ROCKWELL MEDICAL, INC.

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(Additional Proxy Soliciting Materials (definitive))

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SCHEDULE 14A

Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934 (Amendment No.)

Filed by the Registrant ☒

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- ☐ Preliminary Proxy Statement
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ROCKWELL MEDICAL, INC.
(Name of Registrant as Specified In Its Charter)

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Filed by Rockwell Medical, Inc.

A copy of an earnings call transcript is being filed herewith under Rule 14a-6 of the Securities Exchange Act of 1934, as amended.

Important Additional Information and Where to Find It

Rockwell Medical, Inc. (the "Company"), its directors and certain of its executive officers may be deemed to be participants in the solicitation of proxies from the Company's shareholders in connection with the matters to be considered at the 2017 Annual Meeting of Shareholders. Information regarding the names and affiliations of individuals who are participants in the solicitation of proxies of the Company's shareholders and their respective direct or indirect interests in the Company, by security holdings or otherwise, can be found in the Company's definitive proxy statement for its 2017 Annual Meeting of Shareholders, including the schedules and appendices thereto, which was filed with the Securities and Exchange Commission ("SEC") on April 21, 2017. **Investors and shareholders are strongly encouraged to read carefully the definitive proxy statement and the accompanying WHITE proxy card and any other documents filed by Rockwell Medical, Inc. with the SEC when they become available, as they will contain important information.** Shareholders can obtain the definitive proxy statement, any amendments or supplements to the definitive proxy statement, the accompanying **WHITE** proxy card, and other documents filed by Rockwell Medical, Inc. with the SEC for no charge at the SEC's website at www.sec.gov. Copies will also be available at no charge by writing to Rockwell Medical, Inc., Attn: Secretary, 30142 S. Wixom Road, Wixom, Michigan, 48393. In addition, copies of the Company's proxy materials may be requested by contacting our proxy solicitor, D.F. King & Co., Inc. 48 Wall Street New York, NY 10005 or by calling toll-free 1-800-844-4725.

Rockwell Medical 1Q17 Earnings Call
May 9, 2017

Corporate Speakers

- Paul Arndt; LifeSci Advisors
- Rob Chioini; Rockwell Medical; Chairman, CEO
- Tom Klema; Rockwell Medical; CFO

Participants

- Charles Haff; Craig-Hallum; Analyst

PRESENTATION

Operator: Good day, everyone. Welcome to the Rockwell Medical First Quarter 2017 Earnings Call. Today's conference is being recorded. At this time, I would like to turn the conference over to Paul Arndt with LifeSci Advisors. Please go ahead.

Paul Arndt: Thank you, Tillari. Good afternoon, everyone. Thank you for attending Rockwell Medical's first quarter financial results conference call. I'm Paul Arndt with LifeSci Advisors. On the call this afternoon are Rob Chioini, Founder, Chairman and CEO of the company; and Tom Klema, Chief Financial Officer.

Before we begin, I'd like to remind everyone that various remarks about future expectations, plans and prospects constitute forward-looking statements for the purposes of Safe Harbor provisions under the Private Securities Litigation Reform Act of 1995. Rockwell cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated.

Among the factors that could cause actual results to differ materially include risks and uncertainties related to Triferic, including the Company's ability to successfully commercialize Triferic, manufacturing capabilities and other risk factors identified from time-to-time in reports filed with the SEC.

Any forward-looking statements made on this conference call speak only as of today's date, Tuesday, May 9, 2017, and the company does not intend to update any of these forward-looking statements to reflect events or circumstances that occur after today's date.

This conference call is being recorded for audio rebroadcast on Rockwell's website at www.rockwellmed.com. All participants on this call will be listen-only. The call will be followed by a brief question-and-answer session.

I'd now like to turn the call over to Rob Chioini, Founder, Chairman and CEO of Rockwell Medical. Rob, please go ahead.

Rob Chioini: Thanks, Paul. Good afternoon. Thank you for joining us. On the call with me today will be our CFO, Tom Klema. So let's get started. Sales for the quarter increased 7% to $14.6 million, $1 million higher than last year, sequentially sales increased approximately 9% over the fourth quarter last year. Gross profit increased to $2.4 million compared to $1.7 million

in Q1 2016. Net loss was $4.7 million versus $4.8 million. Cash and investments were about $53 million as of March 31, 2016.

