed.
- We have invested significant resources to enable fully enzymatic nucleic acid synthesis, which is based on novel ideas and technologies that are largely unproven.
- Future revenues from our sales of CDX-616 to Pfizer are subject to a number of factors which are outside of our control and may not materialize.
- Ethical, legal and social concerns about genetically engineered products and processes could limit or prevent the use of our products, processes, and technologies and limit our revenues.
- We have recently enhanced our strategic focus to concentrate on certain programs and business lines. As a result of this refined focus on returning the foundational, revenue-generating pharmaceutical manufacturing business and the ECO Synthesis™ manufacturing platform, we may fail to capitalize on other opportunities that may be more profitable or for which there is a greater likelihood of success.
- Given our recent change in strategic direction, we may receive limited revenue or no future value from certain of our existing license agreements.
- We use hazardous materials in our business, and we must comply with environmental laws and regulations.

- As a public reporting company, we are subject to rules and regulations established from time to time by the SEC and Nasdaq regarding our internal controls over financial reporting. We may not complete needed improvements to our internal controls over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our common stock and your investment.
- We may need additional capital in the future in order to expand our business.
- We may not be able to comply with the terms of our five-year loan and security agreement (our“Loan Agreement”) with Innovatus Life Sciences Lending Fund, I, LP, an affiliate of Innovatus Capital Partners (“Innovatus”).
- Our ongoing efforts to deploy our technology in the life science tools market may fail.
- Even if our customers or collaborators obtain regulatory approval for any products utilizing our enzymes, such products will remain subject to ongoing regulatory requirements, which may result in significant additional expense.
- If we or our customers fail to comply with certain healthcare laws, including fraud and abuse laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.
- Our efforts to prosecute, maintain, protect and/or defend our intellectual property rights may not be successful.
- Our ability to compete may decline if we do not adequately prosecute, maintain, protect and/or defend our proprietary technology, products or services or our intellectual property rights.
- Third parties may claim that we are infringing, violating or misappropriating their intellectual property rights, which may subject us to costly and time-consuming litigation and prevent us from developing or commercializing our technology, products or services.
- We may be involved in lawsuits to protect or enforce our intellectual property rights, which could be expensive, time-consuming and unsuccessful.
- We may not be able to enforce our intellectual property rights throughout the world.
- If our biocatalysts are stolen, misappropriated or reverse engineered, others could use these biocatalysts to produce competing products.
- We are subject to anti-takeover provisions in our certificate of incorporation and bylaws and under Delaware law that could delay or prevent an acquisition of our company.
- Market and economic conditions may negatively impact our business, financial condition, and share price.
- Business interruptions resulting from disasters or other disturbances could delay us in the process of developing our products and could disrupt our sales.
- Evolving expectations around environmental, social and governance matters may expose us to reputational and other risks.

Risks Related to Our Business and Strategy

We have a history of net losses and we may not achieve or maintain profitability.

We have incurred net losses since our inception, including losses of \$76.2 million, \$33.6 million, and \$21.3 million for the years ended December 31, 2023, 2022, and 2021, respectively, and \$11.5 million and \$22.6 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024 and December 31, 2023, we had an accumulated deficit of \$509.0 million and \$497.5 million, respectively. If we are unable to continue to successfully develop and commercialize products in our pharmaceutical manufacturing business, increase sales of existing products and services, develop and commercialize our ECO Synthesis™ manufacturing platform, and/or develop new products or services, or otherwise expand our business, whether through new or expanded collaborations or other products and services, our net losses may increase and we may never achieve profitability. In addition, some of our agreements, including the agreements with GSK, Merck, Novartis, Nestlé Health Science, Aldevron and Roche provide for milestone payments, usage payments, and/or future royalty or other payments, which we will only receive if we and/or our collaborators develop and commercialize products or achieve technical milestones. We also intend to continue to fund the development of additional proprietary performance enzyme products and advance new technologies like our ECO Synthesis™ manufacturing platform. There can be no assurance that any of these products or services will become commercially viable or that we will ever achieve profitability on a quarterly or annual basis. If we fail to achieve profitability, or if the time required to achieve profitability is longer than we anticipate, we may not be able to continue our business. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Biotherapeutic programs are highly regulated and expensive, and our enzyme products are complex and subject to quality control requirements. The ability of our customers, future customers or collaborators, including any company developing RNAi therapeutics, to advance product candidates utilizing our products to clinical trials and to ultimately receive regulatory approvals is highly uncertain.

Although we are no longer developing our own portfolio of biotherapeutics product candidates, we continue to develop enzyme products, including our ECO Synthesis™ manufacturing platform, that may be used by our customers, future customers or collaborators in connection with their biotherapeutic product candidates. The successful development of biotherapeutic candidates involves many risks and uncertainties, requires long timelines and may lead to uncertain results.

Our customers are subject to extensive regulations by the FDA and similar regulatory authorities in other countries for conducting clinical trials and commercializing products for therapeutic, vaccine or diagnostic use. These regulations result in our customers imposing quality requirements on us for the manufacture of our enzyme products through supplier qualification processes and customer contracts and specifications

In order to market a biologic or drug product in the United States, our customers, future customers or collaborators must undergo the following process required by the FDA:

- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice requirements;
- submission to the FDA of an Investigational New Drug Application ("IND"), which must become effective before human clinical studies may begin in the United States;
- approval by an independent institutional review board ("IRB") representing each clinical site before the clinical study may be initiated at the site;
- performance of adequate and well-controlled human clinical studies in accordance with Good Clinical Practice ("GCP") requirements to establish the safety, purity and potency (or efficacy) of the product candidate for each proposed indication;
- preparation of and submission to the FDA of a Biologics License Application ("BLA") or New Drug Application ("NDA") after completion of all clinical studies;
- potential review of the product candidate by an FDA advisory committee;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities where the product candidate is produced to assess compliance with current Good Manufacturing Practice ("cGMP") requirements;
- FDA review and approval of a BLA or NDA prior to any commercial marketing or sale of the product in the United States; and

- any post-approval requirements, if applicable.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and the results are inherently unpredictable. If our customers, future customers or collaborators are ultimately unable to obtain regulatory approval for their biotherapeutic product candidates utilizing our enzyme products, our business may be harmed. In addition, if our customers, future customers or collaborators fail to comply with applicable FDA or other regulatory requirements at any time during the drug development process, clinical testing, the approval process or after approval, they may become subject to administrative or judicial penalties, including the FDA's refusal to approve a pending application, withdrawal of an approval, warning letters, product recalls and additional enforcement actions, any of which may have an adverse effect on our financial condition.

We believe our enzyme products are exempt from compliance with the Food, Drug, and Cosmetic Act ("FDCA") and the current GMP ("cGMP") regulations of the FDA, as our products are further processed and incorporated into final drug or biologic products by our customers and we do not make claims related to their safety or effectiveness. Our products are manufactured following the voluntary quality standards of ISO 9001:2015. In the event we, or our suppliers, produce products that fail to comply with required quality standards, we may incur delays in fulfilling orders, write-downs, damages resulting from product liability claims and harm to our reputation.

In the future, our products could become subject to more onerous regulation, or the FDA could disagree with our assessment that our enzyme products are exempt from current GMP regulations. In addition, the FDA could conclude that the products we provide to our customers are actually subject to the pharmaceutical, drug or biologic quality-related regulations for manufacturing, processing, packing or holding of drugs, biologics, or finished pharmaceuticals, and could take enforcement action against us, including requiring us to stop distribution of our products until we are in compliance with applicable regulations, which would reduce our revenue, increase our costs and adversely affect our business, prospects, results of operations and financial condition.

We are dependent on a limited number of customers.

Although we continue to expand our customer base, our current revenues are derived from a limited number of key customers. For the three months ended March 31, 2024 and 2023, customers that each individually contributed 10% or more of our total revenue accounted for 60% and 60% of our total revenues, respectively. We expect a limited number of customers to continue to account for a significant portion of our revenues for the foreseeable future. This customer concentration increases the risk of quarterly fluctuations in our revenues and operating results. The loss or reduction of business from one or a combination of our significant customers could, materially adversely affect our revenues, financial condition and results of operations.

Our product supply agreements with customers have finite duration, may not be extended or renewed and generally do not require the customer to purchase any particular quantity or quantities of our products.

Our product supply agreements with customers generally have a finite duration, may not be extended or renewed and generally do not require the customer to purchase any particular quantity or quantities of our products. While our products are not considered commodities and may not be easily substituted for by our customers, particularly when our products are used in the manufacture of active pharmaceutical ingredients, our customers may nevertheless terminate or fail to renew their product supply agreements with us or significantly curtail their purchases thereunder under certain circumstances. We are working to develop new relationships with existing or new customers, but despite these efforts we may not, at the time that any of our existing product supply agreements expire or are terminated, or purchases thereunder curtailed, have other contracts in place generating similar or material revenue. Any such expiration, termination or reduction could materially adversely affect our revenues, financial condition and results of operations. For the three months ended March 31, 2024, we derived a majority of our product revenue from these product supply agreements.

The demand for our products depends in part on our customers' research and development and the clinical and market success of their products. Our business, financial condition, and results of operations may be harmed if our customers spend less on, or are less successful in, these activities. In addition, customer spending may be affected by, among other things, general market and economic conditions beyond our control.

Our customers are engaged in research, development, production, and marketing of pharmaceutical products and intermediates. The amount our customers spend on research, development, production, and marketing, as well as the outcomes of such research, development, and marketing activities, have a large impact on our sales and profitability, particularly the amount our customers choose to spend on our offerings. Available resources, the need to develop new products, and consolidation in the industries in which our customers operate may have an impact on such spending. Our customers and potential customers finance their research and development spending from private and public sources. A reduction in available financing for and spending by our customers, for these reasons or because of continued unstable or unpredictable economic and marketplace conditions, could have a material adverse effect on our business, financial condition, and results of operations. If our customers are not successful in attaining or retaining product sales due to market conditions, reimbursement issues, or other factors, our results of operations may be materially adversely affected.

With respect to customers purchasing our products for the manufacture of APIs for which they have exclusivity due to patent protection, the termination or expiration of such patent protection and any resulting generic competition may materially and adversely affect our revenues, financial condition or results of operations.

With respect to customers purchasing our products for the manufacture of API, or lead to the manufacture of API, for which exclusivity due to patent protection has or is about to expire, we can expect that the quantity of our products sold to such customers for such products may decline as generic competition for the API increases. While we anticipate that we may, in some cases, also be able to sell products to these generic competitors for the manufacture of these APIs, or lead to the manufacture of these APIs, the overall effect on our revenues, financial condition and results of operations could be materially adverse.

We are dependent on a limited number of contract manufacturers for large scale production of substantially all of our enzymes. We are working to qualify new contract manufacturers to produce certain of our enzymes, however those efforts may not be successful and therefore we may experience limitations on our ability to supply our enzymes to customers.

