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, 2023

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	**71-0872999**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
200 Penobscot Drive, Redwood City, California	**94063**
(Address of principal executive offices)	**(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	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the 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 May 1, 2023, there were 66,767,717 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, 2023

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

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

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 102,831	$ 113,984
Restricted cash, current	525	521
Financial assets:		
Accounts receivable	9,934	31,904
Contract assets	2,449	2,116
Unbilled receivables	7,797	7,016
Total financial assets	20,180	41,036
Less: allowances	(163)	(163)
Total financial assets, net	20,017	40,873
Inventories	1,996	2,029
Prepaid expenses and other current assets	4,585	5,487
Total current assets	129,954	162,894
Restricted cash	1,526	1,521
Investment in non-marketable equity securities ($0 and $13,921 with a related party)	21,310	20,510
Right-of-use assets - Operating leases, net	38,013	39,263
Property and equipment, net	23,609	22,614
Goodwill	3,241	3,241
Other non-current assets	415	350
Total assets	$ 218,068	$ 250,393
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,494	$ 3,246
Accrued compensation	6,611	11,453
Other accrued liabilities	8,340	15,279
Current portion of lease obligations - Operating leases	5,492	5,360
Deferred revenue	13,374	13,728
Total current liabilities	38,311	49,066
Deferred revenue, net of current portion	15,508	16,881
Long-term lease obligations - Operating leases	36,845	38,278
Other long-term liabilities	1,388	1,371
Total liabilities	92,052	105,596
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; 100,000 shares authorized; 66,696 shares and 65,811 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	6	6
Additional paid-in capital	569,917	566,081
Accumulated deficit	(443,907)	(421,290)
Total stockholders' equity	126,016	144,797
Total liabilities and stockholders' equity	$ 218,068	$ 250,393

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,	
	2023	**2022**
Revenues:		
Product revenue	$ 8,364	$ 30,690
Research and development revenue ($0 and $245 from a related party)	4,618	4,650
Total revenues	12,982	35,340
Costs and operating expenses:		
Cost of product revenue	4,521	8,521
Research and development	16,655	19,500
Selling, general and administrative	15,399	15,705
Restructuring charges	72	—
Total costs and operating expenses	36,647	43,726
Loss from operations	(23,665)	(8,386)
Interest income	1,089	42
Other expense, net	(25)	(3)
Loss before income taxes	(22,601)	(8,347)
Provision for income taxes	16	9
Net loss	$ (22,617)	$ (8,356)
Net loss per share, basic and diluted	$ (0.34)	$ (0.13)
Weighted average common stock shares used in computing net loss per share, basic and diluted	65,931	65,096

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, 2023	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
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	—	—	—	—
Employee 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	66,696	$ 6	$ 569,917	$ (443,907)	$ 126,016

Three Months Ended March 31, 2022	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance as of January 1, 2022	65,109	$ 6	$ 552,083	$ (387,698)	$ 164,391
Exercise of stock options	78	—	181	—	181
Release of stock awards	190	—	—	—	—
Employee stock-based compensation	—	—	3,777	—	3,777
Non-employee stock-based compensation	—	—	61	—	61
Taxes paid related to net share settlement of equity awards	(73)	—	(1,419)	—	(1,419)
Net loss	—	—	—	(8,356)	(8,356)
Balance as of March 31, 2022	65,304	$ 6	$ 554,683	$ (396,054)	$ 158,635

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,	
	2023	**2022**
Operating activities:		
Net loss	$ (22,617)	$ (8,356)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,466	1,215
Amortization expense - right-of-use assets - operating and finance leases	1,249	1,200
Stock-based compensation	2,809	3,838
Equity securities earned from research and development activities ($0 and ($245) from a related party)	(50)	(245)
Other non-cash items	(5)	(7)
Changes in operating assets and liabilities:		
Financial assets	20,856	(6,463)
Inventories	33	(400)
Prepaid expenses and other assets	586	1,397
Accounts payable	694	(1,029)
Accrued compensation and other accrued liabilities	(11,091)	(121)
Other long-term liabilities	(1,415)	(1,192)
Deferred revenue	(1,727)	(1,023)
Net cash used in operating activities	(9,212)	(11,186)
Investing activities:		
Purchase of property and equipment	(2,539)	(5,089)
Proceeds from sale of property and equipment	5	7
Investment in non-marketable securities	(750)	(5,000)
Net cash used in investing activities	(3,284)	(10,082)
Financing activities:		
Proceeds from exercises of stock options	281	181
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	(65)	(42)
Taxes paid related to net share settlement of equity awards	(404)	(1,419)
Net cash provided by (used in) financing activities	1,352	(1,280)
Net decrease in cash, cash equivalents and restricted cash	(11,144)	(22,548)
Cash, cash equivalents and restricted cash at the beginning of the period	116,026	118,895
Cash, cash equivalents and restricted cash at the end of the period	$ 104,882	$ 96,347
Supplemental disclosure of cash flow information:		
Interest paid	$ 7	$ 5
Income taxes paid	$ 193	$ —
Supplemental non-cash investing and financing activities:		
Capital expenditures incurred but not yet paid	$ 819	$ 789

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, 2023 and 2022 to the total of the same such amounts shown above in the unaudited condensed consolidated statements of cash flows:

	March 31,	
	2023	**2022**
Cash and cash equivalents	$ 102,831	$ 94,260
Restricted cash, current and non-current	2,051	2,087
Total cash, cash equivalents and restricted cash	$ 104,882	$ 96,347

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 are a leading enzyme engineering company leveraging our CodeEvolver® technology platform to discover, develop, enhance, and commercialize novel, high performance enzymes and other classes of proteins.

We report our financial results based on two reportable segments: Performance Enzymes and Novel Biotherapeutics. Our Novel Biotherapeutics business includes a diverse pipeline of product candidates in clinical and preclinical development. Our Performance Enzymes business consists primarily of two focus areas: i) biocatalysts for the sustainable manufacturing of pharmaceuticals and ii) enzymes for life science applications, including genomic sequencing and nucleic acid synthesis. The segment information aligns with how the chief operating decision maker (CODM), who is our Chief Executive Officer (CEO), reviews and manages the business.

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, 2022. The condensed consolidated balance sheet at December 31, 2022 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, 2023 and 2022, are consistent with those discussed in Note 2 to the audited consolidated financial statements in the Company's 2022 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, 2022.

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, 2023, results of our operations for the three months ended March 31, 2023 and 2022, changes in stockholders' equity for the three months ended March 31, 2023 and 2022, and cash flows for the three months ended March 31, 2023 and 2022. 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, 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 consolidated financial statements. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, including sales, expenses, reserves and allowances, manufacturing, research and development costs and employee-related amounts, will depend on future developments that are highly uncertain, and may not be accurately predicted, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19, as well as the economic impact on local, regional, national and international customers, markets and economies.

Accounting Pronouncements

Recently adopted accounting pronouncements or recently issued accounting pronouncements not yet adopted

There were no recent accounting pronouncements or changes in accounting pronouncements during the three months ended March 31, 2023, that are of significance or potential significance to us.

Note 3. Revenue Recognition

Disaggregation of Revenue

The following table provides information about disaggregated revenue from contracts with customers into the nature of the products and services, and geographic regions, and includes a reconciliation of the disaggregated revenue with reportable segments. 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).

Segment information is as follows (in thousands):

	Three Months Ended March 31, 2023			Three Months Ended March 31, 2022		
	Performance Enzymes	Novel Biotherapeutics	Total	Performance Enzymes	Novel Biotherapeutics	Total
Major products and service:						
Product revenue	$ 8,364	$ —	$ 8,364	$ 30,690	$ —	$ 30,690
Research and development revenue	1,122	3,496	4,618	2,409	2,241	4,650
Total revenues	$ 9,486	$ 3,496	$ 12,982	$ 33,099	$ 2,241	$ 35,340
Primary geographical markets:						
Americas	$ 918	$ 1,666	$ 2,584	$ 2,553	$ 1,179	$ 3,732
EMEA	1,259	1,830	3,089	3,065	1,062	4,127
APAC	7,309	—	7,309	27,481	—	27,481
Total revenues	$ 9,486	$ 3,496	$ 12,982	$ 33,099	$ 2,241	$ 35,340

Contract Balances

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

	March 31, 2023	December 31, 2022
Contract assets	$ 2,449	$ 2,116
Unbilled receivables	$ 7,797	$ 7,016
Contract costs	$ 2	$ 19
Contract liabilities: deferred revenue	$ 28,882	$ 30,609

We had no asset impairment charges related to financial assets in the three months ended March 31, 2023 and 2022.

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

We recognized the following revenues (in thousands):

	Three Months Ended March 31,	
Revenue recognized in the period for:	2023	2022
Amounts included in contract liabilities at the beginning of the period:		
Performance obligations satisfied	$ 1,602	$ 1,094
Changes in the period:		
Changes in the estimated transaction price allocated to performance obligations satisfied in prior periods	(216)	215
Performance obligations satisfied from new activities in the period - contract revenue	11,596	34,031
Total revenues	$ 12,982	$ 35,340

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, 2023.

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, 2023 (in thousands):

	Remainder of 2023	2024	2025	2026 and Thereafter	Total
Product revenue	$ 5,891	$ 12,050	$ 100	$ 3,339	$ 21,380
Research and development revenue	7,480	22	—	—	7,502
Total revenues	$ 13,371	$ 12,072	$ 100	$ 3,339	$ 28,882

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,	
	2023	2022
Shares issuable under the Equity Incentive Plan	9,397	5,899

Note 5. Investments in Non-Marketable Securities

Non-Marketable Equity Securities

In March 2023, we purchased an additional 985,545 shares of Molecular Assemblies, Inc. (“MAI”) Series B preferred stock for $0.8 million. As of March 31, 2023, we hold an aggregate of 19,277,914 shares of MAI's Series A and B preferred stock that we have earned or purchased from MAI. See Note 11“Related Party Transactions” for additional information on our investment in MAI.

In March 2022, we entered into a Stock Purchase Agreement with seqWell, Inc. (“seqWell”), a privately held biotechnology company, pursuant to which we purchased 1,000,000 shares of seqWell's Series C preferred stock for $5.0 million. In March 2023, we entered into a Master Collaboration Agreement and Research Agreement with seqWell (the “seqWell Agreement”), pursuant to which we are providing research and experimental screening and protein engineering activities in exchange for compensation in the form of additional shares of seqWell's common stock. We received 47,933 shares of seqWell's common stock from research and development services with seqWell and we recognized $50 thousand in research and development revenue from these services with seqWell during the three months ended March 31, 2023.

We own 207,070 shares of Series B-2 preferred stock of Arzeda Corp. (“Arzeda”), an early-stage computational protein design company.

Our non-marketable equity securities are investments in privately held companies without readily determinable market value and primarily relate to our investments in MAI, seqWell and 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 because 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. 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, 2023 and 2022. We recognized no realized gains or losses during the three months ended March 31, 2023 and 2022.

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

	March 31, 2023	December 31, 2022
MAI	$ 14,671	$ 13,921
seqWell	5,050	5,000
Arzeda	1,289	1,289
Other investments in non-marketable equity securities	300	300
Total non-marketable equity securities	$ 21,310	$ 20,510

Note 6. Fair Value Measurements

The following tables present the financial instruments that were measured at fair value on a recurring basis within the fair value hierarchy (in thousands):

	March 31, 2023			
	Level 1	Level 2	Level 3	Total
Money market funds	$ 100,165	$ —	$ —	$ 100,165

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Money market funds	$ 77,309	$ —	$ —	$ 77,309

During the three months ended March 31, 2023 and 2022,we did not recognize any significant credit losses nor other-than-temporary impairment losses on non-marketable securities.

Note 7. Balance Sheets Details

Cash Equivalents

Cash equivalents consisted of the following (in thousands):

	March 31, 2023		December 31, 2022	
	Adjusted Cost	Estimated Fair Value	Adjusted Cost	Estimated Fair Value
Money market funds [1]	$ 100,165	$ 100,165	$ 77,309	$ 77,309

[1] Money market funds are classified in cash and cash equivalents on our unaudited condensed consolidated balance sheets. Average contractual maturities (in days) is not applicable.

As of March 31, 2023, the total cash and cash equivalents balance of $102.8 million consisted of money market funds of $100.2 million and cash of $2.6 million held with major financial institutions. As of December 31, 2022, the total cash and cash equivalents balance of $114.0 million consisted of money market funds of $77.3 million and cash of $36.7 million held with major financial institutions.

