

#### **NEWS RELEASE**

# Coya Therapeutics Reports Second Quarter Financial Results and Provides a Corporate Update

#### 2025-08-12

HOUSTON, Aug. 12, 2025 /PRNewswire/ -- Coya Therapeutics, Inc. (NASDAQ: COYA) ("Coya" or the "Company"), a clinical-stage biotechnology company focused on developing biologics that enhance regulatory T cell (Treg) function in patients with neurodegenerative disorders, provides a corporate update and announces its financial results for the quarter ended June 30, 2025.

### **Recent Corporate Highlights**

- Submitted to FDA on June 30, 2025, additional nonclinical data to support the start of the COYA 302 Phase 2 trial in patients with ALS
- Published results of scientific research linking inflammation and oxidative stress to the progression of Parkinson's Disease (PD). Study demonstrated correlation between peripheral pro-inflammatory mechanisms, particularly monocytes and oxidative stress, in the progression and severity PD. It was published in the scientific journal Frontiers of Immunology
- Announced U.S. patent (US 12,312,389 B2) for a stable ready-to-use liquid IL-2 formulation; Coya holds exclusive in-vivo rights across multiple indications

## <u>Upcoming Expected Catalysts for 2025</u>

- Decision from the US FDA on the IND for COYA 302 in ALS, expected by or before August 29, 2025
- Upon IND acceptance and first patient dosing of COYA 302 in ALS, Coya will receive milestone payments of \$8.4 million from strategic partner, Dr. Reddy's Laboratories (DRL)
- ALS Biomarker data. Publication of longitudinal data on Neurofilament Light Chain (NfL) and oxidative stress

markers in tracking progression and survival in patients with ALS

- Report new proteomics data from the completed investigator-initiated, 21-week, double-blind, placebocontrolled, exploratory Phase 2 study of low-dose interleukin-2 (LD IL-2) in patients with Alzheimer's disease (AD)
- Top-line clinical data release for an investigator-initiated trial combining LD IL-2 + CTLA4-Ig in patients with Frontotemporal Dementia (FTD)
- Top-line data for COYA 303 in an in-vivo inflammatory animal model
- Filing of IND for the COYA-302 Phase 2 trial in patients with FTD\*
   (\*Clinical trial will be initiated after FDA IND approval for FTD)

Coya's Chief Executive Officer Arun Swaminathan, Ph.D. commented, "As we look ahead, we are focused on several key catalysts, including a decision from the FDA on our IND application for COYA 302 in ALS, anticipated by the end of August. We are encouraged by the growing body of data supporting our regulatory T cell enhancement approach, including the recent findings from the investigator-initiated trial in FTD and promising pre-clinical results with COYA 303. These advances strengthen our confidence in the potential of COYA 302 in neurodegenerative diseases like ALS and FTD."

Coya's Chief Medical Officer Dr. Fred Grossman commented, "We look forward to the FDA's decision on our IND submission for COYA 302 in ALS, which represents a significant milestone for our lead program. Pending clearance, we are prepared to initiate our controlled Phase 2 clinical trial in ALS. We also plan to submit an IND for FTD by the end of the year."

#### Financial Results

As of June 30, 2025, Coya had cash and cash equivalents of \$29.8 million.

Collaboration revenues were \$0.2 million for the three months ended June 30, 2025, compared to \$3.4 million for the three months ended June 30, 2024, a change of approximately \$3.3 million. The decrease was primarily due to the immediate recognition of license revenue upon executing the First Amendment to the DRL Development Agreement during the three months ended June 30, 2024.

Research and development expenses were \$3.7 million for the three months ended June 30, 2025, compared to \$4.6 million for the three months ended June 30, 2024, a decrease of approximately \$0.9 million. The decrease was primarily due to a \$1.2 million decrease in our preclinical expenses primarily due to our preclinical work on COYA 302 in ALS, partially offset by a \$0.2 million increase in internal research and development expenses, and a \$0.1 million increase in sponsored research.

General and administrative expenses were \$2.9 million for the three months ended June 30, 2025, and \$2.1 million for the three months ended June 30, 2024, an increase e of approximately \$0.8 million. The increase was primarily due to a \$0.3 million increase in stock-based compensation, a \$0.4 million increase in professional services, and a \$0.1 million increase in investor relation related expenses.

Net loss was \$6.1 million for the three months ended June 30, 2025, compared to net loss of \$2.9 million for the three months ended June 30, 2024.

#### About COYA 302

COYA 302 is an investigational and proprietary biologic combination therapy with a dual immunomodulatory mechanism of action intended to enhance the anti-inflammatory function of regulatory T cells (Tregs) and suppress the inflammation produced by activated monocytes and macrophages. COYA 302 comprises proprietary low dose interleukin-2 (LD IL-2) and CTLA-4 Ig and is being developed for subcutaneous administration for the treatment of patients with ALS. These mechanisms may have additive or synergistic effects.

