ROCKWELL MEDICAL, INC.
Form 10-Q
November 09, 2018
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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 September 30, 2018

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

APPLICABLE ONLY TO CORPORATE ISSUERS:

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding as of November 8, 2018
Common Stock, no par value	56,977,656 shares

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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

(Unaudited)

	September 30, 2018	December 31, 2017
ASSETS		
Cash and Cash Equivalents	$ 4,292,328	$ 8,406,917
Investments Available for Sale	13,410,151	24,648,459
Insurance Receivable	500,000	—
Accounts Receivable, net of a reserve of $7,800 in 2018 and $11,000 in 2017	7,581,699	6,355,566
Inventory	4,646,522	7,637,384
Prepaid and Other Current Assets	1,662,398	1,779,992
Total Current Assets	32,093,098	48,828,318
Property and Equipment, net	2,667,760	2,548,978
Inventory, Non-Current	1,865,834	5,986,752
Goodwill	920,745	920,745
Other Non-current Assets	536,605	494,847
Total Assets	$ 38,084,042	$ 58,779,640
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts Payable	$ 6,931,292	$ 4,222,159
Accrued Liabilities	2,724,777	4,715,712
Settlement Payable	666,667	—
Current Portion of Deferred License Revenue	2,276,139	—
Customer Deposits	86,435	205,303
Total Current Liabilities	12,685,310	9,143,174
Deferred License Revenue	12,729,052	16,723,318
Total Liabilities	25,414,362	25,866,492

Commitments and Contingencies (See Note 10)		
Shareholders' Equity:		
Common Shares, no par value, 51,769,294 shares issued and outstanding at September 30, 2018 and 51,768,424 shares issued and outstanding at December 31, 2017	275,634,848	273,210,907
Accumulated Deficit	(263,012,321)	(240,262,376)
Accumulated Other Comprehensive Income (Loss)	47,153	(35,383)
Total Shareholders' Equity	12,669,680	32,913,148
Total Liabilities And Shareholders' Equity	$ 38,084,042	$ 58,779,640

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Sales	$ 16,672,416	$ 14,626,904	$ 46,534,358	$ 42,462,265
Cost of Sales	14,703,606	13,555,853	49,303,048	37,535,454
Gross Profit (Loss)	1,968,810	1,071,051	(2,768,690)	4,926,811
Selling, General and Administrative	6,159,141	4,791,636	15,182,048	17,433,530
Settlement Expense, net of Reimbursement	—	—	1,030,000	—
Research and Product Development	808,192	1,304,658	4,033,494	4,195,003
Operating Loss	(4,998,523)	(5,025,243)	(23,014,232)	(16,701,722)
Interest and Investment Income (Loss)	28,891	(31,751)	264,287	(180,279)
Net Loss	$ (4,969,632)	$ (5,056,994)	$ (22,749,945)	$ (16,882,001)
Basic and Diluted Net Loss per Share	$ (0.10)	$ (0.10)	$ (0.44)	$ (0.33)
Basic and Diluted Weighted Average Shares Outstanding	51,288,537	51,260,975	51,288,462	50,995,079

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Net Loss	$ (4,969,632)	$ (5,056,994)	$ (22,749,945)	$ (16,882,001)
Unrealized Gain on Available-for-Sale Investments	143,868	248,628	96,327	860,752
Foreign Currency Translation Adjustments	(6,402)	132	(13,791)	(142)
Comprehensive Loss	$ (4,832,166)	$ (4,808,234)	$ (22,667,409)	$ (16,021,391)

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

For the nine months ended September 30, 2018

(Unaudited)

	COMMON SHARES		ACCUMULATED	ACCUMULATED OTHER COMPREHENSIVE INCOME /	TOTAL SHAREHOLDER'S
	SHARES	AMOUNT	DEFICIT	(LOSS)	EQUITY
Balance as of December 31, 2017	51,768,424	$ 273,210,907	$ (240,262,376)	$ (35,383)	$ 32,913,148
Net Loss	—	—	(22,749,945)	—	(22,749,945)
Unrealized Gain (Loss) on Available-for-Sale Investments	—	—	—	96,327	96,327
Foreign Currency Translation Adjustments	—	—	—	(13,791)	(13,791)
Exercise of Employee Stock Options, Net of Tax	870	(1,978)	—	—	(1,978)
Stock-based compensation	—	2,425,919	—	—	2,425,919
Balance as of September 30, 2018	51,769,294	$ 275,634,848	$ (263,012,321)	$ 47,153	$ 12,669,680

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

For the nine months ended September 30, 2018 and 2017

(Unaudited)

	2018	2017
Cash Flows From Operating Activities:		
Net Loss	$ (22,749,945)	$ (16,882,001)
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	466,994	384,835
Stock-based Compensation	2,425,919	6,033,436
Increase in Inventory Reserves	3,442,547	—
Loss on Disposal of Assets	4,030	4,084
Realized Loss on Sale of Investments Available-for-Sale	222,014	704,695
Changes in Assets and Liabilities:		
(Increase) in Insurance Receivable	(500,000)	-
(Increase) Decrease in Accounts Receivable	(1,226,133)	(149,429)
Decrease (Increase) in Inventory	3,669,233	(2,391,191)
Decrease (Increase) in Other Assets	75,570	224,635
(Decrease) in Accounts Payable	2,709,133	(1,669,651)
Increase in Settlement Payable	666,667	—
(Decrease) in Other Liabilities	(2,109,802)	(863,034)
(Decrease) in Deferred License Revenue	(1,718,127)	(1,698,903)
Changes in Assets and Liabilities	1,566,541	(6,547,573)
Cash Used In Operating Activities	(14,621,900)	(16,302,524)
Cash Flows From Investing Activities:		
Purchase of Investments Available-for-Sale	(18,483,694)	(34,235,347)
Sale of Investments Available-for-Sale	29,596,315	40,122,266
Purchase of Equipment	(589,541)	(706,346)
Proceeds on Sale of Assets	—	450
Cash Provided By Investing Activities	10,523,080	5,181,023
Cash Flows From Financing Activities:		
Proceeds from Issuance of Common Shares	—	116,105
Restricted Stock Retained in Satisfaction of Tax Liabilities	—	(2,287,231)
Stock Retained in Satisfaction of Tax Liabilities	(1,978)	—