Tom will provide greater detail on the financial shortly. I think it's important to provide some background information and perspective. Especially as it pertains to how Rockwell has grown, evolved and executed on a strategy to become a major drug company. In 2002, we recognized the value and potential opportunity of an innovative iron delivery technology, at the time it was called SFP.

We felt it had great promise, we evaluated it and we licensed it. We then determined it was best to take what is now Triferic to clinical development and get FDA approval and sell it into the commercial market ourselves, allowing us to keep full ownership of Triferic. We determined it was best to maximize the full value of Triferic for the company and its shareholders. We raised $150 million in the capital markets over several years, to fund our clinical development program. And we did so carefully, keeping shares low. So when it was all set and done, we had just 51 million shares outstanding.

We built the top level clinical team from scratch in Michigan. We designed the clinical program and we successfully met the endpoints of the studies. We then went in front of the FDA Advisory Committee and successfully achieved a favorable outcome for Triferic to be approved. Then we obtained FDA approval for Triferic. In less time and at a significantly lower cost than it was found typical in drug development.

As you know obtaining FDA approval for any drug is an enormous task and the odds of gaining approval are very low. The standards set by the FDA are very high and companies have to go through multiple challenges. We were able to get FDA approval on our first drug, on our first attempt. Along the way we also close to $52 million distribution deal with Baxter, our concentrate product line, we licensed Triferic in Calcitriol to Wanbang Pharma in China for $39 million in milestone payments.

We licensed Triferic and Calcitriol in Saudi Arabia, Egypt and 12 other Middle East countries. We created a new wholly owned Rockwell subsidiary in India, and we started new Triferic development programs, targeting at least four additional therapeutic indication. After receiving FDA approval of Triferic, we successfully secured a reimbursement code.

We fin tuned large scale production of the API secured contract suppliers for both Triferic API and finished product and set up distribution throughout the U.S. In a structure that we expect will save the company millions of dollars versus traditional distribution.

We also gained FDA approval on multiple packaging presentations for Triferic, including the powder packet, which will lead to a much greater profit margin for the company. We launched Triferic commercially in September 2015 in line with our guidance. So we could begin our marketing campaign and educate dialysis providers on the clinical use and cost saving benefits of this new revolutionary way to deliver iron.

And importantly, we saw the opportunity to secure transitional add-on reimbursement for Triferic. We met the CMS in December of 2015. They responded to us at the end of January 2016. Informing us the Triferic was in the bundle for reimbursement. This was the initial response we'd expected from CMS. And we plan to go to Congress and begin working with them to support add-on reimbursement for Triferic.

I made my first trip to Washington D.C. to meet with members of Congress in late February last year. Since that time, I have made many trips and had several productive meetings. In addition to Triferic meeting the guidelines for a new innovative therapy, to receive add-on reimbursement, we also saw that Amgen's new bone and mineral drug had just secured add-on reimbursement. That with congressional support, after CMS initially told them it would be in the bundle.

We believe it took Amgen approximately 18 months to gain add-on reimbursement after first being denied by CMS. We are about 14 months into our initiative. I want to reiterate, that we expect to be successful in gaining add-on reimbursement for Triferic. I felt it was important to provide this background for clarity.

My intent is to give you confidence in knowing that we have executed through the very difficult multi-step process of drug development in FDA approval. And now we have one last step, add-on reimbursement, and we feel confident about completing it.

We believe we are on the cost of gaining this reimbursement and booking Triferic sales in the U.S. Now the easy short sighted thing to do would have been to book sales in the bundle, could have reported some sales which may have made some investors feel good for the moment and maybe would have resulted in a short-term pop in the share price.

But that would have been the wrong decision and those who try to convince us otherwise, do not have the shareholders best interested heart. We have done everything right in regard to positioning Triferic for success and we're in the last leg of the race and we expect to cross the finish line soon.

We are committed to continue strengthening the solid foundation we have in place and to delivering significant long-term value for our shareholders. Add-on reimbursement for Triferic is the absolute right thing to do. It's right for the 470,000 dialysis patients in the U.S. and its right for the Rockwell shareholders.

