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United States
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2019

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 000-23661

ROCKWELL MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Michigan	**38-3317208**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
30142 Wixom Road, Wixom, Michigan	**48393**
(Address of principal executive offices)	(Zip Code)

(248) 960-9009

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☒
	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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	Trading Symbol	Name of each exchange on which registered:
Common Stock, no par value	RMTI	Nasdaq Global Market

The number of shares of common stock outstanding as of May 8, 2019 was 57,565,370.

Rockwell Medical, Inc. and Subsidiaries
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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2019 (Unaudited)	December 31, 2018
ASSETS		
Cash and Cash Equivalents	$ 20,919,518	$ 22,713,980
Investments Available-for -Sale	6,876,221	10,818,059
Accounts Receivable, net of a reserve of $2,240 in 2019 and $2,104 in 2018	6,711,410	6,979,514
Insurance Receivable	—	371,217
Inventory	4,001,570	4,038,778
Prepaid and Other Current Assets	1,680,818	1,903,682
Total Current Assets	**40,189,537**	**46,825,230**
Property and Equipment, net	2,572,680	2,638,293
Inventory, Non-Current	1,501,000	1,637,000
Right of Use Assets, net	3,005,792	—
Goodwill	920,745	920,745
Other Non-current Assets	555,310	536,516
Total Assets	$ **48,745,064**	$ **52,557,784**
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts Payable	$ 4,522,225	$ 4,492,071
Accrued Liabilities	6,272,040	5,129,761
Settlement Payable	166,669	416,668
Lease Liability - Current	1,680,475	—
Deferred License Revenue - Current	2,248,062	2,252,868
Customer Deposits	240,239	63,143
Other Current Liability - Related Party	600,000	850,000
Total Current Liabilities	**15,729,710**	**13,204,511**
Lease Liability - Long-Term	1,336,319	—
Deferred License Revenue - Long-Term	11,517,988	12,076,399
Total Liabilities	**28,584,017**	**25,280,910**
Commitments and Contingencies (See Note 14)		
Shareholders' Equity:		
Preferred Shares, no par value, no shares issued and outstanding at March 31, 2019 and December 31, 2018	—	—
Common Shares, no par value, 57,128,327 and 57,034,154 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	301,171,733	299,601,960
Accumulated Deficit	(281,066,581)	(272,388,234)
Accumulated Other Comprehensive Income	55,895	63,148
Total Shareholders' Equity	**20,161,047**	**27,276,874**
Total Liabilities And Shareholders' Equity	$ **48,745,064**	$ **52,557,784**

The accompanying notes are an integral part of the condensed consolidated financial statements.

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended March 31, 2019	Three Months Ended March 31, 2018
Net Sales	$ 15,559,439	$ 14,948,579
Cost of Sales	14,549,047	15,669,072
Gross Profit (Loss)	1,010,392	(720,493)
Selling and Marketing	3,102,378	215,083
General and Administrative	6,220,499	3,116,872
Research and Product Development	497,276	1,666,356
Operating Loss	(8,809,761)	(5,718,804)
Other Income (Expense)		
Realized Gain (Loss) on Investments	13,888	(2,892)
Interest Income	117,526	175,307
Other Income	—	(3,132)
Total Other Income (Expense)	131,414	169,283
Net Loss	$ (8,678,347)	$ (5,549,521)
Basic and Diluted Net Loss per Share	$ (0.15)	$ (0.11)
Basic and Diluted Weighted Average Shares Outstanding	57,098,947	51,288,424

The accompanying notes are an integral part of the condensed consolidated financial statements.

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended March 31, 2019	Three Months Ended March 31, 2018
Net Loss	**$ (8,678,347)**	**$ (5,549,521)**
Unrealized Loss on Available-for-Sale Debt Instrument Investments	(7,161)	(189,995)
Foreign Currency Translation Adjustments	(92)	(2,485)
Comprehensive Loss	**$ (8,685,600)**	**$ (5,742,001)**

The accompanying notes are an integral part of the condensed consolidated financial statements.

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

For the three months ended March 31, 2019

(Unaudited)

	COMMON SHARES		ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME / (LOSS)	TOTAL SHAREHOLDER'S EQUITY
	SHARES	AMOUNT			
Balance as of December 31, 2018	**57,034,154**	**$ 299,601,960**	**$ (272,388,234)**	**$ 63,148**	**$ 27,276,874**
Net Loss	—	—	(8,678,347)	—	(8,678,347)
Unrealized Loss on Available-for-Sale Investments	—	—	—	(7,161)	(7,161)
Foreign Currency Translation Adjustments	—	—	—	(92)	(92)
Exercise of Employee Stock Options	30,000	147,900	—	—	147,900
Delivery of common stock underlying restricted stock units, net of tax	64,173	(95,429)	—	—	(95,429)
Stock-based Compensation	—	1,517,302	—	—	1,517,302
Balance as of March 31, 2019	**57,128,327**	**$ 301,171,733**	**$ (281,066,581)**	**$ 55,895**	**$ 20,161,047**

The accompanying notes are an integral part of the condensed consolidated financial statements.

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

For the three months ended March 31, 2018

(Unaudited)

	COMMON SHARES		ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME / (LOSS)	TOTAL SHAREHOLDER'S EQUITY
	SHARES	AMOUNT			
Balance as of December 31, 2017	**51,768,424**	**$ 273,210,907**	**$ (240,262,376)**	**$ (35,383)**	**$ 32,913,148**
Net Loss	—	—	(5,549,521)	—	(5,549,521)
Unrealized Loss on Available-for-Sale Investments	—	—	—	(189,995)	(189,995)
Foreign Currency Translation Adjustments	—	—	—	(2,485)	(2,485)
Stock-based Compensation	—	446,003	—	—	446,003
Balance as of March 31, 2018	**51,768,424**	**$ 273,656,910**	**$ (245,811,897)**	**$ (227,863)**	**$ 27,617,150**

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

For the three months ended March 31, 2019 and 2018

(Unaudited)

	2019	2018
Cash Flows From Operating Activities:		
Net Loss	**$ (8,678,347)**	**$ (5,549,521)**
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	187,527	129,076
Stock-based Compensation	1,517,302	446,003
Increase in Inventory Reserves	11,000	2,046,954
Amortization of Right of Use Asset	478,442	—
Loss on Disposal of Assets	—	3,083
Realized (Gain) Loss on Sale of Investments Available-for-Sale	(13,888)	2,892
Foreign Currency Translation Adjustment	(92)	(2,446)
Changes in Assets and Liabilities:		
Decrease in Accounts Receivable	268,104	295,973
Decrease in Insurance Receivable	371,217	—
Decrease in Inventory	162,208	59,427
Decrease in Other Assets	203,982	238,438
Increase (Decrease) in Accounts Payable	30,154	(209,208)
Decrease in Settlement Payable	(249,999)	—
Decrease in Lease Liability	(467,440)	—
Increase (Decrease) in Other Liabilities	1,319,375	(1,494,969)
Decrease in Deferred License Revenue	(563,217)	(572,709)
Changes in Assets and Liabilities	1,074,384	(1,683,048)
Cash Used In Operating Activities	**(5,423,672)**	**(4,607,007)**
Cash Flows From Investing Activities:		
Purchase of Investments Available-for-Sale	(8,812,954)	(1,416,665)
Sale of Investments Available-for-Sale	12,761,519	1,050,554
Purchase of Equipment	(121,826)	(155,712)
Purchase of Research and Development Licenses (Related Party)	(250,000)	—
Cash Provided By (Used In) Investing Activities	**3,576,739**	**(521,823)**
Cash Flows From Financing Activities:		
Proceeds from the Exercise of Employee Stock Options	147,900	—
Repurchase of Common Shares to Pay Employee Withholding Taxes	(95,429)	—
Cash Provided By Financing Activities	**52,471**	**—**
Decrease In Cash and Cash Equivalents	(1,794,462)	(5,128,830)
Cash At Beginning Of Period	22,713,980	8,406,917
Cash At End Of Period	**$ 20,919,518**	**$ 3,278,087**
Supplemental Disclosure of Noncash Investing Activities:		
Change in Unrealized Loss on Marketable Securities Available-for-Sale	$ (7,161)	$ (189,995)
Delivery of Common Stock Underlying Restricted Stock Units	$ 273,830	$ —

The accompanying notes are an integral part of the condensed consolidated financial statements.

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Description of Business

Rockwell Medical, Inc. and subsidiaries (collectively, "we", "our", "us", or the "Company"), is a specialty pharmaceutical company targeting end-stage renal disease and chronic kidney disease with products for the treatment of iron deficiency and hemodialysis. We are also a manufacturer of hemodialysis concentrates for dialysis providers and distributors in the United States and abroad. We supply the domestic market with dialysis concentrates and we also supply dialysis concentrates to distributors serving a number of foreign countries, primarily in the Americas and the Pacific Rim. Substantially, all of our sales have been concentrate products and ancillary items.

Our business strategy is developing unique, proprietary renal drug therapies that we can commercialize or out-license, while also expanding our dialysis products business. These renal drug therapies support disease management initiatives to improve the quality of life and care of dialysis patients and are designed to deliver safe and effective therapy, while decreasing drug administration costs and improving patient convenience and outcome.

Triferic® is a registered trademark of Rockwell Medical, Inc.

2. Going Concern

As of March 31, 2019, the Company had approximate balances of $20.9 million of cash and cash equivalents, $6.9 million of investments available-for-sale, working capital of $24.5 million and an accumulated deficit of $281.1 million. Net cash used in operating activities for the three months ended March 31, 2019 was approximately $5.4 million.