Inventories

Inventories consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Raw materials	$ 108	$ 108
Work in process	36	91
Finished goods	1,852	1,830
Total Inventories	$ 1,996	$ 2,029

Inventories are recorded net of reserves of $1.2 million as of March 31, 2023 and December 31, 2022.

Property and Equipment, net

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

	March 31, 2023	December 31, 2022
Laboratory equipment	$ 40,489	$ 39,679
Leasehold improvements	16,694	16,633
Computer equipment and software	3,039	3,039
Office equipment and furniture	1,360	1,345
Construction in progress	3,189	1,739
Property and equipment	64,771	62,435
Less: accumulated depreciation and amortization	(41,162)	(39,821)
Property and equipment, net	$ 23,609	$ 22,614

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,	
	2023	2022
Depreciation expense	$ 1,466	$ 1,215

Goodwill

Goodwill had a carrying value of $3.2 million as of March 31, 2023 and December 31, 2022.

Other Accrued Liabilities

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

	March 31, 2023	December 31, 2022
Accrued professional and outside service fees	$ 4,256	$ 3,495
Accrued purchases	2,896	10,852
Other	1,188	932
Total other accrued liabilities	$ 8,340	$ 15,279

Note 8. Stock-based Compensation

Equity Incentive Plans

In January 2023, our board of directors (the "Board") approved the 2022 Employment Inducement Award Plan (the "2022 Inducement Plan") which provides for the grant of non-qualified stock options, restricted stock awards ("RSAs"), restricted stock units ("RSUs"), performance awards, other stock awards and dividend equivalents to eligible employees with respect to an aggregate of up to 2,000,000 shares of our common stock.

In 2019, the Board and stockholders approved the 2019 Incentive Award Plan (the "2019 Plan"). The 2019 Plan superseded and replaced in its entirety our 2010 Equity Incentive Plan (the "2010 Plan") which was effective in March 2010, and no further awards will be granted under the 2010 Plan; however, the terms and conditions of the 2010 Plan will continue to govern any outstanding awards thereunder. The 2019 Plan provides for the grant of stock options, including incentive stock options and non-qualified stock options, stock appreciation rights, RSA, RSUs, performance-contingent restricted stock units ("PSUs"), performance based options ("PBOs"), other stock or cash based awards and dividend equivalents to eligible employees and consultants of the Company or any parent or subsidiary, as well as members of the Board.

The number of shares of our common stock available for issuance under the 2019 Plan is equal to the sum of (i)7,897,144 shares, and (ii) any shares subject to awards granted under the 2010 Plan that were outstanding as of April 22, 2019 and thereafter terminate, expire, lapse or are forfeited; provided that no more than 14,000,000 shares may be issued upon the exercise of incentive stock options ("ISOs"). In June 2019, 8.1 million shares authorized for issuance under the 2019 Plan were registered under the Securities Act of 1933, as amended (the "Securities Act").

The 2010 Plan provided for the grant of incentive stock options, non-statutory stock options, RSUs, RSAs, PSUs, PBOs, stock appreciation rights, and stock purchase rights to our employees, non-employee directors and consultants.

Stock Options

The option exercise price for incentive stock options must be at least100% of the fair value of our common stock on the date of grant and the option exercise price for non-statutory stock options is at least 85% of the fair value of our common stock on the date of grant, as determined by the Board. If, at the time of a grant, the optionee directly or by attribution owns stock possessing more than 10% of the total combined voting power of all of our outstanding capital stock, the exercise price for these options must be at least 110% of the fair value of the underlying common stock. Stock options granted to employees generally have a maximum term often 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. We may grant options with different vesting terms from time to time. Unless an employee's termination of service is due to disability or death, upon termination of service, any unexercised vested options will be forfeited at the end of three months or the expiration of the option, whichever is earlier.

Restricted Stock Units ("RSUs")

We also grant employees RSUs, which generally vest over either a three-year period with 33% of the shares subject to the RSUs vesting on each yearly anniversary of the vesting commencement date or over a four-year period with 25% of the shares subject to the RSU vesting on each yearly anniversary of the vesting commencement date, in each case contingent upon such employee's continued service on such vesting date. RSUs are generally subject to forfeiture if employment terminates prior to the release of vesting restrictions. We may grant RSUs with different vesting terms from time to time.

Performance-contingent Restricted Stock Units ("PSUs") and Performance Based Options ("PBOs")

The compensation committee of the Board approved, solely in respect of non-executive employees, delegated to our CEO the authority to approve grants of PSUs. The compensation committee of the Board also approved grants of PBOs and PSUs to our executives. The PSUs and PBOs vest based upon both the successful achievement of certain corporate operating milestones in specified timelines and continued employment through the applicable vesting date. When the performance goals are deemed to be probable of achievement for these types of awards, recognition of stock-based compensation expense commences. Once the number of shares eligible to vest is determined, those shares vest in two equal installments with 50% vesting upon achievement, as determined by the compensation committee of the Board, and the remaining 50% vesting on the first anniversary of achievement, in each case, subject to the recipient's continued service through the applicable vesting date. If the performance goals are achieved at the threshold level, the number of shares eligible to vest in respect of the PSUs and PBOs would be equal to half the number of PSUs granted and one-quarter the number of shares underlying the PBOs granted. If the performance goals are achieved at the target level, the number of shares eligible to vest in respect of the PSUs and PBOs would be equal to the number of PSUs granted and half of the shares underlying the PBOs granted. If the performance goals are achieved at the superior level, the number of shares eligible to vest in respect of the PSUs would be equal to two times the number of PSUs granted and equal to the number of PBOs granted. The number of shares issuable upon achievement of the performance goals at the levels between the threshold and target levels for the PSUs and PBOs or between the target level and superior levels for the PSUs would be determined using linear interpolation. Achievement below the threshold level would result in no shares being eligible to vest in respect of the PSUs and PBOs.

No PSUs and PBOs were granted during the first quarter of 2023. In 2022, we awarded PSUs ("2022 PSUs") and PBOs ("2022 PBOs"), each of which commence vesting based upon the achievement of various weighted performance goals, including finance and corporate strategy, performance enzymes and biotherapeutics deliverables, research plans, and organizational development. In the first quarter of 2023, the compensation committee of the Board determined that the 2022 PSUs and 2022 PBOs performance goals had been achieved at 85% and 42.5% of the target level, respectively, and recognized stock-based compensation expenses accordingly. Accordingly, 50% of the shares underlying the 2022 PSUs and PBOs vested in the first quarter of 2023 and 50% of the shares underlying the 2022 PSUs and PBOs will vest in the first quarter of 2024, in each case subject to the recipient's continued service on each vesting date.

In 2021, we awarded PSUs ("2021 PSUs") and PBOs ("2021 PBOs"), each of which commence vesting based upon the determination by the compensation committee of the Board of the achievement of various weighted performance goals, including total revenues, product revenue, performance enzymes pipeline advancements, biotherapeutics pipeline advancements, organization and infrastructure upgrades, and significant events that can be publicly announced. In the first quarter of 2022, we determined that the 2021 PSUs and 2021 PBOs performance goals had been achieved at 146% and 73% of the target level, respectively, and recognized stock-based compensation expenses accordingly. Accordingly, 50% of the shares underlying the 2021 PSUs and PBOs vested in the first quarter of 2022 and 50% of the shares underlying the 2021 PSUs and PBOs vested in the first quarter of 2023, in each case, subject to the recipient's continued service on each vesting date.

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,	
	2023	**2022**
Cost of product revenue	$ 129	$ 100
Research and development	722	1,039
Selling, general and administrative	1,958	2,699
Total	$ 2,809	$ 3,838

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,	
	2023	2022
Stock options	$ 922	$ 806
RSUs and RSAs	1,126	1,162
PSUs	837	872
PBOs	(76)	998
Total	$ 2,809	$ 3,838

As of March 31, 2023, unrecognized stock-based compensation expense, net of expected forfeitures, was $11.9 million related to unvested stock options, $8.6 million related to unvested RSUs and RSAs, $1.1 million related to unvested PSUs, and $0.2 million related to unvested PBOs based on current estimates of the level of achievement. Stock-based compensation expense for these awards will be recognized through 2027.

Note 9. Capital Stock

Exercise of Options

For the three months ended March 31, 2023 and March 31, 2022, we issued 142,856 and 77,600 shares, respectively, upon option exercises at a weighted-average exercise price of $1.97 and $2.33 per share, respectively, with net cash proceeds of $0.3 million and $0.2 million, respectively.

Equity Distribution Agreement

In May 2021, we filed a Registration Statement on Form S-3 with the SEC, 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 that Registration on Form S-3. 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.

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, 2023, 327,480 shares of our common stock were issued pursuant to the EDA. 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, 2023, $48.5 million worth of shares remained available for sale under the EDA. During the three months ended March 31, 2022, no shares of our common stock were issued pursuant to the EDA.

Note 10. Commitments and Contingencies

Operating Leases

Our headquarters are located in Redwood City, California, where we occupy approximately 77,300 square feet of office and laboratory space in multiple buildings within the same business park of Metropolitan Life Insurance Company ("MetLife"). Our lease agreement with MetLife ("RWC Lease") includes approximately 28,200 square feet of space located at 200 and 220 Penobscot Drive, Redwood City, California (the "200/220 Penobscot Space") and approximately 37,900 square feet of space located at 400 Penobscot Drive, Redwood City, California (the "400 Penobscot Space") (the 200/220 Penobscot Space and the 400 Penobscot Space are collectively referred to as the "Penobscot Space"), and approximately 11,200 square feet of space located at 501 Chesapeake Drive, Redwood City, California (the "501 Chesapeake Space").

We entered into the initial lease with MetLife for our facilities in Redwood City in 2004 and the RWC Lease has been amended multiple times since then to adjust the leased space and terms of the Lease. In February 2019, we entered into an Eighth Amendment to the Lease (the "Eighth Amendment") with MetLife with respect to the Penobscot Space and the 501 Chesapeake Space to extend the term of the Lease for additional periods. Pursuant to the Eighth Amendment, the term of the lease of the Penobscot Space has been extended through May 2027. The lease term for the 501 Chesapeake Space has been extended to May 2029. We have one (1) option to extend the term of the lease for the Penobscot Space for five (5) years, and one (1) separate option to extend the term of the lease for the 501 Chesapeake Space for five (5) years.

Pursuant to the terms of the RWC Lease, we exercised our right to deliver a letter of credit in lieu of a security deposit. The letter of credit is collateralized by deposit balances held by the bank in the amount of $1.1 million as of March 31, 2023 and December 31, 2022, and are recorded as non-current restricted cash on the unaudited condensed consolidated balance sheets.

In January 2021, we entered into a lease agreement with ARE-San Francisco No. 63, LLC ("ARE") to lease a portion of a facility consisted of approximately 36,593 rentable square feet in San Carlos, California to serve as additional office and research and development laboratory space (the "San Carlos Space"). The lease has a 10-year term from the lease commencement date of November 30, 2021 with one option to extend the term for an additional period of 5 years. We have provided ARE with a $0.5 million security deposit in the form of a letter of credit and is recorded as non-current restricted cash on the consolidated balance sheets.

We are required to restore certain areas of the Redwood City and San Carlos facilities that we are renting to their original form. We are expensing the asset retirement obligation over the terms of the respective leases. We review the estimated obligation each reporting period and make adjustments if our estimates change. We recorded asset retirement obligations of $0.5 million as of March 31, 2023 and December 31, 2022, which are included in other liabilities on the unaudited condensed consolidated balance sheets. Accretion expense related to our asset retirement obligations was nominal in the three months ended March 31, 2023 and 2022.

Lease and other information

Lease costs, amounts included in measurement of lease obligations and other information related to non-cancellable operating leases and finance leases were as follows (in thousands):

	Three Months Ended March 31,	
	2023	**2022**
Finance lease costs	$ —	$ 18
Operating lease cost	1,830	1,831
Short-term lease costs [1]	—	30
Total lease cost [2]	$ 1,830	$ 1,879

[1] Short-term lease costs on leases with terms of over one month and less than one year.

[2] The Company had no variable lease costs.

