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Rockwell Medical, Inc.

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Earnings Call

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Call Participants

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Presentation

Operator

Good morning, and welcome to Rockwell Medical's First Quarter 2024 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, 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 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, 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 quarterly report on Form 10-Q for the 3 months ended March 31, 2024, was filed prior to this call and provides a full analysis of the company's business strategy as well as the company's first quarter 2024 results. The reconciliation of non-GAAP measures we discussed can be found in today's press release, our Form 10-Q and other reports filed with the SEC along with today's press release, our 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 Chief Executive Officer, Dr. Mark Strobeck.

Mark Strobeck
President, CEO & Director

Thank you, Heather. Good morning, and thank you for joining us today for Rockwell Medical's First Quarter 2024 Results Conference Call and Webcast. Rockwell had another good quarter, reporting our sixth quarter of growth in net sales and gross profit along with improved net loss and adjusted EBITDA over the last 7 quarters. The fundamentals of our business continue to improve, and we are making progress every day as we focus on optimizing our business to drive profitability, meaningful cash flow and increased shareholder value.

Let's take a minute and discuss what's happening in the U.S. hemodialysis concentrates market. With our acquisition last year of the hemodialysis concentrates business from Evoqua, the #3 player in the space at the time, the market has now consolidated to 2 primary players to supply the over 12,000 dialysis clinics in the United States. With this consolidation, Rockwell now sits as the only independent supplier of concentrates with the scale and distribution to service these in-center and hospital-based clinics.

In addition, we are now the leading supplier of liquid bicarbonate in the country. What does this mean for Rockwell? First, Rockwell is able to accurately price our products in the hemodialysis market. At the beginning of this year, we undertook a new program to adjust our product pricing to reflect the inherent value our products bring to providers. Second, leading dialysis providers are seeing patient censuses return to pre-COVID levels. So while concentrates volumes previously stagnated, concentrate volumes are now growing again from customers who already purchased product from Rockwell.

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Additionally, we continue to see increasing interest in market demand for our products from medical equipment suppliers and distributors, along with health systems, dialysis centers and skilled nursing facilities inside and outside the United States. Third, we have seen a number of customers convert over to Rockwell from our primary competitor.

In addition, we continue to expand sales within our existing customer base. It's important to note that while we continue to add new customers and expand agreements with our existing customers, we are not always able to permit -- not always able -- permitted to announce these new agreements for a variety of reasons, including publicity restrictions. We are working to change this paradigm but change will take time.

Bottom line, we believe the underlying fundamentals of this market are all moving in Rockwell's direction, and we are prepared to take full advantage of these favorable dynamics. During the first quarter, we entered into and were able to subsequently announce several new and expanded agreements both domestically and internationally. We entered into a 5-year distribution agreement with BioNuclear through which BioNuclear may import, sell, promote and distribute Rockwell's hemodialysis concentrates products within the Dominican Republic.

The agreement will remain in effect for 5 years, and BioNuclear has the option to extend the agreement for an additional 5 years beyond the original term. We also entered into a new product purchase agreement with 1 of the largest health systems in the Mountain West region of the U.S. in the first quarter. Under the terms of this agreement, Rockwell will supply this health system with the company's liquid and dry acid and bicarbonate hemodialysis concentrates, cleaning agents, hemodialysis concentrates mixers and other additional products we offer. In addition, we entered into an expanded distribution agreement with an existing customer, Atlantic Medical International, which is Bermuda's leading supplier of medical products and equipment for acute and continuing care markets. AMI has been a distributor of Rockwell products since 2022, at which time we signed a 5-year distribution agreement with the option for AMI to extend that agreement.

The amended distribution agreement between Rockwell and AMI expands the list of hemodialysis products that AMI is purchasing from us, includes purchasing commitments and will generate a profit margin consistent with Rockwell Medical's gross margin guidance for 2024. AMI is just 1 of several existing customers in the U.S. for which we have increased volumes and expanded our distribution to supply and support their new clinics.

During the first quarter of 2024, we generated record net sales of $22.7 million and record gross profit of $3.1 million, exclusively with our hemodialysis concentrates products. Additionally, our gross margin for the first quarter was 14%, the highest it's been to date. We believe gross margin will continue to trend upward as we further optimize our business through improved processes automated manufacturing and enhanced distribution capabilities through the modernization of our infrastructure and technology solutions.

As a result of our expanded contracts and projected new volume increases and considering our first quarter results, we have adjusted our guidance for 2024 upward as follows: we now expect net sales for 2024 to be between $90 million and $94 million, an increase from our initial guidance of $84 million to $88 million. This updated net sales guidance represents a 13% to 18% increase over $79.8 million in net product sales for 2023.

