

CODX Earnings Call Transcript

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Quarter: 3

Operator: Hello, and thank you for standing by. My name is Tiffany, and I will be your conference operator today. At this time, I would like to welcome everyone to the Co-Diagnostics, Inc. Third Quarter 2025 Earnings Webcast. [Operator Instructions] I would now like to turn the call over to Andrew Benson, Head of Investor Relations. Andrew, please go ahead.

Andrew Benson: Good afternoon, everyone. Thank you all for participating in today's conference call. On the line today from Co-Diagnostics, we have Dwight Egan, Chief Executive Officer; and Brian Brown, Chief Financial Officer. Earlier today, Co-Diagnostics released financial results from the third quarter ended September 30, 2025. A copy of the press release is available on the company's website. We will begin with management's prepared remarks and then open the call to analyst Q&A.; Before we begin, we would like to inform listeners that certain statements made by Co-Diagnostics during this call, which are not historical facts are forward-looking statements. In addition to diagnostic test developments and timing for commencement of clinical evaluations, this includes statements concerning the company's Co-Dx PCR testing platform, which requires regulatory approval and marketing authorization for diagnostic use and is not currently for sale. Actual outcomes and results may differ materially from what is expressed or implied in any statement. Important factors, which could cause actual results to differ materially from those in these forward-looking statements are detailed in Co-Diagnostics filings with the SEC. Co-Diagnostics assumes no obligation and expressly disclaims any duty to update any forward-looking statements to reflect events or circumstances occurring after this call or to reflect the occurrence of unanticipated events. In addition, the company may discuss certain non-GAAP financial measures during today's call. These non-GAAP financial measures should not be considered a replacement for and should be read together with GAAP results. We refer you to the company's earnings release issued shortly before this call, which contains reconciliations to the non-GAAP financial measures presented to their most comparable GAAP results. At this time, I would like to turn the call over to Co-Diagnostics Chief Executive Officer, Dwight Egan. Dwight?

Dwight Egan: Thank you, everyone, for joining us today and for your continued support of Co-Diagnostics. As we head into the final stretch of the year, it is shaping up to be one of the most active and important times for our business. Over the past 45 days alone, we've shared several important updates, which are all part of our plan to position Co-Diagnostics for its next phase of growth. Each of these steps brings us closer to our goal, building a stronger, more resilient Co-Diagnostics operationally, financially and strategically. Importantly, these developments are the effect of cumulative growth and every initiative that we are currently working on connects to a broader strategy designed to create lasting value for shareholders. Over the coming months, our team is focused on executing across four main growth pillars. First, we recently announced the engagement of Maxim Group to assist in identifying potential strategic alternatives for the company's Indian joint venture, CoSara Diagnostics, which may include a merger with a Special Purpose Acquisition Company, or SPAC, or similar entity listed on a U.S. National Securities Exchange. We believe such a transaction may unlock value from our joint venture project in India and support our long-term funding strategy. Second, the CoMira joint venture with Arabian Eagle, which marks the next step in our international expansion and commercial footprint as we expand our presence in Saudi Arabia and 18 additional MENA nations. Third, our AI business unit, which is driving innovation, operational efficiency and new data-driven opportunities. And

