February 23, 2023

Codexis Reports Fourth Quarter and Fiscal Year 2022 Financial Results

Biotherapeutics Application of CodeEvolver® Validated by Recent Data Supporting the Potential for Three Upcoming Investigational New Drug Applications

Cash Runway Through End of 2024 Funds Important Upcoming Milestones

Company Provides 2023 Revenue Guidance

REDWOOD CITY, Calif., Feb. 23, 2023 (GLOBE NEWSWIRE) -- Codexis, Inc. (NASDAQ: CDXS), a leading enzyme engineering company, today announced financial results for the fourth quarter and fiscal year ended December 31, 2022 and provided a business update.

“2022 was an important year for Codexis as we prioritized programs in our life sciences, biotherapeutics, and pharmaceutical manufacturing businesses that align with our focused strategy and best position the Company for long-term success,” said Stephen Dilly, MBBS, PhD, President and CEO of Codexis. “In addition to our strong financial performance last year, I am especially pleased with the first patient data set from our study of CDX-7108 for exocrine pancreatic insufficiency in partnership with Nestlé Health Science and with the pre-clinical data recently presented by Takeda in Fabry disease, which validates the potential of our CodeEvolver® platform in gene therapy. We also continue to make great progress in our life sciences business and recently launched our newly engineered DNA ligase which is designed to improve sensitivity of next generation sequencing testing and easily fit into existing workflows. With two years of cash runway and numerous catalysts ahead, we are well positioned to demonstrate the commercial potential and strategic optionality that exists within Codexis.”

2022 Business Highlights

Corporate Highlights

- In November 2022, Codexis announced a plan to prioritize time and resources on areas where the Company believes it has the strongest commercial opportunity and greatest probability of success. As part of this plan, the Company decided to discontinue investment in certain internal development programs, expand investment in high potential development programs, and realign its workforce.

- Throughout 2022 and early 2023, the Company strengthened its management team and Board of Directors with individuals who possess the strategic acumen, operational experience, and commercial mindset to deliver on its prioritized corporate goals. These changes include the addition of Dr. Stephen Dilly as President and CEO, Kevin Norrett as Chief Operating Officer, Sri Ryali as Chief Financial Officer, Meg Fitzgerald, JD, as Chief Legal Officer and General Counsel, and the additions of both H. Stewart Parker and Rahul Singhvi, ScD, to the Board of Directors.

Life Sciences

- In February 2023, at the Advances in Genome Biology and Technology (AGBT) General Meeting, Codexis launched a newly engineered DNA ligase for next-generation sequencing, or NGS. Subsequently, Roche exercised its right of first negotiation (ROFN) on the newly engineered DNA ligase. For additional details, please see the white paper available at https://www.codexis.com/resources/detail/11503/a-ligase-with-superior-ligation-efficiency.

- In August 2022, Codexis and Molecular Assemblies, Inc. (MAI) announced the execution of a Commercial License and Enzyme Supply Agreement, enabling MAI to utilize an evolved terminal deoxynucleotidyl transferase (TdT) enzyme in MAI's Fully Enzymatic Synthesis™ (or FES™) technology. The companies collaborated to develop this TdT enzyme to advance fully enzymatic DNA synthesis for the production of long, pure, accurate oligonucleotides to accelerate innovation in many fields.

- In April 2022, Codexis announced a partnership and strategic investment with seqWell, Inc., a developer of transformative library preparation products for next generation sequencing applications.

Biotherapeutics

- In February 2023, Codexis announced interim results from the Phase 1 clinical trial of CDX-7108, which is being co-developed with Nestlé Health Science S.A., for the treatment of exocrine pancreatic insufficiency (EPI). Data from five subjects with EPI in the proof-of-concept arm indicated improved lipid absorption when patients are administered CDX-7108 versus placebo. Importantly, no safety issues were noted in the 48 healthy subjects that participated in the single ascending dose and multiple ascending dose portion of the study.

- In February 2023, Takeda Pharmaceutical Company Limited (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 a-GAL enzyme, which is designed to have improved serum and lysosomal stability and a predicted reduced immunogenicity.

Pharmaceutical Manufacturing

- In September 2022, Codexis hosted its 2022 Protein Engineering Forum, bringing more than 100 top scientists and innovators together for presentations and networking events to facilitate the sharing of insights and recent technological advancements throughout genomics, nucleic acid synthesis and synthetic biology.

- In June 2022, Merck and Codexis published a paper in the peer-reviewed journal *Science*, detailing the development of a suite of enzymes and their application for site-selective synthesis of insulin bioconjugates. The publication describes the development and optimization of enzymes using the CodeEvolver® technology platform.