Cash Used In Financing Activities	(1,978)	(2,171,126)
Effects of Exchange Rate Changes	(13,791)	(44)
Decrease In Cash and Cash Equivalents	(4,114,589)	(13,292,671)
Cash At Beginning Of Period	8,406,917	17,180,594
Cash At End Of Period	$ 4,292,328	$ 3,887,923

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

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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, secondary hyperparathyroidism and hemodialysis. We are also a manufacturer of hemodialysis concentrates/dialysates for 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. 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. Liquidity and Financial Condition

As of September 30, 2018, the Company had approximate balances of $4.3 million of cash and cash equivalents, $13.4 million of investments available-for-sale, working capital of $19.4 million and an accumulated deficit of $263.0 million. Net cash used in operating activities for the nine months ended September 30, 2018 was approximately $14.6 million. On October 15, 2018, the Company raised $22.0 million in capital from the offering and sale of 5,541,562 shares of common stock at a price of $3.97 per share, along with warrants to purchase up to an additional 2,770,781 shares of common stock at a price of $4.96 per share. (See Note 11 – Subsequent Events).

Based on the additional capital raised from the October 2018 offering, management currently believes the Company currently has sufficient funds to meet its operating requirements for at least the next twelve months from the date of report filing.

The Company will require additional capital to sustain its short-term operations and make the investments it needs to execute its long-term business plan, including the commercial launch of Dialysate Triferic and IV Triferic (if approved). If the Company is unable to generate sufficient revenue from its existing long-term business plan, the Company will need to obtain additional debt or equity financing. If the Company attempts to obtain additional debt or equity financing, the Company cannot assume that such financing will be available on favorable terms, if at all.

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

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.

The accompanying condensed consolidated financial statements have been prepared in accordance with the accounting principles generally accepted in the United States ("U.S.") of America ("GAAP") for interim financial information and pursuant to the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the U. S. Securities and Exchange Commission ("SEC") and on the same basis as the Company prepares its annual audited consolidated financial statements. The condensed consolidated balance sheet at September 30, 2018, condensed consolidated statements of operations for the three and nine months ended September 30, 2018 and 2017, condensed consolidated statements of cash flows for the nine months ended September 30, 2018 and 2017, and condensed consolidated statement of changes in shareholder's equity for the nine months ended September 30, 2018 are unaudited, but include all adjustments, consisting of normal recurring adjustments, that the Company considers necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented. The results for the three and nine months ended September 30, 2018 are not necessarily indicative of results to be expected for the year ending December 31, 2018 or for any future interim period. The condensed consolidated balance sheet at December 31, 2017 has been derived from audited financial statements,

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(Unaudited)

however, it does not include all of the information and notes required by GAAP for complete financial statements. The accompanying condensed consolidated financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2017 and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 as filed with the SEC (the "2017 Annual Report"). The Company's consolidated subsidiaries consisted of its wholly-owned subsidiaries, Rockwell Transportation, Inc. and Rockwell Medical India Private Limited.

Certain reclassifications have been made to the 2017 financial statements and notes to conform to the 2018 presentation.

Revenue Recognition

The Company recognizes revenue under Accounting Standards Codification ("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.

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(Unaudited)

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.

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 September 30, 2018			Nine Months Ended September 30, 2018		
Products By Geographic Area	Total	U.S.	Rest of World	Total	U.S.	Rest of World
Drug Revenues						
License Fee – Over time	$ 68	$ —	$ 68	$ 205	$ —	$ 205
Concentrate Products						
Product Sales – Point-in-time	16,099	13,208	2,891	44,815	38,536	6,279
License Fee – Point-in-time	505	505	—	1,514	1,514	—
Total Concentrate Products	16,604	13,713	2,891	46,329	40,050	6,279
Net Revenue	$ 16,672	$ 13,713	$ 2,959	$ 46,534	$ 40,050	$ 6,484

For the three and nine months ended September 30, 2017, license fee revenue was $556 and $1,655 respectively. For the three and nine months ended September 30, 2017 product sales revenue was $14,061 and $40,807 respectively.

Contract balances

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

In thousands of US dollars ($)	September 30, 2018	December 31, 2017
Receivables, which are included in "Trade and other receivables"	$ 7,593	$ 5,544
Contract liabilities	$ 15,005	$ 16,723

There were no impairment losses recognized related to any receivables arising from the Company’s contracts with customers for the nine months ended September 30, 2018.

For the three and nine months ended September 30, 2018 and 2017, the Company did not recognize material bad-debt expense and there were no material contract assets recorded on the consolidated balance sheet as of September 30, 2018. The Company does not generally accept returns of its concentrate products and no reserve for returns of concentrate products was established as of September 30, 2018 or December 31, 2017.

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 and nine months ended September 30, 2018, revenue recognized from performance obligations related to prior periods was not material.

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(Unaudited)

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 recognized as invoiced and contracts with variable consideration related to undelivered performance obligations, totaled $15,005,000 as of September 30, 2018. 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 $11,732,000, which will be amortized through expiration of the agreement on October 2, 2024.

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.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents. Cash and cash equivalents include cash held in banks, money market mutual funds and unrestricted certificates of deposit.

Fair Value Measurement

The Company applies the guidance issued with ASC 820, Fair Value Measurements, which provides guidance on the development and disclosure of fair value measurements. Under this accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly

transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance classifies fair value measurements in one of the following three categories for disclosure purposes:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs which are supported by little or no market activity ad values determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgement or estimation.

