



NEWS RELEASE

Coya Therapeutics Provides a Corporate Update and Reports Fiscal 2024 Financial Results

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HOUSTON--(BUSINESS WIRE)-- Coya Therapeutics, Inc. (Nasdaq: COYA) ("Coya" or the "Company"), a clinical-stage biotechnology company developing biologics intended to enhance regulatory T cell (Treg) function, provides a corporate update and announces its financial results for the year ended December 31, 2024.

Corporate Highlights FY2024 to Date

- Announced significant improvements of inflammatory blood markers from an investigator-initiated, 21-week, double-blind, placebo-controlled, exploratory Phase 2 study of low-dose interleukin-2 (LD IL-2) in patients with Alzheimer's disease (AD)
- Announced that five of eight patients have been enrolled in the investigator-initiated academic study of LD IL-2 + CTLA4-Ig combination in patients with Frontotemporal Dementia (FTD)
- Announced positive results from an investigator initiated double-blind study of low-dose interleukin-2 (LD IL-2) in patients with mild to moderate Alzheimer's Disease (AD) at the Clinical Trials on Alzheimer's Disease Conference (CTAD24) in Madrid. The study was titled, "A Phase II Clinical Trial of Interleukin-2 (IL-2) in Patients with Mild to Moderate Alzheimer's Disease"
- Aligned with FDA on the non-clinical data needed to support the planned randomized, double-blind, placebo-controlled, Phase 2b trial of COYA-302 in patients with Amyotrophic Lateral Sclerosis (ALS)
- Announced expansion of pipeline- COYA 303; COYA 301 in combination with GLP-1 Receptor Agonist for treatment of inflammatory diseases and filing of new intellectual property portfolio for the combination

Financial Highlights FY 2024

- Raised \$10.0M in a private placement of 1.38M shares of common stock. The majority of investors in the offering were existing institutional shareholders of company
- Received \$5.0 million strategic investment by the Alzheimer's Drug Discovery Foundation (ADDF) to help support the development of COYA 302 for the treatment of Frontotemporal Dementia (FTD)
- Received \$3.85 million from the previously announced First Amendment and License Agreement with Dr. Reddy's Laboratories, Inc., which is earmarked for funding the first Phase 2 clinical trial of COYA 302 in ALS in the United States. The original agreement was entered into on December 5, 2023.

Upcoming Expected Catalysts for 2025

- Q2 2025: Submission of additional nonclinical data to support the start of the COYA-302 Phase 2 trial in patients with ALS
- Upon IND acceptance and first patient dosing of COYA-302 in ALS, eligible to receive milestone payments of \$8.4 million from strategic partner, Dr. Reddy's Laboratories (DRL)
- Q2 2025: Publication of COYA-303 combination mechanistic data
- Q2 2025: Publication of data documenting role of inflammation in Parkinson's Disease
- Q2 2025: ALS Biomarker data. Publication of longitudinal data on Neurofilament Light Chain (NfL) and oxidative stress markers in patients with ALS
- 2H 2025: Additional single cell proteomics data from the completed investigator-initiated, 21-week, double-blind, placebo-controlled, exploratory Phase 2 study of low-dose interleukin-2 (LD IL-2) in patients with Alzheimer's disease (AD)
- 2H 2025: Top-line clinical data release for an investigator-initiated trial combining LD IL-2 + CTLA4-Ig in patients with FTD
- 2H 2025: Filing of IND for the COYA-302 Phase 2 trial in patients with FTD*
(*Clinical trial initiated upon FDA IND approval)

Coya CEO Arun Swaminathan, Ph.D. commented, "We remain encouraged by the progress we made in 2024 and are well positioned for continued success in 2025. We continue to expand our pipeline while making significant progress on our ongoing programs in neurodegenerative diseases with high unmet need, and we are on track to initiate the randomized, double-blind controlled Phase 2b trial in patients with ALS upon IND acceptance.

"Our drug candidates all target neuroinflammation, which we see as a key driving factor towards disease progression in the neurological conditions we are addressing. Moreover, our approach to potential combination therapies for treatment of these neurodegenerative diseases differentiates us from other companies and offers, what we believe, a more potent treatment paradigm that could potentially lead to new options for patients and create meaningful shareholder value.

"The strong scientific and clinical rationale, our strong cash position and potential for new business development opportunities all together strengthens our optimism about our ability to execute on our corporate, clinical and regulatory goals and continue to build value. I look forward to sharing additional corporate, clinical, and regulatory progress as appropriate," concluded Swaminathan.

