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Rockwell Medical, Inc.

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Earnings Call

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Call Participants

EXECUTIVES

Heather H. Hunter
Senior VP & COO

Jesse Neri
Senior VP & CFO

Mark Strobeck
President, CEO & Director

ANALYSTS

Anthony V. Vendetti
Maxim Group LLC, Research Division

Raghuram Selvaraju
H.C. Wainwright & Co, LLC, Research Division

Presentation

Operator

Good morning, and welcome to Rockwell Medical's Fourth Quarter and Full Year 2025 Results Conference Call and Webcast. Please note, this event is being recorded. At this time, I would like to turn the conference call over to Heather Hunter, Chief Operating Officer at Rockwell Medical. Heather, please go ahead.

Heather H. Hunter
Senior VP & COO

Good morning, and thank you for joining us for this update on Rockwell Medical. Joining me on today's conference call are Rockwell Medical's President and Chief Executive Officer, Dr. Mark Strobeck; and Rockwell Medical's Chief Financial Officer, Jesse Neri.

Before we begin, I would like to remind you that this conference call will contain forward-looking statements about Rockwell Medical within the meaning of the federal securities laws, including, but not limited to, the types of statements identified as forward-looking in our annual report on Form 10-K and our subsequent periodic reports filed with the SEC. These statements are subject to risks and uncertainties that could cause actual results to differ.

Please note that these forward-looking statements reflect our opinions and expectations only as of today. Except as required by law, we specifically disclaim any obligation to update or revise these forward-looking statements in light of new information or future events. Factors that could cause actual results or outcomes to differ materially from those expressed in or implied by such forward-looking statements are discussed in greater detail in our periodic reports filed with the SEC.

Rockwell Medical's annual report on Form 10-K for the year ended December 31, 2025, was filed prior to this call and provides a full analysis of the company's business strategy as well as the company's full year 2025 results. The reconciliation of non-GAAP measures we discuss on today's call can also be found in today's press release. Our Form 10-K and other reports filed with the SEC along with today's press release, our updated investor presentation and a webcast replay of today's call can be found on our website under the Investors section.

Now I will turn the call over to Rockwell Medical's President and CEO, Dr. Mark Strobeck.

Mark Strobeck
President, CEO & Director

Thank you, Heather, and good morning, everyone. Thank you for joining us today on Rockwell Medical's fourth quarter and full year 2025 earnings conference call and webcast. 2025 represented a defining year for Rockwell Medical. We successfully navigated changes in our customer base, changes in our customer purchasing volumes and changes in our distribution footprint all while maintaining profitability on an adjusted EBITDA basis for the second consecutive year.

We made significant operational changes to further align our infrastructure to match demand, the benefits of which began to be realized in the fourth quarter and delivered one of the highest quarterly gross margin in the company's history. Additionally, in the fourth quarter 2025, we generated positive cash flow from operations, resulting in a higher cash position at year-end. We exited 2025 with a business that we expect to remain stable and well positioned to deliver sustainable profitability for years to come.

Now let me delve into the details of our operational results. A central focus of our strategy over the past several years and especially throughout 2025 has been building a more durable business to reduce volatility, support more consistent margin performance and enable us to plan our operations with greater confidence. Reducing customer concentration risk and improving revenue stability have been essential priorities for Rockwell, and we believe we have made significant progress on both fronts. Today, our customer mix is diverse. We serve approximately 300 customers throughout the United States, including all 5 of the leading dialysis providers in the U.S. along with university medical centers, community hospital systems and other renal care organizations. In addition, we supply hemodialysis concentrates to more than 30 countries outside the United States.

Let's start with Fresenius, the largest provider of renal care solutions in the world. Based on the agreement we signed back in 2024, we consistently and reliably supplied them with our concentrate products throughout 2025, and based on their projections for 2026, we expect that business to grow. As for DaVita, the second largest provider of kidney care services in the world, while they originally intended to completely transition away from Rockwell by the middle of 2025, they did not. Instead for a variety of reasons, including our reliability, consistency and quality, DaVita ended up extending our agreement through the end of '26, during which product pricing will be increased. We are excited to continue to supply and support DaVita and look forward to finding ways to reestablish a larger supply agreement with them.

