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Earnings Call

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Presentation

Operator

Good morning, and welcome to Rockwell Medical's Fourth Quarter and Full Year 2023 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 annual report on Form 10-K for the year ended December 31, 2023, will be filed today and will provide a full analysis of the company's business strategy as well as the company's fourth quarter and full year 2023 results.

Our Form 10-K and other reports filed with the SEC along with today's press release, our 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. The reconciliations of non-GAAP measures we discuss can be found in today's press release on our website.

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 Fourth Quarter and Full Year 2023 Results Conference Call and Webcast.

2023 was a transformative year for Rockwell Medical. For the first time in our company's history for the fourth quarter, we achieved profitability on an adjusted EBITDA basis. This milestone doesn't come easily. It is a direct result of our team's deep commitment to expanding our customer base, improving efficiencies, streamlining processes, reducing expenses and focusing on key business fundamentals.

Additionally, we achieved record net sales, record net product sales and record gross profit for the second year in a row, meeting or exceeding guidance that we issued at the beginning of 2023. And our gross margin continued to improve. Bottom line, we have significantly transformed Rockwell Medical's overall financial health.

Before we delve into the details of our fourth quarter and full year 2023 results, it's important to remind everyone how far we've come over the last 1.5 years. When I joined Rockwell in the middle of 2022, the

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company's revenue was consistently stagnant annually generating around $60 million. We were operating at a loss, generating a gross loss. We're heavily levered and we're at risk for being delisted from the NASDAQ.

During the third quarter of 2022, we evaluated our business and the potential for short- and long-term value and determine that going forward, we would focus our efforts on growing our revenue-generating business, pause further investment in capital-intensive pharmaceutical development programs and achieve profitability to put Rockwell in a stronger and more stable financial position.

In turn, as a result of these efforts, we gave guidance that we expected to achieve profitability in 2024 and that once we achieve profitability and sustained cash flow from our revenue-generating business, we would then consider investments in higher value, longer-term opportunities to develop a broader portfolio of products. Fast forward to today, we are successfully executing against that plan.

We reported record net sales 2 years in a row, first generating over $70 million in net sales in 2022 and now over $80 million of net sales in 2023. We reported record gross profit for the second year in a row, generating over $4 million in 2022 and now approximately $9 million in 2023.

We achieved profitability on an adjusted EBITDA basis in the fourth quarter of 2023 ahead of guidance. We completed 2 acquisitions, renegotiated a number of customer product and supply agreements securing multiyear agreements with minimums. We expanded our geographic footprint, both domestically and internationally, and we significantly improved efficiencies in our manufacturing processes.

These improvements are being realized through our improved gross margin, which was 10% in 2023, the highest in Rockwell's history, an increase from 6% in 2022 and a significant improvement from a gross loss of minus 4% in 2021. We are continuing to execute against the strategy that we put forth in the fourth quarter of 2022, and it continues to have a direct impact on our top and bottom line.

We believe that this trajectory will continue in 2024 and beyond. We are working purposely every day to fortify our market share and ensure our life-sustaining hemodialysis solutions continue to positively impact patients with end-stage kidney disease. At this time last year, we presented to you with our anticipated milestones for 2023.

We plan to focus on commercially growing our business by expanding into new geographies. We plan to optimize agreements with existing customers and add new customers with long-term supply agreements with preferred economics. We expected to continue to focus on reducing our expenses and operating our business more efficiently. We plan to continue to find ways to enhance our financial condition and seek ways to further reduce our debt and most critically, we believe that we would drive our business to achieve profitability and put the company in a stronger, more financially stable position.

As evidenced by the results we issued this morning, I am pleased to share that we accomplished all of these corporate milestones for 2023, and we believe we have set the stage for continued growth in 2024 and beyond. During the fourth quarter of 2023, we generated record net sales of $22.1 million, which was comprised entirely of hemodialysis concentrates product sales. This represented a 15% increase in net sales and a 22% increase in net product sales over the same period in 2022.