Upcoming Milestones

- Phenylketonuria (PKU): The Company anticipates that its partner Nestlé Health Science will file an Investigational New Drug (IND) application for CDX-6114 for PKU,

one of the most common inborn errors of metabolism (IEM) in the second half of 2023.

- Exocrine Pancreatic Insufficiency (EPI): The Company anticipates that Nestlé Health Science will file an IND application for the Phase 2 study of CDX-7108 for the treatment of EPI by the end of 2023. The Phase 2 study is expected to be conducted over approximately 12 months, with topline data anticipated in 2025.

- Fabry disease: The Company anticipates that its partner Takeda will file an IND application for a Phase 1 study in Fabry disease as soon as late 2023.

Fiscal Year 2022 Financial Highlights

- Total revenues for fiscal year 2022 were $138.6 million, an increase of 32% from $104.8 million the prior year. Excluding enzyme sales related to PAXLOVID™, which were $75.4 million and $34.5 million for 2022 and 2021, respectively, total revenues for fiscal year 2022 were $63.2 million, a decrease of 10% from $70.3 million in the prior year.

- Product revenues for fiscal year 2022 were $116.7 million, an increase of 65% from $70.7 million the prior year, primarily driven by enzyme sales related to PAXLOVID™. Excluding these sales, total product sales for fiscal year 2022 were $41.3 million, an increase of 14% from $36.1 million in the prior year.

- R&D revenues were $21.9 million for fiscal year 2022, compared to $34.1 million the prior year. The decrease was driven by lower license fees, decreased revenue from milestone payments, and lower R&D fees from existing collaborating agreements.

- Product gross margin for fiscal year 2022 was 67%, compared to 69% the prior year. The decrease was primarily driven by sales mix and higher shipping costs.

- R&D expenses for fiscal year 2022 increased to $80.1 million, compared to $55.9 million the prior year. The increase in R&D expenses was driven by higher costs associated with increased headcount, facilities, lab supplies, depreciation, and outside services.

- Selling, General & Administrative expenses for fiscal year 2022 were $52.2 million, compared to $49.3 million the prior year. The increase in SG&A expense was the result of higher costs associated with headcount, and outside services, partially offset by lower legal fees.

- Fiscal year 2022 includes $3.2 million in restructuring charges related to the workforce reduction plan that occurred in the fourth quarter.

- The net loss for fiscal year 2022 was $33.6 million, or $0.51 per share, compared to $21.3 million, or $0.33 per share, for fiscal year 2021.

- As of December 31, 2022, Codexis had $114.0 million in cash and cash equivalents.

Fourth Quarter 2022 Financial Highlights

- Total revenues for the fourth quarter 2022 were $30.4 million, an increase of 24% from $24.5 million in the fourth quarter 2021. Excluding fourth quarter enzyme sales related

to PAXLOVID™, which were $17.4 million and $11.3 million for 2022 and 2021, respectively, total revenues for the fourth quarter 2022 were $13.0 million, a decrease of 2% from $13.2 million in the prior year.

- Product revenues for the fourth quarter 2022 were $23.3 million compared to $17.0 million in the fourth quarter 2021, driven by enzyme sales related to PAXLOVID™.

- R&D revenues for the fourth quarter 2022 were $7.1 million compared to $7.5 million in the fourth quarter 2021. The decrease was driven by lower license fees, decreased revenue from milestone payments, and lower R&D fees from collaboration agreements.

- Product gross margin for the fourth quarter 2022 was 64% compared to 60% in the fourth quarter 2021, driven by changes in sales mix.

- R&D expenses for the fourth quarter 2022 were $19.7 million compared to $16.4 million in the fourth quarter 2021, driven by higher costs associated with increased headcount, facilities, outside services, lab supplies, and depreciation.

- Selling, General & Administrative expenses for the fourth quarter 2022 were $12.3 million, compared to $11.7 million in the fourth quarter 2021. The increase was primarily the result of higher costs associated with increased headcount, freight, and outside services.

- Fourth quarter 2022 includes $3.2 million in restructuring charges related to the workforce reduction plan.

- The net loss for the fourth quarter 2022 was $12.6 million, or $0.19 per share, compared to $10.2 million, or $0.16 per share, for the fourth quarter 2021.

2023 Guidance

Codexis is introducing financial guidance for 2023, as follows:

- Total revenues are expected to be in the range of $63 million to $68 million. This range excludes revenue from enzyme sales related to PAXLOVID™.

- Product revenues are expected to be in the range of $35 million to $40 million, excluding enzyme sales related to PAXLOVID™.