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 each of the three months ended September 30, 2018 and 2017, respectively, and $1.5 million for each of the nine months ended September 30, 2018 and 2017, respectively.

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(Unaudited)

Research and Product Development

The Company recognizes research and product development expenses as incurred. The Company incurred product development and research costs related to the commercial development, patent approval and regulatory approval of new products aggregating approximately $0.8 million and $1.3 million for the three months ended September 30, 2018 and 2017, respectively, and $4.0 million and $4.2 million for the nine months ended September 30, 2018 and 2017, respectively.

Stock-Based Compensation

The Company expenses stock-based compensation to employees over the requisite service period based on the estimated grant-date fair value of the awards. For stock-based compensation awards to non-employees, the Company re-measures the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these non-employee awards are recognized as compensation expense in the period of change. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management’s best estimates and involve inherent uncertainties and the application of management’s judgement. For the three and nine months ended September 30, 2018 and 2017, the Company recorded stock-based compensation expense on its options granted under the Company’s equity compensation plans to its directors and officers, and its employees.

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 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 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 and nine months ended September 30, 2018 and 2017 were as follows:

	As of September 30,	
	2018	2017
Options to purchase common stock	8,048,105	7,326,501
Unvested restricted stock awards	-	480,000
Unvested restricted stock units	1,293,750	-
	9,341,855	7,806,501

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 May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers (Topic 606), as modified by ASU 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, ASU 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(Unaudited)

Considerations (Reporting Revenue Gross versus Net), ASU 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, and ASU 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients. The revenue recognition principle in ASU 2014-09 is that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In addition, new and enhanced disclosures will be required. Companies may adopt the new standard either using the full retrospective approach, a modified retrospective approach with practical expedients, or a cumulative effect upon the adoption approach. The Company adopted the new standard on January 1, 2018, using the modified retrospective approach. The adoption of ASU 2014-09 did not have a material impact on the Company’s condensed consolidated financial statements and related disclosures.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) and subsequent amendments to the initial guidance: ASU 2017-13, ASU 2018-10 and ASU 2018-11 (collectively, Topic 842). Topic 842 requires companies to generally recognize on the balance sheet operating and financing lease liabilities and corresponding right-of-use assets. Topic 842 is effective for the Company in its first quarter 2020, and earlier adoption is permitted. The Company is currently evaluating the impact of its pending adoption of Topic 842 on its condensed consolidated financial statements. The Company currently expects that most of its operating lease commitments will be subject to the new standard and recognized as operating lease liabilities and right-of-use assets upon its adoption of Topic 842, which will increase its total assets and total liabilities that the Company reports relative to such amounts prior to adoption.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholder’s equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholder’s equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance and the ending balance of each period for which a statement of comprehensive income is required to be filed. This rule is effective on November 5, 2018. The Company is evaluating the impact of this guidance on its condensed consolidated financial statements.

4. Investments - Available-for-Sale

Investments available-for-sale are short-term investments, consisting of investments in short-term notes and bonds and are stated at fair value based upon observed market prices (Level 1 in the fair value hierarchy). The portfolio generally consists of high credit quality short-term debt instruments. These instruments are subject to changes in fair market value due primarily to changes in interest rates. The fair value of these investments was $13,410,151 and $24,648,459 as of September 30, 2018 and December 31, 2017, respectively. Unrealized holding gains or losses on these securities are included in accumulated other comprehensive income (loss). Realized gains and losses, including declines in value judged to be other-than-temporary on available-for-sale securities are included as a component of other income or expense. Gross unrealized losses for the three months ended September 30, 2018 was $157,982. There were no unrealized gains for the three months ended September 30, 2018. Gross unrealized gains for the three months ended September 30, 2017 $248,628. There were no unrealized losses for the three months ended September 30, 2017. Realized gains were $2,411 and $57 for the three months ended September 30, 2018 and 2017 respectively. Realized losses were $99,439 and $199,758 for the three months ended September 30, 2018 and 2017 respectively. There were no gross unrealized losses for the nine months ended September 30, 2018 and gross unrealized gains were $96,591 as of September 30, 2018. Gross unrealized losses were $76,399 and gross unrealized gains were $35,274 for the nine months ended September 30, 2017. There were realized gains of $6,050 and $57 for the nine months ended September 30, 2018 and 2017 respectively. There were realized losses of $228,064 and $704,752 during the nine months ended September 30, 2018 and 2017 respectively.

The Company has evaluated the near term interest rate environment and the expected holding period of the investments along with the duration of the portfolio assets in assessing the severity and duration of potential impairments. Based on

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our evaluation, the Company does not consider those investments to be other-than-temporarily impaired at September 30, 2018.

5. Inventory

Components of inventory, net of reserves as of September 30, 2018 and December 31, 2017 are as follows:

	September 30, 2018	December 31, 2017
Raw Materials	$ 4,122,432	$ 10,604,232
Work in Process	203,498	212,505
Finished Goods	2,186,426	2,807,399
Total	$ 6,512,356	$ 13,624,136

As of September 30, 2018, we classified $1,865,834 of inventory as non-current all of which was related to Triferic or the active pharmaceutical ingredient for Triferic. As of September 30, 2018 and December 31, 2017, we had total Triferic inventory aggregating $9,467,795 and $13,424,779 respectively against which we had reserved $6,900,000 and $3,460,801 respectively.

For the three and nine months ended September 30, 2018, the Company increased its inventory reserve by $0.1 million and $7.8 million respectively. For the three and nine months ended September 30, 2017 the Company increased its inventory reserve by $0.7 million and $0.8 million respectively.

6. Property and Equipment

As of September 30, 2018 and December 31 2017, the Company’s property and equipment consisted of the following:

	September 30, 2018	December 31, 2017
Leasehold Improvements	$ 909,846	$ 824,087
Machinery and Equipment	4,882,489	7,893,566
Information Technology & Office Equipment	2,459,832	2,327,524
Laboratory Equipment	614,733	631,666
Transportation	—	242,277
	8,866,900	11,919,120
Accumulated Depreciation	(6,199,140)	(9,370,142)
Net Property and Equipment	$ 2,667,760	$ 2,548,978

Depreciation expense for the three months ended September 30, 2018 and 2017, totaled $185,579 and $125,839. Depreciation expense for the nine months ended September 30, 2018 and 2017, totaled $466,729 and $384,835.