The Company will require significant additional capital to sustain its operations and make the investments it needs to execute upon its longer-term business plan. The Company's existing liquidity is not sufficient to fund its operations and anticipated capital expenditures within one year of the issuance of the accompanying condensed consolidated financial statements. On March 22, 2019, the Company entered into a sales agreement with Cantor Fitzgerald & Co. (the "Agent"), pursuant to which the Company may offer and sell from time to time shares of the Company's common stock, no par value, through the Agent up to $40,000,000. We are not required to sell any shares at any time during the term of the facility. Our ability to sell common stock under the facility may be limited by several factors including, among other things, the trading volume of our common stock and certain black-out periods that we may impose upon the facility, among other things. The Company intends to seek additional equity or debt financing; however, there are currently no commitments in place for further financing nor is there any assurance that such financing will be available to the Company on favorable terms, if at all.

The Company's recurring operating losses, net operating cash flow deficits, and an accumulated deficit, raise substantial doubt about the Company's ability to continue as a going concern for one year from the issuance of the accompanying condensed consolidated financial statements. The condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company has not made any adjustments to the accompanying condensed consolidated financial statements related to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

3. Basis of Presentation, Summary of Significant Accounting Policies and Recent Accounting Pronouncements

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with the accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and pursuant to the instructions to Form 10-Q and Article 8 of Regulation S-X of the Securities and Exchange Commission ("SEC") and on the same basis as the Company prepares its annual audited consolidated financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation of such interim results.

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements
(Unaudited)

The results for the condensed consolidated statement of operations are not necessarily indicative of results to be expected for the year ending December 31, 2019 or for any future interim period. The condensed consolidated balance sheet at March 31, 2019 has been derived from unaudited financial statements; however, it does not include all of the information and notes required by U.S. GAAP for complete financial statements. The accompanying condensed consolidated financial statements should be read in conjunction with the consolidated financial statements for the year ended December 31, 2018 and notes thereto included in the Company's annual report on Form 10-K filed on March 18, 2019.

The accompanying condensed consolidated interim financial statements include the accounts of the Company and its subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Certain reclassifications have been made to the 2018 financial statements and notes to conform to the 2019 presentation.

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that may affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Significant Accounting Policies

Other than leases, there have been no material changes in the Company's significant accounting policies to those previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

Leases

Effective January 1, 2019, the Company accounts for its leases under Accounting Standards Codification ("ASC") 842, *Leases*. Under this guidance, arrangements meeting the definition of a lease are classified as operating or financing leases, and are recorded on the consolidated balance sheet as both a right of use asset and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company's incremental borrowing rate. Lease liabilities are increased by interest and reduced by payments each period, and the right of use asset is amortized over the lease term. For operating leases, interest on the lease liability and the amortization of the right of use asset result in straight-line rent expense over the lease term. Variable lease expenses, if any, are recorded when incurred.

In calculating the right of use asset and lease liability, the Company elects to combine lease and non-lease components. The Company excludes short-term leases having initial terms of 12 months or less from the new guidance as an accounting policy election, and recognizes rent expense on a straight-line basis over the lease term.

The Company continues to account for leases in the prior period financial statements in accordance with ASC Topic 840.

Loss Per Share

ASC 260, Earnings Per Share, requires dual presentation of basic and diluted earnings per share ("EPS"), with a reconciliation of the numerator and denominator of the basic EPS computation to the numerator and denominator of the diluted EPS computation. Basic EPS excludes dilution. Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issued common stock were exercised or converted into common stock or resulted in the issuance of common stock that are then shared in the earnings of the entity.

Basic net loss per share of common stock excludes dilution and is computed by dividing the net loss by the weighted average number of shares outstanding during the period. Diluted net loss per share of common stock reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements
(Unaudited)

common stock or resulted in the issuance of common stock that then shared in the earnings of the entity unless inclusion of such shares would be anti-dilutive. The Company has only incurred losses, therefore, basic and diluted net loss per share is the same. Securities that could potentially dilute loss per share in the future that were not included in the computation of diluted loss per share for the three months ended March 31, 2019 and 2018 were as follows:

	As of March 31,	
	2019	2018
Options to purchase common stock	8,289,605	6,881,001
Unvested restricted stock awards	146,800	480,000
Unvested restricted stock units	1,461,917	-
	9,898,322	7,361,001

Adoption of Recent Accounting Pronouncements

The Company continually assesses any new accounting pronouncements to determine their applicability. When it is determined that a new accounting pronouncement affects the Company's financial reporting, the Company undertakes a study to determine the consequences of the change to its consolidated financial statements and assures that there are proper controls in place to ascertain that the Company's consolidated financial statements properly reflect the change.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which amended the guidance on accounting for leases. The FASB issued this update to increase transparency and comparability among organizations. This update requires the recognition of lease assets and lease liabilities on the balance sheet and the disclosure of key information about leasing arrangements. The Company adopted this ASU effective January 1, 2019 using the additional (optional) approach by recording a right of use asset and a lease liability of approximately $3.5 million; there was no effect on opening retained earnings, and the Company continues to account for leases in the prior period consolidated financial statements under ASC Topic 840. In adopting the new standard, the Company elected to apply the practical expedients regarding identification of leases, lease classification, indirect costs, and the combination of lease and non-lease components.

In June 2018, the FASB issued ASU 2018-17, *Improvements to Nonemployee Share-Based Payment Accounting,* which simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under ASU 2018-17, most of the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. The amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity's adoption of Topic 606. The Company adopted this new standard on January 1, 2019 and the adoption did not have a material impact on its condensed consolidated financial statements and related disclosures.

4. Revenue Recognition

The Company recognizes revenue under ASC 606, *Revenue from Contracts with Customers.* The core principle of the new revenue standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The following five steps are applied to achieve that core principle:

- Step 1: Identify the contract with the customer
- Step 2: Identify the performance obligations in the contract
- Step 3: Determine the transaction price
- Step 4: Allocate the transaction price to the performance obligations in the contract
- Step 5: Recognize revenue when the company satisfies a performance obligation

Taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction, that are collected by us from a customer, are excluded from revenue.

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements
(Unaudited)

Shipping and handling costs associated with outbound freight related to contracts with customers are accounted for as a fulfillment cost and are included in cost of sales when control of the goods transfers to the customer.

Nature of goods and services

The following is a description of principal activities from which the Company generates its revenue.

Product sales –The Company accounts for individual products and services separately if they are distinct (i.e., if a product or service is separately identifiable from other items and if a customer can benefit from it on its own or with other resources that are readily available to the customer). The consideration, including any discounts, is allocated between separate products and services based on their stand-alone selling prices. The stand-alone selling prices are determined based on the cost plus margin approach.

Drug and dialysis concentrate products are sold directly to dialysis clinics and to wholesale distributors in both domestic and international markets. Distribution and license agreements for which upfront fees are received are evaluated upon execution or modification of the agreement to determine if the agreement creates a separate performance obligation from the underlying product sales. For all existing distribution and license agreements, the distribution and license agreement is not a distinct performance obligation from the product sales. In instances where regulatory approval of the product has not been established and the Company does not have sufficient experience with the foreign regulatory body to conclude that regulatory approval is probable, the revenue for the performance obligation is recognized over the term of the license agreement (over time recognition). Conversely, when regulatory approval already exists or is probable, revenue is recognized at the point in time that control of the product transfers to the customer.

The Company received upfront fees under two distribution and license agreements that have been deferred as a contract liability. The amounts received from Wanbang Biopharmaceuticals Co., Ltd. (“Wanbang”) are recognized as revenue over the estimated term of the distribution and license agreement as regulatory approval was not received and the Company did not have sufficient experience in China to determine that regulatory approval was probable as of the execution of the agreement. The amounts received from Baxter Healthcare Corporation (“Baxter”), are recognized as revenue at the point in time that the estimated product sales under the agreement occur.

For the business under the Company’s distribution agreement with Baxter (the “Baxter Agreement”), and for the majority of the Company’s international customers, the Company recognizes revenue at the shipping point, which is generally the Company’s plant or warehouse. For other business, the Company recognizes revenue based on when the customer takes control of the product. The amount of revenue recognized is based on the purchase order less returns and adjusted for any rebates, discounts, chargebacks or other amounts paid to customers. There were no such adjustments for the periods reported. Customers typically pay for the product based on customary business practices with payment terms averaging 30 days, while distributor payment terms average 45 days.

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements
(Unaudited)

Disaggregation of revenue

Revenue is disaggregated by primary geographical market, major product line, and timing of revenue recognition.

In thousands of US dollars ($)	Three Months Ended March 31, 2019		
Products By Geographic Area	Total	U.S.	Rest of World
Drug Revenues			
License Fee – Over time	$ 68	$ —	$ 68
Concentrate Products			
Product Sales – Point-in-time	14,996	12,923	2,073
License Fee – Point-in-time	495	495	—
Total Concentrate Products	15,491	13,418	2,073
Net Revenue	$ 15,559	$ 13,418	$ 2,141

	Three Months Ended March 31, 2018		
Products By Geographic Area	Total	U.S.	Rest of World
Drug Revenues			
License Fee – Over time	$ 68	—	$ 68
Concentrate Products			
Product Sales – Point-in-time	14,376	12,472	1,904
License Fee – Point-in-time	504	504	—
Total Concentrate Products	14,880	12,976	1,904
Net Revenue	$ 14,948	$ 12,976	$ 1,972

Contract balances

The following table provides information about receivables, contract assets, and contract liabilities from contracts with customers.