Manufacturing of our enzymes is conducted primarily in four locations: our in-house facility in Redwood City, California, and at three third-party contract manufacturing organizations, Lactosan in Kapfenberg, Austria, ACSD in Anagni, Italy, Alphazyme in Jupiter, Florida, and Sekisui in Maidstone, United Kingdom. Generally, we perform smaller scale manufacturing in-house and outsource the larger scale manufacturing to these contract manufacturers. We have limited internal capacity to manufacture enzymes. As a result, we are dependent upon the performance and capacity of third-party manufacturers for the larger scale manufacturing of the enzymes used in our pharmaceutical and life sciences businesses.

Accordingly, we face risks of difficulties with, and interruptions in, performance by third party manufacturers, the occurrence of which could adversely impact the availability, launch and/or sales of our enzymes in the future. Enzyme manufacturing capacity limitations at our third-party manufacturers and manufacturing delays could negatively affect our business, reputation, results of operations and financial condition. The failure of any contract manufacturer to supply us our required volumes of enzyme on a timely basis, or to manufacture our enzymes in compliance with our specifications or applicable quality requirements or in volumes sufficient to meet demand, would adversely affect our ability to sell pharmaceutical and complex chemicals products, could harm our relationships with our customers or collaborators and could negatively affect our revenues and operating results. We may be forced to secure alternative sources of supply, which may be unavailable on commercially acceptable terms, and could cause delays in our ability to deliver products to our customers, increase our costs and decrease our profit margins.

We currently have supply agreements in place with Lactosan, ACSD and Alphazyme. In the absence of a supply agreement, a contract manufacturer will be under no obligation to manufacture our enzymes and could elect to discontinue their manufacture at any time. If we require additional manufacturing capacity and are unable to obtain it in sufficient quantity, we may not be able to increase our product sales, or we may be required to make substantial capital investments to build that capacity or to contract with other manufacturers on terms that may be less favorable than the terms we currently have with our suppliers. If we choose to build our own additional manufacturing facility, it could take several years or longer before our facility is able to produce commercial volumes of our enzymes. Any resources we expend on acquiring or building internal manufacturing capabilities could be at the expense of other potentially more profitable opportunities. In addition, if we contract with other manufacturers, we may experience delays of several months in qualifying them, which could harm our relationships with our customers or collaborators and could negatively affect our revenues or operating results.

We are dependent on our collaborators, and our failure to successfully manage these relationships could prevent us from developing and commercializing many of our products and achieving or sustaining profitability, and could lead to disagreements with our current or former collaborators.

Our ability to maintain and manage collaborations in our markets is fundamental to the success of our business. We currently have license agreements, research and development agreements, supply agreements and/or distribution agreements with various collaborators. For example, we have ongoing collaborations and agreements with GSK, Merck, Novartis, Roche and Aldevron that are important to our business and financial results. We may have limited or no control over the amount or timing of resources that any collaborator is able or willing to devote to our partnered products or collaborative efforts. Any of our collaborators may fail to perform its obligations. These collaborators may breach or terminate their agreements with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner. Further, our collaborators may not develop products arising out of our collaborative arrangements or devote sufficient resources to the development, manufacture, marketing or sale of these products. Moreover, disagreements with a collaborator could develop, and any conflict with a collaborator could lead to litigation, reduce our ability to enter into future collaboration agreements and negatively impact our relationships with one or more existing collaborators. If any of these events occur, especially if they occur in our collaborations with GSK, Merck or Novartis, or if we fail to maintain our agreements with our collaborators, we may not be able to commercialize our existing and potential products or grow our business or generate sufficient revenues to support our operations, we may not receive contemplated milestone payments and royalties under the collaboration, and we may be involved in litigation. Our collaboration opportunities could be harmed and our financial condition and results of operations could be negatively affected if:

- we do not achieve our research and development objectives under our collaboration agreements in a timely manner or at all;
- we develop products and processes or enter into additional collaborations that conflict with the business objectives of our other collaborators;
- our collaborators and/or our contract manufacturers do not receive the required regulatory and other approvals necessary for the commercialization of the applicable product;
- we disagree with our collaborators as to rights to intellectual property that are developed during the collaboration, or their research programs or commercialization activities;
- we are unable to manage multiple simultaneous collaborations;
- our collaborators or licensees are unable or unwilling to implement or use the technology or products that we provide or license to them;
- our collaborators become competitors of ours or enter into agreements with our competitors;
- our collaborators become unable or less willing to expend their resources on research and development or commercialization efforts due to general market conditions, their financial condition or other circumstances beyond our control; or
- our collaborators experience business difficulties, which could eliminate or impair their ability to effectively perform under our agreements.

Takeda recently confirmed that it will end research, discovery and preclinical work in certain rare disease areas that may overlap with the programs on which we collaborate under the Strategic Collaboration and License Agreement (the “Takeda Agreement”) we entered into with Shire Human Genetic Therapies, Inc., a wholly-owned subsidiary of Takeda, in March 2020. Takeda announced in April 2023 the discontinuance of these development programs.

Even after collaboration relationships expire or terminate, some elements of the collaboration may survive. For instance, certain rights, licenses and obligations of each party with respect to intellectual property and program materials may survive the expiration or termination of the collaboration. Disagreements or conflicts between and among the parties could develop even though the collaboration has ended. These disagreements or conflicts could result in expensive arbitration or litigation, which may not be resolved in our favor.

Finally, our business could be negatively affected if any of our collaborators or suppliers undergoes a change of control or were to otherwise assign the rights or obligations under any of our agreements.

If we are unable to develop and commercialize new products for the pharmaceutical, biotherapeutics, diagnostics and life science tools markets, our business and prospects will be harmed.

We plan to launch new products for the pharmaceutical, biotherapeutics, diagnostics and other life science tools markets such as our ECO Synthesis™ manufacturing platform. These efforts are subject to numerous risks, including the following:

- customers in these markets may be reluctant to adopt new manufacturing processes that use our enzymes;
- we may be unable to successfully develop the enzymes or manufacturing processes for our products in a timely and cost-effective manner, if at all;
- we may face difficulties in transferring the developed technologies to our customers and the contract manufacturers that we may use for commercial scale production of intermediates and enzymes in these markets;
- the biotherapeutics products that use our tools may not receive regulatory approval or be commercially viable;
- the contract manufacturers that we may use may be unable to scale their manufacturing operations to meet the demand for these products and we may be unable to secure additional manufacturing capacity;
- customers may not be willing to purchase these products for these markets from us on favorable terms, if at all;
- we may face product liability litigation, unexpected safety or efficacy concerns and product recalls or withdrawals;
- our customers' products may experience adverse events or face competition from new products, which would reduce demand for our products;
- we may face pressure from existing or new competitive products; and
- we may face pricing pressures from existing or new competitors, some of which may benefit from government subsidies or other incentives.

We have invested significant resources to enable fully enzymatic nucleic acid synthesis, which is based on novel ideas and technologies that are largely unproven.

Our ECO Synthesis™ manufacturing platform is currently in development to enable the commercial-scale manufacture of RNAi therapeutics through an enzymatic route. While we believe fully enzymatic nucleic acid synthesis will offer certain improvements over phosphoramidite chemistry, including with respect to required infrastructure investments, batch size limitations and waste disposal challenges, the enzymatic route is novel and has not yet been commercialized. As such, we may be faced with unforeseen results, delays and setbacks, in addition to the other foreseeable risks and uncertainties associated with the ongoing development of the ECO Synthesis™ manufacturing platform and other products.

Other challenges with a new technology such as our ECO Synthesis™ manufacturing platform include having an unknown and unproven regulatory path, uncertainty around the value that we can realize from the technology, uncertainty around the timeline for adoption of the technology by customers, and uncertainty around our ability to manufacture and partner with customers on manufacturing and utilizing the technology.

There can be no assurance that these events we may experience in the future related to enzymatic synthesis will not cause significant delays or unanticipated costs, or that such development problems can be solved. Any delay or difficulties in developing and commercializing our ECO Synthesis™ manufacturing platform or any of our other current or future products could adversely affect our business and operations.

Competitors and potential competitors who have greater resources and experience than we do may develop products and technologies that make ours obsolete or may use their greater resources to gain market share at our expense.

The biocatalysis and performance enzyme industries and each of our target markets are characterized by rapid technological change. Our future success will depend on our ability to maintain a competitive position with respect to technological advances. In addition, as we enter new markets, we will face new competition and will need to adapt to competitive factors that may be different from those we face today.

We are aware that other companies, including DSM, BASF, Bayer and Novozymes have alternative methods for obtaining and generating genetic diversity or use mutagenesis techniques to produce genetic diversity. Academic institutions such as the California Institute of Technology, the Max Planck Institute and the Austrian Centre of Industrial Biotechnology are also working in this field. Technological development by others may result in our technology, products and services, as well as products developed by our customers using our biocatalysts, becoming obsolete.

Our primary competitors in the performance enzymes for the pharmaceutical products markets include (i) companies marketing either conventional, non-enzymatic processes or biocatalytic enzymes; (ii) manufacturers of pharmaceutical intermediates and APIs; and (iii) existing in-house technologies (both biocatalysts and conventional catalysts) within our client and potential client companies. The principal methods of competition and competitive differentiation in this market are price, product quality and performance, including manufacturing yield, safety and environmental benefits, and speed of delivery of product. Pharmaceutical manufacturers that use biocatalytic processes can face increased competition from manufacturers that use more conventional processes and/or manufacturers that are based in regions (such as India and China) with lower regulatory, safety and environmental costs.

The market for the manufacture and supply of APIs and intermediates is large with many established companies. These companies include many of our large innovator and generic pharmaceutical customers, such as Merck, GSK, Novartis, Pfizer, Bristol-Myers, Kyorin, Urovant, and Teva which have significant internal research and development efforts directed at developing processes to manufacture APIs and intermediates. The processes used by these companies include classical conventional organic chemistry reactions, chemo catalytic reactions, biocatalytic reactions or combinations thereof. Our biocatalytic based manufacturing processes must compete with these internally developed routes. Additionally, we also face competition from companies developing and marketing conventional catalysts such as Solvias Inc., BASF and Takasago International Corporation.

The market for supplying enzymes for use in pharmaceutical manufacturing is quite fragmented. There is competition from large industrial enzyme companies, such as Novozymes and DuPont, as well as subsidiaries of larger contract research/contract manufacturing organizations, such as DSM, Cambrex Corporation, Lonza, WuXi STA and Almac Group Ltd. Some fermentation pathway design companies, like Ginkgo Bioworks (who recently acquired Zymergen), whose traditional focus has been to design microorganisms that express small molecule chemicals, could extend into designing organisms that express enzymes. There is also competition in the enzyme customization and optimization area from several smaller companies, such as BRAIN AG, Arzeda, c-LEcta GmbH and Evocatol GmbH.

