ROCKWELL MEDICAL, INC.
Form 10-Q
August 14, 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 June 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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	(Do not check if a smaller reporting company)	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 August 6, 2018
Common Stock, no par value	51,768,424 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)

	June 30, 2018	December 31, 2017
ASSETS		
Cash and Cash Equivalents	$ 1,748,135	$ 8,406,917
Investments Available for Sale	20,936,973	24,648,459
Insurance Receivable	500,000	—
Accounts Receivable, net of a reserve of $3,400 in 2018 and $11,000 in 2017	5,354,406	6,355,566
Inventory	4,519,807	7,637,384
Prepaid and Other Current Assets	2,471,740	1,779,992
Total Current Assets	35,531,061	48,828,318
Property and Equipment, net	2,606,145	2,548,978
Inventory, Non-Current	1,865,834	5,986,752
Goodwill	920,745	920,745
Other Non-current Assets	494,238	494,847
Total Assets	$ 41,418,023	$ 58,779,640
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts Payable	$ 3,206,620	$ 4,222,159
Accrued Liabilities	4,040,868	4,715,712
Settlement Payable	1,530,000	—
Current Portion of Deferred License Revenue	2,281,034	—
Customer Deposits	173,396	205,303
Total Current Liabilities	11,231,918	9,143,174
Deferred License Revenue	13,296,866	16,723,318
Total Liabilities	24,528,784	25,866,492

Commitments and Contingencies		
Shareholders' Equity:		
Common Shares, no par value, 51,768,424 shares issued and outstanding at June 30, 2018 and December 31, 2017	275,022,242	273,210,907
Accumulated Deficit	(258,042,689)	(240,262,376)
Accumulated Other Comprehensive Loss	(90,314)	(35,383)
Total Shareholders' Equity	16,889,239	32,913,148
Total Liabilities And Shareholders' Equity	$ 41,418,023	$ 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 June 30, 2018	Three Months Ended June 30, 2017	Six Months Ended June 30, 2018	Six Months Ended June 30, 2017
Sales	$ 14,913,363	$ 13,243,107	$ 29,861,943	$ 27,835,361
Cost of Sales	18,930,371	11,744,819	34,599,442	23,979,601
Gross Profit (Loss)	(4,017,008)	1,498,288	(4,737,499)	3,855,760
Selling, General and Administrative	5,690,949	6,541,179	9,022,906	12,641,894
Settlement Expense, net of Reimbursement	1,030,000	—	1,030,000	—
Research and Product Development	1,558,946	1,675,494	3,225,302	2,890,345
Operating Loss	(12,296,903)	(6,718,385)	(18,015,707)	(11,676,479)
Interest and Investment Income (Loss)	66,111	(364,599)	235,394	(148,528)
Net Loss	$ (12,230,792)	$ (7,082,984)	$ (17,780,313)	$ (11,825,007)
Basic and Diluted Net Loss per Share	$ (0.24)	$ (0.14)	$ (0.35)	$ (0.23)
Basic and Diluted Weighted Average Shares Outstanding	51,288,424	51,031,899	51,288,424	50,859,927

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 June 30, 2018	Three Months Ended June 30, 2017	Six Months Ended June 30, 2018	Six Months Ended June 30, 2017
Net Loss	$ (12,230,792)	$ (7,082,984)	$ (17,780,313)	$ (11,825,007)
Unrealized Gain (Loss) on Available-for-Sale Investments	142,454	500,122	(47,542)	612,124
Foreign Currency Translation Adjustments	(4,904)	(65)	(7,389)	(274)
Comprehensive Loss	$ (12,093,242)	$ (6,582,927)	$ (17,835,244)	$ (11,213,157)

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 six months ended June 30, 2018

(Unaudited)

	COMMON SHARES		ACCUMULATED	ACCUMULATED OTHER COMPREHENSIVE	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	—	—	(17,780,313)	—	(17,780,313)
Unrealized Loss on Available-for-Sale Investments	—	—	—	(47,542)	(47,542)
Foreign Currency Rate Changes	—	—	—	(7,389)	(7,389)
Stock-based compensation	—	1,811,335	—	—	1,811,335
Balance as of June 30, 2018	51,768,424	$ 275,022,242	$ (258,042,689)	$ (90,314)	$ 16,889,239

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 six months ended June 30, 2018 and 2017

(Unaudited)