In thousands of US dollars ($)	March 31, 2019	December 31, 2018
Receivables, which are included in "Trade and other receivables"	$ 6,711	$ 6,980
Contract liabilities	$ 13,766	$ 14,329

There were no impairment losses recognized related to any receivables arising from the Company's contracts with customers for the three months ended March 31, 2019 and 2018.

For the three months ended March 31, 2019 and March 31, 2018, the Company did not recognize material bad-debt expense and there were no material contract assets recorded on the condensed consolidated balance sheet as of March 31, 2019 and December 31, 2018. The Company does not generally accept returns of its concentrate products and no reserve for returns of concentrate products was established as of March 31, 2019 or December 31, 2018.

The contract liabilities primarily relate to upfront payments and consideration received from customers that are received in advance of the customer assuming control of the related products.

Transaction price allocated to remaining performance obligations

For the three months ended March 31, 2019, revenue recognized from performance obligations related to prior periods was not material.

Revenue expected to be recognized in any future year related to remaining performance obligations, excluding revenue pertaining to contracts that have an original expected duration of one year or less, contracts where revenue is

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements
(Unaudited)

recognized as invoiced and contracts with variable consideration related to undelivered performance obligations, totaled $13.8 million as of March 31, 2019. The amount relates primarily to upfront payments and consideration received from customers that are received in advance of the customer assuming control of the related products. The Company applies the practical expedient in paragraph 606-10-50-14 and does not disclose information about remaining performance obligations that have original expected durations of one year or less. The Baxter Agreement includes minimum commitments of product sales over the duration of the agreement. Unfulfilled performance obligations related to the Baxter Agreement are product sales of $10.6 million, which will be amortized through expiration of the agreement on October 2, 2024.

5. Investments - Available-for-Sale

Investments available-for-sale consisted of the following as of March 31, 2019 and December 31, 2018:

	March 31, 2019			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Available-for-Sale Securities				
Bonds	$ 6,869,060	$ 7,210	$ (49)	$ 6,876,221

	December 31, 2018			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Available-for-Sale Securities				
Bonds	$ 10,801,836	$ 17,415	$ (1,192)	$ 10,818,059

The fair value of investments available-for-sale are determined using quoted market prices from daily exchange-traded markets based on the closing price as of the balance sheet date and are classified as Level 1, as described in Note 3, Fair Value Measurement to our condensed consolidated financial statements.

As of March 31, 2019 and December 31, 2018, the amortized cost and estimated fair value of our available-for-sale securities were due in one year or less.

6. Inventory

Components of inventory, net of reserves as of March 31, 2019 and December 31, 2018 are as follows:

	March 31, 2019	December 31, 2018
Raw Materials	$ 3,344,878	$ 3,621,548
Work in Process	240,402	256,129
Finished Goods	1,917,290	1,798,101
Total	$ 5,502,570	$ 5,675,778

As of March 31, 2019 and December 31, 2018, we classified $1.5 million and $1.6 million, respectively, of inventory as non-current, all of which was related to Triferic or the active pharmaceutical ingredient for Triferic. As of March 31, 2019 and December 31, 2018 we had total Triferic inventory aggregating $5.5 million and $8.0 million respectively, against which we had reserved $3.4 million and $5.8 million respectively.

The $2.1 million net value of Triferic inventory consisted of $0.4 million of Dialysate Triferic finished goods sellable through 2020, and $1.7 million of Triferic API with estimated useful lives extending through 2023.

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements
(Unaudited)

7. Property and Equipment

As of March 31, 2019 and December 31 2018, the Company's property and equipment consisted of the following:

	March 31, 2019	December 31, 2018
Leasehold Improvements	$ 1,040,890	$ 929,849
Machinery and Equipment	4,723,090	4,800,774
Information Technology & Office Equipment	1,664,568	2,459,832
Laboratory Equipment	668,977	668,977
	8,097,525	8,859,432
Accumulated Depreciation	(5,524,845)	(6,221,139)
Net Property and Equipment	$ 2,572,680	$ 2,638,293

Depreciation expense for the three months ended March 31, 2019 and 2018, totaled $0.2 million and $0.1 million.

8. Accrued Liabilities

Accrued liabilities as of March 31, 2019 and December 31, 2018 consisted of the following:

	March 31, 2019	December 31, 2018
Accrued Research & Development Expense	$ 99,259	$ 86,820
Accrued Compensation and Benefits	1,810,456	1,525,599
Accrued Legal Expenses	1,054,924	170,334
Accrued Marketing Expenses	771,656	5,000
Other Accrued Liabilities	2,535,745	3,342,008
Total Accrued Liabilities	$ 6,272,040	$ 5,129,761

9. Deferred Revenue

In October of 2014, the Company entered into a 10 year distribution agreement with Baxter and received an upfront fee of $20 million. The upfront fee was recorded as deferred revenue and is being recognized based on the proportion of product shipments to Baxter in each period, compared with total expected sales volume over the term of the Distribution Agreement. The Company recognized revenue of approximately $0.5 million during the three months ended March 31, 2019 and 2018, respectively. Deferred revenue related to the Baxter agreement totaled $10.6 million as of March 31, 2019 and $11.1 million as of December 31, 2018.

If a "Refund Trigger Event" occurs, we would be obligated to repay a portion of the upfront fee and any paid portion of the facility fee. In the event of a Refund Trigger Event occurring from January 1, 2019 to December 31, 2021, Baxter would be eligible for a 25% refund of the Agreement's Upfront Payment. In addition, if Baxter terminates the Distribution Agreement because Baxter has been enjoined by a court of competent jurisdiction from selling in the United States any product covered by the Distribution Agreement due to a claim of intellectual property infringement or misappropriation relating to such product prior to the end of 2019, Baxter would be eligible for a partial refund of $6.6 million. In no event would more than one refund be required to be paid.

During the year ended December 31, 2016, the Company entered into a distribution agreement with Wanbang and received an upfront fee of $4.0 million. The upfront fee was recorded as deferred revenue and is being recognized as revenue based on the agreement term. The Company recognized revenue of approximately $0.1 million during the three months ended March 31, 2019 and 2018. Deferred revenue related to the Wanbang agreement totaled $3.1 million as of March 31, 2019 and $3.2 million as of December 31, 2018.

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10. Shareholders' Equity

Preferred Stock

As of March 31, 2019 and December 31, 2018, there were 2,000,000 shares of preferred stock authorized and no shares of preferred stock issued or outstanding.

Common Stock

During the three months ended March 31, 2019, 30,000 vested employee stock options were exercised for cash proceeds of $147,900, at a weighted average exercise price of $4.93.

Controlled Equity Offering

On March 22, 2019, the Company entered into a sales agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. (the "Agent"), pursuant to which the Company may offer and sell from time to time shares of the Company's common stock, no par value, through the Agent. The offering and sale of up to $40,000,000 of the shares has been registered under the Securities Act of 1933, as amended, pursuant to the Company's registration statement on Form S-3 (File No. 333-227363), which was originally filed with the SEC on September 14, 2018 and declared effective by the SEC on October 1, 2018. The base prospectus contained within the registration statement, and a prospectus supplement that was filed with the SEC on March 22, 2019.

Sales of the shares, if any, pursuant to the Sales Agreement, may be made in sales deemed to be a "at the market offering" as defined in Rule 415 (a)(14) of the Securities Act, including sales made directly through the Nasdaq Global Market or on any other existing trading market for the Company's common stock. The Company intends to use the proceeds from the offering for working capital and other general corporate purposes. The Company may suspend or terminate the Sales Agreement at any time.

During the three months ended March 31, 2019, the Company did not sell any shares of common stock under the Sales Agreement. As of March 31, 2019, $40 million of common stock remained available to be sold under this facility.

Subsequent to March 31, 2019, the Company sold 437,043 shares of its common stock for gross proceeds of $2,296,235, at a weighted average selling price of approximately $5.25. The Company paid $57,406 in commissions related to the sale of the common shares.

Restricted Common Stock

During the three months ended March 31, 2019, 98,500 shares of common stock related to fully vested restricted stock units were delivered to an officer of the Company. The Company withheld 34,327 of these common shares at a fair value of $95,429 to cover the officer's withholding taxes related to the vesting of restricted stock units.

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11. Stock-Based Compensation

The Company recognized total stock-based compensation expense during the three months ended March 31, 2019 and 2018 as follows:

	Three Months Ended March 31,	
	2019	2018
Service based awards:		
Restricted stock awards	$ -	$ 240,827
Restricted stock units	344,351	-
Stock option awards	652,024	205,176
	996,375	446,003
Performance based awards:		
Restricted stock units	398,388	-
Stock option awards	122,539	-
	520,927	-
Total	$ 1,517,302	$ 446,003

Restricted Stock

A summary of the Company's restricted stock awards during the three months ended March 31, 2019 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at December 31, 2018	146,800	$ 5.70
Unvested at March 31, 2019	146,800	$ 5.70

A summary of the Company's restricted stock awards during the three months ended March 31, 2018 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at December 31, 2017	480,000	$ 7.27
Unvested at March 31, 2018	480,000	$ 7.27

The fair value of restricted stock awards are measured based on their fair value on the date of grant and amortized over the vesting period of 20 months. As of March 31, 2019 unvested restricted stock awards of 146,800 were related to performance based awards.

