



NEWS RELEASE

Coya Therapeutics Provides a Corporate Update and Reports Unaudited First Quarter 2024 Financial Results

5/9/2024

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 quarter ended March 31, 2024.

Recent Corporate Highlights

- Announced successful pre-IND and Type C meetings with FDA in January 2024 to advance the development of COYA 302 for the treatment of ALS; IND expected to be filed in 2Q24 followed by initiation of Ph. 2 trial with COYA 302 in ALS
- Expanded pipeline of COYA 302 in January 2024 beyond ALS to also include Frontotemporal Dementia (FTD), with an IND planned in 2H24, and Parkinson's disease (PD), with animal data to be released in 2H24
- Expanded patent estate surrounding next-generation immune modulatory biologics in February 2024 through a license from the University of Nebraska Medical Center to cover multiple LD IL-2 combinations, including those with Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF)
- Expanded pipeline of COYA 302 in February 2024 to include AD; COYA 302 to now be explored in four neurodegenerative diseases (ALS, PD, FTD, and AD) – Coya to leverage data from the Ph. 2 LD IL-2 study in AD to inform on strategy and next steps for COYA 302 in AD
- Presented data in March 2024 on immune system and Regulatory T Cell (Treg) contribution in Frontotemporal Dementia (FTD) patients at the AD/PD 2024 Conference
- Presented novel biomarker data in March 2024 documenting serum levels of a biomarker (4-HNE) that

strongly correlate with rate of progression and survival in patients with ALS at the Society of Neuroimmune Pharmacology conference. Coya has filed intellectual property on multiple uses of 4-HNE in ALS

- Presented updated biomarker data in late April 2024 at the 2nd Annual Johnson Center Symposium that showed 4-HNE levels were predictive of survival in ALS patients and are elevated at diagnosis in bulbar vs. limb onset ALS

“During the first quarter of 2024, we expanded our clinical pipeline with our lead asset COYA 302 beyond the initial indication of ALS and into FTD, Parkinson’s, and Alzheimer’s diseases,” stated Howard Berman, Ph.D., Coya’s Chief Executive Officer. “Based on our work to date, we believe the dual mechanism of action from COYA 302, a combination of our proprietary low-dose IL-2 and CTLA4-Ig, holds immense potential in treating such neurodegenerative diseases that have complex immune pathways. The combination effect of restoring Tregs via low-dose IL-2 and inhibiting other inflammatory cell types via CTLA4-Ig could be a significant breakthrough therapeutic approach, much like the growing acceptance of combination therapy in treating cancer or viral diseases. Many patients, families, and caregivers are looking for meaningful new therapies for these neurodegenerative diseases.

“We expect to report clinical progress from a number of initiatives over the balance of 2024 with COYA 302, our ‘pipeline in a product.’ In ALS, our lead indication, we expect to file the IND for COYA 302 in 2Q24 and subsequently initiate the Ph. 2 trial. Over the last two months, we have presented encouraging data in patients with ALS that strongly correlates the biomarker 4-HNE with the rate of progression and survival in patients with ALS. We are in discussions with the FDA about the inclusion of 4-HNE in the expected Ph. 2 trial. Additionally, clinical data from the previously completed investigator-initiated trial in patients with ALS is also anticipated in the second quarter.

“In Alzheimer’s disease, data from the Ph. 2 investigator-initiated trial involving COYA 301, or low-dose IL-2 alone, is expected in the summer of 2024. Given our previously announced decision to move forward in Alzheimer’s with COYA 302, data from this trial will help guide us in the subsequent trial design of COYA 302 in AD. Obviously, Alzheimer’s disease is a huge unmet need, so we eagerly anticipate results from the Ph. 2 trial of COYA 301.

“In 2H24, we expect to file the IND in FTD and subsequently initiate a Ph. 2 trial thereafter. Data shared in March 2024 at the AD/PD 2024 Conference in Lisbon highlighted the reduction in Treg suppressive function and the simultaneous elevated inflammatory environment in patients with FTD. This data in FTD is consistent with Treg dysfunction and increased inflammatory levels in other progressive and neurodegenerative diseases and supports the multi-pathway combination approach of COYA 302.

“The potential therapeutic applications with COYA 302 in neurodegenerative diseases are vast. Dr. Reddy’s Laboratories was granted an exclusive license in December 2023 for COYA 302 in ALS patients in the U.S., Canada, the EU, and the U.K. We continue to have discussions about additional commercial partnerships and license

opportunities for COYA 302 in other indications outside of ALS, including FTD, Parkinson's and Alzheimer's diseases. Our cash and cash equivalents balance of \$36.0 million provides us a runway into 2026, so we can be patient with any future commercial negotiations in order to maximize shareholder value. I look forward to sharing additional corporate, clinical, and regulatory progress as warranted," concluded Berman.

Unaudited Financial Results

As of March 31, 2024, Coya had cash and cash equivalents of \$36.0 million.

Research and development (R&D) expenses were \$3.1 million for the three months ended March 31, 2024, compared to \$1.2 million for the three months ended March 31, 2023. The change was primarily due to a \$1.7 million increase in our preclinical expenses and a \$0.2 million increase in internal research and development expenses.

