

December 27, 2018

Dear Shareholders,

As 2018 draws to a close, I want to share a few highlights of our progress since I joined Rockwell Medical, Inc. (“Rockwell Medical”) in September 2018.

Over the past several months, we took several meaningful actions to reposition Rockwell Medical in order to further advance the company in 2019:

- We assembled a world-class management team with deep expertise in the renal sector, along with global execution capabilities;
- We secured a \$22.0 million investment in the company to advance and support our clinical and commercial efforts;
- We refined our strategy and now have a focused plan to leverage the market potential of our Triferic platform, with alignment around new CMS pricing guidelines that will result in the launch of Dialysate Triferic within the CMS pricing bundle in 2019;
- We plan to file an NDA for I.V. Triferic in the first half 2019, with a potential FDA approval in the first half of 2020, which we believe would make the product eligible for 24 months of transitional pricing starting in 2020, if approved by CMS;
- We began our Triferic clinical trial in China through our local partner in China, and we in-licensed intellectual property rights for I.V. Triferic worldwide, so that we can continue to protect the value of this important asset globally; and
- We have taken actions that will allow us to improve the economics of our base concentrates business going forward.

As we look ahead, we are confident that our intensive internal review efforts have led to greater clarity – and intention – in crafting our path forward. We are singularly focused on realizing the full potential of Rockwell Medical's valuable assets to improve patient outcomes and to enhance shareholder value.

### **Triferic**

We believe that Triferic has the potential to transform anemia management in patients with hemodialysis-dependent chronic kidney disease. With more than 500,000 dialysis patients in the United States, most of whom receive hemodialysis, and an additional 1.2 million in-center hemodialysis patients in key markets across the globe, there are significant market and product expansion opportunities. Through the launch of Dialysate Triferic, the first and only FDA-approved drug indicated to replace iron and maintain hemoglobin in hemodialysis patients suffering from anemia, we will establish a commercial infrastructure that we can leverage for the potential launch of I.V. Triferic, which we believe will have even broader global appeal.

The recent Centers for Medicare & Medicaid Services (“CMS”) ruling on reimbursement provides us with much greater clarity around commercial pricing for both I.V. Triferic and Dialysate Triferic. As set forth in the CMS guidance materials, Dialysate Triferic is not eligible for add-on reimbursement under the CMS Transitional Drug Add-On Pricing Adjustment (“TDAPA”) Program. As such, we are continuing our previously announced plan to launch Dialysate Triferic “within the bundle,” during the first half of 2019. To prepare, we are finalizing our commercialization plans, including manufacturing scale-up and implementation, as well as developing strong marketing, sales and medical education efforts. During 2019, we plan to initiate additional studies, including a pediatric study to satisfy the post-marketing regulatory requirements, further supporting the value of this asset.

And, while today's main focus is on our U.S. commercialization plans for Triferic, there is a significant international opportunity, which we have also begun moving forward to capture. In China, our licensee, Wanbang Biopharmaceutical Co., a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd, has started the first of two clinical studies. We expect both studies to be completed in 2019 and expect Wanbang will file for approval if the endpoints are met, based upon an agreed regulatory pathway with the Chinese FDA. Our agreement with Wanbang includes potential regulatory and commercial milestone payments of up to \$35 million. In 2019, we will also share details of our clinical development plan for I.V. Triferic in the European Union, including study endpoints and the expected regulatory pathway with the European Medicines Agency (EMA). More details will also be forthcoming regarding our planned 2019 NDA filing in Canada for I.V. Triferic and expansion plans for our products in Latin America.

Based upon CMS' recent guidance, if I.V. Triferic is approved by the FDA after January 1, 2020, we believe it would be eligible for separate sole source payment with a unique J-Code for a two-year timeframe. In accordance with the current guidance, separate TDAPA payments would last for two years following launch, after which I.V. Triferic would be priced within the bundle. We intend to apply with CMS seeking separate TDAPA payments for I.V. Triferic. We are actively engaged with our regulatory and clinical experts to evaluate our pending New Drug Application (“NDA”) to help ensure the greatest chance of regulatory and commercial success, allowing for a launch in the first half of 2020, subject to receiving FDA approval.

In 2019, we will remain focused on building and executing on the strategic framework to support Triferic throughout its lifecycle, including:

- Aligning organizational resources;
- Optimizing our commercial model;
- Securing optimal pricing and access; and
- Establishing a leadership position in anemia through a patient-centric model.

In addition to aligning our resources around our Dialysate Triferic and I.V. Triferic opportunities, we are taking action to refine the strategy for our base concentrates business as well. We are engaging with key partners in an effort to improve the economics of this business.