Service Based Restricted Stock Units

A summary of the Company's service based restricted stock units during the three months ended March 31, 2019 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at December 31, 2018	472,959	$ 4.32
Unvested at March 31, 2019	472,959	$ 4.32

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The fair value of service based restricted stock units are measured based on their fair value on the date of grant and amortized over the vesting period. The vesting periods range from 1-3 years. Stock-based compensation expense of $0.3 million was recognized during the three months ended March 31, 2019. No stock-based compensation was recognized during the three months ended March 31, 2018, since there were no service based restricted stock units granted during that period. As of March 31, 2019, the unrecognized stock-based compensation expense was $1.3 million.

Performance Based Restricted Stock Units

A summary of the Company's performance based restricted stock units during the three months ended March 31, 2019 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at December 31, 2018	988,958	$ 4.48
Unvested at March 31, 2019	988,958	$ 4.48

Stock-based compensation expense recognized for performance based restricted stock units was $0.4 million during the three months ended March 31, 2019. No stock-based compensation was recognized during the three months ended March 31, 2018, since there were no performance based restricted stock units granted during that period. As of March 31, 2019, the unrecognized stock-based compensation expense related to performance restricted stock units was $2.3 million.

Service Based Stock Options

The fair value of the service based stock options granted for the three months ended March 31, 2019 were based on the following assumptions:

	March 31, 2019
Exercise price	$3.08 - $6.21
Expected stock price volatility	67.5% - 68.4%
Risk-free interest rate	2.5% - 2.6%
Term (years)	5.5 -6.5

A summary of the Company's service based stock option activity for the three months ended March 31, 2019 is as follows:

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2018	7,856,480	$ 7.50	5.2	$ -
Granted	75,000	$ 3.49	9.8	
Exercised	(30,000)	$ 4.93	-	
Outstanding at March 31, 2019	7,901,480	$ 7.47	5.0	$ 1,959,736
Exercisable at March 31, 2019	6,707,693	$ 8.05	4.2	$ 206,872

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A summary of the Company's service based stock option activity for the three months ended March 31, 2018 is as follows:

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2017	6,906,001	$ 7.92	5.1	$ 976,335
Forfeited	(25,000)	$ 8.23	-	
Outstanding at March 31, 2018	6,881,001	$ 7.92	4.8	$ -
Exercisable at March 31, 2018	6,323,160	$ 7.90	4.5	$ 738,740

The aggregate intrinsic value in the table above is calculated as the difference between the closing price of our common stock and the exercise price of the stock options that had strike prices below the closing price.

During the three months ended March 31, 2019, the Company granted to certain employees stock options to purchase up to 75,000 shares of common stock. The vested options were exercisable at an average price of $8.05 per share and the unvested options were exercisable at an average of $4.23 per share.

As of March 31, 2019 and 2018, stock-based compensation expense of $0.7 million and $0.2 million was recognized, respectively. As of March 31, 2019, total stock-based compensation expense related to unvested options not yet recognized totaled approximately $2.2 million.

Performance Based Stock Options

A summary of the performance based stock options for the three months ended March 31, 2019, is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2018	388,125	$ 4.70
Outstanding at March 31, 2019	388,125	$ 4.70
Exercisable at March 31, 2019	-	$ -

Stock-based compensation expense recognized for performance based stock options was $0.1 million during the three months ended March 31, 2019. No stock-based compensation was recognized during the three months ended March 31, 2018, since there were no performance based stock options granted during that period. As of March 31, 2019, the unrecognized stock-based compensation expense related to performance based stock options was $0.8 million.

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12. Related Party Transactions

Product License Agreements

The Company is a party to an in-license agreement for exclusive worldwide rights to certain patents and information related to our Triferic® product. On October 7, 2018, the Company entered into a Master Services and IP Agreement (the "Charak MSA") with Charak, LLC and Dr. Ajay Gupta (collectively "Charak"), who serves as Executive Vice President and Chief Scientific Officer of the Company. Pursuant to the MSA, the parties entered into three additional agreements described below related to the license of certain soluble ferric pyrophosphate ("SFP") intellectual property owned by Charak, as well as the Employment Agreement (defined below). The Charak MSA provides for a payment of $1.0 million to Dr. Gupta, payable in four quarterly installments of $250,000 each on October 15, 2018, January 15, 2019, April 15, 2019 and July 15, 2019, and reimbursement for certain legal fees incurred in connection with the Charak MSA. The Company recorded $1.1 million as Research and Development Expense – License Acquired (Related Party) for the twelve months ended December 31, 2018. As of March 31, 2019, the Company paid two of the quarterly installments totaling $500,000 and accrued $100,000 for the reimbursement of certain legal expenses. As of March 31, 2019 and December 31, 2018, the Company accrued $600,000 and $850,000, respectively, as a related party payable on the condensed consolidated balance sheet.

Pursuant to the Charak MSA, the aforementioned parties entered into an Amendment, dated as of October 7, 2018 (the "Charak Amendment"), to the Licensing Agreement between the Company and Charak, dated January 7, 2002, as amended (the "2002 Agreement"), under which Charak granted the Company an exclusive, worldwide, non-transferable license to commercialize SFP for the treatment of patients with renal failure. The Charak Amendment amends the royalty payments due to Charak under the 2002 Agreement such that the Company is liable to pay Charak royalties on net sales by the Company of products developed under the license, which includes the Company's Triferic® product, at a specified rate until December 31, 2021 and thereafter at a reduced rate from January 1, 2022 until February 1, 2034. Additionally, the Company shall pay Charak a percentage of any sublicense income during the term of the agreement, which amount shall not be less than a minimum specified percentage of net sales of the licensed products by the sublicensee in jurisdictions where there exists a valid claim, on a country-by-country basis, and be no less than a lower rate of the net sales of the licensed products by the sublicensee in jurisdictions where there exists no valid claim, on a country-by-country basis.

Also pursuant to the Charak MSA, the Company and Charak entered into a Commercialization and Technology License Agreement IV Triferic®, dated as of October 7, 2018 (the "IV Agreement"), under which Charak granted the Company an exclusive, sublicensable, royalty-bearing license to SFP for the purpose of commercializing certain intravenous-delivered products incorporating SFP for the treatment of iron disorders worldwide for a term that expires on the later of February 1, 2034 or upon the expiration or termination of a valid claim of a licensed patent. The Company is liable to pay Charak royalties on net sales by the Company of products developed under the license at a specified rate until December 31, 2021. From January 1, 2022 until February 1, 2034, the Company is liable to pay Charak a base royalty at a reduced rate on net sales and an additional royalty on net sales while there exists a valid claim of a licensed patent, on a country-by-country basis. The Company shall also pay to Charak a percentage of any sublicense income received during the term of the IV Agreement, which amount shall not be less than a minimum specified percentage of net sales of the licensed products by the sublicensee in jurisdictions where there exists a valid claim, on a country-by-country basis, and not be less than a lower rate of the net sales of the licensed products by the sublicensee in jurisdictions where there exists no valid claim, on a country-by-country basis.

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Also pursuant to the Charak MSA, the Company and Charak entered into a Technology License Agreement TPN Triferic®, dated as of October 7, 2018 (the "TPN Agreement"), pursuant to which Charak granted the Company an exclusive, sublicensable, royalty-bearing license to SFP for the purpose of commercializing worldwide certain parenteral nutritional (TPN") products incorporating SFP. The license grant under the TPN Agreement continues for a term that expires on the later of February 1, 2034 or upon the expiration or termination of a valid claim of a licensed patent. During the term of the TPN Agreement, the Company is liable to pay Charak a base royalty on net sales and an additional royalty on net sales while there exists a valid claim of a licensed patent, on a country-by-country basis. The Company shall also pay to Charak a percentage of any sublicense income received during the term of the TPN Agreement, which amount shall not be less than a minimum royalty on net sales of the licensed products by the sublicensee in jurisdictions where there exists a valid claim, on a country-by-country basis, and not be less than a lower rate of the net sales of the licensed products by the sublicensee in jurisdictions where there exists no valid claim, on a country-by-country basis.

The transaction was accounted for as an asset acquisition pursuant to ASU 2017-01, *Business Combinations (Topic 805), Clarifying the Definition of a Business,* as the majority of the fair value of the assets acquired was concentrated in a group of similar assets, and the acquired assets did not have outputs or employees. The assets acquired under the MSA include a license of SFP. Because SFP has not yet received regulatory approval, the $1.1 million purchase price paid and accrued for these assets has been expensed in the Company's statement of operations for the year ended December 31, 2018. In addition, the potential milestone payments are not yet considered probable, and no milestone payments have been accrued at March 31, 2019.

13. Leases

We lease our production facilities and administrative offices as well as certain equipment used in our operations including leases on transportation equipment used in the delivery of our products. The lease terms range from monthly to seven years. We occupy a 51,000 square foot facility and a 17,500 square foot facility in Wixom, Michigan under a lease expiring in August 2021. We also occupy two other manufacturing facilities, a 51,000 square foot facility in Grapevine, Texas under a lease expiring in December 2020, and a 57,000 square foot facility in Greer, South Carolina under a lease expiring February 2020. In addition, we occupy a 1,408 square foot office space in Greer, South Carolina under a lease expiring April 2021 and on December 28, 2018 we executed a lease for 4,100 square feet of office space in Hackensack, New Jersey with a lease term commencing in June 2019 and expiring on July 1, 2024.

At March 31, 2019, the Company had operating lease liabilities of $3.0 million and right of use assets of $3.0 million, which are included in the consolidated balance sheet.