General and administrative expenses were \$2.4 million for the three months ended March 31, 2024 and \$1.7 million for the three months ended March 31, 2023, a change of approximately \$0.7 million. The increase was primarily due to an increase in personnel related expenses and consulting fees as we continue to expand our operations to support our research and development efforts.

Net loss was \$5.1 million for the three months ended March 31, 2024, compared to net loss of \$2.7 million for the three months ended March 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.

| CONDENSED BALANCE SHEETS | | |
|---|----------------------------------|----------------------|
| | March 31, 2024 (unaudited) | December 31, 2023 |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 35,989,406 | \$ 32,626,768 |
| Collaboration receivable | - | 7,500,000 |
| Prepays and other current assets | 1,344,955 | 1,069,557 |
| Total current assets | 37,334,361 | 41,196,325 |
| Fixed assets, net | 59,109 | 65,949 |
| Total assets | \$ 37,393,470 | \$ 41,262,274 |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 1,587,943 | \$ 1,155,656 |
| Accrued expenses | 2,041,530 | 2,973,215 |
| Deferred collaboration revenue | 689,669 | 923,109 |
| Total current liabilities | 4,319,142 | 5,051,980 |
| Deferred collaboration revenue | 681,287 | 574,685 |
| Total liabilities | 5,000,429 | 5,626,665 |
| Stockholders' equity: | | |
| Series A convertible preferred stock, \$0.0001 par value; 10,000,000 shares authorized, none issued or outstanding as of March 31, 2024 or December 31, 2023 | - | - |
| Common stock, \$0.0001 par value; 200,000,000 shares authorized; 14,613,172 and 14,405,325 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively | 1,462 | 1,441 |
| Additional paid-in capital | 63,449,125 | 61,501,801 |
| Subscription receivable | (149,250) | (11,250) |
| Accumulated deficit | (30,908,296) | (25,856,383) |
| Total stockholders' equity | 32,393,041 | 35,635,609 |

| | | |
|--|---------------|---------------|
| Total liabilities and stockholders' equity | \$ 37,393,470 | \$ 41,262,274 |
|--|---------------|---------------|

CONDENSED UNAUDITED INTERIM STATEMENTS OF OPERATIONS

| | Three Months Ended March 31, | |
|--|------------------------------|----------------|
| | 2024 | 2023 |
| Collaboration revenue | \$ 126,838 | \$ - |
| Operating expenses: | | |
| Research and development | 3,138,159 | 1,231,712 |
| In-process research and development | 25,000 | - |
| General and administrative | 2,439,841 | 1,661,544 |
| Depreciation | 6,840 | 6,840 |
| Total operating expenses | 5,609,840 | 2,900,096 |
| Loss from operations | (5,483,002) | (2,900,096) |
| Other income: | | |
| Other income, net | 431,089 | 163,634 |
| Net loss | \$ (5,051,913) | \$ (2,736,462) |
| Per share information: | | |
| Net loss per share of common stock, basic and diluted | \$ (0.35) | \$ (0.28) |
| Weighted-average shares of common stock outstanding, basic and diluted | 14,457,839 | 9,721,847 |

CONDENSED UNAUDITED INTERIM STATEMENTS OF CASH FLOWS

| | Three Months Ended March 31, | |
|--|------------------------------|----------------|
| | 2024 | 2023 |
| Cash flows from operating activities: | | |
| Net loss | \$ (5,051,913) | \$ (2,736,462) |
| Adjustment to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 6,840 | 6,840 |
| Stock-based compensation, including the issuance of restricted stock | 435,663 | 180,387 |
| Acquired in-process research and development assets | 25,000 | - |
| Changes in operating assets and liabilities: | | |
| Collaboration receivable | 7,500,000 | - |
| Prepays and other current assets | (275,398) | 239,295 |
| Accounts payable | 477,265 | (270,111) |
| Accrued expenses | (844,745) | (1,283,674) |
| Deferred collaboration revenue | (126,838) | - |
| Net cash provided by (used in) operating activities | 2,145,874 | (3,863,725) |
| Cash flows from investing activities: | | |
| Purchase of in-process research and development assets | (25,000) | - |
| Net cash used in investing activities | (25,000) | - |
| Cash flows from financing activities: | | |
| Proceeds from issuance of common stock upon initial public offering, net of offering costs | - | 14,250,311 |
| Proceeds from subscription receivable | 11,250 | - |
| Payment of financing costs related to the 2023 Private Placement | (131,918) | - |
| Proceeds from the exercise of stock options | 1,975 | - |
| Proceeds from the exercise of warrants | 1,360,457 | - |
| Net cash provided by financing activities | 1,241,764 | 14,250,311 |
| Net increase in cash and cash equivalents | 3,362,638 | 10,386,586 |
| Cash and cash equivalents as of beginning of the period | 32,626,768 | 5,933,702 |
| Cash and cash equivalents as of end of the period | \$ 35,989,406 | \$ 16,320,288 |
| Supplemental disclosures of non-cash financing and investing activities: | | |
| Conversion of convertible preferred stock upon initial public offering | \$ - | \$ 8,793,637 |
| Conversion of convertible promissory notes upon initial public offering | \$ - | \$ 12,965,480 |
| Subscription receivable related to warrant exercise | \$ 149,250 | \$ - |

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