We expanded our relationship with innovative renal care, the fourth largest dialysis service provider in the United States. We signed a multiyear agreement with IRC to support their goals to invest in high-quality hemodialysis products, streamlined workflows and help avoid potential supply chain disruptions. This multimillion dollar purchase agreement has utilization commitments and will remain in effect for 3 years with the option to extend for an additional 1-year period. Since announcing this transition in July of last year, our partnership with IRC continues to grow stronger, and we now reliably supply 70% of their clinics with our hemodialysis concentrates. Efficient processes, high-quality products, business continuity and supply chain reliability were key drivers for IRC to expand their relationship with us. We are excited to be a part of their mission.

Another customer to highlight is DCI, which is 1 of the top 5 dialysis providers in the U.S. and the nation's largest not-for-profit dialysis provider. Rockwell is currently under a long-term agreement with DCI through which we supply and deliver to over 80% of their clinics. In 2025, we also signed a product purchase agreement with Concerto Renal Services, the largest provider of dialysis and skilled nursing facilities in the United States. This 3-year agreement has an option to renew for 1 additional year and includes supply and purchasing minimums for our liquid and dry acid, bicarbonate concentrates including our bicarbonate cartridges. We currently supply 100% of their facilities where Concerto provides dialysis services.

Last year, there was a major hemodialysis concentrate supply chain disruption due to another concentrate supplier in the western part of the U.S. winding down operations due to regulatory and compliance-related concerns. To stabilize the market, we move quickly to ensure product availability by rapidly scaling production and expanding our logistics infrastructure to address vital customer demand created by this disruption. As a result, we added 30 new customers in the West, increasing the clinics we serve and opening the possibility for further expansion.

We also further diversified our hemodialysis concentrate product portfolio by adding a single use bicarbonate cartridge that is 510(k) approved by the FDA and comes in 2 sizes, 720 and 900 grams. Interest in this disposable, which is compatible with a range of dialysis machines continues to increase with our existing customer base as well as with prospective customers. In 2026, we expect to generate approximately $1 million in net sales from our bicarbonate cartridges. As we look ahead, our pipeline remains active and diversified across customer segments and geographies. We continue to see strong interest from customers who increasingly recognize the importance of quality and supply chain reliability for our hemodialysis products. While we remain disciplined, we believe our diverse customer mix positions us well for sustainable growth and expansion.

As our customer mix evolved in 2025, we took a hard look at our operations, not just to reduce cost but to strengthen the foundation of our business. Throughout the year, we executed a series of targeted actions across manufacturing, supply chain, logistics and overhead. The objective was straightforward, operate more efficiently while continuing to meet the high expectations of our customers to ensure quality, safety, reliability and top-tier customer service.

As our business evolved, we took the opportunity to further standardize processes and optimize how we deploy resources across the organization. By reducing complexity, improving planning and better aligning capacity with demand, we were able to operate more predictably and with greater discipline. These changes support our ability to respond more efficiently as volumes and customer need shift, the impact of which is clearly being reflected in our gross margin. It's important to emphasize that our margin expansion, especially in the fourth quarter of 2025 is not the result of temporary actions or onetime benefits. Instead, these changes reflect structural improvements in how we run our business from how we manage production to how we align resources with demand.

Our margin improvement is being driven by several factors. First, we are improving our pricing discipline across a more diversified customer base, which is allowing us to better align contract economics with the value we provide. Second, operational efficiencies are reducing costs and improving throughput. Third, a more stable production and logistics environment is enabling better planning and execution. As volume shift in customer needs evolved, this disciplined operating model gives us flexibility to respond efficiently while maintaining high service levels.

