UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **February 11, 2019**

ROCKWELL MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Michigan	**000-23661**	**38-3317208**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

30142 Wixom Road, Wixom, Michigan 48393
(Address of principal executive offices, including zip code)

(248) 960-9009
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On February 11, 2019, Rockwell Medical, Inc. (the "Company") presented at the 2019 BIO CEO & Investor Conference in New York City. A copy of the transcript from the presentation (the "Transcript") is attached hereto as Exhibit 99.1 and is incorporated herein by reference. Additionally, the Company estimates that sales for the year ended December 31, 2018 will be in the range of $62 million to $63.5 million.

The information contained in this Item 2.02, including the related information set forth in the Transcript attached hereto and incorporated by reference herein, is being "furnished" and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise. The information in this Item 2.02 shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, or into any filing or other document pursuant to the Exchange Act, except as otherwise expressly stated in any such filing. Additionally, readers are cautioned that estimated result of operations for the period ended December 31, 2018 are unaudited and preliminary.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*. The following exhibit is being furnished herewith:

EXHIBIT INDEX

Exhibit No.	Description
99.1	Transcript of Rockwell Medical, Inc. presentation at the 2019 BIO CEO & Investor Conference, dated February 11, 2019.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ROCKWELL MEDICAL, INC.

Date: February 15, 2019

By: /s/ Stuart Paul
Stuart Paul
Chief Executive Officer

Exhibit 99.1

Transcript of
Rockwell Medical, lnc.
Presentation at the 2019
BIO CEO & lnvestor
Conference
February 11,
2019

Female Speaker: I would like to introduce Rockwell Biopharmaceutical right now. Paul Stuart is here, the president and CEO.

Stuart Paul: Thank you, good afternoon. Thanks for joining us and thanks for being here for the presentation on Rockwell Medical.

We are a biopharmaceutical company focused on the renal space. I'll flip through the forward language here and get straight to the investment highlights.

So, essentially, we're repositioning the company for growth. It's a fully integrated biopharmaceutical company targeting end-stage renal disease and chronic kidney disease, dialysis patients who are on hemodialysis. And we have an expanded focus around anemia management.

I came on board in September. We've taken the last quarter or so to form a new executive management team. We've strengthened the board of directors, strengthened our scientific advisory board, and we have a team that's very deep in pharmaceutical and renal experience.

Triferic is an innovative therapeutic that is a first and only FDA approved therapy indicated to maintain hemoglobin and replace iron that is lost in every single hemodialysis treatment, and that occurs in every dialysis treatment. It works very physiologically like dietary iron in the body and avoids iron toxicity, so it has a wonderful safety profile. And we are planning our commercial launch in the first half of 2019 for our, what we would call our dialysate version. It's actually added to the dialysate, which is one of the liquids used in the hemodialysis procedure.

And we're planning on filing our NDA for the I.V. version for Triferic in the first half of 2019, as well, for a potential FDA approval in 2020. And we're really excited about the I.V. version because we believe it also has global market appeal and global market potential.

And then, of course, we also have an orange book listing for our patents with expiry in 2029. So, the IP is quite solid. And, as it turns out, we're already an in-market company. We are the number two supplier of concentrates to the dialysis industry, and we have over $50 million in revenues and relationships with the leading, largest dialysis companies in the United States, which is, essentially for us, a strategic asset and a base from which we can expand and develop our pharmaceutical and market portfolio further.

As I mentioned, we assembled a world-class management team. I have been with Baxter, Abbot and other companies. Gambro was another global dialysis company that I was part of with the senior management team, and we had a great exit back in 2013 in selling the company to Baxter. I brought some of the folks that were along for that ride with us here, who are very skilled in the renal space, but have also a great mix of others. Our new CFO background in Cantor Fitzgerald, the Wall Street, as well as other pharmaceutical company experience across the team.

And the market opportunity is quite significant. We believe Triferic has a potential to exceed a billion dollars worldwide. There are over two million people who are on hemodialysis and get hemodialysis treatments around the world today, and that leaves us with just under 300 million annual hemodialysis treatments, and it's a market that continues to grow, along with the increased rates of diabetes, obesity, hypertension, etcetera. So, we're very excited about the global market potential. And, as I mentioned, we are launching our dialysate version, but we think we have multiple opportunities to drive long-term value.

We are currently building our sales and marketing capability and are launching, in the coming months, in the United States, as I mentioned, we expect reimbursement within what we would call the CMS bundle, the Medicare bundled reimbursement level for dialysis.

But we're also planning to file our NDA, as I mentioned, which in on a 505B1 pathway with the FDA, for our I.V. Triferic product, expecting approval sometime in early 2020.

And what's great about this is that there is an eligibility for what CMS has defined as a transitional payment structure. It's known as TDAPA, which stands for the transitional dialysis add-on payment adjustment. But it's essentially a 24-month window of transitional payment outside the bundle, so the opportunity to price higher outside the bundle is certainly on the table, and we believe a great opportunity for our I.V. Triferic.

And then, on a global basis, we have a number of activities underway, working with a partner in China, Wanbang Pharmaceuticals, with several clinical trials underway and nearing completion. We expect to file in China.

We have agreement with the European's Medicine Agency on a Phase 3 Design in Europe to conduct our study and our study for approval in Europe. And we're seeking partners in key geographies, including Japan, and intend to file our NDA in Canada this year.

As I mentioned, the unmet need here is really that every single patient undergoing hemodialysis loses iron. The current standard of care for

anemia in hemodialysis patients has been the use of I.V. iron and ESAs. There's certainly risks with iron toxicity and cardiovascular risks of ESA, not to mention the high cost of therapy.