We face competitive challenges related to our ECO Synthesis™ manufacturing platform. Phosphoramidite chemistry is the current and long-established industry standard for the manufacture of RNA therapeutics. Primary competitors in this space include CDMOs, such as Agilent Technologies, which has made significant capital investment to expand their RNA manufacturing capabilities using phosphoramidite chemistry. In addition, CDMOs and large pharmaceutical companies are seeking to make incremental improvements to phosphoramidite chemistry, including the development of ligation-based approaches, liquid-phase synthesis, and solvent recycling. There are also multiple early-stage competitors who are pursuing fully enzymatic approaches to the manufacture of RNA, including EnPlusOne, a private startup company, and a UK-based consortium led by CPI and consisting of multiple academic and research organizations, including The University of Manchester and large pharmaceutical companies, including AstraZeneca plc and Novartis.

Our ability to compete successfully in any of these markets will depend on our ability to develop proprietary products that reach the market in a timely manner and are technologically superior to and/or are less expensive than other products on the market. Many of our competitors have substantially greater production, financial, research and development, personnel and marketing resources than we do. They also started developing products earlier than we did, which may allow them to establish blocking intellectual property positions or bring products to market before we can. In addition, certain of our competitors may also benefit from local government subsidies and other incentives that are not available to us. As a result, our competitors may be able to develop competing and/or superior technologies and processes and compete more aggressively and sustain that competition over a longer period of time than we could. Our technologies and products may be rendered obsolete or uneconomical by technological advances or entirely different approaches developed by one or more of our competitors. We cannot be certain that any products we develop in the future will compare favorably to products offered by our competitors or that our existing or future products will compare favorably to any new products that are developed by our competitors. As more companies develop new intellectual property in our markets, the possibility of a competitor acquiring patent or other rights that may limit our products or potential products increases, and could additionally lead to litigation.

Our limited resources relative to many of our competitors may cause us to fail to anticipate or respond adequately to new developments and other competitive pressures. This failure could reduce our competitiveness and market share, adversely affect our results of operations and financial position, and prevent us from obtaining or maintaining profitability.

Revenues in future years from our sales of CDX-616 to Pfizer are subject to a number of factors which are outside of our control and may not materialize.

Starting the first and second quarters of 2021, we began to receive purchase orders from Pfizer for large quantities of our proprietary enzyme product, CDX-616, for use by Pfizer in the manufacture of a critical intermediate for its proprietary active pharmaceutical ingredient, nirmatrelvir. Pfizer markets, sells and distributes nirmatrelvir, in combination with the active pharmaceutical ingredient ritonavir, as its PAXLOVID™ (nirmatrelvir tablets; ritonavir tablets) product, which received FDA approval in May 2023 for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death.

Potential revenues in future years from our sales of CDX-616 to Pfizer and other potential customers (including sublicensees of Pfizer technology from The Medicines Patent Pool (the “MPP”)) are subject to a number of factors which are outside of our control, including, without limitation, the following, all of which could reduce or eliminate our sales of CDX-616, and therefore materially and adversely affect our business, results of operations and financial condition:

- Pfizer has no future binding commitment to purchase any particular quantity or quantities of CDX-616 from us, and we are dependent upon Pfizer continuing to place orders with us (whether on a spot basis or under a long-term agreement, when and if executed) for their requirements, if any, for CDX-616;
- to our knowledge, sublicensees of Pfizer technology from the MPP have no obligation to purchase CDX-616 from us under their sublicenses with the MPP;
- future vaccine development and usage and the development and usage of other new therapies for the treatment or elimination of COVID-19 may eliminate or reduce demand for PAXLOVID™;
- new variants of COVID-19 may emerge which PAXLOVID™ is not effective in treating;
- Pfizer could reformulate or make changes in the manufacturing process for nirmatrelvir which would eliminate or reduce demand for the use of CDX-616 in its manufacture;
- sublicensees of Pfizer technology for the manufacture, sale and distribution of PAXLOVID™ from the MPP may not utilize CDX-616 in the manufacture of nirmatrelvir;
- national and regional governmental authorities (including those of the United States government) may mandate that raw materials and intermediates used in the manufacture of PAXLOVID™ to be marketed, sold and distributed within the borders of that country be domestically produced, which could eliminate or reduce demand for the use of CDX-616 in such country; and
- we may be unable (because of lack of available manufacturing capacity at our contract manufacturers, supply chain disruptions or an inability to obtain applicable regulatory approvals) to manufacture the quantities of CDX-616 that Pfizer may desire to purchase from us.

We have investments in non-marketable securities, which may subject us to significant impairment charges.

We have investments in illiquid or non-marketable equity securities acquired in private transactions. As of March 31, 2024, 6.5% of our consolidated assets consisted of investment securities, which are illiquid investments. Investments in non-marketable, securities are inherently risky and difficult to value. We account for our non-marketable equity securities under the measurement alternative. Under the measurement alternative, the carrying value of our non-marketable equity investments is adjusted to fair value for observable transactions for identical or similar investments of the same issuer or impairment. We evaluate our investment in non-marketable securities when circumstances indicate that we may not be able to recover the carrying value. We may impair these securities and establish an allowance for a credit loss when we determine that there has been an “other-than-temporary” decline in estimated fair value of the equity security compared to its carrying value. The impairment analysis requires significant judgment to identify events or circumstances that would likely have a material adverse effect on the fair value of the investment. Because over 5% of our total assets consisted of non-marketable investment securities, any future impairment charges from the write down in value of these securities could have a material adverse effect on our financial condition or results of operations.

Ethical, legal and social concerns about genetically engineered products and processes could limit or prevent the use of our technology, products and processes and limit our revenues.

Some of our technology, products and services, such as our ECO Synthesis™ manufacturing platform, are genetically engineered or involve the use of genetically engineered products or genetic engineering technologies. If we and/or our collaborators are not able to overcome the ethical, legal, and social concerns relating to genetic engineering, our technology, products and services may not be accepted. Any of the risks discussed below could result in increased expenses, delays, or other impediments to our programs or the public acceptance and commercialization of products and processes dependent on our technologies or inventions. Our ability to develop and commercialize one or more of our technologies, products, or processes could be limited by the following factors:

- public attitudes about the safety and environmental hazards of, and ethical concerns over, genetic research and genetically engineered products and processes, which could influence public acceptance of our technologies, products and processes;
- public attitudes regarding, and potential changes to laws governing ownership of, genetic material, which could harm our intellectual property rights with respect to our genetic material and/or discourage collaborators from supporting, developing, or commercializing our technology, products and services; and
- governmental reaction to negative publicity concerning genetically modified organisms, which could result in greater government regulation of genetic research and derivative products.

The subject of genetically modified organisms has received negative publicity, which has aroused public debate. This adverse publicity could lead to greater regulation and trade restrictions on imports of genetically altered products. The biocatalysts that we develop have significantly enhanced characteristics compared to those found in naturally occurring enzymes or microbes. While we produce our biocatalysts only for use in a controlled industrial environment, the release of such biocatalysts into uncontrolled environments could have unintended consequences. Any adverse effect resulting from such a release could have a material adverse effect on our business and financial condition, damage our reputation, and/or expose us to liability for any resulting harm.

We have recently enhanced our strategic focus to concentrate on certain programs and business lines. As a result of this refined focus, we may fail to capitalize on other opportunities that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we have recently focused our efforts on developing certain programs and business lines. As a result, we may forego or delay pursuit of business opportunities that later prove to have greater commercial potential. Further our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. In addition, our spending on current and future research and development programs, such as ECO Synthesis™ manufacturing platform that is in development, may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular program or business line, our business and results of operations could be harmed.

Given our recent change in strategic direction, we may receive limited revenue or no future value from certain of our existing license agreements

While we have historically invested significant time and financial resources in the development of biotherapeutics assets, including candidates for the treatment of Fabry disease and Pompe disease, which are included in the Takeda Agreement, in July 2023, we announced we are terminating investment in our biotherapeutics business and in other programs. As a result, we are renegotiating some of these, along with other license agreements for product candidates in our biotherapeutics, food and feed, and non-core life science assets. For example, we entered into the Acquisition Agreement with Nestlé under which they acquired rights to our co-developed lipase enzyme CDX-7108 and we received an upfront payment and the right to downstream milestones and royalties, terminating our prior SCA and development agreement with Nestlé. While we are working to amend or terminate some of our agreements and enter into new agreements in such a way that we may be able to receive future revenue or other benefits, we may be unsuccessful in doing so. As a result, it remains uncertain as to whether we will receive any value or benefit from these license agreements going forward. Further, renegotiating these agreements may be costly and could divert management attention, which could have an adverse impact on our business and results of operations.

Our ongoing efforts to deploy our technology in the life science tools markets may fail.

We have used our CodeEvolver[®] directed evolution technology platform to develop new products for customers using NGS and PCR/qPCR *for in vitro* molecular diagnostic applications. While we have entered into license agreements for products in this market, we do not know if we can successfully compete in this new market. This new market is well established and consists of numerous large, well-funded entrenched market participants who have long and established track records and customer relationships.

We have also developed a newly engineered ligase designed to address sequencing challenges. These enzymes, and any additional products that we may develop in the future for this market, may not succeed in displacing current products. If we succeed in commercializing new products for this market, we may not generate significant revenues and cash flows from these activities. The failure to successfully deploy products on a timely basis in this space may limit our growth and have a material adverse effect on our financial condition, operating results and business prospects.

We use hazardous materials in our business and we must comply with environmental laws and regulations. Any claims relating to improper handling, storage or disposal of these materials or noncompliance of applicable laws and regulations could be time consuming and costly and could adversely affect our business and results of operations.

Our research and development and commercial processes involve the use of hazardous materials, including chemical, radioactive and biological materials. Our operations also produce hazardous waste. We cannot eliminate entirely the risk of accidental contamination or discharge and any resultant injury from these materials. Federal, state, local and foreign laws and regulations govern the use, manufacture, storage, handling and disposal of, and human exposure to, these materials. We may face liability for any injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed our total assets. Although we believe that our activities comply in all material respects with environmental laws, there can be no assurance that violations of environmental, health and safety laws will not occur in the future as a result of human error, accident, equipment failure or other causes. Compliance with applicable environmental laws and regulations may be expensive, and the failure to comply with past, present or future laws could result in the imposition of fines, third party property damage, product liability and personal injury claims, investigation and remediation costs, the suspension of production or a cessation of operations, and our liability may exceed our total assets. Liability under environmental laws can be joint and several and without regard to comparative fault. Environmental laws could become more stringent over time imposing greater compliance costs and increasing risks and penalties associated with violations, which could impair our research, development or production efforts and harm our business. In addition, we may be required to indemnify some of our customers or suppliers for losses related to our failure to comply with environmental laws, which could expose us to significant liabilities.