7. Shareholders' Equity

Preferred Stock

As of September 30, 2018 and December 31, 2017, there were 2,000,000 shares of preferred stock authorized and no shares of preferred stock issued or outstanding.

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Common Stock

On September 19, 2018, an employee of the Company exercised 5,000 stock options at an exercise price of $15,450 or $3.09 per share. The Company withheld 4,130 of these common shares at a cost of $17,428 or $4.22 per share, to cover the employee withholding taxes and other expenses related to this exercise.

8. Stock-Based Compensation

The Company recognized total stock-based compensation expense during the three and nine months ended September 30, 2018 and 2017 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Restricted stock awards	$ 20,222	$ 564,854	$ 1,292,125	$ 2,751,239
Stock option awards	427,944	1,071,653	967,377	3,275,339
Restricted stock units	166,417	-	166,417	-
	$ 614,583	$ 1,636,507	$ 2,425,919	$ 6,026,578

Restricted Stock

A summary of the Company’s restricted stock awards during the nine months ended September 30, 2018 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value

Granted at December 31, 2017	1,380,000	$ 7.27
Granted	-	-
Forfeited	(333,200)	5.70
Granted at September 30, 2018	1,046,800	$ 7.77

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.

During the nine months ended September 30, 2018, the Company granted 388,125 restricted stock units and 905,625 performance-based restricted stock units to an employee. The Company did not record stock-based compensation expenses related to the performance-based grants, because vesting is not probable as of September 30, 2018. The restricted stock units are priced at $4.70 per share and were unvested at September 30, 2018. The 388,125 restricted stock units have a three year time based vesting period and the 905,625 performance-based grants will be subject to the satisfaction of performance based conditions.

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Stock Options

A summary of the Company's stock option activity for the nine months ended September 30, 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	5.0	
Granted	1,337,271	4.96	9.4	
Exercised	(5,000)	6.59	-	
Forfeited	(190,167)	6.59	-	
Outstanding at September 30, 2018	8,048,105	$ 7.46	5.2	$ 365,135
Exercisable at September 30, 2018	6,248,160	$ 7.90	4.1	$ 365,135

The aggregate intrinsic value in the table above represents the total intrinsic (the difference between the Company's closing stock price on September 30, 2018 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders, had all option holders been able to, and in fact had, exercised their options on September 30, 2018.

During the nine months ended September 30, 2018, the stock options granted consisted of 949,146 options granted to employees, and 388,125 performance-based options granted to an employee. The vested options were exercisable at an average price of $7.90 per share and the unvested options were exercisable at an average of $5.92 per share.

The fair value of the options granted for the nine months ended September 30, 2018 and 2017 were based on the following assumptions:

	Nine Months Ended September 30,	
	2018	2017
Exercise price	$4.52 - $5.75	$6.09
Expected stock price volatility	67.5%	66.3%
Risk-free interest rate	2.7% - 2.9%	2.2%
Term (years)	5.0 - 6.5	5.5 - 6.5

In accordance with the original terms of their employment agreements of the former Chief Executive Officer (“CEO”) and the Chief Financial Officer (“CFO”) and in accordance with the terms of the Settlement Agreement (defined below), the Company accelerated the vesting of 258,334 and 71,667 unvested stock options on the termination date. As a result of this acceleration of stock options, the Company recorded additional stock-based compensation of approximately $162,000.

As of September 30, 2018, total stock-based compensation expense related to unvested options not yet recognized totaled approximately $2.2 million.

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9. Settlement Agreement and Related Director and Officer Insurance Receivable

On August 7, 2018, the Company entered into a confidential settlement agreement and mutual release (the "Settlement Agreement") with its former CEO, former CFO and a former and then current director. For more details see Note 10. The Company accrued approximately $1.5 million related to this Settlement Agreement and as of September 30, 2018, the Company has paid $0.8 million. The Company is also entitled to a partial reimbursement for this accrual from the Company's insurance company of approximately $0.5 million which was collected in October 2018. This resulted in a net settlement expense of approximately $1.0 million for the nine months ended September 30, 2018.

10. Commitments and Contingencies

Litigation

Circuit Court for Oakland County, Michigan

Following the Board's termination of the Company's former CEO on May 22, 2018, and in response to his continued assertion that he remained the duly appointed Chief Executive Officer of the Company, on May 23, 2018, the Company filed a complaint in the Oakland County Circuit Court in Michigan ("State Court") seeking declaratory relief and a temporary restraining order. On May 24, 2018, the Board terminated its then-serving CFO. Following the State Court-ordered mediation, the Company, its former CEO, former CFO and a former and then current director, agreed to a term sheet (the "Term Sheet") that outlined the terms of a withdrawal of the State Court proceeding while the parties continued to litigate their claims in the Federal Court actions described below. On July 11, 2018, the State Court entered a stipulated order permitting the Company to withdraw its complaint in accordance with the Term Sheet. On July 17, 2018, the lawsuit in the State Court action was dismissed and closed.

United States District Court for the Eastern District of Michigan

On June 13, 2018, the Company's former CEO and CFO filed a complaint in the United States District Court for the Eastern District of Michigan ("Federal Court") against the Company and certain directors (collectively, the "Defendants"). The complaint requested that the Federal Court reinstate the former CEO to his former position of Chief Executive Officer, reinstate the former CFO to his former position of Chief Financial Officer and order the Defendants

to pay all costs associated with the matter. The complaint alleged that the Defendants possibly violated their duties of loyalty and care to the Company; rules under Regulation Fair Disclosure; and various federal securities laws, including Section 10(b) of the Exchange Act and SEC Rule 10b-5. On July 2, 2018, the Company filed an answer and counterclaim against the Company's former CEO, former CFO, a former director and a then-serving director. On August 7, 2018, the parties entered into the Settlement Agreement by which the parties agreed to dismiss the Federal Court action with prejudice.