In the fourth quarter, we appointed a new Head of Manufacturing and Operations, Rashad Brown, as Vice President of Manufacturing and Supply Chain. Rashad brings deep operational expertise and a strong track record in regulated manufacturing environments specifically hemodialysis concentrates having previously worked with Fresenius and other leading medical device manufacturers. His leadership is already having a significant impact on our operations through improved execution, consistency and discipline. We expect further improvements in our manufacturing efficiencies in 2026 and beyond.

Our financial performance in 2025 reflected an organization that was in transition but also laser-focused on maintaining profitability and stabilizing its business to ensure future growth. Revenue changes throughout the year reflected the combination of a change in our customer base and product mix along with additional organic growth. Similarly, we made adjustments to our organizational and manufacturing infrastructure to match the changes in our customer base, which produced consistent improvements quarter-over-quarter.

Gross margin expanded meaningfully, making the fourth quarter 2025, one of the strongest quarters of gross margin in Rockwell's history. Operating loss narrowed, the overall financial profile of our organization improved and we delivered positive adjusted EBITDA for the full year 2025. We also generated cash in the fourth quarter, supported by margin expansion and better working capital management. That progress further reinforces the strength of our underlying business. In short, we are doing more with less and doing it better. The business is becoming more focused and more predictable, and we believe it is increasingly well positioned to generate sustainable returns over time.

We initiated a strategic shift nearly 4 years ago to fundamentally revitalize Rockwell. Our main objective at the time was to reestablish credibility with all stakeholders, especially with the investment community. This is and remains incredibly important to our success. We are pleased to report for the third year in a row, our annual performance was aligned with our annual guidance. We have strengthened the core fundamentals of this business and clarified the key drivers for its success, positioning it to become increasingly consistent, reliable and repeatable over time.

For our 2026 guidance, we believe we are well positioned to advance our strategy to drive sustainable revenue growth, expand our profitability and further diversify our portfolio. As a result, we project our business operations in 2026 will generate adjusted EBITDA between $1 million and $2 million and operating cash flow to be positive. Because we are currently in negotiations with several large customers, the outcome of which has the potential to positively impact both net sales and gross margin in 2026, we expect to provide guidance on those financial metrics in the near future. Bottom line, in 2026, we believe that our business is projected to be profitable and generate cash. As new opportunities arise, we anticipate that these projections have the potential to strengthen, reflecting our business' ongoing adaptability and growth prospects.

Looking ahead, we continue to focus on long-term value creation for our shareholders. Our strategy over the next 3 years is centered on 3 core elements. First, we are focused on growing our profitable leading hemodialysis concentrates business, serving dialysis centers in the United States and around the world. This remains our core foundation, our ability to deliver reliable supply, consistent quality and strong service supported by a more efficient operating model enables us to be a dependable partner to our customers while sustaining margin performance and supporting shareholder returns.

Second, we are focused on building a broader portfolio of renal care products that integrate seamlessly into our existing commercial manufacturing and distribution infrastructure. We see meaningful opportunity to leverage that platform we have built, including our customer relationships, operational capabilities and logistics network to support additional products that align with our expertise and enhance the overall offering we provide to customers.

Third and longer term, we continue to seek the next advancement in renal care, innovations that can drive improved treatment options and outcomes for patients. While inherently deliberate and discipline, this work reflects our commitment to remaining forward-looking and strategically positioned within an evolving health care landscape. Beyond these core areas of focus and based on what we see today, we believe that over the next 3 years, we have a path to meaningfully grow our business.

By 2029, we believe that we will be well positioned to generate annual net sales above $100 million while continuing to broaden and diversify our portfolio that a smaller share of revenue comes from our concentrates business as it exists today. Over that same period, we expect gross margins to trend upward, potentially approaching 30% range and our business to move toward annual profitability in the range of $5 million to $10 million. These are our goals, and we see a path to achieve these goals. Of course, I'd emphasize that these are longer-term directional views based on our current expectations, and they are subject to a range of risks and uncertainties, so actual results could differ.

Now I will turn the call over to Jesse to review in further detail our fourth quarter and full year 2025 financial results.