Our platform is different. We have a novel platform that addresses the daily iron needs of patients. It's a very safe, gentle uptake. We actually—all the fancy diagram on the left—all it says is we bypass the liver. Our product donates iron to transferrin. We bypass the liver, and it goes straight to the bone marrow and is a much safer application of, and potentially a paradigm shifting methodology of treatment for these patients who are under considerable duress.

And you'll note the last bullet point on the right, that we actually demonstrated a 35 percent reduction in prescribed ESA dose over nine months compared to placebo in our prime study. And that's not insignificant.

In addition to the 35 percent reduction in ESA, we also saw 74 percent reduction in ESA hypo-responder patients, and hemoglobin was maintained throughout the study, as you can see in the graph.

We also showed a 51 percent sparing of I.V. iron in the prime study, and no increase in ferritin levels. Again, going around the liver, we feel this is a very significant finding.

And I.V. Triferic, as I mentioned, is eligible for the transitional payment known as TDAPA--TDAPA is the CMS policy -- and also has applicability, as I mentioned earlier, to the global markets. So we're planning the filing of our NDA in the U.S. in the coming months, within the first half. We believe we'll be eligible for TDAPA pricing for the CMS for a window of 24 months after approval.

And the international markets are highly dependent on a different methodology of online bicarb generation, which will require the I.V. product as opposed to the dialysate products. We're very excited about taking the I.V. product for both in the U.S. and outside the U.S.

And the U.S. dialysis market is quite large. Over 500,000 ESRD patients translates to over 70 million hemodialysis treatments in the U.S. each year.

And we are essentially launching into a market that today is spending over $4 billion in the U.S. on both ESA erythropoiesis stimulating agents, and I.V. iron therapeutics. So, a significant potential to penetrate this segment with our product portfolio.

And around pricing on dialysis and IVS, I mentioned on the dialysate version of Triferic, we'll be pricing inside the bundle. We still think we'll have a nice, a very good margin profile inside the bundle, but outside the

bundle, with the TDAPA transitional payment structure from CMS, and an approval from FDA post-January 1, 2020, will put us in position to secure a transitional pricing for the I.V. product outside the bundle going forward. So, we're very excited about that.

Internationally, there are a number of opportunities that we're pursuing, as I mentioned earlier. And, in Europe, we're currently actively in discussions and aiming to identify a partner to work with us in our pharmaceutical development program.

We plan on initiating our Phase 3 program sometime in 2020 in Europe. As I mentioned, in China, we're partnered with Wanbang Biopharmaceuticals. Two studies underway. And we'll be filing later this year. There are roughly $35 million in potential regulatory and other milestone payments that will be forthcoming as we move forward in China alone.

And then, of course, we're looking at partner potential in Japan, as well. And, at this time, working on clarifying our I.V. regulatory requirements for the I.V. product in Japan.

Although we didn't press release it, we actually got our first international approval just recently in the country of Peru. So, we do have a team in Latin America. I have some of the Gambro team working for me down there that was with me in the prior endeavor that I mentioned earlier. And we're quite excited about the opportunities to expand across Latin America as we go forward.

And then, of course, we're filing our NDA in Canada, as well, in the first half of 2019, most likely.

Upcoming milestones, then, our U.S. dialysate Triferic launch is happening within the coming months. The sales team is being finalized in the field, and our medical science liaison team is moving into place, and we are quite excited about our U.S. launch.

Moving on, the filing of the NDA for I.V. Triferic, moving into 2020, approval of the I.V. Triferic in the U.S., and launch of the I.V. Triferic product in the U.S.

Some of the clinical milestones that we're pursuing in 2019, initiating a pediatric study as a requirement to satisfy FDA, and then initiation of our I.V. study in 2020, as I mentioned, in Europe.

And then, of course, outside the U.S., our FDA submissions, as I mentioned, in China, in Canada, and other partnerships that we are endeavoring to sign this year.

Some select financials here, again, interesting. So, you know, we are a biopharmaceutical company in the throes of launching some really great new therapeutics, but we also currently have revenue based upon the concentrate business, as I mentioned, since we supply a significant amount of concentrates to DaVita for their own use, as well as distribute through Baxter in the United States.

So, we have a significant position with both of these significant players, and that gives us entre to further development opportunities with both of them around our therapeutic portfolio.

The company—we haven't announced our 2018 financials, but the company was in the range of 60 million for the year. So, that is the starting point at which we are, the jumping off point as we begin to ready our launch for Triferic.

So, in conclusion, why Rockwell, why now? Right?

So we really feel we've done a great job of repositioning the company for launch and for growth, and moving the company into a full biopharmaceutical stage, really focused now in bringing very novel paradigm shifting therapeutics to the hemodialysis space, and therapeutics which will have broader application, we believe, in other anemia management adjacent areas and other therapeutic indications.

So, that's the path we are on. We've got a fantastic new management team that's in place, a great board of directors, it's very capable and experienced and successful with a great track record.

And we're a first and only drug approved to replace iron and maintain hemoglobin in a very, very important patient base in terms of hemodialysis patients.

We're planning our launch, as I said, this year. We plan our NDA filing for I.V., expect to be on market with our I.V. Triferic next year, and we continue to leverage our relationships with the top renal companies in this space as we move forward. Very excited about the opportunity. Thanks for joining us today, and we will see you. Thanks so much.

[END OF TRANSCRIPT]