



NEWS RELEASE

# Coya Therapeutics CEO Dr. Arun Swaminathan Issues Letter to Stockholders

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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 Treg function, releases the following letter to stockholders from Chief Executive Officer Dr. Arun Swaminathan.

Dear Fellow Stockholder,

Given my recent transition to the role of CEO, I wanted to share my thoughts on Coya and our future and to express my gratitude to our founder and Executive Chair, Dr. Howard Berman, whose bold vision has instilled the "innovation and get-it-done" culture in Coya's DNA. We have made tremendous strides in 2024, repeatedly executing on our promises. As I look to 2025, I am confident that our nimble and highly experienced team will continue to exceed expectations.

I have spent my entire 25-year career in the biotech space, and I believe that Coya has the most promise of any company that I have represented. I truly believe our novel science, strong clinical proof of concept data, pharmaceutical partnership validation, cash runway, and clear path to a commercial drug differentiates us. Prior to serving at Coya, I helped spearhead and lead pharmaceutical transactions worth billions of dollars that led to significant value creation. I believe the opportunities ahead of us in 2025 and beyond are what investors, stockholders, and patients should be most excited about. Our science and approach of regulating Tregs is now validated in multiple trials across multiple neurodegenerative diseases, we have a track record of executing value-creating non-dilutive deals, and our strong cash position allows us to be prudent in our decisions.

## Year Ahead

We expect our activities in 2025 to be focused on the following indications:

**ALS (Amyotrophic Lateral Sclerosis) Program:** We have alignment with the FDA on the data required to initiate our potentially pivotal COYA 302 Phase 2 double-blind randomized study in patients with ALS. We are targeting the submission of the requested data package by 2Q 2025 and initiation of the clinical trial upon FDA clearance. The roadmap to topline results is now clear with reduced uncertainty. In late 2023, we partnered with Dr. Reddy's Laboratories, a multi-billion-dollar drug developer, to license COYA 302 in ALS in a deal that is worth up to \$700 million. We still retain the rights to COYA 302 in ALS in Japan and South/Central America and Mexico, thus providing us direct upside and optionality in this indication alone.

**FTD (Frontotemporal Dementia) Program:** We expect to see topline results in 2H 2025 from the investigator-initiated, open-label study of Low Dose IL-2 (LD IL-2) + CTLA4-Ig in FTD. Study endpoints will measure safety, peripheral and central inflammation, FTD progression, and pharmacodynamic effects on Treg cell populations. The data are expected to guide our planned COYA 302 Phase 2 double-blind randomized study (which will be funded by the Alzheimer's Drug Discovery Foundation) and further optimize the design for success. The guidance from the FDA on the ALS IND reduces uncertainty on the planned IND filing for FTD in 2H of 2025. We have retained full commercial rights on this program thus far, providing us optionality to develop the program to BLA approval ourselves and capture the full potential upside or partner at a later stage once we obtain additional clinical data.

**AD (Alzheimer's disease) Program:** Complementing the promising data that was presented at CTAD in Madrid for LD IL-2 in mild to moderate AD, the investigators will disclose additional data in 1H 2025 that summarizes the changes in inflammation in the peripheral system (blood) and central nervous system (CSF and brain) and other molecular measurements for the two IL-2 dosing arms vs. placebo. These important data will help to further address the basic science associated with the promising clinical response observed in the lower dose IL-2 arm and its association with better Treg enhancement. We retain full rights to the AD indication for COYA 302 and are already in the process of exploring non-dilutive and strategic partnering opportunities. While the CTAD data was based on LD IL-2 alone and proved highly promising in and of itself, COYA 302, which is a proprietary combination of LD IL-2 and CTLA4-Ig, targets multiple pathways and is developed to more significantly and durably enhance Treg function, which we believe will be highly attractive to potential partners.

## Strategic Partnerships

**Dr. Reddy's Partnership:** Our partnership with Dr. Reddy's Laboratories is approaching its one-year anniversary, and our collaboration could not be stronger. We have a reliable partner for ALS, and leveraging its

resources and expertise has created value beyond the milestone payments. In 2025, we anticipate receiving \$8.4 million upon initiation of the Phase 2 ALS clinical trial and will continue to evaluate opportunities to further deepen the relationship.

**Other Strategic Possibilities:** As I have described, my background is one of deal-making, and I intend to leverage my network and capabilities to maximize opportunities for Coya in 2025. We have only partnered COYA 302 in ALS, and the optionality to partner, co-develop, or license the asset in other indications exists. Any potential transaction will be evaluated based on maximizing stockholder value. The positive data from the investigator-initiated trial of LD IL-2 in patients with Alzheimer's disease increases our confidence in obtaining value-creating pharma partnerships that combine our proprietary LD IL-2, COYA 301, with other modalities. I can envision multiple opportunities with LD IL-2 serving as a backbone adjuvant with standard of care agents and other novel pathways.

Moreover, the opportunity for grant funding and financial support from foundations exists and will be vigorously pursued. We believe the data emerging on Tregs in autoimmune disease (such as lupus, rheumatoid arthritis, and scleroderma) and, in particular, treatment with LD IL-2 is compelling and may strengthen the role of COYA 302 and LD IL-2 combinations in this space. I intend to actively pursue partnerships in this arena that would further place us in a strong position to pursue value-creating deals.

## Value-Creating Pipeline

Like many experts in the scientific community, we believe combination strategies are the future to address devastating neurodegenerative diseases. We believe targeting one mechanism or pathway is likely insufficient to achieve maximal effect - hence our approach with COYA 302. COYA 302 is a "Pipeline within a Product" and has strong potential in ALS, FTD, AD, Parkinson's disease, and other indications.

We are continuously building our intellectual property to further enhance the value of Coya. One recent development is the combination of COYA 301 and GLP-1 agonists. Data suggests that the mechanism of action appears additive and/or synergistic in ameliorating inflammation. This is yet another opportunity for value-creating strategic partnerships. We intend to publish more detailed data in 1Q 2025.

## Conclusion

As you can see from our past performance, our entire management team is committed to the success of Coya. We expect to recognize a number of clinical, regulatory, and/or commercial milestones in 2025 that will help us advance the treatment of neurodegenerative diseases.

On behalf of the entire Coya team, please accept our sincere gratitude for both your support and belief in our

science, our story, and our team. We look forward to presenting additional clinical data and updating you on our additional corporate developments as they unfold. Onwards and upwards!

## 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](http://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 because of new information, future developments or otherwise.

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