Jesse Neri
Senior VP & CFO

Thank you, Mark. Good morning, everyone. As you can see from this morning's press release, we presented our financial highlights as a quarterly trend from Q4 2024 through Q4 2025. We believe the most meaningful comparisons are quarter-to-quarter progression given the changes to our business over the past year.

As Mark mentioned, we remain focused on continuing to optimize our cost structure to match the changes in our customer base. We measure our progress against this objective by focusing on 3 metrics: cash, gross margin and adjusted EBITDA. We have shown consistent improvement throughout the year in each of these areas. First, we increased our cash position from $17.3 million at the end of March 2025 to $25 million by the end of the year. Gross margin grew from 16% in Q1 to 21% in Q4. And adjusted EBITDA improved each quarter, starting at negative $400,000 in Q1 of '25 and ended with a positive $1 million in Q4. We believe adjusted EBITDA is the best indicator of profitability because we removed noncash items, nonoperating items, restructuring costs and other items that are not part of our core concentrates business.

Now let me walk through our financial results for the fourth quarter and full year 2025. Net sales for the fourth quarter of 2025 were $18.3 million, which was 15% higher than net sales for the third quarter of 2025 and represents a 26% decrease over net sales of $24.7 million for the fourth quarter of 2024. Net sales for the full year 2025 were $69.3 million, which represents a 32% decrease over net sales of $101.5 million for the same period in 2024. The decrease in net sales was driven by the expected reduction in purchase volumes by one of our customers.

Gross profit for the fourth quarter of 2025 was $3.9 million, which was 70% greater than gross profit for the third quarter of 2025 and in line with gross profit for the fourth quarter of 2024. Gross profit for the full year 2025 was $11.7 million, down from $17.5 million for the same period in 2024. The decrease in gross profit was driven by the reduction in purchase volumes by the customer mentioned earlier. Gross margin for the fourth quarter 2025 was 21% which represents one of the strongest quarters of gross margin in Rockwell's history and represents a meaningful increase over 14% gross margin in Q3 and 15%

gross margin in the fourth quarter of 2024. Gross margin for the full year of 2025 was 17%, which was in line with our 2025 annual guidance and in line with our gross margin in 2024.

As Mark mentioned earlier, we made adjustments to our infrastructure and operations last year to better match demand, and the result of these activities began to be reflected in our fourth quarter numbers. Net loss for Q4 2025 was $600,000, which represents a threefold improvement over our net loss of $1.8 million in Q3 of 2025 and a slight improvement over a net loss of $800,000 for Q4 of 2024. Net loss for the full year of 2025 was $5.3 million compared to a net loss of $500,000 in 2024. Net loss for 2025 includes $4 million of noncash, depreciation, amortization and stock compensation expense as well as $1.2 million of severance and other restructuring costs associated with facility transitions.

Rockwell Medical was profitable on an adjusted EBITDA basis for the fourth quarter and full year 2025. Adjusted EBITDA for Q4 2025 was a positive $1 million, which represents a $900,000 increase over Q3 of 2025 and generally in line with Q4 of 2024. Adjusted EBITDA for the full year of 2025 was a positive $300,000 compared to a positive $5 million for the full year of 2024. Cash, cash equivalents and investments available for sale at year-end 2025 was $25 million, an increase of $1.3 million from the end of Q3. During the fourth quarter, we generated positive cash flow from operations of $2.3 million, which was partially offset by cash paid in connection with our Evoqua asset acquisition. Since the end of 2024, we increased our cash position by $3.4 million. Our $25 million cash balance not only provides a stable foundation for the business but also provides the growth capital necessary to pursue the strategic activities Mark outlined earlier.

Now I will turn the call back over to Mark.

Mark Strobeck
President, CEO & Director
Thank you, Jesse. Operator, please open the phone lines for any questions.

Question and Answer

Operator

[Operator Instructions] Your first question comes from the line of Anthony Vendetti with Maxim Group.