Other information:	**Operating Leases**
Weighted-average remaining lease term (in years)	7.0 years
Weighted-average discount rate	5.4 %

Cash paid (in thousands):	Three Months Ended March 31, 2023	2022
Operating cash flows from operating leases	$ 1,882	$ 1,022

As of March 31, 2023, 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
2023 (remaining 9 months)	$ 5,686
2024	7,783
2025	8,004
2026	8,232
2027	5,835
Thereafter	14,871
Total minimum lease payments	50,411
Less: imputed interest	8,074
Lease obligations	$ 42,337

Reconciliation of operating lease liabilities as shown within the unaudited condensed consolidated balance sheets:	
Current portion of lease obligations - Operating leases	$ 5,492
Long-term lease obligations - Operating leases	36,845
Total operating lease liabilities	$ 42,337

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 and certain studies. Commitments under service agreements are 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	2023 (Remaining 9 Months)	2024 and Thereafter
Development and manufacturing services agreements	$ 3,734	$ 2,543	$ 1,191
Facility maintenance agreement	2,491	2,491	—
Total other commitments	$ 6,225	$ 5,034	$ 1,191

Credit Facility

In June 30, 2017, we entered into a credit facility (the “Credit Facility”) with Western Alliance Bank consisting of term loans (“Term Debt”) up to $0.0 million, and advances (“Advances”) under a revolving line of credit ("Revolving Line of Credit") up to $5.0 million with an accounts receivable borrowing base of80% of eligible accounts receivable. The right to take draws on the Term Debt expired on December 31, 2022. We terminated the loan agreement with Western Alliance Bank in March 2023.

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. Related Party Transactions

Molecular Assemblies, Inc.

In June 2020, we entered into a Stock Purchase Agreement with MAI pursuant to which we purchased1,587,050 shares of MAI's Series A preferred stock for $1.0 million. Mr. Nicols, our former President and CEO until August 2022, also joined MAI's board of directors in June 2020. Concurrently with our initial equity investment, we entered into a Master Collaboration and Research Agreement with MAI (the "MAI Agreement"), pursuant to which performed services utilizing our CodeEvolver® protein engineering platform technology to improve DNA polymerase enzymes in exchange for compensation in the form of additional shares of MAI's Series A and B preferred stock which are valued based on the observed transaction price of similar securities that MAI issued to third parties. We completed the R&D service with MAI pursuant to the MAI Agreement during the first quarter of 2022. In addition to our initial equity investment and the shares we have received under the MAI Agreement, in April 2021, we purchased an additional 1,000,000 shares of MAI's Series A preferred stock for $0.6 million and in September 2021, we purchased 9,198,423 shares of MAI's Series B preferred stock for $7.0 million.

Revenues recognized from transactions with MAI in the three months ended March 31, 2023, and subsequent to the related party period which ended in August 2022, are included in the condensed consolidated statement of operations. We recognized $0.2 million in research and development revenue from transactions with MAI in thethree months ended March 31, 2022 and during the related party period.

Note 12. Segment, Geographical and Other Revenue Information

Segment Information

We manage our business astwo business segments: Performance Enzymes and Novel Biotherapeutics. Our business segments are primarily based on our organizational structure and our operating results as used by our CODM in assessing performance and allocating resources for the Company.

We report corporate-related expenses such as legal, accounting, information technology, and other costs that are not otherwise included in our reportable business segments as "corporate costs." All items not included in income (loss) from operations are excluded from the business segments.

We manage our assets on a total company basis, not by business segment, as the majority of our operating assets are shared or commingled. Our CODM does not review asset information by business segment in assessing performance or allocating resources, and accordingly, we do not report asset information by business segment. All of our long-lived assets are located in the United States.

Factors considered in determining the two reportable segments of the Company include the nature of business activities, the management structure directly accountable to our CODM for operating and administrative activities, availability of discrete financial information and information presented to the Board of Directors. Our CODM regularly reviews our segments and the approach provided by management for performance evaluation and resource allocation.

Operating expenses that directly support the segment activity are allocated based on segment headcount, revenue contribution or activity of the business units within the segments, based on the corporate activity type provided to the segment. The expense allocation excludes certain corporate costs that are separately managed from the segments. This provides the CODM with more meaningful segment profitability reporting to support operating decisions and allocate resources.

The following table provides financial information by our reportable business segments along with a reconciliation to consolidated loss before income taxes (in thousands):

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

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

[2] Corporate costs include unallocated selling, general and administrative expenses, interest income, and other expense, net.

The following table provides stock-based compensation expense included in income (loss) from operations (in thousands):

	Three Months Ended March 31,							
	2023				2022			
	Performance Enzymes	Novel Biotherapeutics	Corporate cost	Total	Performance Enzymes	Novel Biotherapeutics	Corporate cost	Total
Stock-based compensation	$ 1,035	$ 413	$ 1,361	$ 2,809	$ 1,690	$ 410	$ 1,738	$ 3,838

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,	
	2023	2022
Customer A	*	61 %
Customer B	23 %	*
Customer C	14 %	*
Customer D	13 %	*
Customer E	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, 2023	December 31, 2022
Customer A	*	53 %
Customer B	21 %	*
Customer C	11 %	10 %
Customer F	14 %	*
Customer G	12 %	*

** Percentage was less than 10%*

Geographical Information

Geographic revenues are identified by the location of the customer and consist of the following (in thousands):

	Three Months Ended March 31,	
	2023	2022
Revenues:		
Americas	$ 2,584	$ 3,732
EMEA	3,089	4,127
APAC	7,309	27,481
Total revenues	$ 12,982	$ 35,340

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

	March 31, 2023	December 31, 2022
United States	$ 61,622	$ 61,877

Identifiable goodwill by reporting unit was as follows (in thousands):

	As of March 31, 2023 and December 31, 2022		
	Performance Enzymes	Novel Biotherapeutics	Total
Goodwill	$ 2,463	$ 778	$ 3,241

Note 13. Allowance for Credit Losses

The following table summarizes the financial assets allowance for credit losses (in thousands):

	Three Months Ended March 31,	
	2023	2022
Balance at beginning of period	$ 163	$ 416
Provision for credit losses	—	—
Write-offs	—	—
Adjustment to the existing allowance	—	—
Balance at end of period	$ 163	$ 416

The following tables summarize accounts receivable by aging category (in thousands):

	March 31, 2023					
	Current	31-60 Days	61-90 Days	91 Days and over	Total over 31 Days	Total balance
Accounts receivable	$ 7,385	$ 508	$ 321	$ 1,720	$ 2,549	$ 9,934

	December 31, 2022					
	Current	31-60 Days	61-90 Days	91 Days and over	Total over 31 Days	Total balance
Accounts receivable	$ 28,896	$ 1,747	$ 469	$ 792	$ 3,008	$ 31,904

Note 14. Restructuring Charges

In November 2022, we announced a plan for a workforce reduction of approximaely 18% of our total employee to realign and optimize our workforce requirements in alignment with our refined corporate strategy. The plan was substantially completed in December 2022 and severance costs were paid through the first quarter of 2023. During the three months ended March 31, 2023, we recorded an additional restructuring charge of $0.1 million related to severance, bonus and other termination benefits in connection with the workforce reduction, which is expected to be paid in the second quarter of 2023. We do not expect to record any significant future charges related to the restructuring plan initiated in 2022.

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, 2022 included in our Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the SEC on February 27, 2023 (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 will 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® 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. The capacity to enhance the properties and performance of enzymes has led to pivotal improvements across three healthcare industry pillars: pharmaceutical manufacturing, life sciences, and biotherapeutics. The enzymes we produce solve for real-world challenges associated with small molecule pharmaceuticals manufacturing, nucleic acid synthesis and genomic sequencing, and – as biotherapeutic candidates – they have the potential to treat challenging diseases. Our unique enzymes drive improvements such as higher yields, reduced energy usage and waste generation, improved efficiency in manufacturing, greater sensitivity in genomic and diagnostic applications, and potentially more efficacious therapeutics.

We manage our business as two business segments: Performance Enzymes and Novel Biotherapeutics. See Note 12, "Segment, Geographical and Other Revenue Information" in the Notes to Unaudited Condensed Consolidated Financial Statements included in this Quarterly Report.

Performance Enzymes

Our performance enzymes business consists primarily of two focus areas: biocatalysts for the sustainable manufacturing of pharmaceuticals and enzymes for life science applications, including genomic sequencing and nucleic acid synthesis. In our pharmaceutical manufacturing business, we utilize our CodeEvolver® 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 some small molecule therapeutics. In life science markets, we use our platform technology to develop enzymes for customers using next generation sequencing ("NGS"), a parallel sequencing technology used to identify genomic information in the study of biological systems, and PCR/qPCR for in vitro molecular diagnostic and molecular biology research applications, as well as for synthesis of nucleic acids such as DNA/RNA.

Novel Biotherapeutics

Our novel biotherapeutics business includes a diverse pipeline of product candidates in clinical and preclinical development. Our initial biotherapeutic product candidates include enzymes that are orally administered for function in the gastrointestinal tract ("GI"), such as our partnered product candidates CDX-7108 for the treatment of exocrine pancreatic insufficiency ("EPI") and CDX-6114 for the treatment of phenylketonuria ("PKU"), which are both in Phase 1 clinical trials. We have also engineered a series of transgenes that code for enzymes that may be used as gene therapies to treat rare lysosomal storage disorders with our partner Takeda, such as Fabry Disease and Pompe Disease, as well as a blood factor disorder.

Business Update Regarding COVID-19

In March 2020, the World Health Organization declared COVID-19 a global pandemic and recommended containment and mitigation measures worldwide. The spread of COVID-19 has affected segments of the global economy and may affect our operations, including the potential interruption of our supply chain. We are monitoring this situation closely, and although operations have not been materially affected by the COVID-19 outbreak to date, the ultimate duration and severity of the outbreak and its impact on the economic environment and our business is uncertain.

As a result of the COVID-19 pandemic, in 2021 and 2022 we received purchase orders from Pfizer Inc. ("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 API, nirmatrelvir, used by Pfizer in combination with the API ritonavir, as its PAXLOVID™ (nirmatrelvir tablets; ritonavir tablets) product for the treatment of COVID-19 infections in humans. We are a party to an Enzyme Supply Agreement with Pfizer Ireland Pharmaceuticals, a subsidiary of Pfizer, Inc. (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 its 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. Subsequent to the end of the quarter, 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 expect to recognize $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 (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. The sale of CDX-616 to Pfizer had a substantial impact on our revenues in 2021 and 2022. Revenues in 2023 and in future years from our sales of CDX-616 to Pfizer and other potential customers (including sublicensees of Pfizer technology from The Medicine Patent Pool) are subject to a number of factors which are outside of our control and could reduce or eliminate our sales of CDX-616, and therefore materially and adversely affect our business, results of operations and financial conditions.

Significant Collaborative Arrangements Update

Merck Sitagliptin Catalyst Supply Agreement

In February 2012, we entered into a five-year Sitagliptin Catalyst Supply Agreement ("Sitagliptin Supply Agreement") with Merck whereby Merck may obtain commercial scale enzyme for use in the manufacture of Januvia®, its product based on the active ingredient sitagliptin. In December 2015, Merck exercised its option under the terms of the Sitagliptin Catalyst Supply Agreement to extend the agreement for an additional five years through February 2022. In September 2021, the Sitagliptin Catalyst Supply Agreement was amended to extend the agreement through December 2026.

We recognized $3.0 million and $1.7 million under this agreement for the three months ended March 31, 2023 and 2022, respectively, which represented 23% and 5% of our total revenues for those periods. As of March 31, 2023, we recorded revenue of $2.0 million from sitagliptin enzyme sales that were recognized over time based on the progress of the manufacturing process. These products will be shipped within the six-month period following the end of the first quarter of 2023.

Global Development, Option and License Agreement and Strategic Collaboration Agreement

In October 2017, we entered into the Nestlé License Agreement with Nestlé Health Science and, solely for the purpose of the integration and the dispute resolution clauses of the Nestlé License Agreement, Nestlé Health Science S.A., to advance CDX-6114, our enzyme biotherapeutic product candidate for the potential treatment of PKU.

In January 2019, we received notice from the U.S. Food and Drug Administration ("FDA") that it had completed its review of our IND for CDX-6114 and concluded that we may proceed with the proposed Phase 1b multiple ascending dose study in healthy volunteers in the United States. In February 2019, Nestlé Health Science exercised its option to obtain an exclusive, worldwide, royalty-bearing, sub-licensable license for the global development and commercialization of CDX-6114 for the management of PKU. Upon exercising its option, Nestlé Health Science made an option payment and assumed all responsibilities for future clinical development and commercialization of CDX-6114. We are also eligible to receive payments from Nestlé Health Science under the Nestlé License Agreement that include (i) development and approval milestones of up to $85.0 million, (ii) sales-based milestones of up to $250.0 million in the aggregate, which aggregate amount is achievable if net sales exceed $1.0 billion in a single year, and (iii) tiered royalties, at percentages ranging from the mid-single digits to low double-digits of net sales of product.