Settlement Agreement

On August 7, 2018, the Company, the Company's former CEO, former CFO, a former director and a then-serving director and the Defendants, entered into the Settlement Agreement, pursuant to which the parties agreed to dismiss the Federal Court action with prejudice and to enter into a broad mutual release of claims. The Company agreed to: (i) pay the Company's former CEO, former CFO, a former director and a then-serving director a total of $1,500,000, one-half of which was paid at execution and the remainder of which will be paid in nine equal monthly installments of $83,333, (ii) pay $30,000 to the then-serving director (who then agreed to resign as a director); (iii) accelerate the vesting of options held by the Company's former CEO and former CFO as of the date of their terminations; and (iv) grant an extended option exercise period for vested options. The Company's former CEO, former CFO, a former director and the resigning director agreed to certain standstill covenants for a period of approximately five years and agreed to forfeit a total of 313,600 unvested shares of restricted common stock.

SEC Inquiry

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As a follow up to its prior inquiry letters, the Company received a subpoena from the SEC during the Company's third quarter requesting, among other things, certain information and documents relating to the status of CMS's determination of separate reimbursement status for Dialysate Triferic and the Board's termination of our former CEO and CFO. The Company is actively cooperating and responding to these requests.

State Court and Federal Court Actions

As reported above, the State Court action was dismissed and closed on July 17, 2018 at the request of the parties. On August 7, 2018, the parties entered into the Settlement Agreement by which the parties agreed to dismiss the Federal Court action with prejudice. On August 15, 2018, the Federal Court action was dismissed and closed.

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. The lawsuits seek damages sustained by the class and an award of plaintiffs' costs and attorney fees.

11. Subsequent Events

Related-Party Transaction

On October 7, 2018, the Company entered into a Master Services and Intellectual Property ("IP") Agreement ("MSA") with the Charak, LLC and Dr. Ajay Gupta (collectively "Charak"), who serves as the Company's Executive Vice President and Chief Scientific Officer. Pursuant to the MSA, the parties entered into three additional agreements related to the license of certain soluble ferric pyrophosphate IP owned by Charak, as well as an employment agreement with Dr. Gupta. The MSA provides for a payment of $1,000,000 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 MSA.

Securities Purchase Agreement

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On October 15, 2018, the Company entered into a Securities Purchase Agreement with an institutional investor (the "Purchaser"), pursuant to which the Company sold 5,541,562 units, with each unit (the "Units") consisting of one share of common stock of the Company (the "Common Stock") and a warrant to purchase 50% of a share of Common Stock (the "Warrant"). The Units were sold at $3.97 per Unit, which was equivalent to the closing price of the Company's common stock on October 12, 2018, the last trading day prior to entering into the Securities Purchase Agreement. The Warrants, which are not exercisable for six months from issuance, have an exercise price of $4.96 per full share of Common Stock and have a five-year term from issuance. The Purchaser had the right to purchase up to an additional $8.0 million in Units at the same price and on the same terms as set forth in the Securities Purchase Agreement. This additional purchase right expired unexercised on October 26, 2018. As a result, no additional Units were sold and the total gross proceeds for the offering were $22.0 million.

CMS Reimbursement Guidance

Also on November 1, 2018, the Centers for Medicare & Medicaid Services ("CMS"), issued interpretive guidance on the availability of Medicare reimbursement for certain products indicated to treat renal disease (the CMS Guidance. As set forth in the CMS Guidance, Dialysate Triferic would not be eligible for add-on reimbursement under the CMS Traditional Drug Add On Pricing Adjustment ("TDAPA") program. Accordingly, the Company is continuing its previously announced plans to commercially launch Dialysate Triferic "within the bundle," with commercial launch for this product planned for the first half of 2019. However, based on the CMS Guidance, the Company believes that, if approved by the FDA on or after January 1, 2020, IV Triferic would 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 IV Triferic would be priced inside the bundle. The Company is working with outside experts to optimize its New Drug Application ("NDA") filing and PDUFA action dates to realize the benefits of separate payment, and is targeting a launch of IV Triferic in the first half of 2020, subject to receipt of FDA approval.

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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 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," "po "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, 2017 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

We are a specialty pharmaceutical company targeting end-stage renal disease and chronic kidney disease with products for the treatment of iron deficiency, secondary hyperparathyroidism 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 IV Triferic, a novel intravenous formulation of Triferic that would be used for the same indication, if approved. A description of Dialysate Triferic and IV Triferic is set forth below.

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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 (following a partial turnover in the Board of Directors and the Company's senior leadership team), 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 provided earlier in 2018 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 IV Triferic (discussed below). At the present time, we expect to commercially launch Dialysate Triferic in the first half of 2019.

While the Company was pursuing the earlier strategy of delaying commercialization until receipt of add-on reimbursement approval, we built up significant inventory of Dialysate Triferic. However, due to the delays in launching and the negative feedback received from CMMI in March 2018 regarding near-term approval, we wrote off a total of $7.8 million of our inventory investment in Dialysate Triferic through September 30, 2018. As of September 30, 2018, we had $5.4 million of Dialysate Triferic finished goods inventory that could expire within the next 12 months and against which we have reserved $4.8 million. As of September 30, 2018, we also had approximately $4.1 million of Dialysate Triferic Active Pharmaceutical Ingredient ("API") against which we have reserved $2.1 million and classified $1.9 million of Dialysate Triferic API as non-current inventory. Depending on the timing and success of our commercial launch of Dialysate Triferic in 2019, additional amounts or all of our current investment in Dialysate Triferic finished goods inventory and some or all of our Dialysate Triferic API inventory will likely need to be written off. Additional inventory write-offs will not have a material negative impact on our cash flow, but would 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 ("IV Triferic") for use by hemodialysis patients in the United States as well as international markets. A clinical equivalence study of IV 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 IV Triferic in the United States for the clinical indication of replacing iron and maintaining hemoglobin in adult hemodialysis patients.

