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Earnings Call

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Call Participants

EXECUTIVES

Heather R. Hunter
Senior VP & Chief Corporate Affairs Officer

Jesse Neri
Senior Vice President of Finance

Mark Strobeck
President, CEO & Director

ANALYSTS

Anthony V. Vendetti
Maxim Group LLC, Research Division

Dipesh A. Patel
H.C. Wainwright & Co, LLC, Research Division

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Presentation

Operator

Good morning, and welcome to Rockwell Medical's Third Quarter 2023 Results 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, Senior Vice President, Chief Corporate Affairs Officer at Rockwell Medical. Heather, please go ahead.

Heather R. Hunter
Senior VP & Chief Corporate Affairs Officer

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

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, 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 quarterly report on Form 10-Q for the three months ended September 30, 2023, was filed prior to this call and provides a full analysis of the company's business strategy as well as the company's third quarter 2023 results. Our Form 10-Q and other reports filed with the SEC, along with today's press release or updated investor presentation and a replay of today's conference call and webcast can be found on Rockwell Medical's website under the Investors section.

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

Mark Strobeck
President, CEO & Director

Thank you, Heather. Good morning, and thank you for joining us today for Rockwell Medical's third quarter 2023 results conference call and webcast. I am pleased to report that we continue to make progress on all the strategic objectives and priorities we outlined this time last year. Our efforts are keenly focused on enhancing our hemodialysis concentrates business by driving top-line revenue, enhancing our gross margins, reducing our expenses and achieving profitability, all while continuing to delever our business. In addition, we made enhancements to our management team and Board of Directors, which we believe will further strengthen our organization and elevate our experience base.

Let's review each of these updates in further detail. During the third quarter of 2023, we generated net sales of $23.8 million, including concentrates product sales of $21.6 million, both of which were the highest sales generated to-date for the company. Additionally, we completed our second acquisition in just under a year, acquiring the hemodialysis concentrates assets from Evoqua Water Technologies. This acquisition adds a number of important strategic elements to Rockwell, including approximately $18 million in annual revenue and over $3 million in EBITDA, which is immediately accretive to our business.

Additionally, this acquisition expands our presence in the concentrates market by adding approximately 1,700 new purchasing facilities to our customer base. As a result, Rockwell now services approximately

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1/3 of all purchasing facilities in the United States, including outpatient dialysis clinics and hospitals. In addition, we have added a fully automated manufacturing process, which when fully unlocked, can manufacture products at a lower cost than we currently manufacture our products today. Lastly, as a result of acquiring these assets, Rockwell is now the leading supplier of liquid bicarbonate hemodialysis concentrates in the United States.

To successfully integrate these assets into Rockwell, we assembled an integration team led by representatives from both Rockwell and Evoqua to transition this business into Rockwell's platform. Additionally, to ensure that there was no disruption in supply and service to clinics and the patients they served, we entered into a 90-day transition services agreement with Evoqua to support the concentrates business on our behalf as we onboarded and integrated Evoqua's customers into Rockwell's system.

I am pleased to report that on October 9, Rockwell successfully completed the transition and integration of Evoqua's assets and customer base and began directly accepting orders from Evoqua's customers. In addition, this important milestone ended the fees associated with the transition services agreement, thereby reducing our expenses going forward. Now we are exploring how best to unleash the value of this acquisition, not only to benefit our customers and the patients we serve, but to reduce our overall manufacturing costs to drive better gross margins. We will have more to say about these plans on future calls.

In addition, during the third quarter, we signed a number of customer agreements, which included significant price increases and long-term supply arrangements with purchasing minimum commitments that we believe will continue to have a meaningful impact on Rockwell's top and bottom-line. First, we entered into an amended and restated products purchase agreement with our largest customer. Under the amended agreement, Rockwell will realize a price increase for our hemodialysis concentrates products, including with a one-time payment on or after December 1.

The extended term goes through December 2024 and our largest customer has the right to extend this agreement for another year, which could take this agreement through December 2025. In the event of such an extension, product pricing will also be increased for the extended term. In addition, we will receive 9 month purchasing forecasts and a commitment to purchase at least the forecasted amounts. In the event these forecasts are not met, Rockwell will be compensated for the amount forecasted. We are excited to continue to work with our largest customer to help provide our products to their clinics throughout the United States.