In 2023, we generated record net sales for the second year in a row of $83.6 million, a 15% increase year-over-year, of which net product sales was $79.8 million. The delta between net sales and net product sales was driven by recognition of the remaining deferred revenue related to the termination of the Baxter distribution agreement and recognition of deferred revenue related to the Wanbang agreement.

In 2024, we project that net sales, which we anticipate will be comprised 100% of hemodialysis concentrates product sales will be between $84 million and $88 million representing between 5% and 10% growth over net product sales in 2023. In 2025 and beyond, we continue to project that net sales will grow in the mid- to high single digits.

Rockwell Medical is also very focused on identifying, pursuing and achieving growth through acquisition opportunities. This is evidenced by the reacquisition of our distribution rights from Baxter in 2022, which has supported our ability to rightsize the pricing on our products, which were historically being sold at

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a loss, and negotiate multiyear agreements with minimums directly with our customers. This is also evidenced by our acquisition of the hemodialysis concentrates assets from Evoqua in July of 2023, which as we noted on our last call, we successfully integrated into Rockwell during the fourth quarter of 2023.

The Evoqua acquisition expanded our footprint in the United States, hemodialysis concentrates market by adding approximately 1,700 new purchasing facilities to our customer base. As a result, Rockwell now services approximately 1/3 of all purchasing facilities in the United States, including outpatient dialysis clinics and hospitals.

Furthermore, Rockwell is now the leading supplier of liquid bicarbonate hemodialysis concentrates in the United States. In 2023, it is also important to note that we entered into an amended and restated products purchase agreement with our largest customer. Under the amended agreement, Rockwell is realizing a significant price increase for our hemodialysis concentrates products. 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 and would include another corresponding price increase.

In addition, we continue to renegotiate our product purchase agreements and construct them in such a way that reflects the inherent benefit our products offer patients. Throughout 2023, we signed a number of customer agreements, which included significant price increases and long-term supply arrangements with purchasing minimum commitments. We believe these adjustments will continue to have a meaningful impact on Rockwell's top and bottom line.

Our commercial team is actively selling our products across the United States and internationally as we continue to pursue our vision of becoming a leading global supplier of hemodialysis concentrates. Another key metric that's important for valuing our business is gross margin. Prior to my joining Rockwell, we were losing money on our hemodialysis concentrates products business. As I noted before, in 2021, gross loss was minus 4%. Today, we reported that our gross margin for the fourth quarter of 2023 was 13%.

We project that gross margin will continue to improve as a result of better pricing and reduced expenses, the latter of which will be driven by improved efficiencies in our manufacturing and delivery of our products. In 2024, our gross margin is projected to be between 14% and 16%. We project gross margin will continue to improve by approximately 20% in 2025 and will reach 25% or higher in 2026 and beyond.

Through purposeful execution of our strategy, we are unlocking the value of our improved processes and expanded automated manufacturing capabilities. Another key milestone for Rockwell was achieving profitability in the fourth quarter of 2023 on an adjusted EBITDA basis, the first time in our company's history and ahead of our previously issued guidance. We believe this is a clear indicator that our business has turned the corner.

Independent of any unforeseen events, we expect Rockwell should continue to be profitable for the foreseeable future. Rockwell's vision is to become the leading global supplier of all hemodialysis concentrates. We continue to put Rockwell in a better position to drive growth and further improve our performance so we can serve more patients, clinics and major medical centers around the world.

As we look at 2024 and beyond, there are a number of factors that are favorably pointing in Rockwell's direction as we continue to focus on growing our business. Both Fresenius and DaVita reported that patient census are returning to pre-COVID levels, which in turn represents more dialysis treatments and therefore, a growing need for our hemodialysis concentrates.