The November 2018 CMS Guidance provided interpretative guidance regarding the CMS Transitional Drug Add On Pricing Adjustment ("TDAPA") program and its potential application to IV Triferic. Based on the CMS Guidance, the Company believes that, if approved by the FDA on or after January 1, 2020, IV Triferic would 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 IV Triferic would be priced inside the bundle. In light of these timing considerations, we are assessing the impact of the CMS Guidance on the planned timing for our NDA submission and may file the NDA in a time period such that the PDUFA action date would be in 2020, with the expectation that we would be able to commence commercializing IV Triferic in 2020. Upon filing of the NDA, we will be required to pay a filing fee to the FDA of approximately $1.2 million.

While we intend to market and sell Dialysate Triferic and IV Triferic directly in the United States, our global 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.

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Dialysis Concentrates

We manufacture, sell, deliver and distribute hemodialysis concentrates, along with a full 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 96% of our revenues for the nine months ended September 30, 2018, 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 which is manufactured for us through a contract manufacturing organization. To date, we have not commercially launched Calcitriol and we are currently assessing business strategic decisions for this product, including pricing, commercial distribution and marketing, manufacturing efficiencies and capacity (including potential capital investment). We do not anticipate Calcitriol sales (if any) will have a material impact on our total revenue for 2018.

Clinical Development

Although 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 IV 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 are planned, one of which has been initiated and the other of which is expected to commence enrollment in early 2019.

As a post-approval requirement under the Pediatric Research Equity Act, we are required to conduct a further clinical study of the effectiveness of Dialysate 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 IV 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 September 30, 2018 and September 30, 2017

Sales

During the third quarter of 2018 our sales were $16.7 million, which is $2.0 million, or 14%, higher than the third quarter of 2017. The increase of $2.0 million was primarily due to higher domestic dialysis concentrate sales primarily due to increased pass through delivery costs billed to Baxter. Our international sales increased by approximately $1.2 million, or 71.4%, over the third quarter of 2017, primarily due to increased purchases from our largest international customers. Revenue recognized from licensing fees was $0.6 million for the three months ended September 30, 2018 and 2017, respectively.

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Gross Profit (Loss)

Cost of sales during the third quarter of 2018 was $14.7 million, resulting in a gross profit of $2.0 million, primarily all from our dialysis concentrates products, and increased by $0.4 million in the third quarter of 2018 compared to the third quarter of 2017. The increase was largely due to increased international revenue. Additionally, included in the gross profit are charges of approximately $0.1 million in the third quarter of 2018, compared to $0.6 million in the third quarter of 2017, attributed to inventory write-offs for Dialysate Triferic.

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Selling, General and Administrative Expense

Selling, general and administrative expenses were $6.1 million during the third quarter of 2018 compared with $4.8 million during the third quarter of 2017. The $1.3 million increase was primarily due to increased expenses, including legal fees, professional fees, recruiting fees, insurance costs, and settlement charges associated with the changes in executive management (CEO and CFO) and certain directors and related litigation that was settled in August 2018. While we expect these fees to decrease in future periods, overall selling, general and administrative expenses are expected to increase in 2019 as the Company prepares for the U.S. commercial launch of Dialysate Triferic and IV Triferic, if approved, and invests in the necessary infrastructure to support these commercial plans.

Research and Product Development Expense

Research and product development expenses were $0.8 million for the third quarter 2018 compared with $1.3 million of expenses incurred during the third quarter of 2017. We incurred research and product development costs due to our investment in future product development, intellectual property and regulatory activities primarily for Dialysate and IV Triferic. Research and product development expenses incurred in the third quarter of 2018 were largely related to Triferic testing and development costs for use in other clinical indications and delivery presentations as well as medical, scientific and technical staffing costs, consulting expenses. We expect our research and product development expenses to increase in the future due to additional clinical development of Dialysate and IV Triferic, including the conduct of the pediatric clinical trial described above, assuming we have the liquidity and capital resources to do so.

Interest and Investment Income, Net

Interest and investment income was approximately $29,000 for the quarter ended September 30, 2018 and interest and investment loss in the third quarter of 2017 totaled approximately $32,000.

Results of Operations for the nine months ended September 30, 2018 and September 30, 2017

Sales

Sales during the nine months ended September 30, 2018 were $46.5 million compared to sales of $42.5 million during the nine months ended September 30, 2017. The increase of $4.0 million was primarily due to higher domestic dialysis concentrate sales primarily due to increased pass through delivery costs billed to Baxter. Our international

sales increased by approximately $1.4 million or 27.8% over the nine months ended September 30, 2017 primarily due to increased purchases from our largest international customers. Revenue recognized from licensing fees was $1.7 million for nine months ended September 30, 2018 and 2017, respectively.

Gross Profit (Loss)

Cost of sales during the nine months ended September 30, 2018 was $49.3 million, resulting in a gross loss of $2.8 million in 2018, compared to a gross profit of $4.9 million in the same nine-month period in 2017. Gross profit was negatively impacted by $8.0 million in additional year-over-year costs, primarily consisting of an increase in our Dialysate Triferic inventory reserve of $7.0 million and a gross profit decrease of $0.5 million in our dialysis concentrates products, which was primarily attributable to increased dialysis concentrate distribution costs and lower pricing under our distribution agreement with Baxter, which was partially offset by increased unit volume growth. Recently implemented government regulation in the trucking industry has further negatively impacted a nationwide driver shortage resulting in increased costs for both incoming materials and shipments within the United States. We expect this trend to continue to increase shipping costs for our dialysis concentrate products in the near term.