Coya CMO, Dr. Fred Grossman said, "As we have indicated in the past, we expect 2025 to hold important milestones for the Company, including initiating the phase 2b trial of COYA 302, which is the combination of LD-IL2 and CTLA 4 IG, in ALS patients. We are on track for submission of all required nonclinical data to the FDA to support the initiation of the Phase 2 trial in patients with ALS. Additionally, we will be submitting an IND for a phase 2b study of COYA 302 in FTD patients. Clinical data from an investigator initiated clinical trial of combination of LD IL-2 and CTLA 4 IG will be reported and will support the planned phase 2b trial of COYA 302 n FTD."

Financial Results

As of December 31, 2024, Coya had cash and cash equivalents of \$38.3 million.

Research and development (R&D) expenses were \$11.9 million for the year ended December 31, 2024, compared to \$5.5 million for the year ended December 31, 2023. The change was primarily due to a \$5.0 million increase in our preclinical expenses, a \$1.1 million increase in internal research and development expenses, and a \$0.3 million increase in costs attributable to our sponsored research agreement with Houston Methodist Hospital.

General and administrative expenses were \$8.9 million for the year ended December 31, 2024, and \$7.8 million for the year ended December 31, 2023, a change of approximately \$1.1 million. The increase was primarily due to a \$1.2 million increase in payroll and employee related benefits, a \$0.3 million increase in franchise taxes and license fees and \$0.2 million increase in our investor and public relations costs, partially offset by a \$0.2 million decrease in insurance fees and a \$0.4 million decrease in professional service fees.

Net loss was \$14.9 million for the year ended December 31, 2024, compared to net loss of \$8.0 million for the year ended December 31, 2023.

About Coya Therapeutics, Inc.

Headquartered in Houston, TX, Coya Therapeutics, Inc. (Nasdaq: COYA) is a clinical-stage biotechnology company developing proprietary treatments focused on the biology and potential therapeutic advantages of regulatory T cells ("Tregs") to target systemic inflammation and neuroinflammation. Dysfunctional Tregs underlie numerous conditions, including neurodegenerative, metabolic, and autoimmune diseases, and this cellular dysfunction may lead to sustained inflammation and oxidative stress resulting in lack of homeostasis of the immune system.

Coya's investigational product candidate pipeline leverages multiple therapeutic modalities aimed at restoring the anti-inflammatory and immunomodulatory functions of Tregs. Coya's therapeutic platforms include Treg-enhancing biologics, Treg-derived exosomes, and autologous Treg cell therapy.

COYA 302 – the Company's lead biologic investigational product or "Pipeline in a Product" – is a proprietary combination of COYA 301 (Coya's proprietary LD IL-2) and CTLA4-Ig for subcutaneous administration with a unique dual mechanism of action that is now being developed for the treatment of Amyotrophic Lateral Sclerosis, Frontotemporal Dementia, Parkinson's Disease, and Alzheimer's Disease. Its multi-targeted approach enhances the number and anti-inflammatory function of Tregs and simultaneously lowers the expression of activated microglia and the secretion of pro-inflammatory mediators. This synergistic mechanism may lead to the re-establishment of immune balance and amelioration of inflammation in a sustained and durable manner that may not be achieved by either low-dose IL-2 or CTLA4-Ig alone.

For more information about Coya, please visit www.coyatherapeutics.com.

Forward-Looking Statements

This press release contains "forward-looking" statements that are based on our management's beliefs and assumptions and on information currently available to management. Forward-looking statements include all statements other than statements of historical fact contained in this presentation, including information concerning our current and future financial performance, business plans and objectives, current and future clinical and preclinical development activities, timing and success of our ongoing and planned clinical trials and related data, the timing of announcements, updates and results of our clinical trials and related data, our ability to obtain and maintain regulatory approval, the potential therapeutic benefits and economic value of our product candidates, competitive position, industry environment and potential market opportunities. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," and similar expressions are intended to identify forward-looking statements.

Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors including, but not limited to, those related to risks associated with the impact of COVID-19; the success, cost and timing of our product candidate development activities and ongoing and planned clinical trials; our plans to develop and commercialize targeted therapeutics; the progress of patient enrollment and dosing in our preclinical or clinical trials; the ability of our product candidates to achieve applicable endpoints in the clinical trials; the safety profile of our product candidates; the potential for data from our clinical trials to support a marketing application, as well as the timing of these events; our ability to obtain funding for our operations; development and commercialization of our product candidates; the timing of and our ability to obtain and maintain regulatory approvals; the rate and

degree of market acceptance and clinical utility of our product candidates; the size and growth potential of the markets for our product candidates, and our ability to serve those markets; our commercialization, marketing and manufacturing capabilities and strategy; future agreements with third parties in connection with the commercialization of our product candidates; our expectations regarding our ability to obtain and maintain intellectual property protection; our dependence on third party manufacturers; the success of competing therapies or products that are or may become available; our ability to attract and retain key scientific or management personnel; our ability to identify additional product candidates with significant commercial potential consistent with our commercial objectives; and our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. Moreover, we operate in a very competitive and rapidly changing environment, and new risks may emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed herein may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Although our management believes that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances described in the forward-looking statements will be achieved or will occur. We undertake no obligation to publicly update any forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