The following summarizes quantitative information about the Company's operating leases:

	Three Months Ended March 31, 2019
Operating leases	
Operating lease cost	$ 534,967
Variable lease cost	89,844
Operating lease expense	624,811
Short-term lease rent expense	4,192
Total rent expense	$ 629,003
Other information	
Operating cash flows from operating leases	$ 523,965
Right of use assets exchanged for operating lease liabilities	$ 3,484,234
Weighted-average remaining lease term – operating leases	1.6 years
Weighted-average discount rate – operating leases	6.8%

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Future minimum rental payments under operating lease agreements are as follows:

Nine months ended December 31, 2019	$ 1,398,078
Year ending December 31, 2020	1,186,720
Year ending December 31, 2021	562,506
Year ending December 31, 2022	96,006
Year ending December 31, 2023	3,440
Total	$ 3,246,750
Less present value discount	(229,956)
Operating lease liabilities	$ 3,016,794

Note 14. Commitments and Contingencies

Litigation

SEC Investigation

As a follow up to certain prior inquiries, the Company received a subpoena from the SEC during the Company's quarter ended September 30, 2018 requesting, among other things, certain information and documents relating to the status of the Company's request to CMS for separate reimbursement status for Dialysate Triferic, the Company's reserving methodology for expiring Triferic inventory, and the basis for the Board's termination of the former CEO and CFO. The Company is cooperating with the SEC and is responding to the SEC's requests for documents and information.

Shareholder Class Action Lawsuits

On July 27, 2018, Plaintiff Ah Kit Too filed a putative class action lawsuit in the United States District Court in the Eastern District of New York against the Company and former officers, Robert Chioini and Thomas Klema. The complaint is a federal securities class action purportedly brought on behalf of a class consisting of all persons and entities, other than Defendants, who purchased or otherwise acquired the publicly traded securities of the Company between March 16, 2018 and June 26, 2018. The Complaint alleges that the Company and Messrs. Chioini and Klema violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"). Specifically, the Complaint alleges that defendants filed reports with the Securities and Exchange Commission that contained purported inaccurate and misleading statements regarding the potential for the Company's drug, Triferic, to quality for separate reimbursement status by the Centers for Medicare and Medicaid Services.

On September 4, 2018, Plaintiff Robert Spock filed a similar putative class action lawsuit in the United States District Court in the Eastern District of New York against the Company and Messrs. Chioini and Klema. The *Spock* complaint is a federal securities class action purportedly brought on behalf of a class consisting of persons who purchased the Company's securities between November 8, 2017 and June 26, 2018. This complaint alleges that the Company and Messrs. Chioini and Klema violated the Exchange Act in that the Company was aware the Centers for Medicare and Medicaid Services would not pursue the Company's proposal for separate reimbursement for Triferic; misstated reserves in the Company's quarterly report for the first quarter of 2018; had a material weakness its internal controls over financial reporting, which rendered those controls ineffective; Mr. Chioini withheld material information regarding Triferic from the Company's auditor, corporate counsel, and independent directors of the Board; and, as a result of these alleged issues, statements about the Company's business were materially false and misleading.

On September 25, 2018, four Company stockholders filed motions to appoint lead plaintiffs, lead counsel, and to consolidate the *Ah Kit Too v. Rockwell* securities class action with the *Spock v. Rockwell* securities class action. On October 10, 2018, the court issued an order consolidating the two actions, appointing co-lead plaintiffs and co-lead counsel. On December 10, 2018, lead Plaintiffs filed a consolidated amended complaint, which included the same allegations as the initial complaints and asserted claims on behalf of a putative class consisting of person who purchased the Company's securities between November 8, 2017 and June 26, 2018. On February 18, 2019, the Company answered

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the consolidated amended complaint. The lawsuits seek damages allegedly sustained by the class and an award of plaintiffs' costs and attorney fees. The case is at an early stage with no significant pre-trial proceedings (such, as substantive motions or discovery) having occurred. The Company believes it has defenses to the claims of liability and damages and is responding accordingly.

On April 23, 2019, Plaintiff Bill Le Clair filed a verified stockholder derivative complaint in the United States District Court in the Easter District of New York, purportedly on behalf of nominal defendant Rockwell and against certain of its current and former directors (the "Individual Defendants"). The Complaint asserts causes of actions against the Individual Defendants for breach of fiduciary duty, waste of corporate assets, and unjust enrichment. The Complaint alleges the Individual Defendants breached duties by, among other things, permitting alleged misstatements to be made in public filings regarding the status of separate reimbursement for Triferic from CMS, the adequacy of Rockwell's reserves, and the adequacy of Rockwell's internal controls. The case is at an early stage, and the Company anticipates filing a motion to dismiss the action.

The Company has tendered the class action and derivative action to its D&O insurance carrier(s) for defense and indemnity under its applicable insurance policies. The Company maintains a $1.0 million self-insured retention under the applicable insurance policies, which can be exhausted by payment of expenses or indemnity.

The Company also has received requests from shareholders to investigate issues relating in part to allegations raised in the securities and derivative lawsuits. The Audit Committee of the Board of Directors engaged independent counsel to investigate these issues. The investigation concluded among other things that there was no merit to the claims raised in the shareholder requests and the investigation has been concluded.

Note 15. Subsequent Events

In April 2019, we entered into an agreement with a contract research organization for the conduct of a pediatric clinical trial for Triferic.

On May 6, 2019, the Company announced the commencement of commercial sales of Dialysate Triferic in the United States. The Company does not expect material sales of Dialysate Triferic in the second quarter of 2019.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with our condensed consolidated financial statements and related notes in "Item 1. Condensed Consolidated Financial Statements". References in this report to the "Company," "we," "our" and "us" are references to Rockwell Medical, Inc. and its subsidiaries.

Forward-Looking Statements

We make forward-looking statements in this report and may make such statements in future filings with the Securities and Exchange Commission, or SEC. We may also make forward-looking statements in our press releases or other public or shareholder communications. Our forward-looking statements are subject to risks and uncertainties and include information about our expectations and possible or assumed future results of our operations. When we use words such as "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "could," "plan," "potential," "predict," "forecast," "project," "intend," or similar expressions, or make statements regarding our intent, belief, or current expectations, we are making forward-looking statements. Our forward looking statements also include, without limitation, statements about our liquidity and capital resources; our plans relating to the commercialization of our products; our timing and ability to obtain add-on reimbursement for our products; our ability to obtain FDA and EMA approval for IV Triferic; whether we can successfully execute on our business strategy; and statements regarding our anticipated future financial condition, operating results, cash flows and business plans.

While we believe that our forward-looking statements are reasonable, you should not place undue reliance on any such forward-looking statements, which are based on information available to us on the date of this report or, if made elsewhere, as of the date made. Because these forward-looking statements are based on estimates and assumptions that are subject to significant business, economic and competitive uncertainties, many of which are beyond our control or are subject to change, actual results could be materially different. Factors that might cause such a difference include, without limitation, the risks and uncertainties discussed in this report, "Item 1A — Risk Factors" in our Form 10-K for the year ended December 31, 2018 and from time to time in our other reports filed with the SEC, including in this Form 10-Q.

Other factors not currently anticipated may also materially and adversely affect our results of operations, cash flow and financial position. There can be no assurance that future results will meet expectations. Forward-looking statements speak only as of the date of this report and we expressly disclaim any intent to update or alter any statements whether as a result of new information, future events or otherwise, except as may be required by applicable law.

Overview and Recent Developments

We are a specialty pharmaceutical company targeting end-stage renal disease and chronic kidney disease with products for the treatment of iron deficiency and hemodialysis. We are also a manufacturer of hemodialysis concentrates/dialysates to dialysis providers and distributors in the United States and abroad. We supply approximately 25% of the United States domestic market with dialysis concentrates and we also supply dialysis concentrates to distributors serving a number of foreign countries, primarily in the Americas and the Pacific Rim. To date, substantially all of our sales have been concentrate products and related ancillary items.

Our business strategy is developing unique, proprietary renal drug therapies that we can commercialize or out-license, while also expanding our dialysis products business. These renal drug therapies support disease management initiatives to improve the quality of life and care of dialysis patients and are designed to deliver safe and effective therapy, while decreasing drug administration costs and improving patient convenience and outcome.

Triferic

Triferic is the Company's proprietary iron therapy that replaces iron and maintains hemoglobin in dialysis patients without increasing iron stores. The Company has developed Dialysate Triferic (Ferric Pyrophosphate Citrate) as the only FDA approved product indicated to replace iron and maintain hemoglobin concentration in adult HDD-CKD hemodialysis patients, and is in the process of developing and seeking FDA approval for I.V. Triferic, a novel intravenous formulation of Triferic that would be used for the same indication, if approved. A description of Dialysate Triferic and I.V. Triferic is set forth below.

Dialysate Triferic

Our dialysate formulation of Triferic ("Dialysate Triferic") received FDA approval in 2015 and remains the only FDA-approved therapy indicated to replace iron and maintain hemoglobin in adult hemodialysis patients. Dialysate Triferic received a Centers for Medicare & Medicaid Services ("CMS") reimbursement J-code on January 1, 2016, providing that Dialysate Triferic would be reimbursed for administration to dialysis patients within the existing fixed-price "bundle" of payments that CMS provides to dialysis providers. Because Dialysate Triferic reimbursement would be included in this bundled payment, we commenced efforts in early 2016 to seek so-called "add-on" or "separate" reimbursement for Dialysate Triferic, which is sometimes available for certain new, innovative therapies.