Our commercial team is aggressively pursuing ways to expand our business within our existing customer base as well as to add new customers. We expect to have announcements soon on some new customer arrangements. We continue to look for ways to establish a more significant presence in the western portion of the United States. And finally, we are actively pursuing more acquisition opportunities that would be revenue generating and immediately accretive to our business.

Over the next 12 months, in addition to the financial guidance we provided today, our other corporate objectives include continuing to optimize our business to improve processes and expanded automated manufacturing capabilities, enhancing our distribution capabilities through the modernization of our

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infrastructure and technology solutions and completing additional business development opportunities to support our strategic objectives.

With that, I will now turn the call over to Jesse to expand on our financial results for the reporting period. Jesse?

Jesse Neri
Senior Vice President of Finance

Thank you, Mark. Good morning, everyone. I will now review our fourth quarter and full year 2023 financial results in more detail, provide you with an update on our cash and debt positions and provide you with additional details on guidance.

Net sales for the fourth quarter of 2023 were $22.1 million, an increase of 15% over the same period in 2022. Net sales for the fourth quarter of 2023 were comprised solely of concentrate product sales, representing the highest quarterly concentrate product sales generated to date for Rockwell and a 22% increase over the net product sales for the same period in 2022.

Net sales for the year ended December 31, 2023, were $83.6 million, which represents a 15% increase over the same period in 2022. Net product sales for the full year 2023 were $79.8 million representing a 15% increase over net product sales of $69.2 million for the same period in 2022.

In 2024, Rockwell projects its net sales, which is expected to comprise solely of net product sales will be between $84 million and $88 million. The company projects net sales will grow in the mid- to high single digits in 2025 and beyond.

Gross profit for the fourth quarter of 2023 was $2.9 million, which represents a 23% increase over the same period in 2022. Gross profit for the full year 2023 was $8.7 million, representing the second year in a row of record gross profit and a 114% increase over the same period in 2022.

Rockwell projects that gross profit in 2024 will be between $12 million and $14 million. Gross margin for the full year of 2023 was 10%, representing an increase from 6% gross margin for the same period in 2022. Gross margin for the fourth quarter of 2023 was 13%. Rockwell projects gross margin to be between 14% and 16% in 2024 to be approximately 20% in 2025 and reaching above 25% in 2026 and beyond.

Net loss for the fourth quarter of 2023 was $1.5 million, representing a 36% improvement over the net loss of $2.4 million for the same period in 2022. Net loss for the full year 2023 was $8.4 million, representing a 55% improvement over a net loss of $18.7 million for the same period in 2022. Adjusted EBITDA for the fourth quarter of 2023 was about $0.5 million, representing a 192% improvement of approximately negative $600,000 for the same period in 2022.

Adjusted EBITDA was negative $3.9 million for the full year 2023, representing a 72% improvement over negative $13.8 million for the same period in 2022. In 2024, we project that Rockwell will be profitable for the entire year, estimating full year adjusted EBITDA to be between $0 and $0.5 million.

Cash, cash equivalents and investments available for sale at December 31, 2023, was $10.9 million compared to $11.7 million at the end of the third quarter of 2023. The decline of approximately $800,000 included a $1.5 million principal payment against our outstanding loan and services agreement with Innovatus.

During the fourth quarter of 2023, we lowered our outstanding debt from $9.5 million to $8 million. In January of this year, 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 2029. This is significant for us. Since prior to the amendment, Rockwell was scheduled to pay $6 million against our principal in 2024. Now we will make interest-only payments for 30 months or up to 36 months as certain conditions are met.

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Our ability to refinance our debt now offers us the opportunity to redeploy this capital back into our business to further optimize our operations through improved business processes and expanded automating manufacturing capabilities.

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 Ram Selvaraju with H.C. Wainwright.

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

Congrats on a very strong finish to 2023. Just wanted to ask in a general sense about how you qualitatively would describe the integration of the Evoqua business and your perspective for growth in that segment of Rockwell Medical's operations, as well as what you would attribute the principal drivers of gross margin improvement to be as we look out ahead to the 2025 time frame.