COYA 302 is an investigational product not yet approved by the FDA or any other regulatory agency.

#### About COYA 303

COYA 303 is an investigational biologic combination of COYA 301 and a glucagon-like-peptide-1 receptor agonist (GLP-1 RA) designed for subcutaneous administration. In a preclinical study, COYA 303 exhibited a dual immunomodulatory mechanism of action resulting in an additive/synergistic anti-inflammatory effect, which the Company believes was due to increased Treg function and suppressed pro-inflammatory myeloid cells and responder T cells.

#### 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. 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.

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 forwardlooking 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 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.

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COYA THERAPEUTICS, INC. CONDENSED BALANCE SHEETS

> (unaudited) June 30, December 31

Assets Current assets:

5

Cash and cash equivalents Prepaids and other current assets Total current assets Fixed assets, net Total assets	\$	29,757,328 3,670,319 33,427,647 24,908 33,452,555	\$ 38,339,762 5,968,666 44,308,428 38,588 44,347,016
Liabilities and Stockholders' Equity Current liabilities: Accounts payable Accrued expenses Deferred collaboration revenue Total current liabilities Deferred collaboration revenue Total liabilities	\$	931,344 2,838,685 731,075 4,501,104 641,158 5,142,262	\$ 1,588,128 1,388,060 848,286 3,824,474 945,447 4,769,921
Stockholders' equity: Series A convertible preferred stock, \$0.0001 par value: 10,000,000 shares authorized, none issued or outstanding as of June 30, 2025 or December 31, 2024 Common stock, \$0.0001 par value; 200,000,000 shares authorized; 16,724,998 and 16,707,441 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively Additional paid-in capital Accumulated deficit Total stockholders' equity Total liabilities and stockholders' equity	<del></del>	1,673 82,447,524 (54,138,904) 28,310,293 33,452,555	\$ 1,671 80,312,594 (40,737,170) 39,577,095 44,347,016

# COYA THERAPEUTICS, INC. CONDENSED UNAUDITED INTERIM STATEMENTS OF OPERATIONS

	Three Months Ended June 30,				
	2025			2024	
Collaboration revenue	\$	163,616	\$	3,425,271	
Operating expenses: Research and development In-process research and development		3,663,103		4,566,152	
General and administrative		2,908,191		2,088,404	
Depreciation		6,840		6,840	
Total operating expenses		6,578,134		6,661,396	
Loss from operations		(6,414,518)		(3,236,125)	
Other income: Other income		319,541		344.445	
Pre-tax loss		(6,094,977)		(2,891,680)	
Income tax expense					
Net loss	\$	(6,094,977)	\$	(2,891,680)	
Per share information:					
Net loss per share of common stock, basic and diluted Weighted-average shares of common stock outstanding, basic and diluted	\$	(0.36) 16,724,998	\$	(0.19) 14.915.217	
violginod divolage shares of common stock obtaining, basic and diluted		10,724,000		14,010,217	

		2025		2024	
Cash flows from operating activities:  Net loss  Adjustment to reconcile net loss to net cash used in operating activities:	\$	(13,401,734)	\$	(7,943,593)	
Depreciation Stock-based compensation, including the issuance of restricted stock Acquired in-process research and development assets		13,680 2,115,795 -		13,680 1,097,984 25,000	
Changes in operating assets and liabilities: Collaboration receivable Prepaids and other current assets Accounts payable		2,298,347 (656,784)		7,500,000 (2,241,700) 716,067	
Accrued expenses Deferred collaboration revenue Net cash used in operating activities		1,450,625 (421,500) (8,601,571)		(1,883,022) 297,891 (2,417,693)	
Cash flows from investing activities: Purchase of in-process research and development assets Net cash used in investing activities		<u>-</u>		(25,000) (25,000)	
Cash flows from financing activities: Proceeds from subscription receivable Proceeds from sale of common stock Payment of financing costs related to the 2023 Private Placement Proceeds from the exercise of stock options Proceeds from the exercise of warrants		19,137		11,250 5,000,000 (131,918) 1,975 1,509,707	
Net cash provided by financing activities  Net (decrease) increase in cash and cash equivalents  Cash and cash equivalents as of beginning of the period  Cash and cash equivalents as of end of the period	\$	19,137 (8,582,434) 38,339,762 29,757,328	\$	6,391,014 3,948,321 32,626,768 36,575,089	
Supplemental disclosures of non-cash financing activities: Financing costs related to the sale of common stock in accounts payable	\$	-	\$	56,332	

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