In October 2017, we entered into the Nestlé Strategic Collaboration Agreement ("SCA") pursuant to which we and Nestlé Health Science are collaborating 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 been extended through December 2023 with an automatic renewal through December 2024.

In January 2020, we entered into a development agreement with Nestlé Health Science pursuant to which we and Nestlé Health Science are collaborating to advance a lead candidate discovered through our Nestlé SCA, CDX-7108, targeting EPI, into preclinical and early clinical studies. The term of the development has been extended through December 2023 with an automatic renewal through December 2024. We, together with Nestlé Health Science, are continuing to advance CDX-7108 and initiated a Phase 1 clinical trial of CDX-7108 for the treatment of EPI in the fourth quarter of 2021 and, on February 23, 2023, we and Nestlé Health Science announced interim results. Interim data from the proof-of-concept arm showed improved lipid absorption when patients were administered CDX-7108 versus placebo. Importantly, no notable safety issues were noted in the 48 subjects that participated in the single ascending dose and multiple ascending dose portion of the study. We believe the interim data support further development of CDX-7108 in partnership with Nestlé Health Science, with potential for the initiation of a Phase 2 study in 2024.

Under the Nestlé SCA and the development agreement, we recognized $1.8 million and $1.1 million in research and development fees for the three months ended March 31, 2023 and 2022, respectively.

Platform Technology Transfer and License Agreement

In May 2019, we entered into the Novartis CodeEvolver® Agreement with Novartis. The Agreement allows Novartis to use our proprietary CodeEvolver® protein engineering platform technology in the field of human healthcare. In July 2021, we announced the completion of the technology transfer period during which we transferred our proprietary CodeEvolver® protein engineering platform technology to Novartis (the "Technology Transfer Period"). As a part of this technology transfer, we provided to Novartis our proprietary enzymes, proprietary protein engineering protocols and methods, and proprietary software algorithms. In addition, our teams and Novartis scientists participated in technology training sessions and collaborative research projects at our laboratories in Redwood City, California and at a designated Novartis laboratory in Basel, Switzerland. Novartis has now installed the CodeEvolver® protein engineering platform technology at its designated laboratory.

Pursuant to the agreement, we received an upfront payment of $5.0 million shortly after the effective date of the Novartis CodeEvolver® Agreement. We completed the second technology milestone transfer under the agreement in 2020 and received a milestone payment of $4.0 million. We have also received an aggregate of $5.0 million for the completion of the third technology milestone in 2021. In consideration for the continued disclosure and license of improvements to the technology and materials during a multi-year period that began on the conclusion of the Technology Transfer Period ("Improvements Term"), Novartis will pay Codexis annual payments over four years which amount to an additional $8.0 million in aggregate. We received the first annual payment of $2.0 million in the fourth quarter of 2022. The Company also has the potential to receive quantity-dependent, usage payments for each API that is manufactured by Novartis using one or more enzymes that have been developed or are in development using the CodeEvolver® protein engineering platform technology during the period that began on the conclusion of the Technology Transfer Period and ends on the expiration date of the last to expire licensed patent. Revenue for the combined initial license and technology transfer performance obligation was recognized using a single measure of progress that depicted our performance in transferring control of the services. Revenue allocated to improvements made during the Improvements Term are being recognized during the Improvements Term.

We recognized $0.3 million and $0.2 million in research and development revenue for the three months ended March 31, 2023 and 2022, respectively.

Strategic Collaboration and License Agreement

In March 2020, we entered into the Takeda Agreement with Shire Human Genetic Therapies, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Co. Ltd. ("Takeda"), under which we are collaborating to research and develop protein sequences for use in gene therapy products for certain diseases in accordance with each applicable program plan.

On execution of the Takeda Agreement, we received an upfront non-refundable cash payment of $8.5 million and we initiated activities under three program plans for Fabry Disease, Pompe Disease, and an undisclosed blood factor deficiency, respectively (the "Initial Programs"). In May 2021, Takeda elected to exercise its option to initiate an additional program for a certain undisclosed rare genetic disorder; as a result, we received the option exercise fee during the third quarter of 2021. Pursuant to the Takeda Agreement, we are eligible to receive other payments that include (i) reimbursement of research and development fees and preclinical development milestones for the Initial Programs of $12.0 million, in aggregate, and $4.2 million for the fourth program, (ii) clinical development and commercialization-based milestones, per target gene, of up to $104.0 million and (iii) tiered royalty payments based on net sales of applicable products at percentages ranging from the mid-single digits to low single-digits.

On February 22, 2023, we announced that Takeda presented pre-clinical data from the Fabry Disease transgene program, part of its Strategic Collaboration and License Agreement with Codexis, at the 19th Annual WORLD*Symposium*™. The gene therapy candidate is being developed to encode the codon optimized, CodeEvolver® engineered-GAL enzyme, which is designed to have improved serum and lysosomal stability and a predicted reduced immunogenicity.

Revenue recognized relating to the functional licenses provided to Takeda was recognized at a point in time when the control of the license transferred to the customer. We recognized research and development revenue related to the Takeda Agreement of $1.7 million and $1.2 million for the three months ended March 31, 2023 and 2022, respectively.

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 its 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. Subsequent to the end of the quarter, 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 expect to recognize $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 (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 revenue was recognized from the Pfizer Supply Agreement during the three months ended March 31, 2023. We recognized product revenue of $21.3 million for the three months ended March 31, 2022 from the sale of quantities of CDX-616 to Pfizer which comprised 60% of our total revenues for the three months ended March 31, 2022. As of March 31, 2023 and December 31, 2022, we had $24.4 million in deferred revenue related to the $25.9 million fee received from Pfizer.

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	
	2023	2022	$	%
Revenues:				
Product revenue	$ 8,364	$ 30,690	$ (22,326)	(73)%
Research and development revenue	4,618	4,650	(32)	(1)%
Total revenues	12,982	35,340	(22,358)	(63)%
Costs and operating expenses:				
Cost of product revenue	4,521	8,521	(4,000)	(47)%
Research and development	16,655	19,500	(2,845)	(15)%
Selling, general and administrative	15,399	15,705	(306)	(2)%
Restructuring charges	72	—	72	100%
Total costs and operating expenses	36,647	43,726	(7,079)	(16)%
Loss from operations	(23,665)	(8,386)	(15,279)	182%
Interest income	1,089	42	1,047	2,493%
Other expense, net	(25)	(3)	(22)	733%
Loss before income taxes	(22,601)	(8,347)	(14,254)	171%
Provision for income taxes	16	9	7	78%
Net loss	$ (22,617)	$ (8,356)	$ (14,261)	171%

Revenues

Our revenues consisted of product revenue and research and development 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	
	2023	2022	$	%
Product revenue	$ 8,364	$ 30,690	$ (22,326)	(73)%
Research and development revenue	4,618	4,650	(32)	(1)%
Total revenues	$ 12,982	$ 35,340	$ (22,358)	(63)%

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 decreased by $22.4 million to $13.0 million in the three months ended March 31, 2023 compared to the same period in 2022, or 63%, primarily due to lower product revenue.

Product revenue, decreased by $22.3 million to $8.4 million in the three months ended March 31, 2023 compared to the same period in 2022, primarily due to decreased sales of CDX-616 to Pfizer.

Research and development revenue remained unchanged in the three months ended March 31, 2023 compared to the same period in 2022, primarily due to higher revenue from Nestlé Health Science under the Nestlé SCA and development agreement which was offset by lower research and development fees from existing collaboration agreements being recognized in the first quarter of 2023 as compared to the same period in the prior year.

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	
	2023	2022	$	%
Cost of product revenue	$ 4,521	$ 8,521	$ (4,000)	(47)%
Research and development	16,655	19,500	(2,845)	(15)%
Selling, general and administrative	15,399	15,705	(306)	(2)%
Restructuring charges	72	—	72	100%
Total costs and operating expenses	$ 36,647	$ 43,726	$ (7,079)	(16)%

Cost of Product Revenue and Product Gross Margin

Our product revenues are derived entirely from our Performance Enzymes segment. Revenues from the Novel Biotherapeutics segment are derived entirely from collaborative research and development activities as we have no approved products available for sale.

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	
	2023	2022	$	%
Product revenue	$ 8,364	$ 30,690	$ (22,326)	(73)%
Cost of product revenue [1]	4,521	8,521	(4,000)	(47)%
Product gross profit	$ 3,843	$ 22,169	$ (18,326)	(83)%
Product gross margin (%)[2]	46 %	72 %		

[1] Cost of product revenue consist 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 decreased by $4.0 million in the three months ended March 31, 2023 compared to the same period in 2022 primarily due to a lower volume of product sales as compared to the same period in prior year. The product gross margin decreased to 46% in the three months ended March 31, 2023 compared to 72% in the three months ended March 31, 2022, primarily due to the sales of lower margin products, including sitagliptin, and variation in prices per volume sold.

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 $16.7 million in the first quarter of 2023, a decrease of $2.8 million, or 15%, from $19.5 million in the first quarter of 2022. The decrease was primarily due to decreases in costs associated with lower headcount, decrease in outside services related to Chemistry, Manufacturing and Controls ("CMC") and regulatory expenses, lower stock-based compensation costs and lower lab supply costs.

Selling, General 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 $15.4 million in the first quarter of 2023, a decrease of $0.3 million, or 2%, compared to $15.7 million in the first quarter of 2022. The decrease was primarily due to lower legal fees and lower stock-based compensation costs, which was partially offset by higher payroll-based expenses andhigher outside and temporary services.

Restructuring Charges

Restructuring charges consist of one-time employee severance and other termination benefits due to a workforce reduction plan that was initiated in the fourth quarter of 2022. 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	
	2023	2022	$	%
Interest income	$ 1,089	$ 42	$ 1,047	2,493 %
Other expense, net	(25)	(3)	(22)	733 %
Total other income, net	$ 1,064	$ 39	$ 1,025	2,628 %

Interest Income

Interest income increased by $1.0 million in the three months ended March 31, 2023 compared to the same period in 2022, primarily due to higher average interest rates on cash balances.

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

	Three Months Ended March 31,		Change	
	2023	2022	$	%
Provision for income taxes	$ 16	$ 9	$ 7	78%

The provision for income taxes for the three months ended March 31, 2023 was primarily for current year state income taxes andthe accrual of interest and penalties on historic uncertain tax positions. The provision for income taxes for the three months ended March 31, 2022 wasprimarily due for the accrual of interest and penalties on historic uncertain tax positions

Net Loss

Net loss for the three months ended March 31, 2023 was $22.6 million, or a net loss per basic and diluted share of $0.34. This compared to a net loss of $8.4 million, or a net loss per basic and diluted share of $0.13 for the three months ended March 31, 2022. The increase in net loss is primarily related to lower product revenues from CDX-616, which was partially offset by lower operating expenses.

RESULTS OF OPERATIONS BY SEGMENT (in thousands, except percentages):

Revenues by segment

	Three Months Ended March 31,						Change			
	2023			2022			Performance Enzymes		Novel Biotherapeutics	
	Performance Enzymes	Novel Biotherapeutics	Total	Performance Enzymes	Novel Biotherapeutics	Total	$	%	$	%
Revenues:										
Product revenue	$ 8,364	$ —	$ 8,364	$ 30,690	$ —	$ 30,690	$ (22,326)	(73)%	$ —	—%
Research and development revenue	1,122	3,496	4,618	2,409	2,241	4,650	(1,287)	(53)%	1,255	56%
Total revenues	$ 9,486	$ 3,496	$ 12,982	$ 33,099	$ 2,241	$ 35,340	$ (23,613)	(71)%	$ 1,255	56%

Revenues from the Performance Enzymes segment decreased by $23.6 million, or 71%, for the three months ended March 31, 2023, compared to the same period in 2022. The decrease in product revenue of $22.3 million, or 73%, in the three months ended March 31, 2023 as compared to the same period in 2022, was primarily due to decreased sales of CDX-616 to Pfizer. The decrease in research and development revenue of $1.3 million, or 53%, to $1.1 million in the three months ended March 31, 2023, as compared to $2.4 million in the three months ended March 31, 2022 was primarily due to lower research and development fees from existing collaboration agreements compared to the same period in the prior year.