Our ability to use our net operating loss carryforwards to offset future taxable income may be subject to certain limitations.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating loss carryforwards ("NOLs"), to offset future taxable income. If the Internal Revenue Service challenges our analysis that our existing NOLs are not subject to limitations arising from previous ownership changes, our ability to utilize NOLs could be limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code. Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. For these reasons, we may not be able to utilize a material portion of the NOLs reflected in our financial statements, even if we attain profitability.

As a public reporting company, we are subject to rules and regulations established from time to time by the SEC and Nasdaq regarding our internal controls over financial reporting. We may not complete needed improvements to our internal controls over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our common stock and your investment.

We are subject to the rules and regulations established from time to time by the SEC and Nasdaq. These rules regulations require, among other things, that we establish and periodically evaluate procedures with respect to our internal controls over financial reporting. As part of these evaluations, material weaknesses in our internal controls over financial reporting may be identified. A material weakness is a deficiency, or a combination of deficiencies, in internal controls over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim consolidated financial statements will not be prevented or detected on a timely basis. While we were able to remediate previously identified material weaknesses in our internal controls over financial reporting, there can be no guarantee we will not identify similar or other material weaknesses in the future and if such material weaknesses are identified, there can be no guarantee we would be able to remediate such material weaknesses. Any material weaknesses in our internal controls may adversely affect our ability to record, process, summarize and accurately report timely financial information and, as a result, our consolidated financial statements may contain material misstatements or omissions.

Reporting obligations as a public company place a considerable strain on our financial and management systems, processes and controls, as well as on our personnel. In addition, as a public company we are required to document and test our internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act so that our management can certify as to the effectiveness of our internal controls over financial reporting. Likewise, our independent registered public accounting firm is required to provide an attestation report on the effectiveness of our internal controls over financial reporting in our Annual Reports on Form 10-K. If our management is unable to certify the effectiveness of our internal controls or if our independent registered public accounting firm cannot deliver a report attesting to the effectiveness of our internal controls over financial reporting, or if we identify or fail to remediate material weaknesses in our internal controls, we could be subject to regulatory scrutiny and a loss of public confidence, which could seriously harm our reputation and the market price of our common stock. In addition, if we do not maintain adequate financial and management personnel, processes and controls, we may not be able to manage our business effectively or accurately report our financial performance on a timely basis, which could cause a decline in our common stock price and may seriously harm our business.

We may need additional capital in the future in order to expand our business.

Our future capital requirements may be substantial, particularly as we continue to develop our business. Although we believe that, based on our current level of operations, our existing cash, cash equivalents and equity securities will provide adequate funds for ongoing operations, planned capital expenditures and working capital requirements for at least the next 12 months, we may need additional capital if our current plans and assumptions change. Our need for additional capital will depend on many factors, including the financial success of our performance enzyme business, our spending to develop and commercialize new and existing enzyme products and the amount of collaboration funding we may receive to help cover the cost of such expenditures, the effect of any acquisitions of other businesses, technologies or facilities that we may make or develop in the future, our spending on new market opportunities, including the ongoing commercialization of our ECO Synthesis™ manufacturing platform, and the filing, prosecution, enforcement and defense of patent claims. If our capital resources are insufficient to meet our capital requirements, and we are unable to enter into or maintain collaborations with partners that are able or willing to fund our development efforts or commercialize any enzyme products that we develop or enable, we will have to raise additional funds to continue the development of our technology and products and complete the commercialization of products, if any, resulting from our technologies.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations, such as funding the ongoing commercialization of our ECO Synthesis™ manufacturing platform, even if we believe we have sufficient funds for our current or future operating plans. We may seek to obtain such additional capital through equity offerings, including pursuant to the EDA, the Cantor Sales Agreement, debt financings, credit facilities and/or strategic collaborations. If future financings involve the issuance of equity securities, our existing stockholders would suffer dilution. In addition, under our Loan Agreement, we are subject to restrictive covenants that limit our ability to conduct our business and could be subject to additional covenants to the extent we seek other debt financing in the future. Strategic collaborations may also place restrictions on our business. We may not be able to raise sufficient additional funds on terms that are favorable to us, if at all. If we fail to raise sufficient funds and fail to generate sufficient revenues to achieve planned gross margins and to control operating costs, our ability to fund our operations, take advantage of strategic opportunities, develop products or technologies, or otherwise respond to competitive pressures could be significantly limited. If this happens, we may be forced to delay or terminate research or development programs or the commercialization of products resulting from our technologies, curtail or cease operations or obtain funds through collaborative and licensing arrangements that may require us to relinquish commercial rights, or grant licenses on terms that are not favorable to us. If adequate funds are not available, we will not be able to successfully execute our business plan or continue our business.

Covenants and other provisions in our Loan Agreement with Innovatus restrict our business and operations in many ways, and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected. In addition, our operations may not provide sufficient cash to meet the repayment obligations of our debt incurred under the Loan Agreement.

Pursuant to the Loan Agreement, Innovatus has been granted a security interest in substantially all of our assets. If an event of default occurs under the Loan Agreement, Innovatus may foreclose on its security interest and liquidate some or all of these assets, which would harm our business, financial condition and results of operations.

In the event of a default in connection with our bankruptcy, insolvency, liquidation, or reorganization, Innovatus would have a prior right to substantially all of our assets to the exclusion of our general unsecured creditors. Only after satisfying the claims of Innovatus and any unsecured creditors would any amount be available for our equity holders.

The pledge of these assets and other restrictions imposed in the Loan Agreement may limit our flexibility in raising capital for other purposes. Because substantially all of our assets are pledged to secure the Loan Agreement obligations, our ability to incur additional indebtedness or to sell or dispose of assets to raise capital may be impaired, which could have an adverse effect on our financial flexibility.

In addition, if we are unable to comply with certain financial and operating restrictions in the Loan Agreement, we may be limited in our business activities and access to credit or may default under the Loan Agreement. Provisions in the Loan Agreement impose restrictions or require prior approval on our ability, and the ability of certain of our subsidiaries to, among other things:

- sell, lease or transfer certain parts of our business or property, including equity interests of our subsidiaries;
- engage in new lines of business;
- acquire new companies and merge or consolidate;
- incur additional debt or guarantee the indebtedness of others or our subsidiaries;
- create liens or encumbrances;
- pay cash dividends and make distributions or redeem or repurchase our capital stock;
- make certain investments;
- enter into transactions with affiliates; and
- terminate or, in certain cases, amend our material agreements.

The Loan Agreement also contains other customary covenants. We may not be able to comply with these covenants in the future. Our failure to comply with these covenants may result in the declaration of an event of default, which, if not cured or waived, may result in the acceleration of the maturity of indebtedness outstanding under the Loan Agreement and would require us to pay all amounts outstanding. If the maturity of our indebtedness is accelerated, we may not have sufficient funds then available for repayment or we may not have the ability to borrow or obtain sufficient funds to replace the accelerated indebtedness on terms acceptable to us or at all. Our failure to repay our obligations under the Loan Agreement would result in Innovatus foreclosing on all or a portion of our assets, which could force us to curtail or cease our operations.

If we engage in any acquisitions, we will incur a variety of costs and may potentially face numerous risks that could adversely affect our business and operations.

We have made acquisitions in the past, and if appropriate opportunities become available, we expect to acquire additional businesses, assets, technologies, or products to enhance our business in the future. For example, in October 2010, we acquired substantially all of the patents and other intellectual property rights associated with Maxygen's directed evolution technology.

In connection with any future acquisitions, we could:

- issue additional equity securities, which would dilute our current stockholders;
- incur substantial debt to fund the acquisitions;
- use our cash to fund the acquisitions; or
- assume significant liabilities including litigation risk.

Acquisitions involve numerous risks, including problems integrating the purchased operations, technologies or products, unanticipated costs and other liabilities, diversion of management's attention from our core businesses, adverse effects on existing business relationships with current and/or prospective collaborators, customers and/or suppliers, risks associated with entering markets in which we have no or limited prior experience and potential loss of key employees. We do not have extensive experience in managing the integration process and we may not be able to successfully integrate any businesses, assets, products, technologies or personnel that we might acquire in the future without a significant expenditure of operating, financial and management resources, if at all. The integration process could divert management's time from focusing on operating our business, result in a decline in employee morale and cause retention issues to arise from changes in compensation, reporting relationships, future prospects or the direction of the business. Acquisitions may also require us to record goodwill and non-amortizable intangible assets that will be subject to impairment testing on a regular basis and potential periodic impairment charges, incur amortization expenses related to certain intangible assets, and incur large and immediate write offs and restructuring and other related expenses, all of which could harm our operating results and financial condition. In addition, we may acquire companies that have insufficient internal financial controls, which could impair our ability to integrate the acquired company and adversely impact our financial reporting. If we fail in our integration efforts with respect to any of our acquisitions and are unable to efficiently operate as a combined organization, our business and financial condition may be adversely affected.

COVID-19 has adversely affected, and any resurgence of COVID-19 pandemic or another global health epidemic may in the future, directly or indirectly, adversely affect our business, results of operations and financial condition.

COVID-19 has had a significant impact globally, prompting governments and businesses to take unprecedented measures in response. In the United States, COVID-19 has and may continue in the future to, directly or indirectly, adversely affect our business, results of operations and financial condition.

In the future, our business could be materially adversely affected, directly or indirectly, by the widespread outbreak of contagious disease, such as COVID-19 or any resurgence thereof. If national, state and local governments in affected regions implement safety precautions, similar to those implemented in response to COVID-19, including quarantines, border closures, increased border controls, travel restrictions, governmental orders and shutdowns, business closures, cancellations of public gatherings and other measures, such precautions could, and for COVID-19 did, disrupt normal business operations both in and outside of affected areas and could have significant negative impacts on businesses and financial markets worldwide.

The impact of COVID-19 has had, and any resurgence of the COVID-19 pandemic or another pandemic or public health crisis, could in the future have, significant repercussions across regional, national and global economies and financial markets, and could trigger a period of regional, national and global economic slowdown or regional, national or global recessions. The outbreak of COVID-19 in many countries adversely impacted regional, national and global economic activity and has continued to contribute to significant volatility and negative pressure in financial markets. As a result, we may experience difficulty accessing debt and equity capital on attractive terms, or at all, due to the severe disruption and instability in the global financial markets. In addition, our customers may terminate or amend their agreements for the purchase of our technology, products and services due to bankruptcy, lack of liquidity, lack of funding, operational failures or other reasons.

Risks Related to Government Regulation

Even if our customers, future customers or collaborators obtain regulatory approval for any products utilizing our enzymes, such products will remain subject to ongoing regulatory requirements, which may result in significant additional expense.