Following receipt of the reimbursement J-code in early 2016 until June 2018, the Company's commercialization strategy for Dialysate Triferic was primarily focused on obtaining add-on reimbursement status from CMS for Dialysate Triferic, at which point the Company planned to commence commercializing the drug.

In June 2018, our Board of Directors determined, based on feedback from CMS's Innovation Center ("CMMI"), that Dialysate Triferic was unlikely to obtain add-on reimbursement in the near term. As a result, the Company changed its commercialization strategy to plan for the commercial launch of Dialysate Triferic with initial reimbursement within the bundle of payments to dialysis providers, while continuing to pursue add-on reimbursement, if possible, and while continuing to develop I.V. Triferic (discussed below). As part of our strategy to launch Dialysate Triferic within the bundle, we requested that CMS provide us with a separate J-code for our powder packet formulation of Dialysate Triferic to distinguish it from our liquid formulation of Dialysate Triferic. On April 26, 2019, pursuant to a request we submitted earlier in 2019, we were notified of a preliminary recommendation by CMS to grant our powder packet formulation of Dialysate Triferic a separate J-Code, effective July 1, 2019. On May 6, 2019, we announced the commencement of commercial sales of Dialysate Triferic.

While the Company was pursuing the earlier strategy of delaying commercialization until receipt of add-on reimbursement approval, we built up significant inventory of active pharmaceutical ingredient ("API") and Dialysate Triferic finished goods. However, due to the delays in launching Triferic and taking into account feedback received from CMMI in March 2018 regarding the prospects for near-term approval of add-on reimbursement for Triferic, we increased our inventory reserves for Triferic by a total of $8.1 million during 2018 from $3.5 million as of December 31, 2017 to $11.6 million as of December 31, 2018. For the period ended March 31, 2019 Triferic inventory reserves increased by approximately $11,000. After deducting inventory destroyed or used for samples, as of March 31, 2019 we had $1.8 million of Dialysate Triferic Finished Goods inventory with $1.4 million reserved leaving a net value of $0.4 million. As of March 31, 2019, we also had approximately $3.7 million of Triferic API against we have reserved $2.0 million leaving a net value of $1.7 million. Depending on the timing and success of our commercial launch of Dialysate Triferic in 2019 and the degree of uptake of the drug commercially, additional amounts or all of our current investment in Dialysate Triferic finished goods inventory and some or all of our API inventory may need to be written off in future periods. Additional write-offs of existing Triferic inventory will not have a material negative impact on our cash flow, but could potentially have a material adverse impact on our reported results of operations and financial position.

IV Triferic

We are also developing an intravenous injection of Triferic ("I.V. Triferic") for use by hemodialysis patients in the United States as well as international markets. A clinical equivalence study of I.V. Triferic infusion presentation has been completed and, on the basis of the clinical and non-clinical data prepared by the Company, we intend to submit a New Drug Application ("NDA") seeking FDA approval to market I.V. Triferic in the United States for the clinical indication of replacing iron and maintaining hemoglobin in adult hemodialysis patients, with an expected submission in the second quarter of 2019.

The November 2018 CMS Guidance provided interpretative guidance regarding the CMS Transitional Drug Add On Pricing Adjustment ("TDAPA") program and its potential application to I.V. Triferic. Based on the CMS Guidance, the Company believes that, if approved by the FDA on or after January 1, 2020, I.V. Triferic may be eligible for separate sole source payment with a separate 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 we expect I.V. Triferic would likely be priced inside the bundle. Upon submission of the NDA, we will be required to pay a filing fee to the FDA of approximately $1.3 million.

While we intend to market and sell Dialysate Triferic and I.V. Triferic directly in the United States, our international strategy is to partner with and license these products to established companies in other regions of the world to assist in the further development (primarily clinical trials and regulatory activities), if necessary, and commercialize in those regions. We continue to pursue international licensing opportunities in a number of countries and specific regions.

Dialysis Concentrates

We manufacture, sell, deliver and distribute hemodialysis concentrates, along with a line of ancillary dialysis products abroad. We use Baxter as our exclusive marketer and distributor in the United States and in select foreign markets. Dialysate concentrates accounted for approximately 97% of our revenues for the three months ended March 31, 2019, with ancillary products accounting for most of the remainder. We receive a pre-defined gross profit margin on our concentrate products sold pursuant to the Baxter Agreement, subject to an annual true-up of costs.

Calcitriol (Active Vitamin D) Injection

Calcitriol, an active Vitamin D injection for the management of hypocalcemia in patients undergoing chronic hemodialysis, is FDA approved under an Abbreviated New Drug Application. To date, we have not commercially launched Calcitriol. Following a strategic review of this product, including pricing, commercial distribution and marketing, manufacturing efficiencies and capacity (including potential capital investment), we have determined commercialization of Calcitriol in the U.S. would not be viable at this time. The decision was based, in part, on the fact that prevailing market prices for similar Vitamin D products are lower than our cost to produce Calcitriol on a dose-equivalent basis, and as a result it would be difficult for us to market Calcitriol profitably. As a result of this decision, we recorded an inventory reserve reflecting the remainder of our Calcitriol inventory. As of December 31, 2018 and March 31, 2019, this reserve totaled $0.7 million.

Clinical Development

Although Dialysate Triferic is approved for commercial sale in the United States, it is not approved for sale in other major markets globally. We have received regulatory guidance from the European Medicines Agency ("EMA") regarding the clinical studies that are needed to file for approval of I.V. Triferic in Europe. At the present time, we do not intend to commence these clinical studies, absent finding a development partner in Europe or raising additional capital. In conjunction with our licensee in the People's Republic of China, Wanbang Biopharmaceutical, two clinical pharmacology studies have been initiated and are expected to be completed during 2019. Pursuant to our license agreement with Wanbang, we are entitled to up to $35 million of regulatory and sales-based milestones, including an $8 million milestone payment upon regulatory approval of Triferic in China, and a royalty on net sales in the low-to-mid 20% range.

As a post-approval requirement under the Pediatric Research Equity Act, we are required to conduct a further clinical study of the effectiveness of Triferic in a pediatric patient population. We have reached agreement with the FDA on the design of this study, which we intend to commence in 2019, assuming we have the liquidity and capital resources to do so. We expect that the data from this study could be used as part of the overall clinical data package to support approval by the EMA, if and when we are able to complete the other clinical trials needed to support making such a filing.

Additionally, we believe that Dialysate Triferic and I.V. Triferic have potential to be developed for use in other iron deficiency anemia indications, as well as other product presentations and other clinical applications, including peritoneal dialysis and total parenteral nutrition.

Results of Operations for the three months ended March 31, 2019 and 2018

Net Sales

During the three months ended March 31, 2019, our net sales were $15.6 million compared to sales of $14.9 million during the three months ended March 31, 2018. The increase of $0.6 million was primarily due to higher domestic dialysis concentrate sales to Baxter of approximately $0.4 million and an increase in international sales of approximately $0.2

million compared to the three months ended March 31, 2018. Revenue recognized from licensing fees was $0.6 million for each of the three months ended March 31, 2019 and 2018.

Gross Profit (Loss)

Cost of sales during the three months ended March 31, 2019 was $14.6 million, resulting in gross profit of $1.0 million during the three months ended March 31, 2019, compared to cost of sales of a $15.7 million and a gross loss of $0.7 million during the three months ended March 31, 2018. Gross profit increased by $1.7 million in the first quarter of 2019 compared to the first quarter of 2018, due primarily to a non-cash charge taken for an inventory reserve for Triferic of $2.2 million for the three months ended March 31, 2018, partially offset by a gross profit decrease of $0.7 million in our dialysis concentrates products. The decrease in gross profit for our dialysis concentrates products was primarily attributable to increased labor, materials and overhead costs, partially offset by increased net sales.

Selling and Marketing Expense

Selling and Marketing Expenses were $3.1 million during the three months ended March 31, 2019 compared with $0.2 million during the three months ended March 31, 2018. The increase of $2.9 million is primarily due to $2.1 million in marketing costs to prepare for the commercial launch of Triferic and $1.0 million in headcount-related costs.

General and Administrative Expense

General and administrative expenses were $6.2 million during the three months ended March 31, 2019 compared with $3.1 million during the three months ended March 31, 2018. The $3.1 million increase was driven primarily by increases to stock compensation, headcount-related expenses, annual reporting and consulting fees. The increase in stock compensation and headcount-related expenses was due primarily to the reversal of certain accruals during the three months ending March 31, 2018, including $0.7 million for stock compensation and $1.0 million for discretionary bonus accrual.

Research and Product Development Expense

Research and product development expenses were $0.5 million for the three months ended March 31, 2019 compared with $1.7 million during the three months ended March 31, 2018. The decrease was due primarily to a reduction in clinical trial and other product development costs. Research and development expenses for the three months ended March 31, 2019 included clinical trials and other product development expenses of $0.5 million for Triferic and $0.0 million for Calcitriol, compared to $1.3 million and $0.4 million, respectively, during the three months ended March 31, 2018. For the three months ended March 31, 2019, research and development expenses included medical, scientific and technical staffing costs and consulting expenses. We expect our research and product development expenses to increase in the future due to additional clinical development of Dialysate and I.V. Triferic, including the conduct of the pediatric clinical trial described above, and an increase in headcount to support medical education efforts for Triferic.