Revenues from the Novel Biotherapeutics segment increased by $1.3 million, or 56%, for the three months ended March 31, 2023, as compared to the same period in 2022, primarily due to higher research and development revenue from Nestlé Health Science under the Nestlé SCA and development agreement.

Costs and operating expenses by segment

	Three Months Ended March 31,						Change			
	2023			2022			Performance Enzymes		Novel Biotherapeutics	
	Performance Enzymes	Novel Biotherapeutics	Total	Performance Enzymes	Novel Biotherapeutics	Total	$	%	$	%
Cost of product revenue	$ 4,521	$ —	$ 4,521	$ 8,521	$ —	$ 8,521	$ (4,000)	(47)%	$ —	—%
Research and development [1]	8,099	7,312	15,411	6,122	12,346	18,468	1,977	32%	(5,034)	(41)%
Selling, general and administrative [1]	2,798	951	3,749	3,541	720	4,261	(743)	(21)%	231	32%
Restructuring charges	—	72	72	—	—	—	—	—%	72	100%
Total segment costs and operating expenses	$ 15,418	$ 8,335	$ 23,753	$ 18,184	$ 13,066	31,250	$ (2,766)	(15)%	$ (4,731)	(36)%
Corporate costs [2]			11,428			11,244				
Unallocated depreciation and amortization			1,466			1,232				
Total costs and operating expenses			$ 36,647			$ 43,726				

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

[2] Corporate costs include unallocated selling and general and administrative expenses.

For a discussion of product cost of revenue, see "*—Results of Operations*".

Research and development expense in the Performance Enzymes segment increased by $2.0 million, or 32%, in the three months ended March 31, 2023, as compared to the same period in 2022, primarily due to higher allocable costs and higher stock-based compensation costs which was offset by decrease in costs associated with lower headcount and decrease in costs associated with outside services and lab supply costs.

Selling, general and administrative expense in the Performance Enzymes segment decreased by $0.7 million, or 21%, in the three months ended March 31, 2023, as compared to the same period in 2022, primarily due to decrease in costs associated with lower headcount and lower stock-based compensation costs.

Research and development expense in the Novel Biotherapeutics segment decreased by $5.0 million, or 41%, in the three months ended March 31, 2023 as compared to the same period in 2022, primarily due to decrease in costs associated with lower headcount, decrease in outside services related to CMC and regulatory expenses and lower lab supply costs.

Selling, general and administrative expense in the Novel Biotherapeutics segment increased by $0.2 million or 32% in the three months ended March 31, 2023, as compared to the same period in 2022, primarily due to higher payroll-based expenses and higher outside and temporary services.

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. 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 are, and we expect will continue to be for the near future, compensation and related expenses, research and development expenses including costs related to the potential clinical development of our product candidates, manufacturing costs, laboratory and related supplies, legal and other regulatory expenses, and general overhead costs. We expect our cash requirements to increase in the near term as we continue to invest in high potential research and development activities with long-term commercial potential, if approved, and see less cash revenue from sales of CDX-616 to Pfizer for PAXLOVID™.

The following summarizes our cash and cash equivalents balance and working capital as of March 31, 2023 and December 31, 2022 (in thousands):

	March 31, 2023	December 31, 2022
Cash and cash equivalents	$ 102,831	$ 113,984
Working capital	$ 91,643	$ 113,828

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 and certain royalty payments under our collaboration agreements with Merck, Novartis and Nestlé Health Science of up to $439.0 million in the aggregate. In addition, under the GSK CodeEvolver® Agreement, we have the potential to receive additional contingent payments that range from $5.8 million to $38.5 million per project. 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.

In addition, pursuant to the terms of the Pfizer Supply Agreement, Pfizer paid us a fee of $25.9 million in August 2022which 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 its 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. Subsequent to the end of the quarter, 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 expect to recognize $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 (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.

We are actively collaborating with new and existing customers. We believe that we can utilize our current products and services, and develop new products and services, to increase our revenues and gross margins in future periods.

We have historically experienced negative cash flows from operations as we continue to invest in key technology development projects and improvements to our CodeEvolver® protein engineering technology 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.

Equity Distribution Agreement

In May 2021, we entered into an Equity DistributionAgreement ("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. During the three months ended March 31, 2023, 327,480 shares of our common stock were issued pursuant to the EDA and we received net proceeds of $1.2 million. As of March 31, 2023, $48.5 million worth of shares remained available for sale under the EDA. Sales of our common stock under this arrangement 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.

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, 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. If we raise debt financing or enter into credit facilities, we may be subject to restrictive covenants that limit our ability to conduct 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.

Cash Flows

The following is a summary of cash flows for three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,	
	2023	2022
Net cash used in operating activities	$ (9,212)	$ (11,186)
Net cash used in investing activities	(3,284)	(10,082)
Net cash provided by (used in) financing activities	1,352	(1,280)
Net decrease in cash, cash equivalents and restricted cash	$ (11,144)	$ (22,548)

Cash Flows from Operating Activities

Cash used in operating activities for the three months ended March 31, 2023 of $9.2 million consisted of net loss adjusted for certain non-cash items and changes in operating assets and liabilities.

The $2.0 million decrease in net cash used in operations for the three months ended March 31, 2023 as compared to the same period in 2022, was primarily due to the net effect of decreases in cash paid for cost of revenues and operating expenses and changes in operating assets and liabilities.

Cash Flows from Investing Activities

Cash used in investing activities for the three months ended March 31, 2023 was primarily attributable to $0.8 million for the purchase of additional shares of MAI's Series B preferred stock in March 2023 and $2.5 million for purchases of property and equipment.

The $6.8 million decrease in net cash used in investing activities for the three months ended March 31, 2023 as compared to the same period in 2022, was primarily due to higher cash utilized for additional investment in equity securities and purchases of property and equipment in prior year.

Cash Flows from Financing Activities

Cash provided by financing activities for the three months ended March 31, 2023 included $1.5 million gross proceeds from issuance of common stock and $0.3 million of proceeds from exercises of stock options, and was partially offset by $0.4 million for taxes paid related to net share settlement of equity awards.

The $2.6 million increase in net cash provided by financing activities for the three months ended March 31, 2023 as compared to the same period in 2022 was primarily due to proceeds from issuance of common stock and lower cash paid on taxes related to net share settlement of equity awards.

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, 2023 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 on Form 10-K.

Interest Rate Sensitivity

Our unrestricted cash and cash equivalents total $102.8 million as of March 31, 2023. We primarily invest these amounts in money market funds which are held for working capital purposes. We do not enter into investments for trading or speculative purposes. As of March 31, 2023, the effect of a hypothetical 10% decrease in market interest rates would have a $0.5 million impact on a potential loss in future interest income and cash flows.

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 USD declines in value as compared to the foreign currencies in which we incur expenses, our foreign-currency based expenses increase when translated into United States dollars. Although substantially all of our sales are denominated in United States dollars, 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, 2023, 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 $42 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 in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, including our principal executive officer and our principal financial and accounting officer, 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 principal executive officer and our principal financial and accounting officer concluded that these disclosure controls and procedures were effective as of March 31, 2023 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

ITEM 1. LEGAL PROCEEDINGS

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 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.
- 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.
- Our biotherapeutic programs are early stage, highly regulated and expensive.
- If either Nestlé Health Science or Takeda terminate their development programs under their respective license agreements with us, any potential revenue from those license agreements will be significantly reduced or non-existent.
- We may need additional capital in the future in order to expand our business.
- 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.
- 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.
- If we are unable to develop and commercialize new products for the target markets, our business and prospects will be harmed.
- 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 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 Securities and Exchange Commission 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 or our customers may not be able to obtain regulatory approval for the use of our products in food and food ingredients, if required.
- Our ongoing efforts to deploy our technology in the life science tools market may fail.

- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and we may be unable to obtain regulatory approval for our product candidates.
- Clinical trials are difficult to design and implement, expensive, time-consuming and involve an uncertain outcome.
- Results of preclinical studies and early clinical trials of product candidates may not be predictive of results of later studies or trials.
- We may not be able to maintain orphan drug designations for certain of our product candidates and may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.
- We have obtained rare pediatric disease designation for CDX-6512 and CDX-6210, however, there is no guarantee that such designation will result in approval of CDX-6512 or CDX-6210, and even if we obtain approval of CDX-6512 or CDX-6210 for the indication for which we have been awarded rare pediatric disease designation, there is no guarantee that such approval will result in an aware of a rare pediatric disease priority review voucher.
- Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner, or at all, which could negatively impact our business.
- Even if we obtain regulatory approval for any products that we develop alone or with collaborators, such products will remain subject to ongoing regulatory requirements.
- Our business operations and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.
- The successful commercialization of product candidates developed by us or our partners will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies.
- We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies, which if not satisfactorily carried out or fail to meet expected deadlines, may have an adverse effect on our business and prospects.
- We contract with third parties for the manufacturing and supply of product candidates, which supply may become limited or interrupted or may not be of satisfactory quality and quantity.
- Our efforts to prosecute, maintain, protect and/or defend our intellectual property rights may not be successful.
- 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 Relating 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 $33.6 million, $21.3 million, and $24.0 million for the years ended December 31, 2022, 2021, and 2020, respectively, and $22.6 million and $8.3 million for the three months ended March 31, 2023 and 2022, respectively. As of March 31, 2023 and December 31, 2022, we had an accumulated deficit of $443.9 million and $421.3 million, respectively. If we are unable to expand our business, through new or expanded collaborations, development of new products or services, or increased sales of existing products and services, our net losses may increase and we may never achieve profitability. In addition, some of our collaboration agreements, including our collaborations with Nestlé Health Science and Takeda, and our performance enzyme agreements, including the agreements with GSK, Merck and Novartis, provide for milestone payments, usage payments, and/or future royalty payments, which we will only receive if we and our collaborators develop and commercialize products. We also may fund development of additional proprietary performance enzymes and/or biotherapeutic products. There can be no assurance that any of these products 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.

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, Nestlé Health Science and Takeda 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 and could 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, Novartis, Nestlé Health Science or Takeda, 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;
- we, 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.

We are aware of media reports that Takeda has communicated internally its desire to end research, discovery and preclinical work in certain rare disease areas that may overlap with the programs on which we collaborate. We continue to engage in discussions with Takeda about their plans related to such programs. It is unclear how any such changes at Takeda, if they occur, might impact our collaborative programs. To our knowledge, Takeda has made no definitive decisions with regards to any programs covered by the Takeda Agreement.

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.

Our biotherapeutic programs are early stage, highly regulated and expensive. Our ability to obtain additional development partners or additional funding for the programs, to advance our product candidates to clinical trials and to ultimately receive regulatory approvals is highly uncertain.

We are developing and have developed novel biotherapeutic candidates, including CDX-6114, the novel oral enzyme product candidate for the treatment of PKU that we licensed to Nestlé Health Science and CDX-7108, the oral recombinant lipase product candidate for the treatment of EPI that we are developing in collaboration with Nestlé Health Science. We are also developing protein sequences for use in gene therapy products for Fabry Disease, Pompe Disease, an undisclosed blood factor deficiency and a certain undisclosed rare genetic disorder for Takeda. The successful development of biotherapeutic candidates involves many risks and uncertainties, requires long timelines and may lead to uncertain results. In addition, drug development is highly regulated and requires areas of expertise and capital resources we do not currently possess. In order to market a biologic product in the United States, we or our 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 GLP requirements;
- submission to the FDA of an IND, which must become effective before human clinical studies may begin in the United States;
- approval by an independent IRB representing each clinical site before the clinical study may be initiated at the site;
- performance of adequate and well-controlled human clinical studies (generally divided into three phases) in accordance with 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") 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 cGMP requirements; and
- FDA review and approval of a BLA prior to any commercial marketing or sale of the product in the United States.

If we 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, we 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.

