



Rockwell Medical, Inc. Provides First Quarter 2020 Financial and Operational Update and Top-line Real-World Triferic Data

May 11, 2020

-Q1 2020 revenue of \$15.9 million-

-Received FDA Approval of Triferic® AVNU™.

-Significant expansion of Triferic (ferric pyrophosphate citrate) Dialysate Evaluation Programs during Q1 2020-

-Retrospective real-world analysis over 18 months shows reduction in ESA and traditional IV iron use, stable-to-increasing hemoglobin levels, reductions in missed treatments, and quality-of-life improvements following clinical adoption of Triferic-

-Strengthened financial position with \$48.9 million in cash, cash equivalents and marketable securities as of March 31, 2020-

-Conference call and webcast scheduled for today at 4:30 p.m. ET-

WIXOM, Mich., May 11, 2020 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (Nasdaq: RMTI) ("Rockwell Medical" or the "Company"), a biopharmaceutical company dedicated to transforming anemia management and improving outcomes for patients around the world, today reported financial results and a business update for quarter ended March 31, 2020.

"In my new role, my charge is to maximize the commercial potential of our two FDA-approved products, Triferic Dialysate and Triferic AVNU, while developing Rockwell Medical into a more medically- and scientifically-driven company, which includes leading the strategic identification and pursuit of new therapeutic areas for our ferric pyrophosphate citrate platform," said Russell Ellison, M.D., M.Sc., President and Chief Executive Officer of Rockwell Medical. "I am pleased to report continued progress in our commercialization of Triferic Dialysate in the first quarter, including an acceleration of Triferic Dialysate Evaluation Programs and a continued increase in contracted clinics. Importantly, we secured FDA approval of Triferic AVNU at the end of March and are working diligently to prepare for a successful launch of this intravenous ("IV") formulation later this year."

Dr. Ellison added: "In addition, we are encouraged by the top-line data announced today from a retrospective real-world analysis of Triferic Dialysate within a dialysis clinic. Following adoption of Triferic within the studied clinic, we observed the reduction of the use of erythropoietin stimulating agents ("ESAs") and traditional IV iron, improvement in hemoglobin levels, fewer missed appointments among patients, and an improvement in patients' quality of life. These measures are important factors in patient care and speak to the value that Triferic can confer to providers, patients and the overall healthcare system."

First Quarter 2020 Operational Highlights

Triferic Dialysate

- The Company currently has active or committed Evaluation Programs with independent dialysis clinics and small dialysis chains representing more than 2,250 patients and 36 clinics, a 260% increase from December 31, 2019.
- Signed contracts with four additional clinics during the first quarter of 2020, and an additional eight clinics that are affiliated with MDO were trained and approved for adoption as of March 31, 2020.
- Nearly 2,000 contracted patients on therapy as of March 31, 2020, representing over 300,000 annualized treatments.
- Triferic net sales were \$0.3 million in the first quarter of 2020.
- Entered into exclusive license and supply agreements with Sun Pharma for the rights to commercialize Triferic Dialysate in India. Rockwell Medical received an upfront fee and will be eligible for milestone payments and royalties on net sales.
- With respect to the COVID-19 pandemic, the Company has implemented precautions to reduce the risk of possible exposure by restricting employee travel, adopting new preventative safety measures within our manufacturing facilities, instituting a work-from-home policy for substantially all employees, excluding our essential manufacturing and distribution employees, and leveraging virtual technology for the sales force to use in its communications with customers. The Company has experienced no material impact on its supply chain to date, and has experienced a small increase in demand for its dialysis concentrates products, believed to be attributed to customers building safety stock and turning to Rockwell Medical in instances where other suppliers have not been able to meet demand.

Triferic AVNU (IV Formulation)

- On March 27, 2020, Rockwell Medical announced that the FDA approved its New Drug Application for Triferic AVNU, its intravenous formulation of Triferic.
- With this approval, Triferic AVNU joins Triferic Dialysate as the only FDA-approved products indicated to replace iron and maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease.

- The Company has initiated a commercial strategy to leverage the experience gained from the 2019 launch of Triferic Dialysate and lay the groundwork for the commercial introduction of Triferic AVNU. The Company expects to launch evaluation programs during the third quarter of 2020 to allow clinics to gain direct experience with Triferic AVNU, and expects Triferic AVNU to be available commercially during the fourth quarter of 2020, following the completion of the initial evaluation programs.

Triferic Real-World Data

Today, the Company announced the top-line results from a retrospective analysis of Triferic Dialysate clinical use. The analysis included patient outcomes from an independent dialysis clinic with approximately 65 patients, from a baseline period of 3 months prior to the adoption of Triferic Dialysate through 18 months post-adoption.