Currently we are limited and what we can disclose. We do not want to jeopardize this opportunity, but add-on reimbursement as our top priority. You can be assured that since our last update, we have made tangible progress.

Since inauguration day there have been frequent promising discussions with agency officials we've taken positions in the new administration. Triferic continues to receive strong support from several key members of Congress who focus on policy for the Medicare program and who have a special interest in the ESRD population and who have made Triferic's reimbursement a top priority.

Policy makers in Congress and the new administration are focused on the need to ensure that ESRD patients have a choice in their treatment. And access to therapies — innovative therapies like Triferic, which improve quality cost and patient outcomes.

As I have said prior, I can't predict exactly when we will secure add-on reimbursement for Triferic. The government has no regulatory deadline and this is not a formal process. I can tell you that we feel confident that we are near the conclusion and the Triferic will get add-on reimbursement.

I mentioned at the last update that we are pleased with the positive clinical findings being reported from dialysis providers using Triferic through our drug sample program. Improved clinical outcomes and cost reduction are being reported. Just like we saw in our clinical studies and as we expected. This program continues to increase as does our outreach through our marketing and selling efforts to nephrologists, nurses and patients. We remained very excited about Triferic's commercial potential in the U.S. and globally.

Now regarding Calcitriol as you know it's been a challenge to have a contract manufacturer supply as with finish product. Calcitriol is a difficult product to make. It's a high potency injectable. And Rockwell's Calcitriol even more challenging, because we are making it in a vial instead of a glass ampoule.

It will be the only Calcitriol injection in a vial in the U.S. market. This is one of the key competitive advantages. We also need Calcitriol made in significant quantity and at a price point that enables us to sell it and make money as further limits the number of suppliers.

Our original FDA approved supplier and committed to manufacturing 10 million vials initially, then just prior to launch — commercial launch they informed us they could no longer meet that commitment. We had already secured another supplier for redundancy who committed to make 20 million vials and we had begun the tech transfer process with them.

They manufactured product for us and we were preparing to launch Calcitriol commercially. And then a stability issue occurred. They corrected the issue manufactured product again, but then the FDA requested we resubmit the application as a prior approval supplement, which requires a four to six-month review time as we informed you in February this year.

We had secured another supplier for Calcitriol during this time. This new supplier has already made product and it has met really specifications. And currently we are on track to have this product launch in October of this year, so we feel very good about our newest supplier and we have two or second manufacturing facility coming online now as well.

So we've had delays in launching Calcitriol, because of contract manufacturing issues that were outside of our control. Our clinical team's efforts and commitment and determination have enabled us to remain on track to launch Calcitriol.

In regards to our global clinical development, I provided an extensive update on our commercial efforts with Triferic on the last call. It covered China, Saudi Arabia, Egypt and 12 other Middle

Eastern countries and Canada where we have secured partners for Triferic distribution. In India, South America, Mexico, Korea and Japan, we hope to update you soon.

We remain on track to meet with the European Medicines Agency before the end of this year and that will help us in securing a partner in Europe. Regarding our clinical development work, as you know we have numerous opportunities that we are pursuing. They include peritoneal dialysis, TPN, oncology and our orphan indication. Development work is progressing and we will update you when appropriate including for intravenous formulation of Triferic.

Now Tom will discuss the financials in more depth.

Tom Klema: Thank you, Rob, and good afternoon. I'll be covering the financial results for the first quarter and also discuss our capital resources. Our concentrate sales in the first quarter of 2017 were $14.6 million, an increase of $1 million or 7.1% in the first quarter last year. We realized increased sales in our domestic concentrate business of $1 million due to higher unit volumes including $600,000 in orders from Baxter in the first quarter which we do not expect to be reoccurring.

Our international sales were $100,000 lower than the first quarter of last year and sequentially first quarter sales were $1.2 million or 9% higher than the fourth quarter. Gross profit in the first quarter was $2.4 million, which was $700,000 higher than in the first quarter of 2016. The increase was due to higher sales in the first quarter compared to the first quarter last year coupled with lower direct cost in our drug business.

The lower cost in 2017 were primarily a result of the payment of $300,000 value-add taxes paid in 2016 related to the licensing payments received following execution of our license agreement Wanbang Pharmaceutical. Comparison with the fourth quarter gross profit was up 18.6% or $360,000 and gross profit margins moved up to 16.2% from 14.8% in the fourth quarter.