In addition, we continue to secure other long-term product purchase agreements with several new and existing customers. The first is Sanderling Renal Services, a full-service provider of in-center and renal telemedicine services focusing on patients in rural and underserved communities. Under the terms of this agreement, Rockwell will be the preferred supplier of liquid and dry acid and bicarbonate hemodialysis concentrates to Sanderling's facilities located throughout California, Colorado, Nevada, Oklahoma, Tennessee, Illinois and Utah. In addition to supplying hemodialysis concentrates and concentrates accessories, Rockwell will also provide Sanderling with our dry acid concentrate mixer to support Sanderling's preference to conveniently mix acid concentrate on site. This products purchase agreement with Sanderling includes supply and purchasing minimum commitment and has the potential to generate millions of dollars in net sales for Rockwell over the course of the contract.

A second agreement we announced during the third quarter was with Centers for Dialysis Care, the largest non-profit independent outpatient dialysis provider in Ohio. As part of this long-term, multi-million dollar products purchase agreement, which includes supply and purchasing commitments, Rockwell Medical will be the preferred supplier of liquid and dry acid and bicarbonate hemodialysis concentrates and related accessories to CDC and its nearly 20 facilities located throughout Ohio.

Third is Dialyze Direct, a leading provider of dialysis services in the skilled nursing facility setting. Under the terms of this agreement, which also includes supply and purchasing minimum commitments, Rockwell Medical will expand its distribution footprint throughout Illinois, Indiana, Kentucky, Maryland, New Jersey, New York, Ohio and Pennsylvania. Rockwell Medical will be the preferred supplier of liquid and dry acid and bicarbonate hemodialysis concentrates to Dialyze Direct and we expect to generate over $1 million in net sales annually with this agreement.

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Lastly is Houston Methodist, a leading academic medical center with 6 community hospitals serving the greater Houston area. We signed a 3-year product purchase agreement that includes minimum purchasing commitments. As we stated previously, we continue to construct these product purchase agreements such that they reflect the inherent value of our products, provide to patients. Our commercial team is actively selling our products across the United States and internationally as we continue to pursue our vision of becoming the leading global supplier of hemodialysis concentrates.

We continue to improve our gross margins through the successful execution of expense reduction associated with manufacturing and delivery of our products. During the third quarter of 2023, we consolidated some of our dry powder production into two of our facilities and completed another small workforce reduction that eliminated redundant roles within Rockwell. In addition, we began a route optimization program that consolidated our delivery schedules, further reducing costs associated with delivering our products to customers.

We are going to aggressively continue down this path of finding additional ways to further reduce our expenses and the costs associated with manufacturing our products. In the coming quarters, we will be looking to unlock the value of our newly acquired fully automated manufacturing process. Additionally, we will look to further automate our manufacturing process at our other manufacturing facilities, all of which we expect will continue to drive our gross margins higher with the goal of achieving gross margins north of 15% on an annual basis. Considering the changes we have made, including the acquisition of the Evoqua's hemodialysis concentrates assets and increasing our concentrates product sales, we expect that Rockwell will be profitable on an adjusted EBITDA basis in the fourth quarter of 2023.

One of the components of our strategic initiative is to enhance our business by adding industry leaders, strategic thinkers and great operators to our business. We are pleased to announce that we have done just that. First, we named Dr. Joan Lau of Rockwell's Board of Directors. Joan was appointed to Rockwell's Board in October. Joan has more than 20 years of experience as an entrepreneur scientist, CEO, operator, investor and board member of public and private biopharmaceutical companies. She has founded, led and scaled a number of biotech companies throughout her career, possessing a significant amount of business development, operational and M&A expertise. Additionally, her experience as a public company board member will be valuable to Rockwell as we continue to grow our customer base and portfolio of products to serve the needs of dialysis clinics and the patients they serve and to position Rockwell to achieve its goal of increasing shareholder value.

Also, I'm incredibly excited to have Jesse Neri join Rockwell Medical as our new Senior Vice President of Finance who oversees all aspects of Rockwell's finance organization. Jesse has more than 20 years of experience leading finance functions at both public and private companies. Prior to joining Rockwell, he was the head of Finance at Hemavant Sciences, a clinical-stage biopharmaceutical company developing therapeutics to improve the lives of patients with blood disorders and hematological malignancies.

Previously, Jesse was Senior Vice President of Finance at Zyla Life Sciences, a public pharmaceutical company with annual revenue of $80 million. As a member of the senior management team, Jesse was responsible for all aspects of its finance organization, including SEC reporting, audit, controllership, and strategic planning. While at Zyla, Jesse played a pivotal role in multiple product acquisitions, financing, commercial product launches, and regulatory approvals, along with Zyla's acquisition by Assertio Therapeutics in May of 2020.

Jesse's expertise will enhance our ability to continue strengthening our financial and operating infrastructure while advancing our ability to meet our strategic objectives. Jesse's extensive experience leading finance organizations within revenue generating, growth oriented healthcare businesses will be valuable to Rockwell Medical as we contemplate various avenues of expansion and growth.