"Today's results, while a snapshot from a single clinic, demonstrate meaningful clinical and real-world trends observed following the adoption of Triferic Dialysate," said Marc Hoffman, M.D., Chief Medical Officer of Rockwell Medical. "The potential clinical and financial implications from this analysis are compelling and we believe they support Triferic's important place in the physician's arsenal for treating adult patients with hemodialysis-dependent chronic kidney disease."

Findings from the analysis include:

- A more than 23% reduction in ESAs utilized per patient, per week during the sixth quarter after Triferic Dialysate administration vs. baseline.
- A 74% reduction in traditional IV iron (ferric gluconate) utilization per patient, per week, beginning at month 3 and continuing through the observation period vs. baseline.
- Stable to increasing hemoglobin levels, with consistent hemoglobin control throughout the observation period.
- A meaningful reduction in missed treatments of nearly one-fifth and one-half for the 5th and 6th quarters, respectively.
- Improvements in key quality of life indicators as measured by KDQOLTM-36.

The Company is evaluating potential publication and/or presentation of the full results of the findings at a future medical meeting.

First Quarter 2020 Corporate Updates

- The Company announced the appointment of Russell H. Ellison, M.D., M.Sc., as President and Chief Executive Officer, effective April 20, 2020. Dr. Ellison, who will continue to serve as a member of the Board of Directors for Rockwell Medical, brings broad medical, clinical development and leadership experience to the role.
- The Company announced the appointment of Robert S. Radie to its Board of Directors, effective March 31, 2020. Mr. Radie brings more than three decades of industry experience, working in senior executive roles with both public and private pharmaceutical and biotech companies across a range of therapeutic areas.
- On March 17, 2020, the Company entered into a debt financing agreement with an affiliate of Innovatus Capital Partners, LLC ("Innovatus") to provide the Company with up to \$35.0 million in term loans. The first \$22.5 million tranche was funded on March 16, 2020. The Company will be eligible to draw on a second tranche of \$5.0 million following the completion of certain milestones, which includes the FDA approval of Triferic AVNU, and a third tranche of \$7.5 million upon the achievement of certain additional milestones, including the achievement of certain Triferic sales thresholds.
- The Company completed the pricing of an underwritten public offering of the Company's common stock in February 2020 for gross proceeds of approximately \$8.1 million, before deducting issuance costs.

First Quarter 2020 Financial Results

Net sales for the first quarter of 2020 were \$15.9 million, an increase of 2% compared to net sales of \$15.6 million for the first quarter of 2019. The increase was primarily due to an increase in U.S. product sales of Triferic Dialysate as a result of the commercial launch in May 2019.

Cost of sales for the first quarter of 2020 was \$14.7 million, resulting in gross profit of \$1.1 million, compared to cost of sales of \$14.5 million and a gross profit of \$1.0 million during the first quarter of 2019. Gross profit increased by \$0.1 million in the first quarter of 2020 compared to the first quarter of 2019 due primarily to an increase in U.S. product sales of Triferic Dialysate as a result of the commercial launch in May 2019, partially offset by a decrease in gross profit for our dialysis concentrate products.

Selling and marketing expenses were \$2.1 million for the first quarter of 2020 compared to \$3.1 million for the first quarter of 2019. The decrease was due primarily to various marketing investments made during the first quarter of 2019 to support the commercial launch of Triferic Dialysate that did not recur in the first quarter of 2020, partially offset by investments in selling and marketing headcount to support the ongoing launch of Triferic Dialysate and the upcoming launch of Triferic AVNU.

General and administrative expenses were \$5.3 million for the first quarter of 2020 compared to \$6.2 million for the first quarter of 2019. The decrease was primarily due to a reduction in legal expenses, stock-based compensation and consulting costs, partially offset by an increase in headcount and insurance expenses.

Research and product development expenses were \$1.8 million for the first quarter of 2020 compared to \$0.5 million for the first quarter of 2019. The increase was due primarily to investments the Company is making in its medical platform to support the development and the global launch of Triferic, including medical, scientific and technical staffing costs, clinical trial costs and consulting expenses. We expect our research and product development expenses to increase in the future due to additional clinical development of our ferric pyrophosphate citrate technology platform, innovations in administration of Triferic, the continuation of the pediatric clinical trial for Triferic, and an increase in headcount to support medical education efforts for

Triferic.

Net loss for the first quarter of 2020 was \$8.0 million, or \$0.12 per basic and diluted share, compared to a net loss for first quarter of 2019 of \$8.7 million, or \$0.15 per basic and diluted share.