Selling, general and administrative expenses during the first quarter of 2017 were $6.1 million compared to $5 million in the first quarter last year, $1.1 million increase in expense was primarily due to $900,000 in higher legal costs and higher cost for the 2017 Annual Meeting.

The increase was also due to increased marketing costs for Triferic of $200,000, compared to the first quarter last year. It was a reduction in equity compensation cost of $400,000, which was partially offset by higher compensation in benefit costs of $300,000.

In R&D, we incurred product development and research costs related to the commercial development, patent approval, and regulatory approval of new products, primarily Triferic aggregating approximately $1.2 million and $1.3 million in the first quarters of 2017 and 2016, respectively.

Cost incurred in 2017 and 2016 were largely related to Triferic testing for use in other indications and for other presentations. On income tax expense, we had no income tax expense in the first quarter 2017 compared to approximately $400,000 in income tax expense in the first quarter of last year, which pertained to foreign income taxes paid related to the license payments received from the Wanbang license agreement.

Our net loss in the first quarter was $4.7 million compared to $4.8 million in the first quarter last year. Reduction loss was primarily due to higher gross profit and lower tax expense offset by higher SG&A. Net loss was $0.09 per share compared to $0.10 per share in the first quarter last year.

On our cash position, our cash position is very strong. We have adequate cash resources to support development of our drug business operations and associated working capital as well as to continue our research and development investments.

As of March 31, we had current assets of $74.8 million, net working capital of $64.4 million, and we have approximately $52.7 million in cash and investments as of March 31. Our uses of cash have primarily been for research and product development, investments and inventory to support our drug product launches, and for operating expenses.

Operating activities used $5.2 million of cash in the first quarter of 2017, which included R&D expense of $1.2 million and an increase of $2.3 million in inventory levels. We increased our Triferic inventory over the last year for commercializing Triferic and believe we have adequate inventory to meet anticipated requirements.

We anticipate that we will increase our accounts receivable as we increase our drug product sales, and we may also increase inventories to a more modest degree as we commercialize Triferic and Calcitriol. We also expect to invest in research and product development throughout 2017, as we work to expand potential applications for Triferic.

We believe that we have adequate capital resources to make these investments in accounts receivable, inventory, and research and product development. We expect to generate positive cash flow from operations upon increased sales of our drug products.

Future research and product development spending on Triferic expected to include clinical testing in connection with peritoneal dialysis, orphan drug indication, pediatric indications and certain other indications, which is spending on such indications is expected to be minor in relation to the Company's cash resources.

We have no long-term debt as of March 31, 2016 and do not expect to incur any interest expense in 2017. And our capital expenditures on our current facilities are not expected to materially exceed depreciation expense. With that, I will now turn the call back to Rob.

Rob Chioini: So before turning to Q&A, I'd like to briefly touch our upcoming Annual Meeting on June 1. We have been speaking and will continue to speak directly with many of Rockwell's shareholders your firsthand, what they think about the direction of the company. The Rockwell Board is actively engaged and committed to ensuring that Rockwell remains well governed and shareholder focused.

The Board has the leadership and pharmaceutical and financial experience necessary to continue executing our proven strategy. The Board also continues in its commitment to evolve with the

changing needs of the business by adding relevant experience and strengthening its corporate governance practices. The purpose of today's call is to discuss our earnings results.

So we ask that you keep questions focused on that topic and thank you for your cooperation in that regard. And the operator can go ahead and field questions.

QUESTIONS AND ANSWERS

Operator: Thank you so much. (Operator Instructions) We'll take our first question from Charles Haff with Craig-Hallum.

Charles Haff: Hi guys, thanks for taking my questions. Can you hear me OK?

Rob Chioini: Yes. We can hear you.

Charles Haff: So for the revenue from Baxter the $600,000 that Tom you referenced was non-recurring. Is there anything unique about that revenue would you expect? Then next quarter to maybe have $600,000 less how should we think about this bolus of revenues impacting your business going forward?

Tom Klema: Charles, I would expect that there was nothing really unusual about that would not expected to repeat. We are continuing to pick up business all the times. So it's hard to predict, if we might get some additional business.

