



NEWS RELEASE

Coya Therapeutics CEO Dr. Arun Swaminathan Issues Letter to Stockholders

2026-01-20

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 Stockholders,

Coya enters 2026 with strong momentum and a clear sense of purpose. I believe we are exceptionally well positioned to advance our mission of delivering potentially transformational therapies for patients suffering from devastating neurodegenerative diseases. Scientifically, the neurodegeneration field increasingly recognizes combination-based therapeutic strategies such as ours as a promising path forward for diseases driven by complex, multifactorial biology. Clinically, we are driving towards major clinical catalysts in ALS and FTD. We believe each program has the potential to meaningfully address unmet needs. Our studies are designed to evaluate whether combination-based regulatory T-cell modulation can stabilize or alter disease progression—an outcome that, if confirmed, would represent a significant advance for patients and a defining milestone for the Company. Moreover, we anticipate additional datasets in 2026 which we believe are poised to add to our body of work on Treg biology.

Operational and Regulatory Execution/Momentum

Last year we received two important IND approvals for COYA 302—one in Amyotrophic Lateral Sclerosis (ALS) and one in Frontotemporal Dementia (FTD). We have now initiated our ALSTARS trial in ALS. That study is advancing as planned. We are actively enrolling and patients are already being dosed. Recruitment has been further

strengthened by acceptance of our Clinical Trial Application (CTA) by Health Canada, enabling the activation of Canadian sites in addition to more than 20 U.S. clinical sites.

Scientific Validation and Expanding Data Generation Built on Nobel Prize-Recognized Treg Biology

Our scientific approach continues to be validated at the highest levels. In 2025, the Nobel Prize in Physiology or Medicine was awarded to our Scientific Advisory Board member, Dr. Shimon Sakaguchi, for his pioneering work in elucidating regulatory T-cell (Treg) biology.

Importantly, across four investigator-initiated clinical studies of our combination-based regulatory T-cell (Treg) modulation approach, we have observed stabilization of disease progression in treated patient cohorts, including ALS and FTD. Stabilizing clinical progression in neurodegenerative diseases, historically characterized by relentless functional decline, is a clinically meaningful signal and reinforces our belief in the potential of Treg-targeted combination strategies to alter disease trajectory. While investigator-initiated studies are not confirmatory, these results suggest a potentially unifying mechanism in neurodegeneration. In sum, we believe these observations provide early clinical validation of our approach and underpin our confidence in advancing COYA 302 in the ALSTARS Trial and a prospective clinical study in patients with FTD. In addition, these observations also encourage our pursuit of later-stage development in other indications.

New Translational Datasets to be provided in 2026

During 2026 we plan to present further translational and clinical datasets across our programs, including biomarker, proteomics, and single-cell data. These data are expected to further elucidate the role of regulatory T cells in modulating neuroinflammation and neurodegeneration, while providing deeper insight into target engagement, pathway modulation, and patient-level biology. We believe these datasets will meaningfully strengthen the mechanistic foundation underlying our combination-based therapeutic approach and support future clinical, regulatory, and partnering discussions.

Financial Strength and Fiduciary Discipline

In 2025, we further strengthened our balance sheet, including the receipt of \$8.4 million in non-dilutive funding from our strategic partner, Dr. Reddy's Laboratories. We enter 2026 with approximately \$46.8 million in cash (unaudited) as of 31st December 2025, no debt, and a projected cash runway into the second half of 2027—extending beyond the anticipated topline readout of the ALSTARS trial.

This financial position allows us to remain highly focused on execution while preserving strategic flexibility.

2026 Priorities and Clinical Programs

Our efforts in 2026 will be squarely focused on advancing our ALS and FTD programs toward key value-creating milestones.

COYA 302 in ALS

The ALSTARS Phase 2 trial is actively enrolling and dosing patients. Additional U.S. and Canadian sites are soon expected to come fully online. We are targeting full enrollment in the second half of 2026, with a topline data readout anticipated in the first quarter of 2027.