Now I will turn the call over to Jesse to provide you with our financial results for the third quarter.

Jesse Neri
Senior Vice President of Finance

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Thank you, Mark. Good morning, everyone. I will now review our third quarter 2023 financial results and provide you with an update on our cash and debt positions as well as our 2023 guidance.

Net sales for the third quarter of 2023 were $23.8 million, including concentrates product sales of $21.6 million, both of which were the highest sales generated to-date for the company. Net sales for the third quarter represented a 31% increase over the second quarter of '23 and a 27% increase over the same period in 2022. The increase of $5.1 million in net sales year-over-year was primarily driven by our Evoqua asset acquisition and our recognition of deferred revenue related to the Wanbang agreement. Net sales for the 9 months ended September 30, 2023 were $61.5 million, which represents a 15% increase over the same period in 2022.

Gross profit for the third quarter of 2023 was $2.2 million, which represents a 183% increase over the same period in '22. Gross profit increased by $1.4 million, primarily due to the lower distribution costs associated with the concentrates business and a recognition of deferred revenue from the Wanbang agreement, partially offset by an increase to the Triferic Inventory Reserve. Gross margin for the third quarter of 2023 was 9% compared to a gross margin of 6% in the second quarter of '23 and 4% for the same period in 2022. We continue to employ strategies to improve our gross margin and anticipate that it will continue to track positively as we close out 2023.

Operating loss for the third quarter of 2023 was $1.7 million, which includes one-time severance expenses of $575,000. This compares to an operating loss of $3 million for the second quarter of 2023 and $3.7 million for the same period in 2022. The improvement in operating loss reflects Rockwell's cost containment efforts as part of our continued business restructuring.

Rockwell's net loss for the third quarter of 2023 was $1.9 million or $0.07 per share compared with the net loss of $4.2 million or $0.23 per share for the same period in 2022. For the 9 months ended September 30, 2023, Rockwell's net loss was $6.9 million or $0.32 per share compared with the net loss of $16.3 million or $1.26 per share for the same period in 2022. Rockwell reiterates its guidance and expects the company to be profitable on an adjusted EBITDA basis in the fourth quarter of '23.

Cash, cash equivalent and investments available for sale at September 30, 2023 was $11.7 million compared to $14.9 million at June 30, 2023. The decrease in cash was driven primarily by $5 million in principal payments on our outstanding long-term loan and a $4 million increase in our accounts receivable, primarily related to the Evoqua asset acquisition. We anticipate collection of these receivables in the fourth quarter of 2023. As mentioned, we began making principal payments on our debt in the third quarter, which decreased our outstanding debt to $9.5 million. The company projects its outstanding debt to further decrease to $8 million by the end of this year.

As we approach the end of the year, we reiterate our 2023 guidance. We expect net sales for 2023 to be between $82 million and $86 million, which represents a 17% to 18% increase over 2022. We expect gross profit for 2023 to be between $8 million and $10 million, which represents a 95% to 144% increase over 2022. And we expect to be profitable on an adjusted EBITDA basis in the fourth quarter of 2023. As for future guidance and expectations, we intend to provide an outlook on 2024 during our fourth quarter conference call.

I will now turn the call back over to Mark.

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

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Question and Answer

Operator

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

Anthony V. Vendetti
Maxim Group LLC, Research Division

So on the fully automated facilities that you acquired from Evoqua, you mentioned, Mark, that you're looking to fully automate your other facilities. How much capital is required to do that? And is that necessary to get to your goal of 15% plus gross margins or could you do that without fully automating your other facilities?

Mark Strobeck
President, CEO & Director

Anthony, thank you for the question. So we're in the process of evaluating that right now. We don't believe, based on our current projections, that we need to fully automate all of our facilities to be able to achieve gross margins that you mentioned. To fully automate our facilities we'll likely drive gross margins higher than that. But we are still in the process of evaluating that and we'll likely begin to make those transitions over a period of time.

Anthony V. Vendetti
Maxim Group LLC, Research Division

Okay, great. And just as a follow-up. So congrats on being the leading provider of all hemodialysis concentrates in the county for 1/3 of all that after the acquisition of Evoqua. As you look to continue to expand, I think one of the areas or one of the -- in terms of geography, the western part of the U.S, it looks like a large opportunity for Rockwell. Can you talk about your expansion plans for the West Coast?