Cash, cash equivalents, and investments available-for-sale totaled \$48.9 million as of March 31, 2020, compared to approximately \$26.0 million on December 31, 2019. Cash used in operating activities was \$6.5 million during the first quarter of 2020. The balance sheet was strengthened by a \$35 million debt financing agreement with Innovatus, announced in March 2020, from which the Company drew \$22.5 million at closing, as well as the underwritten public offering of the Company's common stock in February 2020 for gross proceeds of approximately \$8.1 million, before deducting issuance costs. Additionally, the Company has approximately \$35 million remaining for issuance under its at-the-market equity offering facility, pursuant to which the Company may sell, at such times and amounts as it deems appropriate, shares of common stock to support its business plan, subject to certain restrictions on use.

First Quarter 2020 and Business Update Conference Call and Webcast

Rockwell Medical's management team will host a conference call and audio webcast today at 4:30 p.m. ET to discuss Q1 2020 financial results and provide a business update.

To access the conference call, please dial (877) 383-7438 (local) or (678) 894-3975 (international) at least 10 minutes prior to the start time and refer to conference ID 9391556. A live webcast of the call will be available under "Events & Presentations" in the Investor section of the Company's website, <https://ir.rockwellmed.com/>. An archived webcast will be available on the Company's website approximately two hours after the event and will be available for 30 days.

About Rockwell Medical

Rockwell Medical is a biopharmaceutical company dedicated to transforming anemia management in a wide variety of therapeutic areas and across the globe, improving the lives of very sick patients. The Company's initial focus is the treatment of anemia in end-stage renal disease (ESRD). Rockwell Medical's exclusive renal drug therapies, Triferic (ferric pyrophosphate citrate) Dialysate and Triferic AVNU, are the only FDA-approved therapeutics indicated for iron replacement and maintenance of hemoglobin in hemodialysis patients. Rockwell Medical is also an established manufacturer, supplier and leader in delivering high-quality hemodialysis concentrates/dialysates to dialysis providers and distributors in the U.S. and abroad.

About Triferic Dialysate and Triferic AVNU

Triferic Dialysate and Triferic AVNU are the only FDA-approved therapies in the U.S. indicated to replace iron and maintain hemoglobin in hemodialysis patients during each dialysis treatment. Triferic Dialysate and Triferic AVNU have a unique and differentiated mechanism of action, which has the potential to benefit patients and health care economics. Triferic Dialysate and Triferic AVNU represent a potential innovative medical advancement in hemodialysis patient iron management – with the potential to become the future standard of care.

Triferic Dialysate and Triferic AVNU both deliver approximately 5-7 mg iron with every hemodialysis treatment to the bone marrow and maintain hemoglobin without increasing iron stores (ferritin). Both formulations donate iron immediately and completely to transferrin (carrier of iron in the body) upon entry into the blood which is then transported directly to the bone marrow to be incorporated into hemoglobin, with no increase in ferritin (stored iron and inflammation) and no reports of anaphylaxis in over 1,000,000 patient administrations, addressing a significant medical need in overcoming Functional Iron Deficiency (FID) in ESRD patients.

Important Safety Information

Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving parenteral iron products. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after hemodialysis until clinically stable. Personnel and therapies should be immediately available for the treatment of serious hypersensitivity reactions. Hypersensitivity reactions have been reported in 1 (0.3%) of 292 patients receiving Triferic in two randomized clinical trials.

Iron status should be determined on pre-dialysis blood samples. Post dialysis serum iron parameters may overestimate serum iron and transferrin saturation.

The most common adverse reactions ($\geq 3\%$ and at least 1% greater than placebo) in controlled clinical studies include: procedural hypotension (21.6%), muscle spasms (9.6%), headache (9.2%), pain in extremity (6.8%), peripheral edema (6.8%), dyspnea (5.8%), back pain (4.5%), pyrexia (4.5%), urinary tract infection (4.5%), asthenia (4.1%), fatigue (3.8%), arteriovenous (AV) fistula thrombosis (3.4%), and AV fistula site hemorrhage (3.4%).

