

CTSO Earnings Call Transcript

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Operator: Good afternoon, ladies and gentlemen, and welcome to the CytoSorbents Corp. Third Quarter 2025 Earnings Conference Call. [Operator Instructions] This call is being recorded on Thursday, November 13 of 2025. I would now like to turn the conference over to Adanna Alexander, Investor Relations Consultant. Please go ahead.

Adanna Alexander: Thank you, Chloe, and good afternoon, everyone. Welcome to CytoSorbents' Third Quarter 2025 Financial Results and recent Business Highlights Conference Call. Joining me today from the company for the prepared remarks are: Dr. Phillip Chan, Chief Executive Officer; and Pete Mariani, Chief Financial Officer. Before I turn the call over to Dr. Chan, I'd like to remind listeners that during the call, management's prepared remarks may contain forward-looking statements, which are subject to risks and uncertainties. Management may make additional forward-looking statements in response to your questions today. Therefore, the company claims protection under the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Actual results may differ from results discussed today. The forward-looking statements we make may reflect our views and estimates as of today, November 13, 2025, and we assume no obligation to update these projections in the future as market conditions change. During today's call, we will have an overview presentation covering the operating and financial highlights for the third quarter 2025. Following the presentation, we will open the line to analysts for questions. And now it is my pleasure to turn the call over to Dr. Phillip Chan. Phil?

Phillip Chan: Thank you very much, Adanna, and good afternoon, everyone. CytoSorbents continues to make solid progress as we execute on our long-term growth strategy. Our company is built around a platform blood purification technology designed to remove harmful substances and toxins from the bloodstream. We have 2 main products that leverage our proprietary polymer bead technology. CytoSorb is used to treat life-threatening conditions in the ICU and during cardiac surgery and DrugSorb-ATR, our investigational device designed to reduce the severity of perioperative bleeding in patients on antiplatelet therapy and other blood thinning therapy. CytoSorb is now approved in the European Union and available in more than 70 countries with nearly 300,000 treatments performed to date. Trailing 12-month core product sales reached a record \$37 million as of September 30, 2025, supported by strong execution across our global network. Our strategy remains centered on 5 key initiatives. The first is to return to higher growth in our core CytoSorb business. The second is to obtain marketing approval and open the U.S. market for DrugSorb-ATR. The third is to achieve near-term cash flow breakeven and future profitability. The fourth is to continue to strengthen the balance sheet. And fifth is to increase and maximize shareholder value. Let's start with an update on our core CytoSorb business. By the way, someone on the line is not on mute. Please go on mute. In the third quarter of 2025, revenue was \$9.5 million, up 10% from \$8.6 million a year ago or 4% on a constant currency basis. This performance was led by record sales in our distributor territories and strong results in our other direct markets. Gross margin remained strong at approximately 70% compared to 61% in the third quarter of 2024. While we've made meaningful structural progress in Germany, we recognize that consistency remains an area of focus. We believe our ongoing work will lead to stronger performance in 2026. On a trailing 12-month basis, core product revenue grew to \$37 million, up from \$33.8 million a year ago. Breaking that down further, distributor and partner sales grew 14% to \$15.6