Anthony V. Vendetti
Maxim Group LLC, Research Division

Mark, I was wondering if based on the current relationship with DaVita, as they continue to purchase in 2025, have they given you any indication what volume levels or commitments for '26 they're considering? Or do you have expectations for '26 from DaVita? Or is that still up in the air, negotiation phase? Any color on that would be really helpful.

Mark Strobeck
President, CEO & Director

Thanks, Anthony. Yes, as part of our agreement with DaVita, they are obligated to provide us a forecast for the year to which they have. At this point, they are purchasing at volumes that are consistent with and slightly above what they have projected for us. So I think that is a positive sign. And again, I think as we continue to work with them and create better ways in which to service them, we are hopeful that there is an opportunity here, not only in establishing a much longer-term relationship, but also the possibility of securing additional business with them.

Anthony V. Vendetti
Maxim Group LLC, Research Division

Okay. Great. And then 2 other quick follow-ups on the West Coast expansion as well at-home dialysis. So you have 30 new accounts on the West Coast. Is there a particular goal for '26 in terms of expansion there? Or is that on a case-by-case basis? And then maybe talk about the progression of the at-home dialysis market. Where is that right now in terms of approximate percentage of revenue? And what do you see as the growth trajectory in '26?

Mark Strobeck
President, CEO & Director

Yes. So on the first question, we took over those customers are now in the process of putting those under long-term agreements with Rockwell. Given the customer base that we already had in the West with the addition of this group really puts us in a position to begin to start to expand further within the West. We're right now designing a commercial strategy to bring forward in part to do that. We'll also be looking to our work with B.Braun, if you recall, the partnership that we have put in place, 2 years ago as they are heavily focused in the West. So collectively, that's going to position us well to target dialysis centers that we otherwise haven't supported in the past.

As it relates to the at-home market, that market, I think, continues to establish itself as an overall percentage, of the dialysis, hemodialysis market, it's probably trending towards what will be about 10%. We worked with some of the largest players in that space. And so we're continuing to support those. As we -- as that market grows, I think we're well positioned to take advantage of that, in part because we have configurations now of our products that work incredibly well at home.

Operator

[Operator Instructions] Your next question comes from the line of Ram Selvaraju with HC Wainwright.

Raghuram Selvaraju
H.C. Wainwright & Co, LLC, Research Division

I wanted to drill down a little bit more on the likely evolution of the relationship with DaVita and ask 3 questions on that front. Firstly, I was wondering if contribution from DaVita factors into your longer-term projections, if it does, to what extent? And if it doesn't, could you confirm that?

Secondly, I was wondering in the context of 2026. Are there any factors that you see potentially driving DaVita to extend the relationship with Rockwell past the end of 2026. In other words, is that even an option? Or do you think that definitively off the table, and we shouldn't be assuming it in any way, shape or form.

And then lastly, I was wondering if you could talk a little bit about the broader markets and competitors with you for DaVita's business and how they might be looking to drive DaVita away? Is it primarily on price? Or are they able to compete on something else? And then I have a few others.

Mark Strobeck
President, CEO & Director

Great. Thanks, Ram. Maybe the first one, I'll let Jesse answer.

Jesse Neri
Senior VP & CFO

Yes. So Ram, in terms of our longer-term projections, we are assuming consistent volumes purchased from DaVita over the next few years. So consistent with essentially what they purchased the last 3 quarters of last year and going forward into this year. So no gigantic growth assumption there for DaVita.

Mark Strobeck
President, CEO & Director

And then on your next question, we continue to have a very strong relationship with DaVita. I think it is their intent and it was their desire to want to put in place a long-term relationship with us. So it's our anticipation that if we continue to supply them consistently over the course of the year with products that have -- of the highest quality that there is a high probability that they will continue to work with us going forward. And depending on how the performance of others continues, I think, may open the possibility for us to expand further and we gain many of the clinics that transitioned away in the middle of next year.