We now expect gross profit for 2024 to be between $13 million and $15 million, an increase from our initial guidance of $12 million to $14 million. This updated gross profit guidance represents a 49% to 72% increase over gross profit of $8.7 million in 2023. Lastly, we now expect to be profitable on an adjusted EBITDA basis between $0.5 million and $1 million, which represents an increase from our initial guidance of between $0 and $0.5 million. This updated profitability on an adjusted EBITDA basis represents a 113% and 126% increase over a loss of $3.9 million on an adjusted EBITDA basis in 2023. With that, I will now turn the call over to Jesse to delve into our financial results for the first quarter of 2024.

Jesse Neri
Senior Vice President of Finance

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Thank you, Mark. Good morning, everyone. I will now review our first quarter 2024 financial results in more detail and provide you with an update on our cash and debt positions. Net sales for the first quarter of 2024 consisted solely of concentrate product sales. Net sales for the same period in 2023 consisted of concentrate product sales and deferred license revenue of $1.5 million related to the termination of the Baxter distribution agreement.

I will walk you through our financials for the current and comparable periods with and without deferred revenue so that you can more accurately highlight the progress we've made in the hemodialysis concentrate segment. Net sales for the first quarter of 2024 were $22.7 million, our highest quarterly concentrate product revenue to date. This represents a 15% increase over net sales of $19.7 million for the same period in 2023. Excluding deferred revenue, net sales for the first quarter of 2024 increased 25% over Q1 2023.

Based on our results in the first quarter and taking into consideration our new and expanded contracts and projected volume increases, we have revised our guidance for 2024 and now expect to achieve between $90 million and $94 million in net sales. Gross profit for Q1 2024 was $3.1 million, representing an 18% increase over $2.6 million for the same period in 2023. Excluding deferred revenue, gross profit for the first quarter of 2024 nearly tripled compared to gross profit of $1.1 million for the same period in 2023.

We now expect 2024 gross profit to range between $13 million and $15 million versus our previous guidance of $12 million to $14 million. Gross margin for the first quarter of 2024 was 14%, representing an increase from 13% for the same period in 2023. Excluding deferred revenue, gross margin for Q1 2023 was 6%. Gross margin for the first quarter of 2024 is within guidance, we projected for the full year of 2024, we expect to continue to fall between 14% and 16%.

For 2025, we expect gross margin to be approximately 20% and for 2026 and beyond, we expect gross margin to exceed 25%. Net loss for Q1 2024 was $1.7 million. representing a slight improvement over a net loss of $1.8 million for the same period in 2023. Excluding deferred revenue, net loss for the first quarter of 2024 improved by $1.5 million compared to a net loss of $3.2 million for the same period in 2023. Adjusted EBITDA for the first quarter of 2024 was negative $0.5 million. Seasonal items typically incurred in the first quarter related to audit fees, payroll taxes and other public company-related expenses drove our adjusted EBITDA slightly negative.

We expect our expenses to normalize for the remainder of 2024. As a result, we have revised our 2024 guidance upward and now estimate that Rockwell will be adjusted EBITDA positive between $0.5 million and $1 million for the full year 2024. Cash, cash equivalents and investments available for sale on March 31, 2024, was $8.6 million compared to $10.9 million at December 31, 2023. The decrease in cash of approximately $2.4 million was driven by changes in net working capital, commonly seen in the first quarter of the year. Since the end of Q1, our cash balance has rebounded back to levels consistent with the end of 2023.

At close of business last Thursday, May 9, our cash, cash equivalents and investments available for sale was $10.2 million. In January of 2024, we amended our loan and security agreement with Innovatus under which we reduced our interest rate and extended the loan maturity date from May 2025 to January of 2029. Now we are making interest-only payments through September 2026 and may extend the interest-only period through March 2027 if certain conditions are met. As we are discussing our fourth quarter and full year -- as we discussed in our fourth quarter and full year 2024 call, this affords us the opportunity to redeploy this capital back into our business and further optimize our operations. I'll 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] Our first question comes from Ram Selvaraju with H.C. Wainwright.

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

Congrats on a very good quarter. Firstly, Mark, I was hoping you could give us some insights into the overall market breakdown as it currently stands in the dialysate business, particularly given the fact that there are now essentially 2 main players. So just can you give us a sense of how market share is currently distributed in this sector?

Mark Strobeck
President, CEO & Director

Yes. Thanks, Ram, for the question. So as I mentioned, with our purchase of the Evoqua concentrates business, this market has now really become a 2-player market. As of right now, Rockwell has about 25% of the market. depending on how you look at it, might be slightly more or less with our primary competitor having the remaining amounts.