Mark Strobeck
President, CEO & Director

Yes. Thanks, Ram. I appreciate the question. So -- as we mentioned, the integration of the Evoqua business has been completed into Rockwell. So we've brought over not only the additional customers that we gained through that acquisition but are now taking advantage of the manufacturing capabilities that came as well with that acquisition.

That's -- we were excited to get that completed ahead of schedule at the -- in 2020 -- at the end of 2023. As far as the drivers around margin going forward, with now us essentially adding the #3 player in concentrates within the United States into the Rockwell portfolio, it really creates a marketplace of 2 companies, us and Fresenius.

And so with that, it's allowed us to not only improve our margins through adjusting the economics of our customer relationships, I think, to reflect the value of our products but then simultaneously to continue to drive efficiencies within our manufacturing process, some of which will come from the acquisition of Evoqua.

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

And then just as a follow-up, there's been some speculation regarding the potential long-term impact of broad spectrum utilization of anti-obesity drugs on diabetes, incidents, diabetes severity and thereby dialysis center utilization rates. Can you confirm that you are not in fact seeing any impact of any of that as of right now? And that you anticipate dialysis utilization rates to continue trending upwards over the course of the foreseeable future?

Mark Strobeck
President, CEO & Director

Yes. So -- we are actively monitoring all of the GLP-1 products and other products that are currently in development. And we can confirm, and certainly, that has been confirmed through the 2 largest dialysis providers in the world, DaVita and Fresenius that although these products will have a meaningful place in the armamentarium of a physician to help treat patients with these conditions that they will not have a meaningful impact -- unfortunately, the patients who ultimately end up in end-stage renal disease and then subsequently those that need to utilize dialysis as a treatment paradigm.

So we are actively monitoring, but we don't see that these will have a near-term, midterm impact on our business. In fact, we're seeing just the opposite. And that is being confirmed, as I mentioned earlier, through DaVita and Fresenius, who've now suggested that patient censuses are on the rise again. And so we will see that translated into more dialysis procedures throughout the year and subsequently a greater consumption of concentrates.

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

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Okay. And then just lastly, very quickly, a housekeeping question on your debt position and how you expect that to evolve? And what role you see for debt in the long-term cap structure of the company. And this pertains specifically to the remaining debt facility and the fact that you now have an interest-only period extending for 36 months, do you anticipate paying off the entire principal amount immediately once the interest-only period ends? Or do you expect to pay down the debt effectively in accordance with the currently envisaged maturity?

Mark Strobeck
President, CEO & Director

Yes. So as Jesse mentioned, it is incredibly important for us to enter into this extension of our loan facility. It's really through the growth of the business that we've been successful at achieving that really allowed us to actually enter into that extension.

So we see that as an opportunity to free up some cash for us that would otherwise have gone to be paying that debt for us to reinvest in our manufacturing capabilities and efficiencies to continue to drive better improvements within our gross margin and subsequently sales. Once the interest-only period ends, I think we're going to have to see where the business is whether we would pay it out on the straight amort schedule or we would try to make a payment sooner. I think that depends.

As far as using debt going forward, I think everyone has hopefully seen, we are very responsible from a financing perspective, we are being very mindful of our cash, right? We're driving the business towards profitability, right, to reduce our need to go out and utilize the capital markets. So we'll continue to be responsible in that perspective.

And if it makes sense for us -- if there's an acquisition opportunity where we feel like we need to raise some additional capital, it makes sense to do it from a debt perspective, we'll consider it. We'll simultaneously consider it from an equity perspective. But this is -- from our view or vantage point will be growth capital that will be used to grow the business further. But that's how we think about it.

Operator

Our next question comes from the line of Anthony Vendetti with Maxim Group.