Forward-Looking Statements

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the federal securities laws, including, but not limited to, Rockwell Medical's intention to commercialize Triferic Dialysate, and Triferic AVNU. Words such as, "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "could," "can," "would," "develop," "plan," "potential," "predict," "forecast," "project," "intend" or the negative of these terms, and similar expressions, or statements regarding intent, belief, or current expectations, are forward looking statements. While Rockwell Medical believes these forward-looking statements are reasonable, undue reliance should not be placed on any such forward-looking statements, which are based on information available to us on the date of this release. These forward-looking statements are based upon current estimates and assumptions and are subject to various risks and uncertainties (including, without limitation, those set forth in Rockwell Medical's SEC filings), many of which are beyond our control and subject to change. Actual results could be materially different. Risks and uncertainties include, but are not limited to: statements about the challenges inherent in new product development and other indications and therapeutics areas for our products; the success of our commercialization strategy; the success and timing of our commercialization of Triferic Dialysate, which was launched in May 2019; the success and timing of our evaluation program for Triferic AVNU and for a commercial launch of Triferic AVNU in the United States; the risk that topline clinical data and real world results may not be predictive of future results; the anticipated number of future clinics with which we may contract for use of Triferic Dialysate; the expected number of annualized treatments for Triferic Dialysate; the potential impact of the COVID-19 pandemic

(including, applicable federal state or local orders) on business and operating results, including our supply chain, dialysis concentrates business and the commercial launch of Triferic AVNU; the timing and availability of future publications and presentations; potential future milestone payments and royalties under our license agreements; expected financial performance, including cash flows, revenues, growth, margins, funding, liquidity and capital resources; and those risks more fully discussed in the "Risk Factors" section of our Quarterly Report on Form 10-Q for the period ended March 31, 2020 and of our Annual Report on Form 10-K for the year ended December 31, 2019, as such description may be amended or updated in any future reports we file with the SEC. Rockwell Medical expressly disclaims any obligation to update our forward-looking statements, except as may be required by law.

Triferic® is a registered trademark of Rockwell Medical, Inc. Triferic AVNU is pending with the U.S. Patent and Trademark Office. All other product names, logos, and brands are property of their respective owners in the United States and/or other countries. All company, product and service names used on this website are for identification purposes only. Use of these names, logos, and brands does not imply endorsement.

Financial Tables Follow

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(unaudited)

	March 31, 2020	December 31, 2019
ASSETS		
Cash and Cash Equivalents	\$ 37,399,801	\$ 11,794,526
Investments Available-for -Sale	11,456,285	14,250,176
Accounts Receivable, net	4,586,748	4,202,725
Inventory	4,292,768	3,646,906
Prepaid and Other Current Assets	1,758,002	2,979,504
Total Current Assets	59,493,604	36,873,837
Property and Equipment, net	2,430,113	2,433,405
Inventory, Non-Current	623,000	441,000
Right of Use Assets, net	2,797,759	3,212,530
Goodwill	920,745	920,745
Other Non-current Assets	560,588	434,935
Total Assets	\$ 66,825,809	\$ 44,316,452
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts Payable	\$ 3,123,181	\$ 3,018,424
Accrued Liabilities	6,160,047	4,517,732
Settlement Payable	57,000	104,000
Lease Liability - Current	1,351,348	1,493,394
Deferred License Revenue - Current	2,179,383	2,233,640
Insurance Financing Note Payable	190,855	763,422
Customer Deposits	146,831	55,100
Other Current Liability - Related Party	148,523	187,849
Total Current Liabilities	13,357,168	12,373,561
Lease Liability - Long-Term	1,559,749	1,780,626
Term Loan, Net of Issuance Costs	20,683,704	—
Deferred License Revenue - Long-Term	9,450,983	9,842,762
Total Liabilities	45,051,604	23,996,949
Stockholders' Equity:		
Preferred Stock, \$0.0001 par value, no shares issued and outstanding at March 31, 2020 and December 31, 2019	—	—
Common Stock, \$0.0001 par value; 170,000,000 shares authorized; 69,049,102 and 65,378,890 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	6,905	6,538
Additional paid-in capital	336,216,422	326,777,250
Accumulated Deficit	(314,500,003)	(306,516,265)

Accumulated Other Comprehensive Income	50,881	51,980
Total Stockholders' Equity	21,774,205	20,319,503
Total Liabilities And Stockholders' Equity	\$ 66,825,809	\$ 44,316,452

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019
Net Sales	\$ 15,856,539	\$ 15,559,439
Cost of Sales	14,743,613	14,549,047
Gross Profit	1,112,926	1,010,392
Selling and Marketing	2,072,798	3,102,378
General and Administrative	5,273,433	6,220,499
Research and Product Development	1,821,488	497,276
Operating Loss	(8,054,793)	(8,809,761)
Other Income (Expense)		
Realized Gain on Investments	1,929	13,888
Interest Expense	(101,951)	—
Interest Income	171,077	117,526
Total Other Income	71,055	131,414
Net Loss	\$ (7,983,738)	\$ (8,678,347)
Basic and Diluted Net Loss per Share	\$ (0.12)	\$ (0.15)
Basic and Diluted Weighted Average Shares Outstanding	67,518,240	57,098,947

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Source: Rockwell Medical, Inc.