Any products that receives FDA approval will remain subject to ongoing regulatory requirements for manufacturing, labeling, packaging, distribution, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information, among other things. Any regulatory approvals received for such products may also be subject to limitations on the approved indicated uses for which they may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing and surveillance studies. For example, the holder of an approved NDA or BLA in the United States is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the NDA or BLA. In the United States, the holder of an approved NDA or BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Similar provisions apply in the European Union (the "EU"). Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. Similarly, in the EU any promotion of medicinal products is highly regulated and, depending on the specific jurisdiction involved, may require prior vetting by the competent national regulatory authority. In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA, BLA or foreign marketing application.

If our customers, future customers or our collaborators or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured or disagrees with the promotion, marketing or labeling of that product, a regulatory agency may impose restrictions relative to that product, the manufacturing facility or our customers or collaborators, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

In addition, if our customers or collaborators fail to comply with applicable regulatory requirements, the FDA and other regulatory authorities may:

- issue an untitled letter or a warning letter asserting a violation of the law;
- seek an injunction, impose civil or criminal penalties, and impose monetary fines, restitution or disgorgement of profits or revenues;
- suspend or withdraw regulatory approval;
- issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- mandate modification of promotional materials and labeling and issuance of corrective information;
- issue consent decrees or corporate integrity agreements, or debar or exclude from federal healthcare programs;
- suspend or terminate any ongoing clinical trials or implement requirements to conduct post-marketing studies or clinical trials;
- refuse to approve a pending NDA, BLA or comparable foreign marketing application (or any supplements thereto);
- restrict the labeling, marketing, distribution, use or manufacturing of products;
- seize or detain products or otherwise require the withdrawal or recall of products from the market;

- refuse to approve pending applications or supplements to approved applications;
- refuse to permit the import or export of products; or
- refuse government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may also inhibit our customers or collaborators' ability to commercialize products and our ability to generate revenues.

In addition, the FDA's policies, and policies of foreign regulatory agencies, may change, and additional regulations may be enacted that could prevent, limit or delay regulatory approval of product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

If we or our customers fail to comply with certain healthcare laws, including fraud and abuse laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

The healthcare industry is highly regulated. We, and our customers, are subject to various local, state, federal, national, and international laws and regulations, which include laws and regulations promulgated by the FDA, HHS, state boards of pharmacy, state health departments, and similar regulatory bodies in other countries. Additionally, our business operations and future arrangements with investigators, healthcare professionals, and consultants, among others, may expose us and our customers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute, the federal civil False Claims Act, the federal Civil Monetary Penalties Law, and analogous state laws. These laws may constrain the business or financial arrangements and relationships through which we will conduct our operations. Because of the breadth of these laws and narrowness of available statutory and regulatory exceptions, it is possible that some of our business activities could be regulated by or subject to challenge under one or more of such laws. We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts of our employees, agents, contractors, or collaborators that turn out to violate any of the laws described above. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, imprisonment and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

In the United States, there have been, and we expect there will continue to be, a number of legislative initiatives to contain healthcare costs. Some of these initiatives, such as ongoing healthcare reform, including with respect to reforming drug pricing, adverse changes in governmental or private funding of healthcare products and services, legislation or regulations governing patient access to care, and the delivery, coverage, pricing, and reimbursement of pharmaceuticals and healthcare services may cause our customers to change the amount of our offerings that they purchase from us or the price they are willing to pay us for these offerings. If cost-containment efforts or other healthcare reform measures limit our customers' profitability, they may decrease research and development spending, which could decrease the demand for our products and services and materially adversely affect our growth prospects. Any of these factors could harm our customers' businesses, which, in turn, could materially adversely affect our business, financial condition, results of operations, cash flows, and prospects.

We cannot predict the likelihood, nature, or extent of other health reform initiatives that may arise from future legislative, administrative, or other action. Any substantial revision of applicable healthcare legislation could have a material adverse effect on the demand for our customers' products, which in turn could have a negative impact on our results of operations, financial condition, or business. Changes in the healthcare industry's pricing, selling, inventory, distribution, or supply policies or practices, or in public or government sentiment for the industry as a whole, could also significantly reduce our revenue and results of operations.

Compliance with European Union chemical regulations could be costly and adversely affect our business and results of operations.

Some of our products are subject to the EU regulatory regime known as The Registration, Evaluation and Authorization of Chemicals (“REACH”). REACH mandates that certain chemicals manufactured in, or imported into, the EU be registered and evaluated for their potential effects on human health and the environment. Under REACH, we and our contract manufacturers located in the EU are required to register certain of our products based on the quantity of such product imported into or manufactured in the EU and on the product’s intended end-use. The registration, evaluation and authorization process under REACH can be costly and time consuming. Problems or delays in the registration, evaluation or authorization process under REACH could delay or prevent the manufacture of some of our products in, or the importation of some of our products into, the EU, which could adversely affect our business and results of operations. In addition, if we or our contract manufacturers fail to comply with REACH, we may be subject to penalties or other enforcement actions, which could have a material adverse effect on our business and results of operations.

Risks Related to Intellectual Property and Information Technology

Our efforts to prosecute, maintain, protect and/or defend our intellectual property rights may not be successful.

We will continue to file and prosecute patent applications and maintain trade secrets in an ongoing effort to protect our intellectual property rights. It is possible that our current patents, or patents which we may later acquire, may be successfully challenged or invalidated, in whole or in part. It is also possible that we may not obtain issued patents from our pending patent applications. We sometimes permit certain patents or patent applications to lapse or go abandoned under appropriate circumstances. Due to uncertainties inherent in prosecuting patent applications, sometimes patent applications are rejected, and we subsequently abandon them. It is also possible that we may develop proprietary technology, products or services in the future that are not patentable or that the patents of others will limit or altogether preclude our ability to conduct business. In addition, any patent issued to us or to our licensor may provide us with little or no competitive advantage, in which case we may abandon such patent, license it to another entity or terminate the license agreement.

Our means of protecting our proprietary rights may not be adequate and our competitors may independently develop technologies, products or services that are identical or similar to ours or that compete with ours. Patent, trademark, copyright and trade secret laws afford only limited protection for our technology, products and services. The laws of many countries do not protect our proprietary rights to as great of an extent as do the laws of the United States. Despite our efforts to protect our proprietary rights, unauthorized parties have in the past attempted, and may in the future attempt, to operate under the aspects of our intellectual property rights, or proprietary technology, products or services or products, or to obtain and use information that we regard as proprietary. Third parties may also design around our proprietary rights, which may render our protected technology, services and products less valuable, if the design around is favorably received in the marketplace. In addition, if any of our technology, products and services are covered by third-party patents or other intellectual property rights, we could be subject to various legal actions. We cannot assure that our technology products and/or services do not infringe, violate or misappropriate any patents or other intellectual property rights owned or controlled by others or that they will not in the future.

Litigation may be necessary to enforce our intellectual property rights, to protect our trade secrets, to determine the validity and scope of the proprietary rights of others, or to defend against claims of infringement, invalidity, misappropriation, or other claims.

Any such litigation could result in substantial costs and diversion of our resources. Moreover, any settlement of or adverse judgment resulting from litigation relating to intellectual property rights could require us to obtain a license to continue to make, use, import, sell or offer for sale the technology, products or services that is the subject of the claim, or otherwise restrict or prohibit our use of the technology, products or services.

Our ability to compete may decline if we do not adequately prosecute, maintain, protect and/or defend our proprietary technology, products or services or our intellectual property rights.

Our success depends in part on our ability to obtain patents and maintain adequate protection of our intellectual property rights directed to our technology, products and services in the United States and other countries. We have adopted a strategy of seeking patent protection in the United States and in foreign countries with respect to certain of the technology used in or relating to our products, services, and processes. As such, as of March 31, 2024, we owned or controlled approximately 2,095 active issued patents and pending patent applications in the United States and in various foreign jurisdictions. As of March 31, 2024, our patents and patent applications, if issued, have terms that expire between 2024 and approximately 2045. We also have license rights to a number of issued patents and pending patent applications in the United States and in various foreign jurisdictions. Our owned and licensed patents and patent applications include those directed to our enabling technology and to the methods and products that support our business in the pharmaceutical manufacturing, life sciences, oligonucleotide synthesis, and other markets. We intend to continue to apply for patents relating to our technology, methods, services and products as we deem appropriate.

Issuance of claims in patent applications and enforceability of such claims once issued involve complex legal and factual questions and, therefore, we cannot predict with any certainty whether any of our issued patents will survive invalidity claims asserted by third parties. Issued patents and patents issuing from pending applications may be challenged, invalidated, circumvented, rendered unenforceable or substantially narrowed in scope. In addition, the inventorship and ownership of the patents and patent applications may be challenged by others. Moreover, the United States Leahy-Smith America Invents Act (“AIA”), enacted in September 2011, brought significant changes to the United States patent system, which include a change to a “first to file” system from a “first to invent” system and changes to the procedures for challenging issued patents and disputing patent applications during the examination process, among other things. While interference proceedings are possible for patent claims filed prior to March 16, 2013, many of our filings will be subject to the post- and pre-grant proceedings set forth in the AIA, including citation of prior art and written statements by third parties, third party pre-issuance submissions, ex parte reexamination, inter partes review, post-grant review, and derivation proceedings. We may need to utilize the processes provided by the AIA for supplemental examination or patent reissuance. These proceedings could result in substantial cost to us even if the outcome is favorable. Even if successful, any proceeding may result in loss of certain claims. Any litigation or proceedings could divert our management's time and efforts. Even unsuccessful claims brought by third parties could result in significant legal fees and other expenses, diversion of management time, and disruption in our business. Uncertainties resulting from initiation and continuation of any patent or related litigation could harm our ability to compete.

Additional uncertainty may result from legal precedent handed down by the United States Federal Circuit Court and Supreme Court as they determine legal issues concerning the scope and construction of patent claims and inconsistent interpretation of patent laws by the lower courts. Accordingly, we cannot ensure that any of our pending patent applications will result in issued patents, or even if issued, predict the breadth of the claims upheld in our, our licensors', and other companies' patents. Given that the degree of future protection for our proprietary rights is uncertain, we cannot ensure that: (i) we or our licensors were the first to invent the inventions covered by each of our pending applications, (ii) we or our licensors were the first to file patent applications for these inventions, or (iii) the proprietary technology, products or services we develop will be patentable. In addition, unauthorized parties may attempt to copy or otherwise obtain and use our technology, products and services. Monitoring unauthorized use of our intellectual property rights is difficult, and we cannot be certain that the steps we have taken will prevent unauthorized use of our technology, products or services, particularly in certain foreign countries where the local laws may not protect our proprietary rights as fully as in the United States. Moreover, third parties could practice our inventions in territories where we do not have patent protection. Such third parties may then try to import products made using our inventions into the United States or other countries. If competitors are able to use our proprietary technology, products or services, our ability to compete effectively could be harmed. In addition, others may independently develop and obtain patents for technologies, products or services that are similar to or superior to our technologies, products or services. If that happens, we may need to license these technologies, products or services, and we may not be able to obtain licenses on reasonable terms, if at all, which could cause harm to our business.

Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. Changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them, or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or may obtain in the future. For example, in some cases, we have filed for unitary patent protection under the rules implemented on June 1, 2023, in the European Patent Office. We will continue to assess this route of protection on a case-by-case basis, as applications are filed and patents are granted through the European Patent Office. This may alter our ability to protect our patents in some European countries. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. For example, in some foreign jurisdictions, governments have the right to compel patent owners to grant others licenses to their intellectual property under certain circumstances. In addition, any protection afforded by foreign patents may be more limited than that provided under U.S. patent and intellectual property laws. We may encounter significant problems in enforcing and defending our intellectual property both in the United States and abroad. For example, if the issuance in a given country of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims or the written description or enablement in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in other countries, our ability to protect our intellectual property rights in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property rights or narrow the scope of our patent protection. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Third parties may claim that we are infringing, violating or misappropriating their intellectual property rights, which may subject us to costly and time-consuming litigation and prevent us from developing or commercializing our technology, products or services.

Our commercial success also depends in part on our ability to operate without infringing, violating or misappropriating patents and other intellectual property rights of third parties, and without breaching any licenses or other agreements that we have entered into with regard to our technologies, products or services. We cannot ensure that patents have not been issued, or will not be issued, to third parties that could block our ability to obtain patents or to operate as we would like. There may be patents in some countries that, if valid, may block our ability to make, use, sell, or offer for sale our technology, products or services in those countries, or import our products into those countries, if we are unsuccessful in circumventing or acquiring rights to these patents. There also may be claims in patent applications filed in some countries that, if granted and valid, may also block our ability to commercialize technology, products, services or processes in these countries if we are unable to circumvent or obtain rights to them.

The industries in which we operate and the biotechnology industry, in particular, are characterized by frequent and extensive litigation regarding patents and other intellectual property rights. Many biotechnology companies have employed intellectual property litigation as a way to gain a competitive advantage. We are aware of some patents and patent applications relating to aspects of our technologies, products or services filed by, and issued to, third parties. We cannot assure that if such third-party patents rights are asserted against us that we would ultimately prevail. Any involvement in litigation or other intellectual property proceedings inside and/or outside of the United States to defend against claims that we infringe, misappropriate or violate the intellectual property rights of others may divert our management's time from focusing on business operations and could cause us to spend significant amounts of money. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop making, using, selling or importing our technologies, products and services that use the subject intellectual property;
- pay monetary damages to the third party asserting claims against us;
- grant or transfer rights to third parties relating to our patents or other intellectual property rights;
- obtain from the third party asserting its intellectual property rights a license to make, sell, offer for sale, import or use the relevant technology, product or service, which license may not be available on reasonable terms, or at all; or

- redesign those technologies, products, services or processes that use any allegedly infringing, misappropriated or violated intellectual property rights, or relocate the operations relating to the allegedly infringing, misappropriated or violated intellectual property rights to another jurisdiction, which may result in significant cost or delay to us, could be technically infeasible or could prevent us from making, selling, offering for sale, using or importing some of our technologies, products or services in the United States or other jurisdictions.

We may be involved in lawsuits to protect or enforce our intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe, violate or misappropriate our intellectual property rights or those of our licensors. To prevent infringement, violation, misappropriation or other unauthorized use, we have in the past filed, and may in the future be required to file, enforcement claims, which can be expensive and time-consuming. In addition, in an enforcement proceeding, a court may decide that the intellectual property right that we own or control is not valid, is unenforceable and/or is not infringed, violated or misappropriated. In addition, in legal proceedings against a third party to enforce a patent directed at one of our technologies, products or services, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent enforcement litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a patent validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark Office (“USPTO”) or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of enforcement litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensors invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on the respective technology, products or services. Such a loss of patent protection could have a material adverse impact on our business.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our expenses and reduce the resources available for operations and research and development activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace. Furthermore, because of the substantial amount of discovery required in connection with U.S. intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries where we do business do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and enforcing intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property rights, particularly those relating to biotechnology technologies. Accordingly, our efforts to protect and enforce our intellectual property rights in such countries may be inadequate. This could make it difficult for us to stop the infringement, violation or misappropriation of our patents or other intellectual property rights. Additionally, proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business.

If our biocatalysts, or the genes that code for our biocatalysts, are stolen, misappropriated or reverse engineered, others could use these biocatalysts or genes to produce competing products.

Third parties, including our contract manufacturers, customers and those involved in shipping our biocatalysts, often have custody or control of our biocatalysts. If our biocatalysts, or the genes that code for our biocatalysts, were stolen, misappropriated or reverse engineered, they could be used by other parties who may be able to reproduce these biocatalysts for their own commercial gain. If this were to occur, it may be difficult for us to challenge this type of use, especially in countries with limited intellectual property rights protection or in countries in which we do not have patents covering the misappropriated biocatalysts.

Confidentiality and non-use agreements with employees, consultants, advisors and other third parties may not adequately prevent disclosures and non-use of trade secrets and other proprietary information.

In addition to patent protection, we also rely on other intellectual property rights, including protection of copyright, trade secrets, know-how and/or other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect, and some courts are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely in part on trade secret law and contractual agreements to protect our confidential and proprietary information and processes. We generally enter into confidentiality and invention assignment agreements with our employees, consultants and third parties working on our behalf upon their commencement of a relationship with us. However, trade secrets and confidential information are difficult to protect and we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes and we may not enter into such agreements with all employees, consultants and third parties who have been involved in the development of our intellectual property rights. Nevertheless, without our permission or awareness, our confidential and proprietary information may be disclosed to third parties, used by the respective individuals for purposes other than for the Company's business, or obtained through illegal means, such that third parties could reverse engineer our biocatalysts, enzyme products and processes, to attempt to develop the same technology or develop substantially equivalent technology.

Costly and time-consuming litigation could be necessary to enforce and determine the scope of our confidential and proprietary rights, and failure to protect our trade secrets could adversely affect our competitive business position. If any of our trade secrets were lawfully obtained, we may be unable to prevent them, or those to whom they communicate it, from using that technology or information to compete with us or disclosing it publicly. Therefore, these events could have a material adverse effect on our business, financial condition and results of operations. In particular, a failure to protect our proprietary rights may allow competitors to copy our technology, which could adversely affect our pricing and market share.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information by maintaining physical security of our premises and electronic security of our information technology systems. Such security measures may not, for example, in the case of misappropriation of a trade secret by an employee, consultant or other third party with authorized access or with unauthorized access but an intent to steal, provide adequate protection for our proprietary information. Our security measures may not prevent such employee, consultant or other third party from misappropriating our trade secrets and using them or providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. While we use commonly accepted security measures, trade secret violations are often a matter of state law in the United States, and the criteria for protection of trade secrets can vary among different jurisdictions. If the steps we have taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

Risks Related to Owning our Common Stock

We are subject to anti-takeover provisions in our certificate of incorporation and bylaws and under Delaware law that could delay or prevent an acquisition of our company, even if the acquisition would be beneficial to our stockholders.

Provisions in our amended and restated certificate of incorporation and our bylaws may delay or prevent an acquisition of the Company. Among other things, our amended and restated certificate of incorporation and bylaws provide for a board of directors which is divided into three classes, with staggered three-year terms and provide that all stockholder action must be effected at a duly called meeting of the stockholders and not by a consent in writing, and further provide that only our board of directors, the chairman of the board of directors, our chief executive officer or president may call a special meeting of the stockholders. In addition, our amended and restated certificate of incorporation allows our board of directors, without further action by our stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These provisions may also frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management team. Furthermore, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law ("DGCL") which prohibits, with some exceptions, stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Finally, our charter documents establish advanced notice requirements for nominations for election to our board of directors and for proposing matters that can be acted upon at stockholder meetings. Although we believe these provisions together provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer to acquire our company may be considered beneficial by some stockholders.

Our bylaws designate a state or federal court located within the State of Delaware as the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us our current or former directors, officers, stockholders, or other employees.

Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of us under Delaware law, (ii) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer, or other employee of the Company to us or our stockholders, (iii) any action asserting a claim against us or any of our directors, officers, or other employees arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws (as either may be amended from time to time), (iv) any action asserting a claim against us governed by the internal affairs doctrine, or (v) any other action asserting an "internal corporate claim," as defined under Section 115 of the DGCL. The forgoing provisions do not apply to any claims arising under the Securities Act and, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will be the sole and exclusive forum for resolving any action asserting a claim arising under the Securities Act.

These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our current or former directors, officers, or other employees, which may discourage lawsuits with respect to such claims. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find the choice of forum provision to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations or financial condition.

Our quarterly or annual operating results may fluctuate in the future. As a result, we may fail to meet or exceed the expectations of research analysts or investors, which could cause our stock price to decline.

Our financial condition and operating results have varied significantly in the past and may continue to fluctuate from quarter to quarter and year to year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following factors, as well as other factors described elsewhere in this report:

- our ability to achieve or maintain profitability;
- our dependence on a limited number of customers;
- our product supply agreements with customers have finite duration, may not be extended or renewed and generally do not require the customer to purchase any particular quantity or quantities of our products;
- with respect to customers purchasing our products for the manufacture of active pharmaceutical ingredients for which they have exclusivity due to patent protection, the termination or expiration of such patent protection and any resulting generic competition may materially and adversely affect our revenues, financial condition or results of operations;
- our dependence on a limited number of products in our performance enzymes business;
- our reliance on a limited number of contract manufacturers for large scale production of substantially all of our enzyme products;
- our relationships with, and dependence on, collaborators in our principal markets;
- our ability to successfully and timely develop and commercialize new products, including our ECO Synthesis™ manufacturing platform, for the markets we serve;
- the potential of GSK, Merck, Novartis or any other performance enzyme customer terminating their agreements with us;
- the success of our customers' products in the market and the ability of such customers to obtain regulatory approvals for products and processes;
- our ability to deploy our technology platform in life science tools markets;
- our dependence on our collaborators or customers' product candidates which could unexpectedly fail at any stage of preclinical or clinical development;

- our dependence on our collaborators or customers' product candidates which may lack the ability to work as intended or cause undesirable side effects;
- our ability to successfully prosecute and protect our intellectual property;
- our ability to compete if we do not adequately protect our proprietary technologies or if we lose some of our intellectual property rights;
- our ability to avoid infringing the intellectual property rights of third parties;
- our involvement in lawsuits to protect or enforce our patents or other intellectual property rights;
- our ability to enforce our intellectual property rights throughout the world;
- our dependence on, and the need to attract and retain, key management and other personnel;
- our ability to prevent the theft or misappropriation of our biocatalysts, the genes that code for our biocatalysts, know-how or technologies;
- our ability to protect our trade secrets and other proprietary information from disclosure by employees and others;
- our ability to obtain substantial additional capital that may be necessary to expand our business;
- our ability to comply with the terms of our Loan Agreement;
- our ability to timely pay debt service obligations;
- our customers' ability to pay amounts owed to us in a timely manner;
- our ability to avoid charges to earnings as a result of any impairment of goodwill, intangible assets or other long-lived assets;
- changes in financial accounting standards or practices may cause adverse, unexpected financial reporting fluctuations and affect our reported results of operations;
- our ability to maintain effective internal control over financial reporting;
- our dependency on information technology systems, infrastructure and data;
- our ability to control and to improve product gross margins;
- our ability to protect against risks associated with the international aspects of our business;
- the cost of compliance with EU chemical regulations;
- potential advantages that our competitors and potential competitors may have in securing funding or developing products;
- our ability to accurately report our financial results in a timely manner;
- results of regulatory tax examinations;
- market and economic conditions may negatively impact our business, financial condition, and share price;
- business interruptions due to natural disasters, disease outbreaks or other events beyond our control;
- public concerns about the ethical, legal and social ramifications of genetically engineered products and processes;
- our ability to integrate our current business with any businesses that we may acquire in the future;
- our ability to properly handle and dispose of hazardous materials in our business;
- potential product liability claims;
- changes to tax law and related regulations could materially affect our tax obligations and effective tax rate; and

- our ability to use our NOLs to offset future taxable income.