- Gross margin on product revenue is expected to be 68% to 73%, excluding enzyme sales related to PAXLOVID™.

- In addition, Codexis expects that its existing cash and cash equivalents, combined with the Company's future expectations for product revenues, R&D revenues and expense management, will be sufficient to fund its planned operations through the end of 2024.

Conference Call and Webcast

Codexis will hold a conference call and webcast today beginning at 4:30 p.m. ET. A live webcast and slide presentation to accompany the conference call will be available on the Investor section of Company website. The conference call dial-in numbers are 877-705-2976

for domestic callers and 201-689-8798 for international callers, and the passcode is 13735352.

A recording of the call will be available for 48 hours beginning approximately two hours after the completion of the call by dialing 877-660-6853 for domestic callers or 201-612-7415 for international callers. Please use the passcode 13726635 to access the recording. A webcast replay will be available on the Investors section of www.codexis.com for 30 days, beginning approximately two hours after the completion of the call.

About Codexis

Codexis is a leading enzyme engineering company leveraging its proprietary CodeEvolver® platform to discover and develop novel, high performance enzymes and biotherapeutics. Codexis enzymes have applications in the sustainable manufacturing of small molecule pharmaceuticals, in RNA and DNA synthesis and the creation of next generation life science tools, and as gene therapies and oral enzyme therapies. Codexis' unique enzymes can drive improvements such as higher yields, reduced energy usage and waste generation, improved return on capital in manufacturing, improved sensitivity in genomic and diagnostic applications, and more efficacious therapeutics. For more information, visit www.codexis.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "positioned," "potential," "predict," "seek," "should," "suggest," "target," "on track," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. All statements other than statements of historical facts contained in this press release are forward-looking statements. Such forward-looking statements include, but are not limited to, statements regarding anticipated milestones, including product launches; timing of data reports; progression of clinical studies; engagement with regulators, including such engagements made by Codexis' partners; Codexis' expectations regarding 2023 total revenues, product revenues and gross margin on product revenue; its ability to fund planned operations through the end of 2024; and the ability of its evolved strategy to drive long-term success and increased market penetration to deliver value for Codexis customers and shareholders. You should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties and other factors that are, in some cases, beyond Codexis' control and that could materially affect actual results, including, but not limited to, Codexis being dependent on its collaborators and any failure to successfully manage these relationships preventing it from developing and commercializing many of its products; Codexis' biotherapeutic programs being early stage, highly regulated and expensive; if Nestlé Health Science, Takeda or any other collaborator terminate their development programs under their respective license agreements with Codexis, any potential revenue from those license agreements will be significantly reduced or non-existent; Codexis may need additional capital in the future in order to expand its business; Codexis' dependency on a limited number of customers and its inability to extend or renew contracts with such customers; if Codexis is unable to develop and commercialize new products for its target markets; if competitors and potential competitors who have greater

resources and experience than Codexis develop products and technologies that make Codexis' products and technologies obsolete; Codexis may be unable to obtain regulatory approval for its product candidates given the lengthy, time consuming and inherently unpredictable nature of such approval processes; clinical trials are difficult to design and implement, expensive, time-consuming and involve an uncertain outcome; results of preclinical studies and early clinical trials of product candidates may not be predictive of results of later studies or trials; Codexis may not be able to maintain orphan drug designations for certain of our product candidates, and may be unable to maintain the benefits associated with orphan drug designation; even if Codexis obtains regulatory approval for any products that it develop alone or with collaborators, such products will remain subject to ongoing regulatory requirements; and market and economic conditions may negatively impact Codexis' business, financial condition, and share price. Additional information about factors that could materially affect actual results can be found in Codexis' Annual Report on Form 10-K that will be filed with the Securities and Exchange Commission (SEC) on or about February 24, 2023, including under the caption "Risk Factors," and in Codexis' other periodic reports filed with the SEC. Codexis expressly disclaims any intent or obligation to update these forward-looking statements, except as required by law. Codexis' results for the quarter and year ended December 31, 2022 are not necessarily indicative of our operating results for any future periods.