finally, the initiation of our upcoming upper respiratory multiplex test clinical evaluations, which highlights our scientific leadership and reinforces our domestic credibility. Together, these initiatives form a complete and aligned strategy focused on financial strength, global reach, technological innovation and disciplined execution. This is how we are approaching the remainder of 2025 and preparing the foundation for 2026 and beyond. This period represents a key inflection point for Co-Diagnostics and reflects years of execution to reach this stage of momentum and readiness. With that context in mind, let's begin with the first and most time-sensitive development, the SPAC. One of the most exciting updates is our planned CoSara SPAC transaction with Maxim Group. This is a major step that we believe can unlock real value for both our operations in India and for Co-Diagnostics as a whole. The funds raised in this transaction are expected to represent a significant infusion of growth capital for CoSara operations in India and to increase Co-Diagnostics' value as well. Preparation for the transaction is progressing according to plan, and we expect to share updates on this project over the next several weeks and months. Combined with recent fundraising activities, this transaction has the potential to provide both flexibility and financial stability as we move into 2026 and begin commercialization of the new platform. This is a proactive step that has the potential to strengthen our balance sheet and create a clear path toward long-term sustainable value creation for our shareholders. I look forward to providing more updates on this transaction as they occur. Shifting focus, the next major component of our growth strategy is the CoMira joint venture. Our recently announced joint venture with Arabian Eagle Manufacturing has led to the formation of a new company named, CoMira Diagnostics, which, along with CoSara will stand as one of the cornerstones of our international expansion strategy. The principles of Arabian Eagle ran the primary distributor in the Middle East and were instrumental in Kingdom of Saudi Arabia, or KSA, being one of the largest international markets for the company's Logix Smart Test. Under the terms of the definitive agreement signed in the KSA, we have established CoMira to localize our Co-Dx PCR platform and other PCR-related intellectual property across the Middle East and North Africa. The partnership covers 19 countries, creating a significant commercial footprint in a high-growth region. CoMira will be headquartered in Riyadh with a dedicated manufacturing and assembly facility designed to produce PCR tests for infectious diseases and other applications relevant to the region's healthcare needs. The venture will initially focus on local manufacturing and distribution of the Co-Dx PCR platform with plans to expand into custom assay development and AI-enhanced diagnostics. The initiative aligns with the KSA's Saudi Vision 2030, supporting technology localization, industrial diversification and regional healthcare innovation. The regulatory pathway is anchored in obtaining Saudi Food and Drug Authority, SFDA clearance to facilitate regional distribution and regulatory acceptance across other MENA markets. CoMira will combine Co-Diagnostics molecular testing technology with Arabian Eagle's expertise in regional operations, infrastructure and local market access. The agreement marks a major step in localizing advanced molecular diagnostics within the Middle East and positions Co-Diagnostics as a strategic partner in regional public health resilience. This milestone demonstrates that our international growth strategy has advanced from concept to execution and reflects the strong high-value partnerships we continue to build globally. While this global initiative expands our reach outside the United States, we remain equally focused on commercialization and on advancing innovation through our AI business unit and other technology-driven initiatives. Another key part of our strategy is our new AI business unit, led by our Chief Technology and AI Officer, Christopher Thurston. This team is bringing all our current and future AI projects under one umbrella, the Co-Dx Primer AI platform. Additionally, our AI business unit is designed to accelerate the development of proprietary AI-powered diagnostics, enhance data analytics and improve operational efficiency across the organization. Integrating AI into our workflows will enable faster, smarter and more scalable testing processes while minimizing human error and improving efficiency at the point of care. These tools will support real-time PCR diagnostics, advance Co-Primers design and optimization and automate interpretation to improve outcomes in both lab and field environments. Our AI models are also being designed to deliver predictive epidemiological insights, giving healthcare providers and public health authorities earlier warning signals and improve situational awareness during potential outbreaks. Over time, the system is expected to leverage analytics from widespread deployment of the Co-Dx PCR Pro to anticipate disease patterns and possibly predict outbreaks before they occur. As necessary, some of these models will be built on a