Due to the various factors mentioned above, and others, the results of any prior quarterly or annual periods should not be relied upon as indications of our future operating performance.

We do not intend to pay cash dividends for the foreseeable future.

We currently intend to retain our future earnings, if any, to finance the further development and expansion of our business and do not intend to pay cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, restrictions contained in future agreements and financing instruments, business prospects and such other factors as our board of directors deems relevant.

General Risk Factors

If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock in a negative manner, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline.

We face risks associated with our international business.

While we have a limited number of employees located outside of the United States, we are and will continue to be dependent upon contract manufacturers located outside of the United States. In addition, we have customers and partners located outside of the United States. Conducting business internationally exposes us to a variety of risks, including:

- changes in or interpretations of U.S. or foreign laws or regulations that may adversely affect our ability to sell our products, repatriate profits to the United States or operate our foreign-located facilities;
- the imposition of tariffs;
- the imposition of limitations on, or increase of, withholding and other taxes on remittances and other payments by foreign subsidiaries or joint ventures;
- the imposition of limitations on genetically-engineered or other products or processes and the production or sale of those products or processes in foreign countries;
- currency exchange rate fluctuations;
- uncertainties relating to foreign laws, regulations and legal proceedings including pharmaceutical, tax, import/export, anti-corruption and exchange control laws;
- the availability of government subsidies or other incentives that benefit competitors in their local markets that are not available to us;
- increased demands on our limited resources created by our operations may constrain the capabilities of our administrative and operational resources and restrict our ability to attract, train, manage and retain qualified management, technicians, scientists and other personnel;
- economic or political instability in foreign countries;
- difficulties associated with staffing and managing foreign operations; and
- the need to comply with a variety of United States and foreign laws applicable to the conduct of international business, including import and export control laws and anti-corruption laws.

Market and economic conditions may negatively impact our business, financial condition, and share price.

Concerns about inflation, energy costs, geopolitical issues, the United States mortgage market and a declining real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth going forward, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions.

Recently, the closures of Silicon Valley Bank (“SVB”) and Signature Bank (“Signature”) and their placement into receivership with the Federal Deposit Insurance Corporation, and the government-brokered sale of the deposits and majority of assets of First Republic Bank to JPMorgan Chase, created bank-specific and broader financial institution liquidity risk and concerns. Although government intervention ensured that depositors at these banks have access to their funds, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur, and we cannot predict the impact or follow-on effects of these insolvencies more broadly or on our business in particular. Further, we cannot guarantee that the government will intervene to provide depositors with access to funds if similar events occur in the future. If other banks and financial institutions enter receivership or become insolvent in the future, our ability to access our existing cash, cash equivalents, and investments may be threatened, which could have a material adverse effect on our business and financial condition.

In addition, if the market and economic conditions described above continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and stock price. Additionally, rising rates of inflation have increased the costs associated with conducting our business, including by causing substantial increases in the costs of materials, including raw materials and consumables, equipment, services, and labor. Moreover, given the unpredictable nature of the current economic climate, including future changes in rates of inflation, it may be increasingly difficult for us to predict and control our future expenses, which may harm our ability to conduct our business.

Business interruptions resulting from disasters or other disturbances could delay us in the process of developing our products and could disrupt our sales. Our business continuity and disaster recovery plans may not adequately protect us from a serious disaster or other disturbance.

Our headquarters and other facilities are located in the San Francisco Bay Area, which in the past has experienced both severe earthquakes and wildfires. Earthquakes, wildfires or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. We are also vulnerable to other types of disasters and other events that could disrupt our operations, such as riot, civil disturbances, war, terrorist acts, public health emergencies, domestic or foreign conflicts, infections in our laboratory or production facilities or those of our customers or contract manufacturers and other events beyond our control. If a natural disaster or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event, and we may incur substantial expenses as a result of the limited nature of such plans. We do not carry insurance for earthquakes and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our cash flows and success as an overall business.

We are dependent on information technology systems, infrastructure and data, and any failure of these systems could harm our business. Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition.

Information technology helps us operate efficiently, interface with customers, maintain financial accuracy and efficiency and accurately produce our financial statements. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology infrastructure, we could be subject to transaction errors, processing inefficiencies, the loss of customers, business disruptions or the loss of or damage to intellectual property through security breach. If our information technology systems do not effectively collect, store, process and report relevant data for the operation of our business, whether due to equipment malfunction or constraints, software deficiencies, or human error, our ability to effectively plan, forecast and execute our business plan and comply with applicable laws and regulations will be impaired, perhaps materially. Our information technology systems and those of our external vendors, strategic partners and other contractors or consultants are vulnerable to attack and damage or interruption from computer viruses and malware (e.g. ransomware), malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. Any such impairment could materially and adversely affect our financial condition, results of operations, cash flows and the timeliness with which we report our internal and external operating results.

Our business may require us to use and store personal information of our customers, employees, and business partners. This may include names, addresses, phone numbers, email addresses, contact preferences, tax identification numbers and payment account information. We require usernames and passwords in order to access our information technology systems. We also use encryption and authentication technologies to secure the transmission and storage of data. However, these security measures may be compromised as a result of security breaches by unauthorized persons, employee error, malfeasance, faulty password management or other irregularity, and result in persons obtaining unauthorized access to our data or accounts. Third parties may attempt to fraudulently induce employees or customers into disclosing usernames, passwords or other sensitive information, which may in turn be used to access our information technology systems. For example, our employees have received “phishing” emails and phone calls attempting to induce them to divulge passwords and other sensitive information.

In addition, unauthorized persons may attempt to hack into our products or systems to obtain personal data relating to employees and other individuals, our confidential or proprietary information or confidential information we hold on behalf of third parties. We also rely on external vendors to supply and/or support certain aspects of our information technology systems. The systems of these external vendors may contain defects in design or manufacture or other problems that could unexpectedly compromise information security of our own systems, and we are dependent on these third parties to deploy appropriate security programs to protect their systems. If we or our third-party vendors were to experience a significant cybersecurity breach of our or their information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counterparties and data subjects could be material. Our remediation efforts may not be successful. Further, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss, corruption or unauthorized disclosure of our trade secrets, personal information or other proprietary or sensitive information or other similar disruptions. Attacks upon information technology systems are also increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the remote work policies we initiated in response to the COVID-19 pandemic, and our continued hybrid working environment, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. We have programs in place to detect, contain and respond to data security incidents, and we make ongoing improvements to our information-sharing products in order to minimize vulnerabilities, in accordance with industry and regulatory standards. However, because the techniques used to obtain unauthorized access to or sabotage systems change frequently and may be difficult to detect, we may not be able to anticipate and prevent these intrusions or mitigate them when and if they occur. Even if identified, we may be unable to adequately and timely investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection and to remove or obfuscate forensic evidence.

We and certain of our external vendors are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident, or security breach to date, if such an event were to occur, it could result in the unauthorized access to or unauthorized use, disclosure, release or other processing of personal information, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to privacy and security laws. Any security compromise affecting us, our service providers, vendors, strategic partners, other contractors, consultants or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures and lead to regulatory scrutiny. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary or personal information, we could incur liability, including litigation exposure, penalties and fines, which may not be covered by insurance or may be in excess of our insurance coverage. Additionally, we could become the subject of regulatory action or investigation, our competitive position could be harmed and the further development of our products could be delayed. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our business and could materially and adversely affect our business, results of operations and financial condition.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to state, federal and foreign laws, regulations, decisions and directives governing the privacy, security, collection, storage, transmission, use, processing, retention and disclosure of personal information. Any failure or perceived failure by us to comply with applicable laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

In the United States, HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of certain individually identifiable health information. Certain states have also adopted and continue to adopt new privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act (“CCPA”) went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA also provides for civil penalties for violations, as well as a private right of action for data breaches (which has increased the likelihood of, and risks associated with, data breach litigation). Further, the California Privacy Rights Act (“CPRA”) significantly amended the CCPA, which went into effect in January 2023. It imposes additional data privacy obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data and opt outs for certain uses of sensitive data. It also created a new California privacy protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may also be required. Similar laws regulating personal information generally or health information in particular have passed in more than a dozen states and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. These developments increase our compliance burden and our risk, including risks of regulatory fines, litigation and associated reputational harm. Any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Furthermore, the Federal Trade Commission (“FTC”) and many state Attorneys General continue to enforce federal and state consumer protection laws against companies for the collection, use, sharing and security of personal information that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers’ personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

In the European Union (“EU”), the EU General Data Protection Regulation (“EU GDPR”) governs the processing of personal data. The UK has implemented the EU GDPR as the UK GDPR which sits alongside the UK Data Protection Act 2018 (the “UK GDPR”, and together with the EU GDPR, the “GDPR”). The GDPR imposes requirements for controllers, including (among others) specific requirements for obtaining valid consent where consent is the legal basis for processing, requirements around accountability and transparency, the obligation to consider data protection when any new products or services are developed, the obligation to comply with individuals’ data protection rights, and the obligation to notify relevant data supervisory authorities of notifiable personal data breaches without undue delay (and no later than 72 hours) after becoming aware of the personal data breach (and affected data subjects where the personal data breach is likely to result in a high risk to their rights and freedoms). The EU GDPR provides that EU member states may enact their own additional national laws and regulations regarding the processing of genetic, biometric or health data, which could affect our ability to use and share personal data or could cause our costs to increase and potentially harm our business and financial condition. Failure to comply with the requirements of the GDPR can result in (among other things) fines of up to the greater of €20 million (under the EU GDPR) or £17.5 million (under the UK GDPR) or 4% of an organization’s total worldwide annual turnover of the preceding financial year and other administrative penalties. To the extent that we are subject to the GDPR, compliance with the GDPR may require substantial amendments to our procedures and policies and these changes could adversely impact our business by increasing operational and compliance costs or impact business practices. Further, there is a risk that the amended policies and procedures will not be implemented correctly or that individuals within the business will not be fully compliant with the new procedures. There is a risk that we could be impacted by a cybersecurity incident that results in loss or unauthorized disclosure of personal data, potentially resulting in us facing harms similar to those described above.