Mark Strobeck
President, CEO & Director

Yes. So that does continue to be a large opportunity which we are looking to aggressively access through the Evoqua acquisition and the activities of our commercial team. We've already begun to expand our presence in the western portion of the United States. So we have more customers now in the west than we've ever had historically here at Rockwell. But I think for us to more meaningfully access that, we're going to have to do more to establish a fundamental presence there. And so that's an opportunity that we are looking and considering now, whether that's establishing our own facility there, whether that's acquiring a facility that may exist out there. But I think for us to really, I think on a cost effective way, address the market in the west, we're going to have to seek a more permanent sort of position there.

Anthony V. Vendetti
Maxim Group LLC, Research Division

Okay. And then just lastly, international. I know the focus is primarily in the United States, but can you talk a little bit about your international opportunity? What is it now as a percent of revenues? And what's sort of the opportunity over the next couple years?

Mark Strobeck
President, CEO & Director

Yes. So right now, it's just around 10% of our overall revenue. We think that there is a big opportunity internationally for us. The majority of international markets are largely being addressed by some smaller hemodialysis concentrates players that, much like in the United States, struggle at times to maintain effective supply and distribution. So we think that there's an opportunity for us, given our expertise, not only manufacturing, but being able to work with organizations outside the United States to distribute the

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product, to expand that. It's a very cost effective business for us, as distribution is usually carried by the customer. So we're looking to expand that aggressively. And I know our commercial team has a number of potential international partnerships that are currently in the pipeline, which we are looking to establish relationships with.

Operator

Our next question comes from the line of Dipesh Patel with H.C. Wainwright. Dipesh, your line is open.

Dipesh A. Patel
H.C. Wainwright & Co, LLC, Research Division

Congrats guys on the update. This is Dipesh on for Ram Selvaraju. You noted some good examples on several product purchase agreements. Could you provide a sense of how you might see the number of agreements evolving through '24 and '25? And perhaps any challenges that you might see around managing these current agreements or obtaining new ones?

Mark Strobeck
President, CEO & Director

Dipesh, Thank you for the question. So we continue to be the largest independent supplier of hemodialysis concentrates here in the United States. And by independent I mean, this is our focus, this is our expertise. We're not bundling these products with other products and thereby forcing customers to buy our other products in an effort to get to our hemodialysis concentrates. So by that fact, that opens up really the entire U.S. market for those organizations that are looking to find a cost effective supplier that has its own distribution capabilities and customer service capabilities to handle their needs around these products.

We continue to see over the course of the next year and the year after, multiple opportunities to continue to not only expand our existing relationships with our current customer base, but then to continue to add new customers as well. If you look at the dialysis clinics and dialysis providers in the United States, although we are working with the top organizations within the marketplace, there are still a number of very large providers that we still are working to establish customer and product purchase arrangements with. So we think that offers us a great opportunity.

And then as Anthony raised, an opportunity to get to the west really allows us to expand our presence with those 2 large customers and the 2 largest providers of dialysis in the United States. So we see an opportunity to continue to grow this business and continue to add revenue and our commercial team is very focused on doing that. But as Jesse mentioned, we're going to provide a much greater sort of details around what 2024 and beyond look like at our fourth quarter conference call.

Dipesh A. Patel
H.C. Wainwright & Co, LLC, Research Division

Okay, great. I appreciate the color. And then final question related to your stated target I guess of the gross margin goal being north of 15% on an annual basis. How soon are you looking to achieve that goal, if you can kind of elaborate on that?

Mark Strobeck
President, CEO & Director

Yes. So I think it's -- I think I'd say a couple of things. I think it's important for everyone to realize that we've come from a place in this business where this business itself, the concentrates business, did not generate a gross profit. It generated a gross loss from Rockwell. And through the strategy that we put in place shortly after I joined and the management team has now been executing on has really turned this business around to the point where we're now not only generating a gross profit, but now we're looking to maximize that gross profit.

So I think that continues to be an important contextual element that folks need to consider in the transition of Rockwell into a meaningful, profitable organization. Our goal is to do that, is to get to the 15% gross margin as quickly as we possibly can. We haven't given guidance as to when we're looking

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to achieve that, but as you can see in this quarter, our gross margin was 9%, as Jesse suggested. We continue to believe that that will trend positively through the remainder of the year and we expect that to continue to trend positively in 2024. So again, I think we'll be able to give everybody greater visibility as to when that will be achieved during our fourth quarter conference call.

Operator

I would now like to turn the call over back to Mark.

Mark Strobeck
President, CEO & Director

Thank you everyone for joining us on today's call. Overall, we are pleased with the progress we continue to make in the financial performance of our business in 2023 and we remain focused on continuing to position Rockwell for future growth. We look forward to sharing our progress on future calls.

Operator
Ladies and gentlemen, that concludes today's call. Thank you all for joining. You may now disconnect.

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