Charles Haff: OK. So there's not going to be a drop off, you're not expecting a drop off next quarter beyond where your original expectations were because of this big order than, is that you're saying?

Tom Klema: That's right, yes.

Charles Haff: OK, OK. And then in terms of operating cash flow for 2017, so you had a negative $5.2 million this quarter. Is that kind of the right run rate to think about for the remaining quarters of the year? Or are you thinking something different than that?

Tom Klema: I think it'll be a little bit less we paid down some accounts payable. So I would anticipate it's going to be closer to $2.5 million to $3 million per quarter.

Charles Haff: OK.

Tom Klema: And we build inventory and I don't expect us to continue to build that level of inventory.

Charles Haff: OK. I thought your previous comments you said that you expect to maybe build up inventory a little bit more. You were just talking about the rate of change wouldn't be is…

Tom Klema: I don't think…

Charles Haff: …dramatic as it was this quarter?

Tom Klema: Right, yes.

Charles Haff: OK, OK. And then Rob, you talked about the 470,000 dialysis patients in the U.S. And I'm wondering when you think about your packet form of Triferic and then hemodialysis and peritoneal dialysis and so forth and all the different permutations. What do you think the size of the target market is out of that 470,000 that you think is kind of your sweet spot for the current formulation of Triferic that you're pursuing? Thanks.

Rob Chioini: So the 400 — so when you look at PD in the U.S., I believe and I don't have these percentages right in front of me, but I'm probably pretty close. I believe the PD market in the U.S. is somewhere around 8% maybe as high as 10%, but maybe not, but probably in that 8%, 9% range. Other than that we look at the entire market. Anybody who's on hemodialysis is a potential market for Triferic.

Charles Haff: OK. But would you say that maybe there's a sweet spot is it younger, healthier or is it older, more acute? Is there kind of a sweet spot that you would pursue in the early days presuming that you get new add-on reimbursement?

Rob Chioini: So that's a good question. And actually the best way to answer that is kind of refresh the mode of action of the drug and what it does right, so when we look at Triferic and we look at IV iron. What we know is that there's been nothing in the market for the last 30 years except IV iron. And IV iron was approved by the FDA with a clinical indication that says treat iron deficiency anemia, which the FDA defines as a ferritin of less than 200. And when IV iron first came into the market, the average ferritin back then was about 200 to 300. But over the last 30 years that ferritin level and ferritin by the way just to remind you is the store — it's the stored iron in the body and it's also a marker of inflammation.

Charles Haff: Sure.

Rob Chioini: So the average iron stored in the body of dialysis patients over 30 years has increased from 200 on average to 800.

Charles Haff: Yes.

Rob Chioini: And because there's been nothing available to treat ongoing or the iron loss that occurs every single treatment three times a week to these patients. So no fault of IV iron, IV iron has been used off label for 30 years to try to do something it's incapable of doing. IV irons are rescue or repletion therapy, you give it to a patient ideally, when they have excessive blood loss and lose a lot of blood and they need like a bolus or rescue dose .

Triferic on the other hand was approved by the FDA, specifically to treat the constant iron loss every treatment and the FDA approved indication is actually very important and it says to replace iron and maintain hemoglobin.

There's no other drug with that indication approved. And so we've got two drugs in the anemia space. One that's designed to be given every single treatment to the patient because they're losing that five to seven milligrams of iron every treatment. And Triferic has been approved to replace it.

And then another IV iron, which can now be used as it was intended as a rescue therapy sparingly when patients have excessive blood loss and they need some quick iron boost, some iron stores. And so the answer is, when you understand Triferic is approved indication and what it's for and that every single patient in the U.S. on dialysis loses iron, whether they come on today for the first time or been on for 10 years, every one of them needs that that dose of Triferic. So when we look at the sweet spot for the market, it's anybody who's on dialysis.

Charles Haff: OK. I appreciate the comprehensive answer there. Thanks sir.

Rob Chioini: Thanks.

Operator: That does conclude our question-and-answer session. At this time everyone, I'll turn the call back over to Rob Chioini for any final or additional comments.

Rob Chioini: So we want to thank the shareholders for their support and we look forward to giving you an update on the next earnings call. Thank you.

Operator: Everyone, that does conclude our conference call for today. We do thank you all for your participation. You may now disconnect.