As to the third part of your question around competitors, this is really what I'll call a 3-party market. And it's us, Fresenius and Nipro. We believe that Nipro continues to struggle to bring products to the market given some of their recent historical issues around the quality of their products. We don't have much visibility into that, but all indications are, but that still continues to present a challenge to them. And we continue to not only work with Fresenius, but also recognize that there are customers that continue to leave Fresenius in preference of Rockwell, not just our ability to provide products that are incredibly high quality, but our ability to distribute those through our Rockwell transportation system, helps reduce the third-party costs that other customers would see if they were to purchase products from Fresenius.

So our competitive advantage continues to be high-quality products. That means products that are manufacturing facilities that do not and haven't had significant issues related to FDA inspections. And then secondly, because we transport our products largely on Rockwell transportation, which is a more cost-effective way to get products to clinics. Those are the 2 areas that put us at a competitive advantage.

And the third is our customer service group. We have a dedicated customer service group that works exclusively with dialysis centers. As you can imagine, many of these are not set up as businesses per se. They're set up as treatment facilities really focused on delivering high-quality therapy to patients with end-stage renal disease, they're not sophisticated in procurement. They're not sophisticated in transportation. They're not sophisticated. And we provide all of that through our customer service, and that is continues to be an advantage for us. So those are the areas that I think differentiate us and continue to generate very positive customer feedback.

Raghuram Selvaraju
H.C. Wainwright & Co, LLC, Research Division

That's very helpful. I wanted to ask 2 other quick ones, if I may. Firstly, can you give us any additional granularity on how the Western expansion is growing? What's the prospects are for additional customer acquisitions in 2026? And how you see that aspect of the business contributing to your longer-term forecast? And then I was wondering if in the, let's call it, late 2020s time frame, the outer years of your longer-term forecast, you can give us any further commentary on where you expect gross margins to be trending at that point?

Mark Strobeck
President, CEO & Director

Yes. So as we mentioned, we stepped in and took over the business of about 30 customers in the West, that is a multimillion dollar revenue base that we've now acquired, and are beginning to support. That, as I mentioned, gives us an even stronger foothold in a region of the country that has largely been supplied by one manufacturer. So once we made that announcement and made it clear to folks that we are now able to provide products to dialysis centers in the west, we received a number of calls from customers that are looking to transition away from their current supplier. So we're in the process of prosecuting those, those can be smaller opportunities all the way up to multimillion dollar opportunities, and we're just going to continue to prosecute those throughout the year, but we certainly think that there's a large opportunity to secure more business out there.

As it relates to our projections through 2029, 2 things I would say in an effort to answer that question. The first is we are -- continue to be actively engaged in a number of business development discussions around acquiring renal care products that fit very squarely into what we are doing, whether that is additional concentrates, whether that is products that are used by dialysis centers, blood tubing sets, dialyzers, et cetera. So we are now working with a couple of organizations to evaluate those, determine the prospects of bringing them to the United States for us to sell alongside our concentrates.

All of those product opportunities that we're looking at are going to be higher-margin opportunities than we are -- than our current business today, which is going to help sort of pull up our overall gross margin. And then in addition, we're also looking at 1 or 2 very innovative therapies in the space that may require additional investment to get to the market. But all of that is what we believe we can successfully accomplish to get to the revenue projections that we provided.

Operator

There are no further questions. I would now like to turn the call back over to Dr. Strobeck.

Mark Strobeck
President, CEO & Director

Thank you for joining us today for an update on Rockwell Medical. We are proud of our achievements in 2025 to navigate changes in our customer base, purchase volumes and distribution footprint, all while maintaining profitability. Our team has done a tremendous job aligning our infrastructure to match demand. In 2026, we remain focused on making Rockwell profitable for what would be the third year in a row and continuing to ensure that we are set up for long-term stability and success, strengthening our top line revenue, expanding our profitability profile and further diversifying our portfolio through product acquisitions and business development opportunities require significant ongoing effort. We believe we are getting close and we'll have more to share with you as we reach key milestones in the coming months.

Operator
This concludes today's call. Thank you for attending. You may now disconnect.