Our efforts to advance our biotherapeutic candidates that we develop are subject to numerous risks, including the following:

- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and the results are inherently unpredictable. If we are ultimately unable to obtain regulatory approval for biotherapeutic product candidates, our business will be harmed. To obtain regulatory approval to market any product candidate, preclinical studies and costly and lengthy clinical trials are required, and the results of the studies and trials are highly uncertain. A failure of one or more preclinical or clinical trials can occur at any stage, and many companies that have believed their drug candidates performed satisfactorily in preclinical and clinical testing have nonetheless failed to obtain marketing approval of their product candidates.
- We may find it difficult to enroll patients in our clinical trials for product candidates. Any enrollment difficulties could delay clinical trials and any potential product approval.
- We may experience difficulty or delay in obtaining the FDA's acceptance of an IND for product candidates we may seek to enter into clinical development, which would delay initiation of Phase 1 clinical testing. Delays in the commencement or completion of clinical testing could significantly affect our product development costs or the product development costs of our present and any future collaborators. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons. For example, a clinical trial may be suspended or terminated by us, by the IRB of the institution in which such trial is being conducted, or by the FDA due to a number of factors, including unforeseen safety issues, changes in governmental regulations or lack of adequate funding to continue the clinical trial.
- We have limited experience in drug development or regulatory matters related to drug development. As a result, we rely or will rely on third parties to conduct our preclinical and clinical studies, assist us with drug manufacturing and formulation and perform other tasks for us. If these third parties do not successfully carry out their responsibilities or comply with regulatory requirements, we may receive lower quality products or services, suffer reputational harm and not be able to obtain regulatory approval for product candidates.
- Our efforts to use CodeEvolver® protein engineering technology platform to generate new lead biotherapeutic candidates, whether under our collaborations with Nestlé Health Science, Takeda or otherwise, may not be successful in creating candidates of value.
- We will be exposed to potential product liability risks through the testing of experimental therapeutics in humans, which may expose us to substantial uninsured liabilities.
- Third parties may develop intellectual property that could limit our ability to develop, market and commercialize product candidates.
- Changes in methods of treatment of disease, such as gene therapy, could cause us to stop development of our product candidates or reduce or eliminate potential demand for CDX-6114 or CDX-7108, if approved, or any other product candidates that we may develop in the future.

If either Nestlé Health Science or Takeda terminate their development programs under their respective license agreements with us, any potential revenue from those license agreements will be significantly reduced or non-existent, and our results of operations and financial condition will be materially and adversely affected.

We have invested significant time and financial resources in the development of CDX-6114 and other product candidates for the treatment of hyperphenylalaninemia, now included in the Nestlé License Agreement, as well as in the development of candidates for the treatment of Fabry disease and Pompe disease, which are now included in the Takeda Agreement.

Under the Nestlé License Agreement, we are eligible to receive payments from Nestlé Health Science that include (i) development and approval milestones of up to $85.0 million, (ii) sales-based milestones of up to $250.0 million in the aggregate, which aggregate amount is achievable if net sales exceed $1.0 billion in a single year, and (iii) tiered royalties, at percentages ranging from the mid-single digits to low double-digits, of net sales of product.

Under the Takeda Agreement, we are eligible to earn potential payments that include (i) reimbursement of research and development fees and preclinical development milestone payments for the three initial programs of $12.0 million, in aggregate, and $4.2 million for the fourth program, (ii) clinical development and commercialization-based milestone, per target gene, of up to $104.0 million, and (iii) tiered royalty payments based on net sales of applicable products at percentages ranging from the mid-single digits to low single-digits. While we have received milestone payments under the Nestlé License Agreement to date there is no guarantee that we will receive further milestone payments under the Nestlé License Agreement or Takeda Agreement in the future. As previously noted, we are aware of media reports that Takeda has communicated internally its desire to end research, discovery and preclinical work in certain rare disease areas that may overlap with the programs on which we collaborate. We continue to engage in discussions with Takeda about their plans related to such programs. It is unclear how any such changes at Takeda, if they occur, might impact our collaborative programs.

Under the Nestlé License Agreement and the Takeda Agreement, either Nestlé Health Science and Takeda, as applicable, may each terminate the entire agreement or specified programs thereunder at will under certain circumstances.

If Nestlé Health Science terminates its rights and obligations with respect to the Nestlé License Agreement and/or Takeda terminates its rights and obligations with respect to the Takeda Agreement, then depending on the timing of such event:

- the development of our product candidates subject to the respective agreements may be terminated or significantly delayed;
- our cash expenditures could increase significantly if it is necessary for us to hire additional employees and allocate scarce resources to the development and commercialization of product candidates;
- we would bear all of the risks and costs related to the further development and commercialization of product candidates that were previously the subject of the respective agreements, including the reimbursement of third parties; and
- in order to fund further development and commercialization of new product candidates or programs, we may need to seek out and establish alternative collaboration arrangements with third-party partners; this may not be possible, or we may not be able to do so on terms which are acceptable to us, in which case it may be necessary for us to limit the size or scope of one or more of our programs or increase our expenditures and seek additional funding by other means.

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 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 opportunities in the biotherapeutics markets, 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 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 investments in our biotherapeutics business, 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, debt financings, credit facilities and/or strategic collaborations. If future financings involve the issuance of equity securities, our existing stockholders would suffer dilution. If we raise debt financing or enter into credit facilities, we may be subject to restrictive covenants that limit our ability to conduct our business. 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.

We are dependent on a limited number of customers.

Our current revenues are derived from a limited number of key customers. For the three months ended March 31, 2023 and 2022, customers that each individually contributed 10% or more of our total revenue accounted for 60% and 61% 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. Any such termination or reduction could materially adversely affect our revenues, financial condition and results of operations. For the three months ended March 31, 2023, we derived a majority of our product revenue from these product supply agreements.

With respect to customers purchasing our products for the manufacture of active pharmaceutical ingredients ("API") 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 GmbH & Co. KG ("Lactosan"), in Kapfenberg, Austria, ACS Dobfar S.p.A. ("ACSD") (formerly known as DPhar S.p.A.), in Anagni, Italy, and Alphazyme LLC in Florida, United States. 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 fine and complex chemicals products, could harm our relationships with our collaborators or customers 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 two 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 collaborators or customers and could negatively affect our revenues or operating results.

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. 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 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.

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 industry 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 Royal DSM, N.V. ("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 pharmaceutical productsare companies marketing either conventional, non-enzymatic processes or biocatalytic enzymes to manufacturers of pharmaceutical intermediates and APIs, and also 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 Evocatal GmbH.

There are numerous companies that participate in the biotherapeutics market generally and the PKU market specifically. Many of these companies are large, successful and well-capitalized. BioMarin Pharmaceutical Inc. ("BioMarin") and Daiichi Sankyo Company market Kuvan® in the United States, Europe and Japan for the treatment of a certain type of PKU. In addition, BioMarin gained US FDA approval in 2018 and began commercial sales of Palynziq™ as an injectable enzyme substitution therapy for the potential treatment of PKU. Several companies, i.e., Synlogic, Homology Medicines and Rubius have reported clinical efforts to develop biotherapeutic candidates for PKU. Beyond targeting PKU, Takeda (who acquired Shire Plc in 2019), Genzyme / Sanofi S.A., BioMarin and other companies market or are actively developing new enzyme therapeutics. There are numerous companies that are developing other forms of therapeutics, such as small molecules, gene therapies, as well as therapies based on gene editing, which could compete with biotherapeutics.

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, which could 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.

The COVID-19 pandemic has adversely affected and may continue in the future to, directly or indirectly, adversely affect our business, results of operations and financial condition.

The COVID-19 pandemic has had a significant impact globally, prompting governments and businesses to take unprecedented measures in response. In the United States, the COVID-19 pandemic 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. If, similar to the response to COIVD-19, national, state and local governments in affected regions implement safety precautions, including quarantines, border closures, increased border controls, travel restrictions, governmental orders and shutdowns, business closures, cancellations of public gatherings and other measures, which 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 potential impact of COVID-19, or another pandemic or public health crisis, has had and could continue to 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 contributed 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.

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 emergency use authorization ("EUA") by the U.S. Food and Drug Administration ("FDA") in late 2021, and which is authorized for the treatment of adults and pediatric patients (12 years of age and older weighing at least 40 kg) with a current diagnosis of mild-to-moderate COVID-19 and who are at high risk for progression to severe COVID-19, including hospitalization or death.

The FDA has the authority to issue an EUA under certain circumstances, such as during a public health emergency ("PHE"), pursuant to a declaration by the Secretary of the Department of Health and Human Services ("HHS"), that an emergency exists justifying the issuance of EUAs for certain types of products (referred to as EUA declarations). On March 27, 2020, the Secretary of HHS declared that circumstances exist justifying authorization of drugs and biologics during the COVID-19 pandemic, subject to the terms of any EUA that is issued for a specific product. Once an EUA declaration has been issued, the FDA can issue EUAs for products that fall within the scope of that declaration. To issue an EUA, the FDA Commissioner must conclude that (1) the chemical, biological, radioactive or nuclear agent ("CBRN") that is referred to in the EUA declaration can cause serious or life-threatening diseases or conditions; (2) based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the disease or condition attributable to the CBRN and that the product's known and potential benefits outweigh its known and potential risks; and (3) there is no adequate, approved, and available alternative to the product. The authorization to market products under an EUA is limited to the period of time the EUA declaration is in effect. If the Secretary of HHS determines that the circumstances justifying the issuance of EUAs have also lapsed, the HHS Secretary will provide advance notice that the EUA declaration will be terminated. After an EUA declaration is terminated, all EUAs issued under that declaration also terminate and therefore emergency use of all products under the EUA declaration is no longer authorized. The FDA can also revoke an EUA in certain circumstances even if the EUA declaration has not been terminated.

The FDA's policies regarding an EUA can change unexpectedly. We cannot predict how long Pfizer's EUA will remain in place. The FDA's policies regarding products used to diagnose, treat or mitigate COVID-19 remain in flux as the FDA responds to new and evolving public health information and clinical evidence and it remains possible that Pfizer's EUA may be revoked in due course. Moreover, the federal government has taken recent steps to terminate distinct emergency authorities related to COVID-19. For example, on April 10, 2023, President Biden signed legislation terminating a national emergency regarding COVID-19 although this action does not affect any EUAs granted by FDA with respect to its authority to authorize drugs and biologics for the diagnosis, treatment, or prevention of COVID-19 and related conditions, including Pfizer's EUA, FDA has announced its intent to adjust policies and operations implemented during the COVID-19 pandemic to a resumption of normal operations, including a transition of products marketed under EUAs, to the ordinary FDA requirements, including premarket authorization requirements. Pfizer has submitted an application for full approval of PAXLOVID™, and an FDA advisory committee has recommend such approval. If the emergency use of the PAXLOVID™ becomes no longer authorized, and if Pfizer does not obtain full approval of the product, our financial condition and results of operations could be adversely affected.

Revenues in 2023 and 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;
- the EUA granted by the FDA for the use of PAXLOVID™ for the treatment of COVID-19 infections in humans could be withdrawn at any time;
- 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 may not ultimately receive full marketing authorization for PAXLOVID™ from the FDA and other international regulatory authorities;
- 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 non-marketable equity securities acquired in private transactions. At March 31, 2023, 9.8% of our consolidated assets consisted of investment securities, which are illiquid investments. Investments in illiquid, or 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 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 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, and we may have exposure to liability for any resulting harm.

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 be sued 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 have 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 Securities and Exchange Commission 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 Securities and Exchange Commission, 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.

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.

Risks Related to Government Regulation and Clinical Product Development

We or our customers may not be able to obtain regulatory approval for the use of our products in food and food ingredients, if required, and, even if approvals are obtained, complying on an ongoing basis with the numerous regulatory requirements applicable to these products will be time-consuming and costly.

The products that we develop for our food and food ingredient customers are, and any other products that we may develop for the food and food ingredients market will likely be, subject to regulation by various government agencies, including the FDA, state and local agencies and similar agencies outside the United States, as well as religious compliance certifying organizations. Food ingredients are regulated by the FDA either as food additives or as substances generally recognized as safe ("GRAS"). A substance can be listed or affirmed as GRAS by the FDA or self-affirmed by its manufacturer upon determination that independent qualified experts would generally agree that the substance is GRAS for a particular use. While we generally self-affirm GRAS status for the ingredients used in the products that we develop for the food market, our customer(s) may be required to submit a GRAS notification to FDA to establish that ingredients in a final commercial product may be considered GRAS. There can be no assurance that our customer(s) will not receive any objections from the FDA with respect to any GRAS notification our customer(s) may submit. If the FDA were to disagree with our customer's determination that their commercial product and/or its ingredients are GRAS or otherwise compliant, the FDA could ask such customer to voluntarily withdraw the final commercial product from the market or could initiate legal action to halt its sale. Such actions by the FDA could have an adverse effect on our business, financial condition, and results of our operations. Food ingredients that are not GRAS are regulated as food additives and require FDA approval prior to commercialization or must be the subject of an existing food additive regulation. The food additive petition process for ingredients that are not already authorized by regulation is generally expensive and time consuming, with approval, if secured, potentially taking years.