secure HIPAA-compliant cloud platform with a new business unit formed to integrate internal data, workflow orchestration and AI-driven analysis into a single cohesive framework. This initiative underscores our commitment to staying at the forefront of innovation by combining advanced AI technology with our proven PCR expertise. Importantly, this program will position Co-Diagnostics to participate in one of the most dynamic growth areas in healthcare technology while building valuable new intellectual property and data assets. This is not simply an upgrade to existing systems. It is a transformational step that redefines what diagnostics can achieve in speed, accuracy and real-time intelligence. As we continue to innovate technologically, we are also executing scientifically through our flu A, B, COVID-19 and RSV multiplex test clinical evaluation program, which further validates our progress and credibility in core diagnostics. We are preparing to initiate clinical evaluations for the upper respiratory multiplex test in the immediate future, a key milestone for Co-Diagnostics. This test is designed to simultaneously detect flu A, flu B, COVID-19 and RSV, making it the most comprehensive respiratory panel in our portfolio. Test has been supported by a RADx Tech grant from the National Institutes of Health, or NIH, underscoring both the credibility and importance of this work. RADx Tech program was created to accelerate innovation in diagnostic testing and our participation validates the strength of our technology and its public health relevance. This trial represents the culmination of extensive planning and development and marks the first Co-Dx multi-pathogen test to enter human clinical evaluation. The upper respiratory panel addresses a critical need in the domestic market by combining accuracy, speed and multiplex capability within a single point-of-care platform. And we are pleased to be delivering on our commitment to initiate clinical evaluations in this flu season. The data from this trial will be used to support future regulatory submissions and commercial readiness for the U.S. market and potentially for regulatory submissions in other markets as well, such as the SFDA in parallel with the U.S. FDA submission. Initiating this study is a major step forward for our domestic business and a meaningful validation of our scientific and technical leadership. This test has generated consistent interest from both investors and potential partners, particularly those focused on high-volume U.S. respiratory testing demand. The global market size for infectious disease diagnostics is expected to grow to \$73.56 billion by 2030, and the demand for rapid accurate point-of-care diagnostics is driving an expanded opportunity for multiplex tests in the infectious disease testing market. The largest single geographical market for these tests is in North America, although the market for respiratory infectious disease testing in the Middle East is also expanding. This is largely influenced by substantial investments in the Kingdom of Saudi Arabia and the KSA's commitment to improving public health in alignment with the Saudi Vision 2030 program. This program represents a rigorous NIH-supported multiplex evaluation with strong commercial potential and is a key component in reinforcing our reputation for execution and reliability within the diagnostics industry. In short, this milestone demonstrates Co-Diagnostics is executing, not just planning and delivering tangible scientific progress that supports both near-term and long-term growth. Looking at our other programs like Co-Dx PCR MTB or tuberculosis test and Co-Dx PCR HPV8-type multiplex test, both remain on track to initiate clinical evaluations before year-end, as stated in previous communications. Both tests have been supported by grants from the Bill & Melinda Gates Foundation and are anticipated to significantly contribute to our international expansion ambitions and represent key components in our goals to provide gold standard solutions for unmet needs in various markets that are only anticipated to expand over the coming years. We believe that the introduction of competitively priced diagnostics into markets anxious to gain the upper hand against the spread of deadly and often devastating infections will position Co-Dx as a leader in innovation and point-of-care PCR diagnostics. Taken together, the initiatives we have discussed today, including the CoSara SPAC transaction, the CoMira joint venture, the launch of our AI business unit, the imminent domestic clinical evaluations and the upcoming clinical evaluations of the other tests in our pipeline all reflect the significant progress Co-Diagnostics has made over the past several months. Each of these milestones strengthens a different part of our business from capital structure and international growth to innovation and scientific validation. Collectively, they demonstrate that our strategy is working, our execution is on track and our team remains focused on creating lasting value for shareholders. Over the last 2 months, we also closed two strategic direct offerings totaling gross proceeds of \$10.8 million. We are entering the next phase of growth from a position of strength, supported by a robust balance sheet, a growing pipeline and a clear

path toward both near-term and long-term milestones. With that, I'll now turn the call over to Brian Brown, our Chief Financial Officer, to provide an update on our financial performance and outlook.

Brian Brown: Thanks, Dwight, and thank you to everyone who joined today's call. For the quarter, total revenue was \$0.1 million compared to \$0.6 million in the same period last year. In the prior year period, revenue from grants represented approximately \$0.4 million, while in Q3 2025, all revenue recognized came from product sales. Total operating expenses for Q3 2025 decreased to \$7.1 million compared to \$10.6 million in Q3 2024. This reduction reflects our continued focus on becoming more operationally efficient. Research and development expenses were \$4.5 million compared to \$4.9 million in the prior year comparable period. Net loss for Q3 2025 was \$5.9 million or a loss of \$0.16 per fully diluted share compared to a \$9.7 million loss or \$0.32 per fully diluted share in the same period last year. Adjusted EBITDA was a loss of \$6.3 million in Q3 2025 compared to a loss of \$8.8 million in Q3 2024. We ended the quarter with \$11.4 million in cash, cash equivalents and marketable investment securities. As always, we are carefully managing our spending to maintain a healthy balance sheet while positioning the company for commercialization. Throughout the year, we will continue to optimize our operating footprint to drive efficiency gains and cost savings. In addition to the strategies outlined by Dwight earlier, we plan to meet other capital requirements through a combination of equity and debt financing, additional grant funding and continued operational efficiencies. We are also evaluating other financing structures to strengthen our financial position and maintain flexibility. In parallel, we continue to pursue grant funding opportunities to support the advancement of our Co-Dx PCR platform. In the near term, our focus remains on progressing our development pipeline, completing clinical evaluations and preparing for regulatory submissions. We are allocating our resources and time strategically to support these priorities. Looking ahead, we are optimistic about multiple commercial launches expected in 2026 and the ongoing development within our test pipeline. I look forward to sharing additional updates and milestones on our next call. With that, I will now turn the time back over to Dwight.