Selling, General and Administrative Expense

Selling, general and administrative expenses during the nine months ended September 30, 2018 were $15.2 million, compared to $17.4 million during the nine months ended September 30, 2017. The $2.2 million decrease was primarily attributable to year-over-year decreases in stock-based compensation expense ($3.6 million) and salary-related expense ($1.9 million), partially offset by a year-over-year increase in legal and professional services fees of $3.0 million, which primarily related to expenses incurred in connection with changes in executive management (CEO and CFO) and certain directors, as well as the related litigation that was settled in August 2018, and legal and settlement expenses associated

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with the contested proxy campaign and related litigation that was settled in March 2018. Legal and professional services fees in 2017 were higher than prior periods due to increased expenses incurred in connection with a contested proxy campaign and related litigation expense. While we expect these fees to decrease in future periods, overall selling, general and administrative expenses are expected to increase in 2019 as the Company prepares for the U.S. commercial launch of Dialysate Triferic and IV Triferic, if approved, and invests in the necessary infrastructure to support these commercial plans.

Research and Product Development Expense

Research and product-development expenses were $4.0 million for the nine months ended September 30, 2018, compared with $4.2 million of expenses incurred during the same period in 2017. We incurred research and product development costs due to our investment in future product development, intellectual property and regulatory activities primarily for Dialysate and IV Triferic. Research and product development expenses incurred during the nine months ended September 30, 2018 were largely related to Triferic testing and development costs for use in other clinical indications and delivery presentations, as well as 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 IV Triferic, including the conduct of the pediatric clinical trial described above, assuming we have the liquidity and capital resources to do so.

Interest and Investment Income, Net

Interest and investment income in the nine months ended September 30, 2018 was $0.3 million as compared to $0.2 million of loss during the nine months ended September 30, 2017.

Liquidity and Capital Resources

As of September 30, 2018, we had approximately $17.7 million of cash, cash equivalents and investments available-for-sale, and working capital of $19.4 million. Net cash used in operating activities for the nine months ended September 30, 2018 was approximately $14.6 million. In October 2018, the Company raised $22.0 million in capital from the offering and sale of 5,541,562 shares of common stock at a price of $3.97 per share, along with warrants to purchase up to an additional 2,770,781 shares of common stock at a price of $4.96 per share. (See Note 11, included in our condensed consolidated financial statements).

Based on the additional capital raised from the October 2018 offering described above, management believes the Company currently has sufficient funds to meet its operating requirements for at least the next twelve months from the

date of report filing. However, the Company anticipates that it will need to raise additional capital in the future to help support the launch of Dialysate Triferic and IV Triferic (if approved), particularly in light of the CMS Guidance and the expectation that Dialysate Triferic will not receive add-on reimbursement prior to the end of 2019, if at all, and that IV Triferic would not be eligible to receive add-on reimbursement until 2020.

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 Triferic and IV 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 IV 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.

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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, IV Triferic. Our commercialization of Dialysate Triferic and IV Triferic (if approved) is subject to significant risks and uncertainties, such that there can be no assurance that we will be successful in completing the commercialization in accordance with our plans, or at all. If our commercialization of Dialysate Triferic and/or IV Triferic should be delayed for any reason, 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 begin commercialization of Dialysate Triferic as planned, if the results are unsuccessful, 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 $14.6 million for the nine months ended September 30, 2018. The net loss for this period was higher than net cash used in operating activities by $8.1 million, which was primarily attributable to non-cash expenses of $6.6 million, consisting of, $3.4 million of inventory reserves, $2.4 million of stock-based compensation, $0.5 million of depreciation and amortization, and $0.2 million of realized losses on sale of investments available-for-sale, offset by a decrease of $3.7 million in inventory related to the destruction of Dialysate Triferic finished goods inventory, a $2.1 million decrease in other liabilities related to related to a reduction in bonus and other payroll accruals, a decrease of $1.7 million in deferred revenue related to the recognition of revenue from our licensing agreements, an increase of $1.2 million in accounts receivable related to increases in revenues related to our international sales, an increase in accounts payable of $2.7 million, as well as increased legal fees accrued, an increase of $0.7 million related to a settlement payable, comprised of the $1.5 million accrued in the second quarter of 2018 for the settlement fee related to the Settlement Agreement between the Company and its former directors and officers, offset by settlement payments of $0.8 million, and a $0.5 million increase due to an insurance settlement receivable related to the Settlement Agreement.

Net cash used in operating activities was $16.3 million for the nine months ended September 30, 2017. The decrease of $1.7 million in cash expenses for the nine months ended September 30, 2018 was primarily attributable to the timing of vendor payments which, on a net basis, were further extended in 2018 as compared to the prior period in 2017.

Cash Provided by Investing Activities

Net cash provided by investing activities was $10.5 million during the nine months ended September 30, 2018. The net cash provided was primarily due to the sale of our available-for-sale investments of $29.6 million, offset by $18.5 million used for the purchase of investments available-for-sale and $0.6 million for the purchase of equipment.

Net cash provided by investing activities was $5.2 million during the nine months ended September 30, 2017. The net cash provided was primarily due to the sale of our available-for-sale investments of $40.1 million, offset by $34.2

million used for the purchase of investments available-for-sale and $0.7 million for the purchase of equipment.

Cash Used in Financing Activities

Net cash used in financing activities was $1,978 during the nine months ended September 30, 2018, for the repurchase of common stock to pay the employee withholding taxes on a stock option exercise in September 2018.

Net cash used in financing activities was $2.2 million during the nine months ended September 30, 2017. The net cash used was related to $2.3 million of restricted stock retained in satisfaction of tax liabilities offset by $0.1 million of proceeds from the issuance of common shares.

Critical Accounting Policies and Significant Judgements and Estimates

Our critical accounting policies and significant estimates are detailed in our 2017 Annual Report on Form 10-K. Our critical accounting policies and significant estimates have not changed from those previously disclosed in our 2017 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.