million. Direct sales outside Germany rose approximately 24% to \$8.8 million, and Germany declined modestly by 3% to \$12.6 million. Overall sales growth, including Germany, in the past trailing 12 months was 9%. And excluding Germany, growth was a stronger 17%. This is the reason why we are in the process of restructuring our sales team and sales approach in Germany. In Germany, we have built a strong foundation with established clinical centers, device reimbursement and experienced sales talent. Our focus now is to strengthen leadership, improve sales processes and accountability, enhance training and sharpen account targeting, particularly among key accounts. We're simplifying our message to emphasize right patient, right timing and right dosage, which we believe will improve adoption and consistency going forward. We continue to see real-world evidence and clinical validation from leading institutions around the world that support the value of CytoSorb therapy in critical care and cardiac surgery. We would encourage investors to explore our corporate website where there is a wealth of clinical data and information supporting the broad use of CytoSorb in a wide range of applications in critical care and cardiac surgery. You can see here just some of the recent webinars that we've had, particularly turning the tide in sepsis and septic shock, which you can find on the Investor web page as well as a white paper talking about the broad application of CytoSorb in the treatment of septic shock. Our next major initiative is to obtain marketing approval and open the U.S. market for DrugSorb-ATR. Our FDA breakthrough designated device DrugSorb-ATR is designed to remove blood thinners such as Brilinta from the bloodstream. These blood thinning drugs improve outcomes in cardiac -- in heart attack patients that can cause severe bleeding during urgent coronary artery bypass graft surgery. Unfortunately, patients often cannot wait the required 3 to 5 days for drug washout, leaving surgeons with a difficult risk-benefit trade-off. DrugSorb-ATR is designed to solve this unmet medical need, representing an initial \$300 million market opportunity that could exceed \$1 billion as Brilinta becomes generic and as we expand to additional indications. Now to give you an update on our FDA regulatory timeline. Following our FDA appeal decision on August 20, the agency upheld the denial of our original de novo submission. But importantly, they confirmed that there were no safety issues with the device. And two, they indicated that the review of a new submission would focus only on the remaining open items from the first application. Because of this, on November 7, 2025, we filed a formal pre-submission meeting request with supporting documentation and anticipate a pre-submission meeting will be held in either late 2025 or early Q1 of '26 to confirm FDA requirements for the new de novo application. We expect to file a new de novo filing in the first quarter of 2026, which will include robust analysis of real-world data demonstrating DrugSorb-ATR's effectiveness in clinical practice that was not available with the first submission and was not eligible for inclusion in the prior review and appeal. We anticipate mid-2026 regulatory decision following a typical 150-day review process, and this review may be expedited as DrugSorb-ATR is still an FDA breakthrough device eligible for priority and interactive review. So with that, let me turn it over to Pete Mariani to go over financial highlights and some additional key initiatives. Pete?

Peter Mariani: Thank you, Phil, and good afternoon, everyone. Today, I'll be reviewing our third quarter financial performance and important updates that strengthen our balance sheet and our outlook through 2026. First of all, revenue was \$9.5 million, an increase of 10% and 4% on a constant currency basis compared to \$8.6 million in the third quarter of 2024. As Phil noted, our growth was led by record sales in our distributor territories and strong sales in our other direct markets. Now this sales growth was partially offset by a decline in our direct German market, where we continue to make progress with the reorganization of our team and are confident that this work will lead to stronger execution and improved performance in 2026. Gross margin for the quarter was 70%, which is consistent with our recent history and an improvement over the 61% in the prior year and the prior year's gross margin were negatively impacted by a planned reduction in unit production to rebalance inventory, coupled with a short-term manufacturing issue, which was resolved in the third quarter of 2024. Q3 operating expenses were \$9.5 million for the quarter, an improvement of 6% compared to prior year. The decrease was led by a \$900,000 reduction in R&D; expenses following the completion of certain projects and other cost reductions implemented last year and partially offset by a \$400,000 increase in SG&A; expenses. The increase in SG&A; was led by regulatory spending related to DrugSorb-ATR filings and initial commercialization expenses in anticipation of DrugSorb approval and launch, offset by lower compensation and royalty expenses in the quarter. Given that we now expect DrugSorb approval