BALANCE SHEETS (Audited)

	December 31,	
	2024	2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 38,339,762	\$ 32,626,768
Collaboration receivables	-	7,500,000
Prepays and other current assets	5,968,666	1,069,557
Total current assets	44,308,428	41,196,325
Fixed assets, net	38,588	65,949
Total assets	<u>\$ 44,347,016</u>	<u>\$ 41,262,274</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,588,128	\$ 1,155,656
Accrued expenses	1,388,060	2,973,215
Deferred collaboration revenue	848,286	923,109

Total current liabilities	3,824,474	5,051,980
Deferred collaboration revenue	945,447	574,685
Total liabilities	4,769,921	5,626,665
Stockholders' equity:		
Series A convertible preferred stock, \$0.0001 par value; 10,000,000 shares authorized, none issued and outstanding as of December 31, 2024 and 2023	-	-
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 16,707,441 and 14,405,325 shares issued and outstanding as of December 31, 2024 and 2023, respectively	1,671	1,441
Additional paid-in capital	80,312,594	61,501,801
Subscription receivable	-	(11,250)
Accumulated deficit	(40,737,170)	(25,856,383)
Total stockholders' equity	39,577,095	35,635,609
Total liabilities and stockholders' equity	\$ 44,347,016	\$ 41,262,274

STATEMENTS OF OPERATIONS (Audited)

	Years Ended December 31,	
	2024	2023
Collaboration revenue	\$ 3,554,061	\$ 6,002,206
Operating expenses:		
Research and development	11,865,654	5,501,527
In-process research and development	25,000	543,186
General and administrative	8,885,757	7,833,481
Depreciation	27,361	27,361
Total operating expenses	20,803,772	13,905,555
Loss from operations	(17,249,711)	(7,903,349)
Other income:		
Other income, net	1,648,637	639,365
Pre-tax loss	(15,601,074)	(7,263,984)
Income tax benefit (expense)	720,287	(723,852)
Net loss	\$ (14,880,787)	\$ (7,987,836)
Share information:		
Net loss per share of common stock, basic and diluted	\$ (0.98)	\$ (0.79)
Weighted-average shares of common stock outstanding, basic and diluted	15,238,919	10,163,850

STATEMENTS OF CASH FLOWS (Audited)

	Years Ended December 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (14,880,787)	\$ (7,987,836)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation	27,361	27,361
Stock-based compensation, including the issuance of restricted stock	2,663,539	872,248
Acquired in-process research and development	25,000	543,186
Changes in operating assets and liabilities:		
Collaboration receivable	7,500,000	(7,500,000)
Prepays and other current assets	(4,899,109)	181,707
Accounts payable	477,450	298,816
Accrued expenses	(1,498,215)	877,913
Deferred collaboration revenue	295,939	1,497,794
Net cash used in operating activities	(10,288,822)	(11,188,811)
Cash flows from investing activities:		
Purchase of in-process research and development assets	(25,000)	(543,186)
Net cash used in investing activities	(25,000)	(543,186)
Cash flows from financing activities:		
Proceeds from sale of common stock from 2023 Private Placement, net of offering costs	-	24,084,805

Proceeds from issuance of common stock upon IPO, net of offering costs	-	14,250,311
Payment of financing costs related to the 2023 Private Placement	(131,918)	-
Proceeds from subscription receivable	11,250	-
Proceeds from the exercise of stock options	1,975	89,947
Proceeds from the exercise of warrants	2,141,128	-
Proceeds from sale of common stock, net of offering costs	14,004,381	-
Net cash provided by financing activities	16,026,816	38,425,063
Net increase in cash and cash equivalents	5,712,994	26,693,066
Cash and cash equivalents as of beginning of the year	32,626,768	5,933,702
Cash and cash equivalents as of end of the year	\$ 38,339,762	\$ 32,626,768
Supplemental disclosures of non-cash financing activities:		
Conversion of convertible preferred stock upon IPO	\$ -	\$ 8,793,637
Conversion of convertible promissory notes upon IPO	\$ -	\$ 12,965,480
Subscription receivable related to warrant exercise	\$ -	\$ 11,250
Financing costs related to the 2023 Private Placement in accrued expenses and accounts payable	\$ -	\$ 131,918

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