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

We have recently begun to use our CodeEvolver® protein engineering technology platform to develop new products for customers using NGS and PCR/qPCR for*in vitro* molecular diagnostic applications. While we have entered into some 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 timely basis in this space may limit our growth and have a material adverse effect on our financial condition, operating results and business prospects.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

We and any collaborators are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Foreign regulatory authorities impose similar requirements. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We and any collaborators must complete additional preclinical or nonclinical studies and clinical trials to demonstrate the safety, purity and potency (or efficacy) of our product candidates in humans to the satisfaction of the regulatory authorities before we will be able to obtain these approvals. Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our or our collaborators' clinical trials;
- we or our collaborators may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we or our collaborators may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our or our collaborators' interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of product candidates may not be sufficient to support the submission of a BLA to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with collaborators; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our or our collaborators' clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may impose significant limitations in the form of narrow indications, warnings, or a REMS. Regulatory authorities may not approve the price we or our collaborators intend to charge for products we may develop, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Clinical trials are difficult to design and implement, expensive, time-consuming and involve an uncertain outcome, and the inability to successfully conduct clinical trials and obtain regulatory approval for our product candidates would substantially harm our business.

Clinical testing is expensive and usually takes many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. We do not know whether planned clinical trials will begin on time, need to be redesigned, recruit and enroll patients on time or be completed on schedule, or at all. Clinical trials can be delayed, suspended or terminated for a variety of reasons, including in connection with:

- the inability to generate sufficient preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation of clinical trials;
- applicable regulatory authorities disagreeing as to the design or implementation of the clinical trials;
- obtaining regulatory authorization to commence a trial;
- reaching an agreement on acceptable terms with prospective contract research organizations ("CROs"), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining IRB approval at each site;
- developing and validating the companion diagnostic to be used in a clinical trial, if applicable;
- insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- recruiting and retaining enough suitable patients to participate in a trial;
- having enough patients complete a trial or return for post-treatment follow-up;
- adding a sufficient number of clinical trial sites;
- inspections of clinical trial sites or operations by applicable regulatory authorities, or the imposition of a clinical hold;
- clinical sites deviating from trial protocol or dropping out of a trial;
- the inability to demonstrate the efficacy and benefits of a product candidate;
- discovering that product candidates have unforeseen safety issues, undesirable side effects or other unexpected characteristics;
- addressing patient safety concerns that arise during the course of a trial; receiving untimely or unfavorable feedback from applicable regulatory authorities regarding the trial or requests from regulatory authorities to modify the design of a trial;
- non-compliance with applicable regulatory requirements by us or third parties or changes in such regulations or administrative actions;
- suspensions or terminations by IRBs of the institutions at which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities due to a number of factors, including those described above;
- third parties being unable or unwilling to satisfy their contractual obligations to us; or
- changes in our financial priorities, greater than anticipated costs of completing a trial or our inability to continue funding the trial.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Additionally, we or our collaborators may experience unforeseen events during or resulting from clinical trials that could delay or prevent receipt of marketing approval for or commercialization of product candidates. For example, clinical trials of product candidates may produce negative, inconsistent or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon development programs. Regulators may also revise the requirements for approving the product candidates, or such requirements may not be as we anticipate. If we or our collaborators are required to conduct additional clinical trials or other testing of product candidates beyond those that we or our collaborators currently contemplate, if we or our collaborators are unable to successfully complete clinical trials or other testing of such product candidates, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining or fail to obtain marketing approval for product candidates;

- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements;
- be subject to changes in the way the product is administered;
- have regulatory authorities withdraw or suspend their approval of the product or impose restrictions on its distribution;
- be sued; or
- experience damage to our reputation.

If we or our collaborators experience delays in the commencement or completion of our clinical trials, or if we or our collaborators terminate a clinical trial prior to completion, we may experience increased costs, have difficulty raising capital and/or be required to slow down the development and approval process timelines. Furthermore, the product candidates that are the subject of such trials may never receive regulatory approval, and their commercial prospects and our ability to generate product revenues from them could be impaired or not realized at all.

Results of preclinical studies and early clinical trials of product candidates may not be predictive of results of later studies or trials. Our product candidates may not have favorable results in later clinical trials, if any, or receive regulatory approval.

Preclinical and clinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the drug development process. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates in our industry is high. The results from preclinical studies or early clinical trials of a product candidate may not be predictive of the results from later preclinical studies or clinical trials, and interim results of a clinical trial are not necessarily indicative of final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials.

Many companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks at later stages of development after achieving positive results in early stages of development, and we may face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including previously unreported adverse events. Moreover, non-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain regulatory approval. Even if any product candidates progress to clinical trials, these product candidates may fail to show the safety and efficacy in clinical development required to obtain regulatory approval, despite the observation of positive results in animal studies. Our or our collaborators' failure to replicate positive results from early research programs and preclinical or greenhouse studies may prevent us from further developing and commercializing those or other product candidates, which would limit our potential to generate revenues from them and harm our business and prospects.

For the foregoing reasons, we cannot be certain that any ongoing or future preclinical studies or clinical trials will be successful. Any safety or efficacy concerns observed in any one of our preclinical studies or clinical trials in a targeted area could limit the prospects for regulatory approval of product candidates in that and other areas, which could have a material adverse effect on our business and prospects.

We may not be able to maintain orphan drug designations for certain of our product candidates, and may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the U.S. and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan product if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the U.S., or a patient population of greater than 200,000 individuals in the U.S., but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. The FDA has granted orphan drug designation to CDX-6512 for the treatment of HCU and to CDX-6210 for the treatment of Maple Syrup Urine Disease (MSUD).

In the U.S., orphan designation entitles a party to financial incentives such as opportunities for grant funding for clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate that has orphan designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same drug for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same disease condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same disease condition if such regulatory authority concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

We have obtained rare pediatric disease designation for CDX-6512 and CDX-6120, however, there is no guarantee that such designation will result in approval of CDX-6512 or CDX-6210, and even if we obtain approval of CDX-6512 or CDX-6210 for the indications for which we have been awarded rare pediatric disease designation, there is no guarantee that such approval will result in an aware of a rare pediatric disease priority review voucher.

In 2012, Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications. This program is designed to encourage development of new drug and biological products for the prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" that meets certain criteria may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product, even if that subsequent marketing application would not otherwise qualify for priority review on its own. The sponsor of a rare pediatric disease product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval.

We have obtained rare pediatric disease designation for CDX-6512 for the treatment of HCU and for CDX-6210 for the treatment of MSUD. Even though we have obtained rare pediatric disease designations, there is no guarantee that we will be able to obtain a priority review voucher, even if CDX-6512 and/or CDX-6210 are approved by the FDA. Moreover, Congress included a sunset provision in the statute authorizing the rare pediatric disease priority review voucher program. On December 27, 2020, the Rare Pediatric Disease Priority Review Voucher Program was extended, and under the current statutory sunset provisions, after September 30, 2024, FDA may only award a voucher for an approved rare pediatric disease product application if the sponsor has rare pediatric disease designation for the drug, and that designation was granted by September 30, 2024. After September 30, 2026, FDA may not award any rare pediatric disease priority review vouchers (unless Congress amends the law to extend the program further).

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner, or at all, which could negatively impact our business.

The ability of the FDA and other government agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, a government agency's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the government agency's ability to perform routine functions. Average review times at the FDA and other government agencies have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologics or modifications to approved drugs or biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the United States government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Even if we obtain regulatory approval for any products that we develop alone or with collaborators, such products will remain subject to ongoing regulatory requirements, which may result in significant additional expense.

Even if products we develop alone or with collaborators receive regulatory approval, they will be 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 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 BLA. In the United States, the holder of an approved 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 BLA or foreign marketing application.

If we, 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 us or our collaborators, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

Moreover, if any of our product candidates are approved, our product labeling, advertising, promotion and distribution will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we or our collaborators fail to comply with applicable regulatory requirements following approval of any potential products we may develop, authorities may:

- issue an untitled enforcement letter or a warning letter asserting a violation of the law;
- seek an injunction, impose civil and criminal penalties, and impose monetary fines, restitution or disgorgement of profits or revenues;
- suspend or withdraw regulatory approval;
- suspend or terminate any ongoing clinical trials or implement requirements to conduct post-marketing studies or clinical trials;
- refuse to approve a pending BLA or comparable foreign marketing application (or any supplements thereto) submitted by us or our collaborators;
- 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 that we or our collaborators submit;
- refuse to permit the import or export of products; or

- refuse to allow us or our collaborators to enter into 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 inhibit our or our 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.

Our business operations and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we will conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal false claims laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners such as physician assistants and nurse practitioners, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; and

- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our future business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations.

The successful commercialization of product candidates developed by us or our partners will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for such product candidates, if approved, could limit our or our partners' ability to market those products and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, assuming FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates. Assuming we obtain coverage for our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the EU or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on our product candidates.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries have and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially-reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for our partners to obtain marketing approval for and commercialize product candidates developed by us.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we develop and our partners obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the Affordable Care Act (the "ACA") was enacted in the United States. The ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the 340B drug pricing program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and establishes a Center for Medicare & Medicaid Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA, and on June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden had issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the healthcare reform measures will impact our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In March 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory cap on the Medicaid drug rebate, currently set at 100% of a drug's average manufacturer price, beginning January 1, 2024. Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for products. Most recently, the Inflation Reduction Act of 2022 (the "IRA"), included a number of significant drug pricing reforms, which include the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services ("HHS") (beginning in 2026) that requires manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers under Medicare Parts B and D to penalize price increases that outpace inflation (first due in 2023), and a redesign of the Part D benefit, as part of which manufacturers are required to provide discounts on Part D drugs (beginning in 2025). The IRA permits the HHS Secretary to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Additional drug pricing proposals could appear in future legislation. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for any product candidate we develop, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

We expect that these new laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize any product candidates we develop, if approved.

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 our Dependence on Third Parties

We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we are and expect to remain dependent on third parties to conduct clinical trials of our product candidates. Specifically, we expect CROs, clinical investigators, and consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing approval process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, clinical trial investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or comparable foreign regulatory authorities concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA or any comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing our product candidates.

We contract with third parties for the manufacturing and supply of product candidates for use in preclinical testing and clinical trials and related services, which supply may become limited or interrupted or may not be of satisfactory quality and quantity.

We do not have any manufacturing facilities. We produce in our laboratory relatively small quantities of products for evaluation in our research programs. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates are approved. We currently have limited manufacturing arrangements and expect that each of our product candidates will only be covered by single source suppliers for the foreseeable future. This reliance increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Furthermore, all entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured in accordance with cGMP requirements. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA on a timely basis and must adhere to the FDA's cGMP regulations enforced by the FDA through its facilities inspection program. Comparable foreign regulatory authorities may require compliance with similar requirements. The facilities and quality systems of our third-party contractor manufacturers must pass a pre-approval inspection for compliance with the applicable regulations as a condition of marketing approval of our product candidates. We do not control the manufacturing activities of, and are completely dependent on, our contract manufacturers for compliance with cGMP regulations.

In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company, and we may therefore experience delays to our development programs if and when we attempt to establish new third party manufacturing arrangements for these product candidates or methods. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

Our or a third party's failure to execute on our manufacturing requirements, do so on commercially reasonable terms and comply with cGMP could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of our product candidates under development;
- delay in submitting regulatory applications, or receiving marketing approvals, for our product candidates;
- loss of the cooperation of future collaborators;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our product candidates; and
- in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product or any other future product candidates.

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 or 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 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 is 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, 2023, we owned or controlled approximately 2,090 issued patents and pending patent applications in the United States and in various foreign jurisdictions. Our patents and patent applications, if issued, as of March 31, 2023, have terms that expire between 2023 and approximately 2044. 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 biotherapeutics, pharma manufacturing, life sciences, food 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 and other companies' patents. Given that the degree of future protection for our proprietary rights is uncertain, we cannot ensure that: (i) we were the first to invent the inventions covered by each of our pending applications, (ii) we 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. 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. Any involvement in litigation or other intellectual property proceedings inside and outside of the United States to defend against claims that we infringe, misappropriate or violate the intellectual property of the 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, misappropriating or violating intellectual property rights, or relocate the operations relating to the allegedly infringing misappropriating or violating 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 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.