Dwight Egan: Thank you, Brian. To close, we want to extend our gratitude to Co-Diagnostics' shareholders and to our employees whose consistent dedication and hard work is one of our most valuable assets to achieving the Co-Dx vision. Let's now open the line up for questions. Operator?

Operator: [Operator Instructions] Your first question comes from the line of [Katherine Degen] with H.C. Wainwright.

Unknown Analyst: This is [Katherine] on for Yi. My question centers around performance of CoSara and CoMira. For CoSara, are they meeting your performance expectations? And if not, what's causing that discrepancy? And how do you kind of expect CoMira to perform financially in comparison?

Dwight Egan: [Katherine,] thank you for the question. With respect to the performance of both CoSara and CoMira, we're very pleased with the performance of both of those entities. Keep in mind that the CoMira entity is newly formed, and it was formed with leadership from previous interactions that we have had from a business standpoint with the distributors of our product in Saudi Arabia. Saudi Arabia has been consistently the largest international customer for Co-Diagnostics. And so it made a lot of sense for us to establish a joint venture where we could participate more actively in the forward-going opportunity in Saudi Arabia, especially as it revolves around the introduction of our new and revolutionary point-of-care device, the Co-Dx PCR Pro. So they played a huge role in what we're doing and what we have been doing for the last several years at Co-Diagnostics, and we expect that they will be a wonderful partner to this joint venture in moving our agenda forward in what, again, has been our largest international customer. With respect to CoSara, we have been involved in this joint venture with CoSara for about 8 years, we have established a real solid footprint in that country. We have sales personnel that cover largely the entire country. We have significant manufacturing operations there, mostly on the Sarabhai family properties where we established our first laboratory for manufacturing in 2019 when we cut the ribbon on that facility. And then last December, if you'll recall, we established on that same acreage, another more sophisticated property for the development of our oligonucleotides, which we can now produce there in country, and we'll continue to progress the manufacturing opportunity there so that they are manufacturing in connection with the Make it in India initiative of Prime Minister, Modi. They will be making the cups or the cartridges along with the instrumentation. And so we're very pleased with the kind of market development that has occurred over there. Co-Diagnostics is a real fan of the leadership of the Sarabhai family and the other scientists and

workers have brought to our company in India. We are well respected in India at the government level, in the academic area and in being able to supply our products to lots of different labs throughout the country. So we have developed a mature business there that is now capable to kind of go off and bring additional value, both to the people at CoSara and also the people at Co-Diagnostics. We think this will be a mutual benefit to both entities, and we're very enthusiastic about our prospects there.

Operator: Your next question comes from the line of Mike Okunewitch with Maxim Group.

Michael Okunewitch: Congrats on all the great progress. I guess to kick things off, I'd just like to see if you could talk a little bit about how a potential spinout of CoSara might interact with the MTB and HPV point-of-care programs. Is this something where they might be licensed over or you get some sort of distribution agreement signed? I'm just curious since it seems like there's quite a significant market in India for these programs.