Other Income, Net

Other income for the three months ended March 31, 2019 was $0.1 million, consisting primarily of interest income. Other income for the three months ended March 31, 2018 was $0.2 million, consisting primarily of $0.2 million of interest income.

Liquidity and Capital Resources

As of March 31, 2019, we had approximately $27.8 million of cash, cash equivalents and investments available-for-sale, and working capital of $24.5 million. Net cash used in operating activities for the three months ended March 31, 2019 was approximately $5.4 million. On March 22, 2019, the Company entered into a sales agreement with Cantor Fitzgerald & Co. (the “Agent”), pursuant to which the Company may offer and sell from time to time shares of the Company’s common stock, no par value, through the Agent up to $40,000,000. We are not required to sell any shares at any time during the term of the facility. Our ability to sell common stock under the facility may be limited by several factors, including, among other things, the trading volume of our common stock and certain black-out periods that we may impose upon the facility, among other things.

The Company will require significant additional capital to sustain its operations and make the investments it needs to execute upon its longer-term business plan. The Company's existing liquidity is not sufficient to fund its operations and anticipated capital expenditures within the next 12 months. The Company intends to seek additional equity or debt financing; however, there are currently no commitments in place for further financing nor is there any assurance that such financing will be available to the Company on favorable terms, if at all.

The Company's recurring operating losses, net operating cash flow deficits, and an accumulated deficit, raise substantial doubt about the Company's ability to continue as a going concern for one year from the issuance of the accompanying consolidated financial statements. The consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company has not made any adjustments to the accompanying consolidated financial statements related to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

General

The actual amount of cash that we will need to execute our business strategy is subject to many factors, including, but not limited to, the expenses and revenue associated with the commercial launch of Dialysate Triferic and I.V. Triferic, if approved, in the United States; the timing and magnitude of cash received from drug product sales; and the timing and expenditures associated with the development of Triferic for international markets; and the costs associated with ongoing litigation and investigatory matters.

We may elect to raise capital in the future through one or more of the following: (i) equity and debt raises through the equity and capital markets, though there can be no assurance that we will be able to secure additional capital or funding on acceptable terms, of if at all; and (ii) strategic transactions, including potential alliances and collaborations focused on markets outside the U.S., as well as potential combinations (including by merger or acquisition) or other corporate transactions. In particular, our Baxter Agreement prohibits us from entering into a contract that would encumber the assets used in our concentrate business without the prior written consent of Baxter. Due to the fact that the assets used in our concentrate business currently constitute a substantial portion of the tangible assets we own other than our drug inventory, we may not be able to, or we may find it difficult, to obtain secured debt financing without the consent of Baxter.

We believe that our ability to fund our activities in the long term will be highly dependent upon our ability to successfully launch Dialysate Triferic and to obtain regulatory approval for, and successfully launch, I.V. Triferic. Our commercialization of Dialysate Triferic and I.V. Triferic (if approved) is subject to significant risks and uncertainties, including risks we will be successful in the commercialization of Triferic in accordance with our plans. If our commercialization of Dialysate Triferic and/or I.V. Triferic should be delayed for any reason or not proceed in accordance with our plans, we may be forced to implement cost-saving measures that may potentially have a negative impact on our activities and potentially the results of our research and development programs. Even if we launch Dialysate Triferic as planned, if the results are unsuccessful or our commercial launch does not proceed as planned, we may be unable to secure the additional capital that we will require to continue our research and development activities and operations, which could have a material adverse effect on our business. If we are unable to raise the required capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to raise sufficient capital, such financings may only be available on unattractive terms, or result in significant dilution of shareholders' interests and, in such event, the market price of our common stock may decline.

Cash Used in Operating Activities

Net cash used in operating activities was $5.4 million for the three months ended March 31, 2019. The net loss for this period was higher than net cash used in operating activities by $3.3 million, which was primarily attributable to non-cash expenses of $2.2 million, consisting primarily of $1.5 million of stock-based compensation, $0.5 million of amortization of the right to use assets, $0.2 million of depreciation and amortization, and $1.1 million net change in assets and liabilities.

Net cash used in operating activities was $4.6 million for the three months ended March 31, 2018, which included $2.6 million in non-cash expenses primarily attributable to $2.0 million increase in inventory reserves and $0.4 million of stock-based compensation. We used $1.7 million for research and development expenses and a settlement payment to an activist group of $0.4 million was paid in the first quarter of 2018.

Cash Provided by Investing Activities

Net cash provided by investing activities was $3.6 million during the three months ended March 31, 2019. The net cash provided was primarily due to the sale of our available-for-sale investments of $12.8 million, offset by $8.8 million used for the purchase of investments available-for-sale, $0.1 million for the purchase of equipment and $0.3 million for the purchase of research and development licenses acquired from a related party.

Net cash used in investing activities was $0.5 million during the three months ended March 31, 2018. The net cash used was primarily due to the sale of our available-for-sale investments of $1.1 million, offset by $1.4 million used for the purchase of investments available-for-sale and $0.2 million for the purchase of equipment.

Cash Used in Financing Activities

Net cash provided by financing activities was $0.1 million during the three months ended March 31, 2019. Additionally, we established an at-the-market offering facility pursuant to which we have the ability to sell from time to time up to $40 million of common stock in at-market transactions.

There were no financing activities during the three months ended March 31, 2018.

Critical Accounting Policies and Significant Judgements and Estimates

Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2018. Our critical accounting policies and significant estimates have not changed from those previously disclosed in our 2018 Annual Report, except for those subjects mentioned in the section of the notes to the condensed consolidated financial statements titled Adoption of Recent Accounting Pronouncements.

Recently issued and adopted accounting pronouncements:

We have evaluated all recently issued accounting pronouncements and believe such pronouncements do not have a material effect our financial statements. See Note 3 of the condensed consolidated financial statements at March 31, 2019.

Item 3.

Not applicable.

Item 4. Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure material information required to be disclosed in our reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required financial disclosure. In designing and evaluating the disclosure controls and procedures, we recognized that a control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision of and with the participation of our management, including the Company's Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of March 31, 2019. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, because of the material weaknesses in our internal controls over financial reporting described in our December 31, 2018 Annual Report, our disclosure controls and procedures were not effective. Notwithstanding the material weaknesses, the Company's management, including the Chief Executive Officer and Chief Financial Officer, have concluded that the condensed consolidated financial statements as of

March 31, 2019, are fairly stated, in all material respects, in accordance with generally accepting accounting principles in the United States for each of the periods presented herein.

In connection with the material weaknesses, management has taken a number of steps with the intention of remediating the control deficiencies. We continue to implement enhanced procedures and controls to remediate our material weaknesses in internal control over financial reporting.

Changes in Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. We maintain internal control over financial reporting designed to provide reasonable, but not absolute, assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, our management evaluated the effectiveness of our internal control over financial reporting as of March 31, 2019.

We continue to make further improvements to our internal controls over financial reporting, in addition to the improvements developed in 2018. During the quarter ended March 31, 2019 and through the date of this report, we implemented the following:

- Hired an internal audit consultant.
- Developed our preliminary 2019 audit program, which includes an in-house audit of entity level and IT general controls.
- Implemented new programs and policies to provide improved control over the accounting for discretionary bonuses and stock-based compensation.
- Updated our process of obtaining information for calculation of our inventory reserves, including a comprehensive sales and operations planning process.
- Migrated the hosting of our ERP system and performed testing of the system before and after the completion of the migration.
- Preparation of our SEC reporting on form 10-K for the year ended December 31, 2018 and on form 10-Q for the quarter ended March 31, 2019, was completed by our Principal Accounting Officer, supported by internal and external resources.

The remediation of the material weaknesses is among our highest priorities. Our Audit Committee continually assesses the progress and sufficiency of these initiatives and make adjustments as and when necessary. As of the date of this report, our management believes that our efforts, when completed, will remediate the material weaknesses in internal control over financial reporting. However, there can be no assurance that our efforts will result in remediation of the material weaknesses in internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

The disclosure set forth above in Note 14 (*Commitments and Contingencies – Litigation*) to our unaudited condensed consolidated financial statements is incorporated herein by reference.

Additionally, we are involved in certain other legal proceedings from time to time before various courts and governmental agencies. We cannot predict the final disposition of such proceedings. We regularly review legal matters and record provisions for claims that are considered probable of loss. The resolution of these pending proceedings is not

expected to have a material effect on our operations or consolidated financial statements in the period in which they are resolved.

Item 1A. Risk Factors

Other than those set forth below, there have been no material changes to the risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2018 under "Item 1A — Risk Factors".

We may not be successful in commercializing Dialysate Triferic, which will impede our development and growth and may limit our long-term prospects.

In June 2018, we announced plans to commence initial steps to prepare for the commercial launch of ***Dialysate*** Triferic without waiting to receive separate reimbursement status. While we have commenced commercialization of Dialysate Triferic as of the date of the report, we will need to add to our sales and marketing infrastructure in order to successfully launch ***Dialysate*** Triferic. We do not know whether we will be able to successfully implement our commercialization strategy for ***Dialysate*** Triferic or whether our new business strategy will ultimately be successful. Additionally, the initial demand for the product will impact our ability to utilize existing product inventory prior to expiration. If the actual or projected commercial launch is later or slower than currently anticipated, we may need to write off additional inventory reserves, which could result in material accounting charges in future periods. Additionally, the expiration of existing product inventory could limit the total inventory available for commercial sales while we ramp-up commercial production and attempt to manage production in light of anticipated demand.