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, product candidates, 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 ob 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 us. 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 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 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 relationships with, and dependence on, collaborators in our principal markets;
- 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 ability to develop and successfully commercialize new products for the markets we serve;
- our ability to obtain additional development partners for our novel biotherapeutic programs;
- potential of Nestlé Health Science or Takeda terminating any development program under their license agreements with us;
- 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 or our customers' ability to obtain regulatory approval for the sale and manufacturing of food products using our enzymes;
- our ability to deploy our technology platform in life science tools markets;
- our ability to successfully achieve domestic and foreign regulatory approval for product candidates;
- our ability to successfully design and execute clinical testing at a reasonable cost and on an acceptable time-frame;
- our dependence on product candidates which could unexpectedly fail at any stage of preclinical or clinical development;
- our dependence on product candidates which may lack the ability to work as intended or cause undesirable side effects;
- our dependency on third parties to conduct clinical trials, research, and preclinical studies;
- 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 credit facility;
- 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.

At our 2023 Annual Meeting of Stockholders, we are asking our stockholders to approve various proposals including increasing the number of authorized shares of our common stock and the shares available for equity awards under our equity incentive plan, as well as adopting an Employee Stock Purchase Plan ("ESPP"). If any of these proposals are not approved, our competitive position, business and prospects could be seriously harmed.

As included in the definitive proxy statement we filed with the SEC on April 27, 2023, at our 2023 Annual Meeting of Stockholders, our board of directors and management is requesting our stockholders approve three proposals that relate to our ability to raise capital and attract and retain talent.

We are actively soliciting proxies from our stockholders and encouraging our stockholders to vote for these three proposals. However, our stockholders may not vote for one or more of these proposals. If our stockholders do not approve the proposed amendment to our certificate of incorporation to increase our authorized common stock, we may not be able to access the capital markets, which could impede our ability to finance our operations including the ongoing and planned research and development and clinical and regulatory activities necessary to advance our biotherapeutic candidates and performance enzymes. Further, if our authorized number of common stock is not increased, it may inhibit or even prevent us from being able to complete future corporate collaborations and partnerships. In addition, if we do not have sufficient shares of common stock reserved for issuance upon the exercise of equity awards, we may not be able to offer such awards which could adversely impact our ability to attract, retain and motivate employees, officers, directors, consultants and/or advisers. Likewise, if our stockholders do not approve the proposed amendment to our 2019 Incentive Award Plan and or the ESPP, our ability to attract, retain and motivate employees, officers, directors, consultants and/or advisers will be hindered. As a result of the foregoing, the failure of any of these three proposals to gain enough stockholder votes to be approved could have a material adverse effect on our competitive position, business and prospects.

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 foreign 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 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 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, 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. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity 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 counter-parties 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 COVID-19 pandemic, and 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 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, 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. Furthermore, federal, state and international laws and regulations can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties, fines and significant legal liability, if our information technology security efforts fail. We may also be exposed to a risk of loss or litigation and potential liability, which 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 individually identifiable health information. Certain states have also adopted comparable 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 that has increased the likelihood of, and risks associated with data breach litigation. Further, the California Privacy Rights Act ("CPRA") significantly amends the CCPA, and generally went into effect in January 2023. It imposes additional data protection 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 has also created a new California data 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 have passed in Virginia, Colorado, Connecticut, Iowa and Utah 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 online collection, use, dissemination and security practices 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 Europe, the General Data Protection Regulation ("GDPR") went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the European Economic Area ("EEA"). The GDPR imposes stringent requirements for controllers and processors of personal data and provides that EEA member states may make their own additional laws and regulations limiting the processing of genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs to increase and harm our business and financial condition. Failure to comply with the requirements of the GDPR can result in fines of up to the greater of €20 million and 4% of the total worldwide annual turnover of the preceding financial year and other administrative penalties. If we are required to comply with the GDPR, such compliance may be onerous and adversely affect our business, financial condition, and results of operations. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in July 2020, the Court of Justice of the EU ("CJEU") limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses ("SCCs"). In March 2022, the United States and EU announced a new regulatory regime intended to replace the invalidated regulations; however, this new EU-US Data Privacy Framework has not been implemented beyond an executive order signed by President Biden on October 7, 2022 on Enhancing Safeguards for United States Signals Intelligence Activities. European court and regulatory decisions subsequent to the CJEU decision of July 2020 have taken a restrictive approach to international data transfers. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, from January 1, 2021, companies have had to comply with the GDPR and also the United Kingdom GDPR ("UK GDPR"), which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (or up to £17.5 million for UK) or 4% of global turnover. 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 which are perceived to have not responded appropriately, may suffer from reputational damage and result in the business, financial condition and/or stock price of a company being materially and adversely affected. Further, this increased focus on ESG issues may result in new regulations and/or third-party requirements that could adversely impact our business, or certain shareholders reducing or eliminating their holdings of our stock. Additionally, an allegation or perception that we have not taken sufficient action in these areas could negatively harm our reputation.

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

Not applicable.

ITEM 6. EXHIBITS

3.1		Amended and Restated Certificate of Incorporation of Codexis, Inc. filed with the Secretary of the State 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		Amended and Restated Bylaws of Codexis, Inc. effective as of April 27, 2010 (incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, filed on May 28, 2010).
4.1		Reference is made to Exhibits 3.1 through 3.3.
10.1	*	Termination of the Loan and Security Agreement by and between the Company and Western Alliance Bank dated as of March 13, 2023.
10.2		Amendment No. 3 to the Enzyme Supply Agreement by and between the Company and Pfizer Ireland Pharmaceuticals effective as of March 31, 2023.
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, 2022, formatted in Inline Extensible Business Reporting Language (iXBRL) includes: (i) Unaudited Condensed Consolidated Balance Sheets at March 31, 2023 and December 31, 2022 (ii) Unaudited Condensed Consolidated Statements of Operations for the Three Months Ended March 31, 2023 and 2022, (iii) Unaudited Condensed Consolidated Statements of Stockholders' Equity for the three months ended March 31, 2023 and 2022, (iv) Unaudited Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2023 and 2022 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, 2023, formatted in Inline XBRL and contained in Exhibit 101.

* Portions of the exhibit, marked by brackets, have been omitted because the omitted information is (i) not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Codexis, Inc.

Date: May 4, 2023

By: /s/ Stephen Dilly

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

Date: May 4, 2023

By: /s/ Sriram Ryali

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

WESTERN ALLIANCE BANK

March 13, 2023

CODEXIS, INC.
200 Penobscot Drive
Redwood City, CA 94063
Attn: Sri Ryali, CFO
FAX: [***]
EMAIL: [***]

Loan Number: 121143260
Borrower: Codexis, Inc.

Reference is made to that certain Loan and Security Agreement, dated June 30, 2017, by and between Western Alliance Bank, an Arizona corporation ("Bank") and Codexis, Inc., a Delaware corporation ("Borrower") (as amended from time to time, the "Loan Agreement"). Capitalized terms used but not otherwise defined herein shall have the meanings given them in the Loan Agreement.

Borrower has advised Bank that it intends to terminate the Loan Agreement. Upon Bank's receipt of a countersigned copy of this letter (the date of such receipt, the "Termination Date"), without further action on the part of the parties hereto (i) all Obligations (as defined in the Loan Agreement) owing from Borrower to Bank under the Loan Documents (other than contingent or indemnification obligations which expressly survive the termination of the applicable documents and obligations owing with respect to credit cards and letter of credit reimbursement obligations) shall be deemed satisfied and terminated in full; (ii) all unfunded commitments to make credit extensions or financial accommodations to Borrower or any other person under the Loan Agreement shall be terminated; (iii) all guarantees, security interests and other liens of every type at any time granted to or held by Bank as security shall be automatically and immediately terminated, released and discharged (other than any security in Borrower's accounts maintained with the Bank provided with respect to credit cards obligations and letter of credit reimbursement obligations), and (iv) all other obligations of Borrower under the Loan Documents shall be deemed terminated; provided, however, (i) all obligations of Borrower pursuant to any credit cards issues by Bank (or any of its affiliates) to Borrower, (ii) all letters of credit reimbursement obligations of Borrower to Bank, if any and (iii) all obligations pursuant to the Loan Documents that are expressly specified in any Loan Document as surviving that respective agreement's termination, including without limitation, Borrower's indemnity obligations set forth in the Loan Agreement, shall survive and continue in accordance with their respective terms.

From and after the Termination Date, Bank (at Borrower's sole cost and expense) (i) authorizes Borrower or Borrower's designee to file any UCC3 termination statements necessary to terminate all UCC financing statements in Bank's favor with respect to Borrower and any other releases, termination statements or intellectual property security releases, account control agreement,

landlord consents or bailee waivers necessary or desirable to terminate or evidence the termination of any other security interest or other lien held by Bank under the Loan Documents), (ii) shall execute and deliver to Borrower or Borrower's designee all collateral with respect to the Loan Documents which are in the possession of Bank, and (iii) shall deliver to Borrower or Borrower's designee any other documents, instruments, releases or other agreements necessary or reasonably requested by Borrower or Borrower's designee to release or terminate any security interest or lien with respect to Borrower's assets or to evidence the release or termination of any guarantee, security interest or lien thereto. All such agreements, documents, and instruments which are requested by Borrower to be delivered by Bank on or after the Termination Date shall be prepared at Borrower's expense and any costs or expenses incurred by Bank with respect to such items (including all reasonable and documented out-of-pocket attorneys' fees) shall be reimbursed promptly by Borrower on demand. Borrower hereby waives any and all claims and releases Bank and its parents, subsidiaries, affiliates, officers, directors, employees, attorneys, and representatives and agents harmless from all claims, liabilities, damages, fees, costs and expenses associated with, caused by, or arising from Bank's preparation of any the aforementioned documents (except, in any case, to the extent resulting from negligence, bad faith or willful misconduct of Bank).

This letter agreement shall be governed by the laws of the State of California and shall become effective only when signed by Bank and accepted by Borrower by its due execution in the space provided below.

WESTERN ALLIANCE BANK, AN ARIZONA CORPORATION

By
Name:
Title:

Acknowledged and Agreed:

CODEXIS, INC., A DELAWARE CORPORATION

By
Name:
Title:

AMENDMENT NO. 3 TO ENZYME SUPPLY AGREEMENT

This Amendment No. 3 to Enzyme Supply Agreement (this "**Amendment**") is made as of March 30, 2023 (the "**Amendment Effective Date**"), between Codexis, Inc., a Delaware corporation having its principal offices at 200 Penobscot Drive, Redwood City, California 94063 ("**Codexis**") and Pfizer Ireland Pharmaceuticals, an Ireland corporation, with its principal place of business at Operations Support Group, Ringaskiddy, Cork, Ireland, and its Affiliates ("**Pfizer**"). Codexis and Pfizer may each be referred to herein individually as a "**Party**" or collectively, as the "**Parties**."

RECITALS

WHEREAS, Pfizer and Codexis are parties to that certain Enzyme Supply Agreement dated as of October 30, 2021 (as amended, the "**Agreement**"); and

WHEREAS, Pfizer and Codexis desire to amend the Agreement in the manner specified in this Amendment;

NOW THEREFORE, in consideration of the promises and undertakings set forth herein, the Agreement is hereby amended as follows:

1. All defined terms shall, unless defined or modified herein, have the meaning set forth in the Agreement.
2. Section 2.5(d)(ii)(b) of the Agreement is deleted in its entirety and replaced with the following:

    "(b) 100% of any fees invoiced by Codexis to Pfizer during the period January 1, 2022 through December 31, 2023 under mutually acceptable, executed, written definitive collaborative development/licensing agreement(s) (not including this Agreement) executed by Codexis and Pfizer from the Effective Date through April 4, 2023. For clarity, such agreements may include standalone purchase orders."

3. All other terms and conditions of the Agreement remain unchanged.

IN WITNESS WHEREOF, a duly authorized representative of each Party has executed this Amendment as of the dates identified below, but this Amendment shall become effective on the Amendment Effective Date.

Codexis, Inc.	**Pfizer Ireland Pharmaceuticals**
Name: Kevin Norrett Title: Chief Operating Officer Date:	Name: Title: Date:

For Codexis, Inc. use only *Reviewed by*	 Legal

Exhibit 31.1

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; and

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 4, 2023

/s/ Stephen Dilly

Stephen Dilly

President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

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; and

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 4, 2023

/s/ Sriram Ryali

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

Exhibit 32.1

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, 2023, 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 4, 2023

/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)