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Financial Tables to Follow

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Revenues:				
Product revenue	$ 23,300	$ 16,983	$ 116,676	$ 70,657
Research and development revenue	7,075	7,518	21,914	34,097
Total revenues	30,375	24,501	138,590	104,754
Costs and operating expenses:				
Cost of product revenue	8,456	6,806	38,033	22,209
Research and development	19,689	16,357	80,099	55,919
Selling, general and administrative	12,314	11,723	52,172	49,323
Restructuring charges	3,167	—	3,167	—
Total costs and operating expenses	43,626	34,886	173,471	127,451
Loss from operations	(13,251)	(10,385)	(34,881)	(22,697)
Interest income	823	36	1,441	459
Other income (expense), net	(26)	227	124	1,148
Loss before income taxes	(12,454)	(10,122)	(33,316)	(21,090)
Provision for income taxes	151	68	276	189
Net loss	$ (12,605)	$ (10,190)	$ (33,592)	$ (21,279)
Net loss per share, basic and diluted	$ (0.19)	$ (0.16)	$ (0.51)	$ (0.33)
Weighted average common stock shares used in computing net loss per share, basic and diluted	65,558	64,914	65,344	64,568

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

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 113,984	$ 116,797
Restricted cash, current	521	579
Financial assets:		
Accounts receivable	31,904	24,953
Contract assets	2,116	4,557
Unbilled receivables	7,016	8,558
Total financial assets	41,036	38,068
Less: allowances	(163)	(416)
Total financial assets, net	40,873	37,652
Inventories	2,029	1,160
Prepaid expenses and other current assets	5,487	5,700
Total current assets	162,894	161,888
Restricted cash	1,521	1,519
Investment in non-marketable equity securities	20,510	14,002
Right-of-use assets - Operating leases, net	39,263	44,095
Right-of-use assets - Finance leases, net	—	17
Property and equipment, net	22,614	21,345
Goodwill	3,241	3,241
Other non-current assets	350	276
Total assets	$ 250,393	$ 246,383
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,246	$ 2,995
Accrued compensation	11,453	11,119
Other accrued liabilities	15,279	12,578
Current portion of lease obligations - Operating leases	5,360	4,093
Deferred revenue	13,728	2,586
Total current liabilities	49,066	33,371
Deferred revenue, net of current portion	16,881	3,749
Long-term lease obligations - Operating leases	38,278	43,561
Other long-term liabilities	1,371	1,311
Total liabilities	105,596	81,992
Stockholders' equity:		
Common stock	6	6
Additional paid-in capital	566,081	552,083
Accumulated deficit	(421,290)	(387,698)
Total stockholders' equity	144,797	164,391
Total liabilities and stockholders' equity	$ 250,393	$ 246,383

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

	Three Months Ended December 31, 2022			Three Months Ended December 31, 2021		
	Performance Enzymes	Novel Biotherapeutics	Total	Performance Enzymes	Novel Biotherapeutics	Total
Revenues:						
Product revenue	$ 23,300	$ —	$ 23,300	$ 16,983	$ —	$ 16,983
Research and development revenue	2,538	4,537	7,075	5,136	2,382	7,518
Total revenues	25,838	4,537	30,375	22,119	2,382	24,501
Costs and operating expenses:						
Cost of product revenue	8,456	—	8,456	6,806	—	6,806
Research and development [1]	6,173	12,295	18,468	5,968	9,569	15,537
Selling, general and administrative [1]	3,513	143	3,656	2,811	703	3,514
Restructuring charges	1,708	966	2,674			
Total segment costs and operating expenses	19,850	13,404	33,254	15,585	10,272	25,857
Income (loss) from operations	$ 5,988	$ (8,867)	(2,879)	$ 6,534	$ (7,890)	(1,356)
Corporate costs [2]			(8,134)			(7,772)
Depreciation and amortization			(1,441)			(994)
Loss before income taxes			$ (12,454)			$ (10,122)

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

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

	Year Ended December 31, 2022			Year Ended December 31, 2021		
	Performance Enzymes	Novel Biotherapeutics	Total	Performance Enzymes	Novel Biotherapeutics	Total
Revenues:						
Product revenue	$ 116,676	$ —	$ 116,676	$ 70,657	$ —	$ 70,657
Research and development revenue	9,936	11,978	21,914	19,858	14,239	34,097
Total revenues	126,612	11,978	138,590	90,515	14,239	104,754
Costs and operating expenses:						
Cost of product revenue	38,033	—	38,033	22,209	—	22,209
Research and development [1]	25,786	49,770	75,556	23,140	30,219	53,359
Selling, general and administrative [1]	14,724	2,421	17,145	12,105	2,755	14,860
Restructuring charges	1,708	966	2,674	—	—	—
Total segment costs and operating expenses	80,251	53,157	133,408	57,454	32,974	90,428
Income (loss) from operations	$ 46,361	$ (41,179)	5,182	$ 33,061	$ (18,735)	14,326
Corporate costs [2]			(33,080)			(32,201)
Depreciation and amortization			(5,418)			(3,215)
Loss before income taxes			$ (33,316)			$ (21,090)

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

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

Source: Codexis, Inc.