in mid-2026, the company has taken steps to reduce these commercialization expenses as part of our strategic workforce and cost reduction program. Our Q2 operating loss improved to approximately \$9.2 million from \$4.8 million in the prior year. And net loss was \$3.2 million for the quarter or \$0.05 per share compared to net loss of \$2.8 million or \$0.05 per share in the prior year. However, after eliminating the impact of foreign currency changes and noncash stock compensation in both periods, adjusted net loss for the quarter improved to \$2.6 million or \$0.04 per share compared to an adjusted net loss of \$4.5 million or \$0.08 per share in the prior year. Adjusted EBITDA loss for the quarter, which also excludes the impact of noncash stock compensation and changes in foreign currency, improved to \$2 million compared to an adjusted EBITDA loss of \$3.6 million in the prior year. Our total cash, cash equivalents and restricted cash was \$9.1 million on September 30 compared to \$11.7 million at the end of the second quarter of this year, reflecting net operating cash burn of \$2.6 million in the quarter. One of our key strategic priorities has been to ensure that our core business is running at cash flow breakeven as we enter 2026. We are pleased with the improvements in operating margins and cash burn over the past year. However, we have determined that the pace of our operating improvements needs to accelerate in order to achieve this important goal. As a result, we have implemented a strategic workforce and cost reduction program. This initiative follows a comprehensive review of company's cost structure and operating model. The actions taken include a workforce reduction of approximately 10% as well as reductions across production and operating expenses, which we believe will allow us to achieve cash flow breakeven beginning in Q1, and do so while continuing to fund key growth initiatives, including regulatory approval and launch of DrugSorb-ATR in the U.S. We expect to record a charge of up to \$900,000 that will include severance and other charges related to the restructuring. Additionally, we are pleased to announce that we have amended our loan and security agreement with Avenue Partners effective today, November 13. The amended terms provide for immediate funding of \$2.5 million of new capital as well as an extension of the interest-only period to December 31, 2026. The amendment also provides for an additional \$2.5 million of capital, along with an additional 6-month extension of the interest-only period to June 30, 2027, both upon FDA approval of DrugSorb-ATR in 2026. The company issued warrants to Avenue Capital to purchase 1.4 million shares of the company's common stock for cash at an exercise price of \$0.70, which expire on November 13, 2030, and the number of warrants and exercise price is fixed. The amendment requires the company to maintain certain operating cash burn targets until U.S. FDA marketing approval of DrugSorb-ATR is achieved. So we're pleased to be able to complete this timely amendment to our credit agreement. We appreciate the partnership with Avenue Capital Partners, and we look forward to continuing to execute our strategy. And finally, we are pleased with the structural improvements we are making across the company to drive improved execution at the top line and provide a more rigorous ROI focus on our spend, leading to improved margins and cash burn. We believe that these improvements will continue to drive efficiencies and allow us to achieve cash flow breakeven beginning Q1 of 2026. We believe these improvements, along with our amended credit agreement, further strengthen our balance sheet with the liquidity and flexibility to continue driving growth across our core business and pursue what we believe is a derisked plan to U.S. marketing approval of DrugSorb-ATR in mid-2026. And now, I'll turn the call back over to Phil.

Phillip Chan: Thanks, Pete. And now I'll cover briefly the last key initiative, which is to increase and maximize shareholder value. To summarize, CytoSorbents has a clear and compelling value proposition. We have a proven international business generating \$37 million in annualized high-margin product sales. We have a scalable recurring revenue model, a razor blade and other people's razor business model that's very attractive, a promising U.S. regulatory path for DrugSorb-ATR and a strengthened balance sheet following our credit amendment and cost reductions. We're pleased with our recent execution against our key initiatives and are confident that these actions will enable us to drive towards profitability and long-term shareholder value creation. We very much appreciate your patience and continued support. And finally, before we move to Q&A, I'd like to take a moment to recognize and honor Dr. Robert Bartlett, our former Chief Medical Officer for 10 years and the Father of Extracorporeal Membrane Oxygenation that has saved more than 100,000 lives around the world since its inception. Dr. Bartlett's vision and contributions to this field and to CytoSorbents have left a lasting legacy. Please see our recent press release highlighting his many contributions to the world. That

concludes our prepared remarks. Operator, please open the line for questions. Thank you.

Operator: [Operator Instructions] There are no questions at this time, please continue. We have a question from Tom Kerr from Zacks Small-Capital Research.