COYA 302 in FTD

Results from an investigator-initiated trial of low-dose IL-2 and CTLA4-Ig demonstrated robust target engagement, including statistically significant and sustained increases in regulatory T-cell numbers and suppressive function beginning as early as two weeks post-dosing and maintained through the 22-week treatment period. The cognitive measures were stable, with no decline on either the Montreal Cognitive Assessment (MoCA) or the CDR-FTLD.

These results support advancement of COYA 302 into a Phase 2a study in patients with FTD, for which we have received FDA clearance. As previously disclosed, the Alzheimer's Drug Discovery Foundation invested \$5 million in Coya based on its conviction in our combination-therapy approach. We are working closely with leading key opinion leaders and expect to initiate this study in the second quarter of 2026. Coya retains full global rights to this indication, which we believe represents a meaningful long-term value opportunity.

COYA 303 in Alzheimer's Disease

COYA 303, our proprietary combination of low-dose IL-2 and a GLP-1 receptor agonist, has demonstrated compelling preclinical synergy across multiple biomarkers relevant to neurodegenerative disease. While recent Novo Nordisk EVOKE and EVOKE+ studies evaluating semaglutide monotherapy in mild Alzheimer's disease did not show clinical efficacy, they did demonstrate some improvement in key biomarkers. We believe the synergy demonstrated from our in vitro and in vivo studies of our proprietary combination of low-dose IL-2 and a GLP-1 receptor agonist (COYA 303) may make this combination a viable approach in Alzheimer's disease.

In 2026, we will continue to pursue capital-efficient strategies to advance this program, including strategic partnerships and non-dilutive funding opportunities.

Strategic Partnerships

Our collaboration with Dr. Reddy's Laboratories continues to strengthen and provides substantial value beyond non-dilutive milestone payments. Our teams remain closely aligned in advancing the ALSTARS trial and preparing for potential future commercialization activities. We expect this partnership to deepen further in 2026.

We are also evaluating additional strategic opportunities. Japan represents a significant ALS market where we retain full rights, and we plan to advance discussions with potential partners accordingly. More broadly, as immunology and neuroscience increasingly converge, we see multiple opportunities to expand the reach of our platform through combination strategies and novel collaborations.

Looking Ahead

In summary, throughout 2026, Coya will be actively advancing two COYA 302 clinical programs: one in ALS and the other in FTD—two diseases with profound unmet medical need and an estimated combined market opportunity of \$2–\$4 billion. Our confidence is grounded in three pillars:

1. Highly validated science rooted in Nobel Prize–recognized discoveries in regulatory T-cell biology that established the central role of Tregs in immune homeostasis and the control of pathologic inflammation.
2. A combination based therapeutic strategy that targets multiple aspects of the immune system increases the probability of technical and regulatory success.
3. Consistent and encouraging clinical and translational data across multiple studies and indications, supplemented by the generation of additional translational biology datasets in 2026 that we anticipate will further elucidate the role of regulatory T cells in modulating neuroinflammation and neurodegeneration and support our mechanistic and clinical rationale.

With a strong balance sheet and runway extending beyond our next major clinical inflection point, we believe Coya is well positioned to execute on its strategy and deliver meaningful long-term value.

On behalf of the entire Coya team, thank you for your continued support and confidence. Our management team and board of directors are considerable shareholders along with you, aligning our collective interests. We only win if you win. We are deeply grateful to our employees, investigators, clinical partners, and—most importantly—the patients and families who make our work possible. We look forward to updating you on our continued progress throughout the year.

Sincerely yours,

Arun Swaminathan, Ph.D.
Chief Executive Officer

Coya Therapeutics, Inc.

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

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 and other neurodegenerative diseases. These mechanisms may have additive or synergistic effects.

Coya is currently conducting the ALSTARS Trial, a Phase 2, randomized, multi-center, double-blind, placebo-controlled study to evaluate the efficacy and safety of COYA 302 for the treatment of ALS ([ClinicalTrials.gov Identifier: NCT 07161999](https://clinicaltrials.gov/ct2/show/NCT07161999)).

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

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, our anticipated cash runway, 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 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 and timing 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; our exploratory clinical signals may not be predictive of outcomes in larger, randomized controlled 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; anticipated interactions with the FDA under Fast Track designation; 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 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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