Dwight Egan: Well, thanks for the question, Mike. Tuberculosis is a disease that is the #1 killer in terms of infectious diseases in the world. And about 25% roughly of those deaths are coming from India. And a similar number is coming from Africa. And so between those two areas of the world, you have about half of all the deaths from -- coming from tuberculosis and tuberculosis is something that is curable. So it's really a shame not to be able to diagnose it effectively and get people treatment because it can be cured if it's caught in time and properly dealt with the therapeutics. So we have a very concrete plan in India with respect to CoSara capitalizing on being able to fill the gap between where they currently have access to PCR tests and where they need to have access. I don't think there's any credible key opinion leader in the world that believes that the main -- that doesn't believe that the main solution to that problem of tuberculosis comes from replacing smear microscopy, which is about 125-year-old diagnostic tool, replacing that with molecular diagnostics is really what has to happen. And in order to make that happen, you have to have a product that has accessibility, that has the kind of accuracy that molecular has, and it also is something that you have to be able to get it down to the end of the row. You can't make it too unaffordable. So we are the -- we -- in our mind, the perfect solution to being able to fill that gap between where they currently have -- and it's not a lot of places, but where they currently have molecular diagnostics and where it will be able to be taken by virtue of the new accessible, affordable and accurate solution that we have. So that applies both to tuberculosis and the human papillomavirus, which has a large presence in India. And I don't want you to think of India or Africa as being just TB and MTB markets. They have a lot of other issues that need to be addressed, and we intend to make those part of what we're addressing in these joint ventures and in the forthcoming transaction that we anticipate and hope for, for CoSara.

Brian Brown: Mike, if I can add something, this is Brian. We are talking about different structures internally and what this might look like, but we don't have anything concrete to share to the market, and we will as we move forward in the process.

Michael Okunewitch: I appreciate the additional color here. I did want to follow up just on the angle of affordability and in particular, for the PCR Pro, I want to see if you could give a little bit more color on how you're actually able to reach a price point that is so much more affordable than your competitors. Does this have something to do with Co-Primers allowing you to use a more -- less complex device? Any additional clarity you could provide on that would be helpful.

Dwight Egan: Again, an excellent question, Mike. And I think one of the reasons that we're able to produce a product at the price point that we've done is that's what we set out to do initially. Shortly after the COVID pandemic kicked in, we looked forward saying, where is this going to go? And we brought in a very, very good team of engineers that -- and scientists with the express idea that they would create a product that could have a price point potentially as low as about \$300 to \$500 at scale. And that's been our goal from the beginning. And one of the remarkable things about the research and development of this product is that in the large measure, we've been able to keep a lid on what we think we will be able to produce this for at scale. And so as to whether other companies, why they haven't been able to do this, I think some of that has to do with the fact that they were making boxes before we even existed. And so they didn't really come at it with a fresh open, clean slate like we did. And so we had certain important discrete goals that we wanted to accomplish as we set out to engineer both scientifically and mechanically this wonderful device. Of course, Co-Primers play a role in the effectiveness of the assays, but that -- the Co-Primer advantages revolve mainly around its ability to multiplex. So for

instance, when you look at the human papillomavirus, this is an 8-plex test for certain specific cancer markers associated with human papillomavirus, plus a ninth marker that is a human DNA control. So that's where Co-Primers kick in. They allow us to do this sort of multiplexing in a class by ourselves because of the way Co-Primers get rid of the formulation of primer-dimers. So I think that's the kind of guidance I could give you and the information about why we've been able to hold the price line. And if you can't make the product at a price point that's relevant to the people that you're trying to serve, it doesn't matter. So we've really held the lid on that. We're excited to take it into the market. There's a huge gap.

Michael Okunewitch: Absolutely. And then one more for me, if you don't mind, and I'll hop back into the queue. When looking at the CoMira JV in Saudi Arabia and the Middle East, are there any particular products, particularly from the PCR Pro that you believe are most relevant for that market?

Dwight Egan: I believe that all of our current pipeline are very relevant to the CoMira market. It's not just tuberculosis and HPV. It also includes the #1 problem in infectious disease. It's not the most deadly, but it's the most cases, and that's the upper respiratory. So our flu A, B plus COVID plus RSV is a very, very important test for that market as well. And then that's just the beginning. We'll continue to develop more and more.

Operator: That concludes our question-and-answer session. Ladies and gentlemen, this concludes today's call. Thank you all for joining. You may now disconnect.