Brian Lantier: This is actually Brian Lantier. Tom is triple booked this afternoon, but he wanted me to jump on the call quickly and ask if you could clarify a little bit about where you see the gross margin in Q4 and 2026. Do you feel like it's sort of normalized now around the 70% level?

Phillip Chan: Thank you, Brian. Well, Pete, do you want to go at that?

Peter Mariani: Well, we -- go ahead. Yes, sure. Yes, Brian, look, we are pleased with the 70% level that we've been able to execute. I do think that we've got opportunities to continue to see improvement. Some efficiencies have begun to come into the [plant.] We're seeing consistency there. And certainly, as we move towards higher volumes and eventually with DrugSorb approval, we do see possibilities for extension of -- or expansion of gross margin in the future.

Brian Lantier: Okay. Great. And have you shared any either internal or external milestones or guideposts that we can sort of look to, to see progress on the German sales force restructuring to see that it's having the effect that you're looking for?

Phillip Chan: Yes. I think that it's a little too soon to say, as I mentioned in my remarks, that it's still a work in progress. But I do think that we are seeing by following certain metrics that we follow improvements in rep performance and efficiency, et cetera. I think that ultimately, we believe that will translate into improvements in sales and returning Germany back to growth. But hopefully, you'll be able to see that in future quarters.

Brian Lantier: Okay. Great. And maybe just to satisfy my own curiosity, can you differentiate a little bit between a pre-submission package that you're going to submit to the FDA and the actual full application that you'll be submitting in 2026?

Phillip Chan: Sure. The pre-submission package or the pre-submission meeting is designed to get on the same wavelength as FDA. And so that we understand what FDA's concerns are. We understand what guidance -- to be able to incorporate FDA guidance into our de novo submission when we finally submit so that there are no surprises. And in the pre-submission document, we lay out basically our strategy of what we are planning on doing. We'll be asking for FDA feedback during the meeting on those; and then, again, taking all of that and putting that into the final de novo submission. And again, I think that we're excited by the opportunity to be able to present data that has been out there and also new analyses that no one has even seen, of course, based upon FDA feedback as well to be able to demonstrate to FDA this probable -- that the probable benefit outweighs the probable risk or that the benefit-to-risk ratio is a positive one, which is the basis of the de novo marketing authorization. So we're very excited that we've now put in for this pre-submission and hope to stay on schedule to be able to submit that de novo in the first quarter of next year.

Brian Lantier: Great. And I guess one last one, and then I'll open it back up for anyone else. Any feedback from the World Sepsis Day webcast that you had?

Phillip Chan: Yes. We've actually had excellent response from that webcast internationally. The statistics are very promising. And I think the important part is that we're getting the message out there that CytoSorb is not just a blood filter to treat cytokine storm. What we've been able to demonstrate and what our collaborators and researchers around the world have been able to demonstrate is that by controlling that cytokine storm, it has broad-ranging effects on the pathophysiology of sepsis and septic shock, helping to ameliorate organ dysfunction and organ failure and importantly, allowing clinicians the next step of getting the fluid, which is essentially drowning the patient from the inside out, out of the patient, which they typically cannot do because of that severe inflammation that is happening. So the feedback that we've gotten so far has been outstanding. And this is actually going to be -- it is one of the focuses of our sales teams around the world to continue highlighting really the significant amount of data that has been generated in the area of sepsis and septic shock and help clinicians solve this critical problem for their patients.

Operator: There are no questions at this time. Please continue.

Phillip Chan: Well, thank you, everyone, for joining the call today. If you do not have any other questions, please feel -- if you do have any other questions, please feel free to reach out to us at ir@cytosorbents.com. We look forward to updating you in the next call. Have a great evening,

everyone, and thank you very much. Have a good night.

Operator: This concludes today's conference call. You may disconnect your lines. Thank you for participating, and have a wonderful day.