And as I've mentioned, because of changes that are going on in their business, we are continuing to see a number of their customers continue to come to Rockwell to purchase their concentrates. given that we are the only supplier now that is able to handle the volumes that a number of those customers are looking to purchase.

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

Great. That's very helpful. With respect to gross margin, can you give us a sense of how you expect that to evolve, on what kind of cadence and what you anticipate might be optimal gross margins for Rockwell's core business at steady state?

Mark Strobeck
President, CEO & Director

Yes. So as we mentioned here in the first quarter, right, we've achieved gross margin of 14%, the highest gross margin we've had to date. We continue to believe that this will trend upward through the year. That will be largely driven now through making our products in a more efficient manner and through the reduction of our cost of goods through not only renegotiation of materials contracts, but then also significantly the automation of our manufacturing process.

We've given guidance for 25% in '26 of gross margins of 20% in '25 and 25% in '26. And our goal is to continue to drive those higher. We think we can get this business to 30% or more. But we're, right now, focused on achieving the guidance that we've given.

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

And with respect to that, just as a corollary, do you anticipate that ultimately this is going to necessitate any kind of change in pricing dynamics? Or are you assuming gross margin evolution in an effectively unchanged pricing dynamics environment?

Mark Strobeck
President, CEO & Director

It's going to be a combination of both. Right now, we're focused on efficiencies within our own organization and optimizing the way that we manufacture our products. But as you look out through '25 and '26, it's going to be driven both a combination of price and efficiencies and reduction of cost of goods.

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

Okay. And lastly, with respect to your attitude towards debt repayment and relative prioritization of debt repayment versus other capital allocation priorities. Just maybe give us a description of where things currently stand, how we should be thinking about your attitude towards debt repayment over the course of the remainder of 2024 and how you expect to continue to involve debt, if at all, in the long-term cap structure of the company?

Mark Strobeck
President, CEO & Director

Yes. So with the renegotiation of the loan agreement that we completed in the first quarter, right now, we are in an interest-only period and we're going to continue to pay within that interest-only period throughout 2024. We've significantly reduced our leverage and get burden within the organization.

And I think as we look forward, as we begin to start to generate meaningful cash flow from this business, we're going to look at different ways in which to continue to enhance this business, whether that's through continued investment within our own processes, whether that's through business development and adding new products and new opportunities to the organization that are more innovative, that are higher margin as well as continuing to reduce our leverage. I mean, I give you -- my personal objective is that, over the next couple of years, I'd like to see this business debt free.

Operator

Our next question comes from Anthony Vendetti with Maxim Group.

Anthony V. Vendetti
Maxim Group LLC, Research Division

Yes. So you touched on the pricing power, and that's one of the components of as well as efficiency for increasing the gross margin. I was just wondering, in terms of this year, are there any contracts coming up? Is your current pricing structure in place for 2024? And then I wanted to talk about the expansion out West and any updates on that?

Mark Strobeck
President, CEO & Director

Yes. So the current pricing structure is largely in place for 2024. There are a handful of smaller agreements that will come up in the middle of the year that we're currently working on. So that is largely set for this year. And that's independent of some larger things that we are also working on that if they come to fruition, may also have a meaningful impact to our business. we continue to focus on driving more and more of our business out West with the signing of this large health center in the Mountain West region continues to add clinics for us in the Western region.

We are actively looking at establishing a firmer presence there. That will allow us to manufacture and distribute products to the West in a more cost-effective manner than we currently do. So that's an active ongoing project for us as we look to expand even further.

Anthony V. Vendetti
Maxim Group LLC, Research Division

Okay. And then just lastly, as a follow-up on homedialysis, can you give us an update on that, Mark?

Mark Strobeck
President, CEO & Director

Yes. So I think as everybody knows, homedialysis continues to be an exciting area of growth within the dialysis market. We are actively working with the #1 player in that space and are currently in the process of -- we currently supply products to that organization and are actively working on a relationship, which we hope to announce here in the near future around new product opportunities with them.

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Operator

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

Mark Strobeck
President, CEO & Director

Thank you. We are very pleased by all the progress we continue to make at Rockwell, successfully transforming this organization into a leader within our therapeutic area. We would not be able to do this without our dedicated team members who are unwavering in their commitment to provide dialysis clinics and the patients they serve with the highest quality products supported by superior customer service.

We go above and beyond for our customers knowing that our products provide a positive impact on the lives of hemodialysis patients with end-stage kidney disease. Thank you for your time today, and we look forward to providing you with more updates on our next call.

Operator
This concludes today's conference call and webcast. You may now disconnect.

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