### **Leadership Team**

Our progress to date and the future of our business rely on having a strong leadership team in place. At this pivotal time in Rockwell Medical's journey, one of my top priorities was to build out the senior leadership team. I am excited that we now have outstanding talent in the right roles to fulfill our vision and execute on our commercial strategy. Over the past few months, we have assembled a leadership team with deep experience in the renal therapy and specialty pharmaceutical space, comprising individuals who bring essential business experience, as well as expertise in key areas that support Rockwell Medical's business plan. We welcome the following new additions to the team:

**Angus Smith**, Chief Financial Officer, oversees all financial operations and investor relations activities. Angus' deep financial expertise, his background advising specialty pharmaceutical and healthcare companies, and his diverse knowledge base will serve our leadership team well as we continue to drive financial and operational performance.

**Anne Boardman**, Vice President, Strategic Accounts, brings extensive experience in renal, biotech and medical sales to this newly created role. Anne has a deep understanding of the reimbursement landscape and a proven track record in building, improving and managing critical business relationships.

**Jim McCarthy**, Senior Vice President, Corporate and Business Development, joins Rockwell on a full-time basis. Jim offers extensive expertise in strategic and commercial business planning and global business development.

**Charlie Shiner**, Vice President, Marketing, is leading our marketing efforts around the commercial launch of Dialysate Triferic. Charlie's marketing prowess and broad understanding of the renal space will enable Rockwell Medical to realize the full value of Triferic.

**Michael DeYoung**, Vice President, Operations, is leading our newly formed Operations Team and overseeing manufacturing operations, logistics and company-wide strategy deployment in support of the launch of Triferic. Mike brings a wealth of experience in operational leadership and strategic program management.

I feel very fortunate to be collaborating with this dedicated group, and I believe that, together, they will support the Company's growth plans.

## **Financing**

Instrumental to achieving our goals is having a strong financial platform in place. In October 2018, we moved to secure \$22.0 million in funding through a private placement. These funds will support our commercialization plans; net proceeds will be used to fund working capital needs that will enable us to continue to implement our growth objectives. We will continue to evaluate all financing options available to us to advance our efforts, including potential partnership opportunities in markets outside the U.S., where we believe the right partner may be able to add value to our clinical, regulatory or commercialization efforts.

## **Conclusion**

Let me close by sharing with you that we are energized about our prospects for the future. I am inspired by Rockwell Medical's dedicated employees, and our talented team of leaders who are committed to realizing the full potential of our valuable assets, to improving patient outcomes and to enhancing shareholder value.

We are looking forward to 2019, which has the potential to be a transformative year for Rockwell Medical.

In the coming year, we plan to:

- Launch Dialysate Triferic;
- File an NDA for I.V. Triferic in the U.S. and Canada;
- Complete two clinical studies with our partner, Wanbang, in China, and file for approval if the endpoints are met;
- Define the clinical studies necessary for I.V. Triferic and the regulatory pathway in the E.U.;
- Define our strategy in Latin America;
- Initiate additional studies in the U.S., including a pediatric study to satisfy post-marketing requirements for regulatory authorities to further support both Dialysate Triferic and I.V. Triferic;
- Improve the economics of our concentrates business; and
- Continue to align our corporate resources.

We are confident that we have defined a clear path forward for the Company that will position it for success.

On behalf of the entire team at Rockwell Medical, we appreciate your continued support and trust, and wish you and your families a happy, healthy and prosperous New Year.

Stuart Paul  
President & CEO

### ***Cautionary Note Regarding Forward-Looking Statements***

Certain statements in this shareholder letter may constitute "forward-looking statements" within the meaning of the federal securities laws. Words such as "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "could," "plan," "potential," "predict," "forecast," "project," "plan", "intend" or similar expressions, or statements regarding intent, belief, or current expectations, are forward-looking statements. While Rockwell 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 communication and which are subject to inherent uncertainty. 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's SEC filings), many of which are beyond our control and subject to change. Actual results could be materially different. Risks and uncertainties include: statements about the timing and success of our planned NDA submission for I.V. Triferic; the potential market opportunity for I.V. Triferic and other Rockwell products, as well as the timing for planned commercial activities, including product launch; pricing and reimbursement status for I.V. Triferic, Dialysate Triferic and other Rockwell products, including eligibility for add-on reimbursement under TDAPA; timing and success of clinical trials for Triferic; plans and timing relating to the planned commercialization of Triferic; and the timing and success of our efforts to renegotiate economic terms of our concentrates business. Rockwell expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.