In assessing our ability to meet these challenges, a potential investor should take into account our recent management turnover, limited cash position, limited sales and marketing personnel and their limited commercialization experience, the competitive conditions existing in our industry and general economic conditions. Our future success is largely dependent on our ability to successfully implement our ***Dialysate*** Triferic commercialization business strategy. Our revenues may be adversely affected if we fail to implement our ***Dialysate*** Triferic commercialization business strategy.

If we are unable to develop and maintain sales, marketing and distribution capabilities to sell and market Dialysate Triferic or any other products we may develop, our product sales may be hindered.

We are in the process of establishing an internal sales organization for the sale, marketing and distribution of Dialysate Triferic, as well as IV Triferic (if approved). In order to successfully commercialize Dialysate Triferic, IV Triferic and any other product we may develop, we must establish and/or increase our sales, marketing, distribution and other non-technical capabilities. The development of a sales organization to market Dialysate Triferic, IV Triferic, or any other product we may develop, is expensive and time-consuming, and we cannot be certain that we will be able to successfully develop this capacity or that this function will execute as expected. If we are unable to establish adequate sales, marketing and distribution capabilities, we may not be able to generate product revenue and our business and results of operations will suffer.

We are and may become the target of additional securities and shareholder litigation, which is costly and time-consuming to defend.

In addition to the purported class action, shareholder derivative action and SEC investigation described in Note 14 "Commitments and Contingencies – Litigation" in the accompanying condensed consolidated financial statements for the quarter ended March 31, 2019, it is possible other legal proceedings could be brought against us in the future. The results of complex legal proceedings are difficult to predict. These lawsuits assert types of claims that, if resolved against us, could give rise to substantial damages, and an unfavorable outcome or settlement of these lawsuits, or any future lawsuits, could have a material adverse effect on our business, financial condition, results of operations and/or stock price. Even if any future lawsuits are not resolved against us, the costs of defending such lawsuits may be material to our business and our operations. Moreover, these lawsuits may divert our Board and our management's attention from the operation of our business. For more information on our legal proceedings, see Note 14 "Commitments and Contingencies – Litigation" in the accompanying condensed consolidated financial statements for the quarter ended March 31, 2019.

We have limited capital resources and will likely need additional funding before we are able to achieve profitability. If we are unable to raise additional capital on attractive terms, or at all, we may be unable to sustain our operations.

We have limited capital resources, a cumulative deficit of approximately $263 million since inception, and expect to incur further losses for the foreseeable future. Although we recently raised $22.0 million in a private placement of equity securities, our ability to sustain our operations is dependent upon generating positive cash flow from commercial operations and/or obtaining additional funding through the sale of debt or equity securities. If we cannot generate sufficient revenues from our operations or obtain funding on attractive terms (if at all) then we may be forced to curtail our operations and limit our growth. Any of these events could have a materially negative impact on our stock price and our long-term prospects.

Because we may be unable to complete our development, manufacturing and commercialization of our products, we could face significant harm to our business plans, prospects, results of operations, financial condition and liquidity.

Commercializing Dialysate Triferic and Calcitriol depends on a number of factors, including but not limited to:

- further product and manufacturing process development;
- completion, refinement and management of our supply chain;
- regulatory requirements for clinical information;
- completion, refinement, and management of our distribution channels;
- demonstration of efficiencies that will make our products attractively priced; and
- development of an adequate sales force and sales channels necessary to distribute our products and achieve
- our desired revenue goals.

We cannot commercialize IV Triferic unless and until we receive FDA approval of our planned NDA submission for this drug. Even if the FDA approves IV Triferic for commercialization, the degree of success in commercializing this drug will depend significantly on our ability to receive add-on reimbursement status, such as through the TDAPA program. If IV Triferic is not considered by CMS to qualify as a new drug (i.e., in light of the prior approval of Dialysate Triferic), then we may be deemed ineligible to participate in the TDAPA program, in which case IV Triferic may also be required to be sold within the bundled payment for dialysis treatment. This would significantly limit the overall commercial opportunity in the United States for IV Triferic.

We cannot assure investors that the strategies we intend to employ will enable us to support the manufacture, distribution and selling of Dialysate Triferic, Calcitriol or IV Triferic (if approved). If we are unable to implement the necessary steps of our business plan, our prospects, results of operations and financial condition will suffer.

The restatement of our previously issued financial statements contained in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 may lead to additional risks and uncertainties, including regulatory, shareholder or other actions, loss of investor confidence and negative impacts on our stock price.

Our Audit Committee, after consultation with management and discussing with outside counsel, external auditors and third-party consultants, concluded on August 12, 2018 that our previously issued consolidated financial statements for the quarter ended March 31, 2018 should be restated for the reasons described in "Explanatory Note" preceding Part I, Item 1 and *Note 3 - Restatement of Unaudited Condensed Consolidated Financial Statements* of the Notes to Consolidated Financial Statements in Part I, Item 1 of the amended Form 10-Q for the quarter ended March 31, 2018. Our amended Form 10-Q for the quarter ended March 31, 2018 includes restated unaudited financial statements and selected financial data (and related disclosures). Financial information included in our previously filed Form 10-Q for the quarter ended March 31, 2018, and all earnings press release and similar communications issued by us, for the period, should not be relied upon and are superseded in their entirety by our amended Form 10-Q for the quarter ended March 31, 2018. The

amended Form 10-Q for the quarter ended March 31, 2018 amends and restates, in its entirety, our Form 10-Q for the quarter ended March 31, 2018.

As a result of this restatement and associated non-reliance on previously issued financial information, we have become subject to a number of additional costs and risks, including unanticipated costs for accounting and legal fees in connection with or related to the restatement and the remediation of our ineffective disclosure controls and procedures and material weakness in internal control over financial reporting. Likewise, the attention of our Board and our management team has been diverted by these efforts. In addition, we could also be subject to additional shareholder, governmental, regulatory or other actions or demands in connection with the restatement or other matters. Any such proceedings will, regardless of the outcome, consume a significant amount of the Board's and management's time and attention and may result in additional legal, accounting, insurance and other costs. If we do not prevail in any such proceedings, we could be required to pay damages or settlement costs. In addition, the restatement and related matters could impair our reputation or could cause our customers, shareholders, or other counterparties to lose confidence in us. Any of these occurrences could have a material adverse effect on our business, results of operations, financial condition and stock price.

Our plan to remediate the identified material weaknesses in our internal control over financial reporting and the restatement of our previously issued financial statements contained in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 may not be sufficient to correct all material weaknesses and deficiencies.

On June 22, 2018, we announced the resignation of our registered independent public accounting firm, Plante & Moran, PLLC ("Plante"). Plante's reports on the Company's financial statements for the years ended December 31, 2016 and December 31, 2017 did not contain an adverse opinion or a disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope, or accounting principles and during the two most recent years ended December 31, 2016 and December 31, 2017 and through June 22, 2018 (the date of Plante's resignation), the Company had no disagreements with Plante on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to Plante's satisfaction, would have caused it to make reference to the subject matter of the disagreements in connection with its reports.

In connection with Plante's resignation and the restatement of our financial statements for the quarter ended March 31, 2018, Plante and our management team identified a material weakness in our internal control over financial reporting with respect to the quarter ended March 31, 2018. Accordingly, the Board and management have concluded that management's reports related to the effectiveness of internal and disclosure controls for the quarter ended March 31, 2018 may not have been correct, as described in Item 4, "Control and Procedures" of this Form 10-Q. Subsequently, we identified several additional material weaknesses. A material weakness is a deficiency, or combination of deficiencies, in internal controls over financial reporting that results in a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Although our Audit Committee and management are implementing improvements to our internal controls to remediate the identified material weaknesses, these improvements may not be effective to fully remediate such material weakness or prevent a material misstatement of our annual or interim financial statements in the future.

Item 6. Exhibits

The following documents are filed as part of this report or were previously filed and incorporated herein by reference to the filing indicated. Exhibits not required for this report have been omitted. Our Commission file number is 000-23661.

EXHIBIT INDEX

Exhibit No.	Description
10.1	Sales Agreement dated March 22, 2019, between Rockwell Medical, Inc. and Cantor Fitzgerald & Co. (Filed as Exhibit 1.1 on the Company's Form 8-K filed March 22, 2019)
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1	Certification pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(b) of the Securities Exchange Act of 1934
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Database
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

SIGNATURES

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 thereunto duly authorized.

ROCKWELL MEDICAL, INC.
(Registrant)

Date: May 9, 2019

/s/ Stuart Paul
Stuart Paul
Chief Executive Officer (Principal Executive Officer)

Date: May 9, 2019

/s/ Angus Smith
Angus Smith
Chief Financial Officer (Principal Financial Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a)

I, Stuart Paul, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Rockwell Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2019

/s/ Stuart Paul
Stuart Paul
Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a)

I, Angus Smith, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Rockwell Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2019

/s/ Angus Smith
Angus Smith
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION OF INTERIM PRINCIPAL EXECUTIVE OFFICER
AND PRINCIPAL ACCOUNTING OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Rockwell Medical, Inc. (the "Company") on Form 10-Q for the quarter ending March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Periodic Report"), I, Stuart Paul, Chief Executive Officer of the Company, and I, Angus Smith, Chief Financial Officer of the Company, each certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that based on my knowledge:

1. the Periodic Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. the information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 9, 2019

/s/ Stuart Paul
Stuart Paul
Chief Executive Officer

Dated: May 9, 2019

/s/ Angus Smith
Angus Smith
Chief Financial Officer