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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 September 30, 2018.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We have invested $13.4 million in available for sale securities that are invested in short-term bonds which typically yield higher returns than the interest realized in money market funds. While these bonds are of short duration, their market value is affected by changes in interest rates. Increases in interest rates will reduce the market value of bonds held and we may incur unrealized losses from the reduction in market value of the bonds. If we sell some or all of our positions, those unrealized losses may result in realized losses which may or may not exceed the interest and dividends earned from those funds. However, due to the short duration of our portfolio of holdings, we do not believe that a hypothetical 100 basis point increase or decrease in interest rates will have a material impact on the value of our investments.

Foreign Currency Exchange Rate Risk

Our international business is conducted in U.S. dollars. It has not been our practice to hedge the risk of appreciation of the U.S. dollar against the predominant currencies of our trading partners. We have no significant foreign currency exposure to foreign supplied materials, and an immediate 10% strengthening or weakening of the U.S. dollar would not have a material impact on our shareholders' equity or net income.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In

designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, 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 Principal Accounting 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 September 30, 2018. Based upon that evaluation, our Chief Executive Officer and Principal Accounting Officer concluded that, because of the material weaknesses in our internal controls over financial reporting described below, our disclosure controls and procedures were not effective for the reasons described below. Notwithstanding the material weaknesses described below, the Company's management, including the Chief Executive Officer and Principal Accounting Officer, has concluded that the consolidated financial statements included in this Quarterly Report 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.

During the nine months ended September 30, 2018, we, together with our independent registered public accounting firm, identified material weaknesses in our internal control over financial reporting, as described below. A "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis.

As of September 30, 2018, our material weaknesses in internal control over financial reporting are:

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- Insufficient segregation of duties, oversight of work performed and lack of compensating controls in our finance and accounting functions due to limited personnel;

- Management has not performed a proper evaluation of our information technology environment and the related disclosure controls and procedures and internal control over financial reporting;

- Management did not design and maintain effective controls related to developing an appropriate methodology to record discretionary bonuses and stock-based compensation, including an on-going review of the assumptions within the methodology to determine the completeness and accuracy of such compensatory amounts; and

- We concluded that errors occurred in establishing our inventory reserves as of March 31, 2018 due to a design deficiency in our controls over the computation and recording of such reserves. Our method of calculating inventory reserves resulted in the misapplication of U.S. GAAP, which caused us to restate our March 31, 2018 condensed consolidated financial statements. Specifically, due to the lack of communication amongst certain former employees, we concluded our controls were not adequately designed to ensure that we were accurately calculating inventory reserves based on the consideration of overall demand assumptions and for our inventory.

Changes in Internal Control over Financial Reporting

In connection with the resignation of Plante & Moran, PLLC (“Plante”) and the restatement of our financial statements for the quarter ended March 31, 2018, Plante and our management identified a material weakness in our internal control over financial reporting. Our Board and our management team determined that control deficiencies existed with respect to oversight of our former Chief Executive Officer and Chief Financial Officer with respect to the quarter ended March 31, 2018. Accordingly, our Board and management team have concluded that management’s reports related to the effectiveness of internal and disclosure controls as of such date may not have been correct.

Accordingly, while our Board’s Audit Committee believes that we have already directly and promptly addressed the cause of any material weakness in its internal control over financial reporting identified by Plante by terminating both our former Chief Executive Officer and Chief Financial Officer, the Audit Committee also directed our management to implement additional processes and procedures to further ensure the accuracy of our periodic SEC reports, registration statements and related financial statements. Additionally, we formed a Disclosure Committee comprised of Company officers and other important employees and advisors who would be in possession of material information with respect to our operations and financial statements (“Key Persons”). Each Key Person is required to participate in the preparation and review, and to certify that he or she has provided all material information to the Chief Executive and Chief Financial Officer in connection with the preparation, review and filing, of our periodic SEC reports, registration statements and related financial statements. The Disclosure Committee is chaired by our external General Counsel, with dual-reporting responsibility to both our Chief Executive Officer and the Board as a whole.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

The disclosure set forth above in Note 10 (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.

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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, 2017 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. 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 ultimate timing for our commercial launch, as well as 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 litigation, which is costly and time-consuming to defend.

In addition to the purported shareholder class action lawsuits filed against us as described in Note 10 “Commitments and Contingencies – Litigation” in the accompanying condensed consolidated financial statements for the quarter ended September 30, 2018, it is possible that other class action securities litigation and derivative lawsuits 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 10 “Commitments and Contingencies – Litigation” in the accompanying condensed consolidated financial statements for the quarter ended September 30, 2018.

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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.

We recently hired a new Chief Executive Officer and announced the hiring of a new Chief Financial Officer. Our inability to successfully manage the transition and integration into our Company of these key executives may have a material adverse impact on our business, results of operations and financial condition.

We hired a new Chief Executive Officer in September 2018 and recently announced the hiring of a new Chief Financial Officer, who is expected to join the Company in late 2018. This leadership transition may be difficult to manage and may cause operational and administrative inefficiencies, added costs, decreased productivity among our employees, and loss of personnel with deep institutional knowledge, which could result in significant disruptions to our operations. In addition, we must successfully integrate our new management team members within our organization in order to achieve our operating objectives, and these changes in key management positions may temporarily affect our financial performance and results of operations as our new management becomes familiar with our businesses. These changes could also increase the volatility of our stock price. If we are unable to mitigate these or other similar risks, our businesses, results of operations, and financial condition may be adversely affected.

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

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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

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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
10.85	Confidential Settlement Agreement and Release, dated August 7, 2018, by and among by and among Rockwell Medical, Inc., Robert Chioini, Thomas Klema, Patrick Bagley and Ronald Boyd*
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2	Certification of Principal Accounting 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

* Confidential treatment requested for portions of this exhibit.

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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: November 9, 2018 /s/ Stuart Paul
Stuart Paul
Chief Executive Officer

Date: November 9, 2018 /s/ David Kull
David Kull
Controller (Principal Accounting Officer)