Among other requirements, the EU GDPR prohibits the international transfer of personal data subject to the GDPR from the European Economic Area (“EEA”) to third countries that the European Commission does not recognize as having an ‘adequate’ level of data protection, unless a data transfer mechanism has been put in place or a derogation under the EU GDPR can be relied on. In July 2020, the Court of Justice of the EU in its Schrems II judgement limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the EU-U.S. Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses (“EU SCCs”), including a requirement for companies to carry out a transfer privacy impact assessment (“TIA”). A TIA, among other things, assesses laws governing access to personal data in the recipient country and considers whether supplementary measures that provide privacy protections additional to those provided under the EU SCCs will need to be implemented to ensure an ‘essentially equivalent’ level of data protection to that afforded in the EEA.

On October 7, 2022, U.S. President Biden introduced an Executive Order to facilitate a new Trans-Atlantic Data Privacy Framework (“DPF”) and in July 2023, the European Commission adopted its Final Implementing Decision granting the United States adequacy (“Adequacy Decision”) for EU-U.S. transfers of personal data for entities self-certified to the DPF. Entities relying on EU SCCs for transfers to the United States are also able to rely on the analysis in the Adequacy Decision as support for their TIA regarding the equivalence of U.S. national security safeguards and redress.

The UK GDPR also imposes similar restrictions on transfers of personal data from the UK to jurisdictions that the UK Government does not consider adequate, including the United States. The UK Government has published its own form of the EU SCCs, known as the International Data Transfer Agreement and an International Data Transfer Addendum to the new EU SCCs. The UK Information Commissioner’s Office has also published its own version of the TIA and guidance on international transfers, although entities may choose to adopt either the EU or UK-style TIA. Further, on September 21, 2023, the UK Secretary of State for Science, Innovation and Technology established a UK-U.S. data bridge (i.e., a UK equivalent of the Adequacy Decision) and adopted UK regulations to implement the UK-U.S. data bridge (“UK Adequacy Regulations”). Personal data may now be transferred from the UK under the UK-U.S. data bridge through the UK extension to the DPF to organizations self-certified under the UK extension to DPF.

As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Various federal, state and foreign legislative or regulatory bodies may enact new or additional laws and regulations concerning privacy, data-retention and data-protection issues, including laws or regulations mandating disclosure to domestic or international law enforcement bodies, which could adversely impact our business or our reputation with customers. For example, some countries have adopted laws mandating that certain personal information regarding customers in their country be maintained solely in their country. Having to maintain local data centers and redesign product, service and business operations to limit processing of personal information to within individual countries could increase our operating costs significantly. Any failure, or perceived failure, by us to comply with federal, state or international privacy, data-retention or data-protection-related laws, regulations, orders or industry self-regulatory principles could result in proceedings or actions against us by governmental entities or others, a loss of customer confidence, damage to our brand and reputation and a loss of customers, any of which could have an adverse effect on our business.

Evolving expectations around corporate responsibility practices, specifically related to environmental, social and governance (“ESG”) matters, may expose us to reputational and other risks.

Investors, stockholders, customers, suppliers and other third parties are increasingly focusing on ESG and corporate social responsibility endeavors and reporting. Companies that do not adapt to or comply with the evolving investor or stakeholder expectations and standards, or that are perceived to have not responded appropriately, may suffer from reputational damage, which could result in the business, financial condition and/or stock price of a company being materially and adversely affected. For example, certain customers have inquired about our ESG practices and may impose ESG guidelines, procurement policies, sustainability standards, mandates or reporting requirements for, and may scrutinize relationships more closely with, their suppliers, including us, which may lengthen sales cycles, increase our costs or impair our ability to attract and retain customers. Further, this increased focus on ESG issues may result in new regulations, international accords and/or third-party requirements that could adversely impact our business, or certain shareholders reducing or eliminating their holdings of our stock. An allegation or perception that we have not taken sufficient action in these areas could negatively harm our reputation. Additionally, the subjective nature and wide variety of methods and processes used by various stakeholders, including investors, to assess environmental, social, and governance criteria could result in a negative perception or misrepresentation of the company's sustainability policies and practices.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Rule 10b5-1 Trading Arrangements

During the three months ended March 31, 2024, none of the directors or executive officers of the Company adopted or terminated a Rule 10b5-1 trading arrangement or a “non-Rule 10b5-1 trading arrangement” (each as defined in Item 408 of Regulation S-K).

Cantor Sales Agreement

On May 2, 2024, we entered into a Controlled Equity OfferingSM Sales Agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co. (“Cantor”), under which we may offer and sell, from time to time at our sole discretion, shares of our common stock, par value \$0.0001 per share (the “Common Stock”), having an aggregate offering price of up to \$75.0 million through Cantor, as sales agent (the “ATM Offering”).

Cantor may sell the Common Stock by any method that is deemed to be an “at the market offering” as defined in Rule 415 of the Securities Act of 1933, as amended, including sales made directly on the Nasdaq Global Select Market (“Nasdaq”) or any other trading market for the Common Stock. Cantor will use commercially reasonable efforts, consistent with its normal sales and trading practices and applicable state and federal laws, rules and regulations and the rules of Nasdaq, to sell the Common Stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions the Company may impose). We will pay Cantor a commission of up to 3.0% of the gross sales proceeds of any Common Stock sold through Cantor under the ATM Offering and have provided Cantor with customary indemnification rights.

We are not obligated to make any sales of Common Stock under the Sales Agreement. The offering of shares of Common Stock pursuant to the Sales Agreement will terminate upon the termination of the Sales Agreement as permitted therein.

The foregoing description of the Sales Agreement is qualified in its entirety by reference to the Sales Agreement, a copy of which will be filed as an exhibit to the 2024 Registration Statement (as defined below).

The shares of Common Stock being offered pursuant to the Sales Agreement will be offered and sold pursuant to a shelf registration statement on Form S-3 (the “2024 Registration Statement”) that we intend to file with the Securities and Exchange Commission and a prospectus relating to the ATM Offering which will be included in the 2024 Registration Statement. None of our securities, including any shares of Common Stock, may be sold under the Sales Agreement, and no offers to buy such securities may be accepted, prior to the time the 2024 Registration Statement becomes effective.

The legal opinion of Sidley Austin LLP relating to the shares of Common Stock being offered pursuant to the Sales Agreement will be filed as Exhibit 5.1 to the 2024 Registration Statement.

This report shall not constitute an offer to sell or the solicitation of an offer to buy the securities discussed herein, nor shall there be any offer, solicitation, or sale of the securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

ITEM 6. EXHIBITS

- 3.1 [Amended and Restated Certificate of Incorporation of Codexis, Inc. filed with the Secretary of the State of Delaware on April 27, 2010 and effective as of April 27, 2010 \(incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, filed on May 28, 2010\).](#)
- 3.2 [Certificate of Designations of Series A Junior Participating Preferred Stock of Codexis, Inc., filed with the Secretary of State of the State of Delaware on September 4, 2012 \(incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed on September 4, 2012\).](#)
- 3.3 [Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Codexis, Inc., filed with the Secretary of the State of Delaware on June 14, 2023 \(incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed on June 16, 2023\).](#)
- 3.4 [Amended and Restated Bylaws of Codexis, Inc. effective as of February 8, 2024 \(incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed on February 9, 2024\).](#)
- 4.1 Reference is made to Exhibits 3.1 through 3.4.
- 4.2 [Form of the Company's Common Stock Certificate \(incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012, filed on August 9, 2012\).](#)
- 4.3 [Form of Warrant to Purchase Common Stock for Codexis, Inc., issued pursuant to the Loan and Security Agreement by and between the Company and Innovatus Life Sciences Fund I, LP. \(incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed on February 13, 2024\).](#)
- 4.4 [Description of Codexis' Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.\(incorporated by reference to Exhibit 4.4 to the Company's Annual Report on Form 10-K, filed on February 28, 2024\).](#)
- 10.1 [Loan and Security Agreement by and between the Company and Innovatus Life Sciences Fund I, LP., effective as of February 13, 2024 \(incorporated by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K for the year ended December 31, 2023, filed on February 28, 2024\).](#)
- 31.1 [Certification of Principal Executive Officer Required Under Rule 13a-14\(a\) and 15d-14\(a\) of the Securities Exchange Act of 1934, as amended.](#)
- 31.2 [Certification of Principal Financial Officer Required Under Rule 13a-14\(a\) and 15d-14\(a\) of the Securities Exchange Act of 1934, as amended.](#)
- 32.1 [Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14\(b\) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.](#)
- 101 The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, formatted in Inline Extensible Business Reporting Language (iXBRL) includes: (i) Unaudited Condensed Consolidated Balance Sheets at March 31, 2024 and December 31, 2023 (ii) Unaudited Condensed Consolidated Statements of Operations for the Three Months Ended March 31, 2024 and 2023, (iii) Unaudited Condensed Consolidated Statements of Comprehensive Loss for the Three Months Ended March 31, 2024 and 2023, (iv) Unaudited Condensed Consolidated Statements of Stockholders' Equity for the three months ended March 31, 2024 and 2023, (v) Unaudited Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2024 and 2023 and (v) Notes to Unaudited Condensed Consolidated Financial Statements.
- 101.SCH Inline XBRL Taxonomy Extension Schema Document
- 101.CAL Inline XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF Inline XBRL Taxonomy Extension Definition Linkbase Document
- 101.LAB Inline XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE Inline XBRL Taxonomy Extension Presentation Linkbase Document
- 104 The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, formatted in Inline XBRL and contained in Exhibit 101.

CERTIFICATION

I, Stephen Dilly, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Codexis, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 2, 2024

/s/ Stephen Dilly

Stephen Dilly

President and Chief Executive Officer
(principal executive officer)

CERTIFICATION

I, Sriram Ryali, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Codexis, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 2, 2024

/s/ Sriram Ryali

Sriram Ryali

Chief Financial Officer

(principal financial and accounting officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Codexis, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended March 31, 2024, as filed with the Securities and Exchange Commission (the "Report"), Stephen Dilly, President and Chief Executive Officer of the Company and Sriram Ryali, Chief Financial Officer of the Company, respectively, do each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- The information in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 2, 2024

/s/ Stephen Dilly

Stephen Dilly
President and Chief Executive Officer
(principal executive officer)

/s/ Sriram Ryali

Sriram Ryali
Chief Financial Officer
(principal financial and accounting officer)