Anthony V. Vendetti
Maxim Group LLC, Research Division

Yes, so on the guidance for revenue growth for 2024, is the guidance organic growth? Or does that include acquisitions? And then in terms of the growth, are you able to break it down in terms of volume and price. Obviously, it's a combination. But if you have a general breakdown of how much of that is driven by volume and price.

Mark Strobeck
President, CEO & Director

Yes. So thanks, Anthony. Growth that we've projected for 2024 is 100% organic, meaning it will come through a combination of both price and volume. We've been conservative in that assessment in putting out the guidance for 2024 as we continue to focus on optimizing our business commercially. So we -- sort of that's what's driving our current guidance.

We're not suggesting at this point, what percentage comes from price, what percentage comes from volume, but know that it's a significant mix of the 2 that drives that.

Anthony V. Vendetti
Maxim Group LLC, Research Division

Okay. And then -- just in terms of the gross margin improvement, obviously given guidance pretty far out into the future, and it's a significant improvement. You've already made significant improvements. It's more than doubling of the gross margin that you had for the full year and almost the doubling of what you have here in the fourth quarter as you go out into the future. What gives you the confidence in that?

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Is it locked in contracts? Is it clear efficiencies you see from your current business as well as the Evoqua acquisition, a combination of those things, maybe just talk about the confidence in those out-year estimates.

Mark Strobeck
President, CEO & Director

Yes. I mean, so I think as everyone is hopefully learning, once we took over this business and determined that it was important for us to provide guidance, right, to the market as to the company's performance. We've been very focused on accuracy and being able to successfully achieve that guidance, and we've -- we've done that now over the last 2 years.

And so when we look forward in 2024 and beyond, we're applying that same level of diligence and accuracy in projecting out what we think is going to happen within this -- with our business within the market. What gives us the confidence in our ability to do that is, as you suggest, we have a number of customers now that have entered into long-term supply agreements with known economics associated with them.

The market dynamics over the last, call it, 9 months have shifted favorably to Rockwell in that we are now in a 2-company market. And so that gives us, I think, also greater confidence around what the commercial opportunity that exists for Rockwell and the pricing that we're able to achieve. And then finally, through the acquisition of Evoqua and other changes that we're making within the manufacturing processes, right, we're seeing a greater amount of efficiencies that are coming through, making our processes more automated that again become reproducible.

So the combination of all of those is what gives us the great -- gives us the confidence to project our business going forward. And we felt like given our understanding of all of that and our expertise now within the space that we felt like we could do that confidently.

Anthony V. Vendetti
Maxim Group LLC, Research Division

Okay. Great. And then just the last follow-up. I think we've discussed the trends of at home dialysis and the trend moving towards that, even though it's still a low percentage of the dialysis market. Can you talk about your plans to address that growing trend? And then I'll hop back in the queue.

Mark Strobeck
President, CEO & Director

Yes. Thanks, Anthony. So you're right. We are certainly monitoring the changes that are going on in the dialysis market. And we are watching the at-home market begin to establish a meaningful presence of the overall dialysis procedures that are administered annually.

It's our belief that this is likely where the market is heading as technology is becoming much easier to use within the home as patients becoming more capable of being able to administer these treatments at home. We think they're probably likely a greater advantage in doing it in the home setting. So we are certainly that this is where the market is going. There's going to be a greater presence of dialysis treatments that occur at the home.

We are working with companies that are focused in the at-home space and are working actually on a product opportunity with the leading provider in this space. We hope to have something a little bit more to say about that in the coming weeks. But our concentrates are -- can be used on all of the products that -- and all the machines that are basically being used in the home setting. So we're perfectly set up to address that part of the market, especially as that market continues to grow.

Operator

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

Mark Strobeck

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President, CEO & Director

Great. Thank you, everyone, for joining us on today's call. We are extremely proud of all the progress we made in 2023, and we are excited for all that lays ahead for Rockwell. I want to personally thank all of the Rockwell employees for all of their hard work. But without them, this progress, we have highlighted here would not have been possible. We look forward to sharing our progress on future calls.

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

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