	2018	2017
Cash Flows From Operating Activities:		
Net Loss	$ (17,780,313)	$ (11,825,007)
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	281,327	259,084
Stock-based Compensation	1,811,335	4,390,072
Increase in Inventory Reserves	5,927,793	—
Loss on Disposal of Assets	2,483	3,634
Realized Loss on Sale of Investments Available-for-Sale	124,987	368,519
Changes in Assets and Liabilities:		
(Increase) in Insurance Receivable	(500,000)	-
Decrease in Accounts Receivable	1,001,160	343,993
Decrease (Increase) in Inventory	1,310,702	(2,532,397)
Decrease (Increase) in Other Assets	(691,139)	349,378
(Decrease) in Accounts Payable	(1,015,539)	(1,988,717)
Increase in Settlement Payable	1,530,000	
(Decrease) in Other Liabilities	(706,929)	(489,857)
(Decrease) in Deferred License Revenue	(1,145,418)	(996,240)
Changes in Assets and Liabilities	(217,163)	(5,313,840)
Cash Used In Operating Activities	(9,849,551)	(12,117,538)
Cash Flows From Investing Activities:		
Purchase of Investments Available-for-Sale	(2,594,349)	(27,262,362)
Sale of Investments Available-for-Sale	6,133,307	33,351,339
Purchase of Equipment	(340,800)	(401,055)
Proceeds on Sale of Assets	—	450
Cash Provided By Investing Activities	3,198,158	5,688,372
Cash Flows From Financing Activities:		
Restricted Stock Retained in Satisfaction of Tax Liabilities	—	(2,287,231)
Cash Used In Financing Activities	—	(2,287,231)

Effects of Exchange Rate Changes	(7,389)	(140)
Decrease In Cash and Cash Equivalents	(6,658,782)	(8,716,537)
Cash At Beginning Of Period	8,406,917	17,180,594
Cash At End Of Period	$ 1,748,135	$ 8,464,057

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 currently marketing and developing unique, proprietary renal drug therapies. 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. We have also obtained licenses for certain dialysis related drugs which we are developing and planning to market in major markets globally either directly or through license partners.

We are also a manufacturer of hemodialysis concentrates/dialysates to dialysis providers and distributors in the United States and abroad. We manufacture, sell and distribute hemodialysis concentrates and other ancillary medical products and supplies used in the treatment of patients with end stage renal disease, or “ESRD”. We also supply dialysis concentrates to distributors serving a number of foreign countries, primarily in the Americas and the Pacific Rim. The majority of our sales occur in the United States.

We are regulated by the United States Food and Drug Administration (“FDA”) under the Federal Drug and Cosmetics Act, as well as by other federal, state and local agencies. We hold several FDA product approvals including both drugs and medical devices.

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

2. Going Concern

As of June 30, 2018, the Company had approximate balances of $1.7 million of cash and cash equivalents, $20.9 million of investments available-for-sale, working capital of $24.3 million and an accumulated deficit of $258.0 million. Net cash used in operating activities for the six months ended June 30, 2018 was approximately $9.8 million.

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

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

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

The accompanying 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.

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(Unaudited)

The condensed consolidated balance sheet at June 30, 2018, condensed consolidated statements of operations for the three and six months ended June 30, 2018 and 2017, condensed consolidated statements of cash flows for the six months ended June 30, 2018 and 2017, and condensed consolidated statement of changes in shareholder's equity for the six months ended June 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 six months ended June 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, 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.

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 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.

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(Unaudited)

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

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

Disaggregation of revenue

In the following table, revenue is disaggregated by primary geographical market, major product line, and timing of revenue recognition.

In thousands of US dollars ($)	Three Months Ended June 30, 2018			Six Months Ended June 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	$ 136	$ —	$ 136
Concentrate Products						
Product Sales – Point-in-time	14,340	12,856	1,484	28,716	25,328	3,388
License Fee – Point-in-time	505	505	—	1,009	1,009	—
Total Concentrate Products	14,845	13,361	1,484	29,725	26,337	3,388
Net Revenue	$ 14,913	$ 13,361	$ 1,552	$ 29,861	$ 26,337	$ 3,524

Contract balances

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

In thousands of US dollars ($)	June 30, 2018	December 31, 2017
Receivables, which are included in "Trade and other receivables"	$ 5,360	$ 5,544
Contract liabilities	$ 15,578	$ 16,723

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

For the three and six months ended June 30, 2018, the Company did not recognize material bad-debt expense and there were no material contract assets recorded on the consolidated balance sheet as of June 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 June 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.

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(Unaudited)

Transaction price allocated to remaining performance obligations

For the three and six months ended June 30, 2018, revenue recognized from performance obligations related to prior periods was not material.

Revenue expected to be recognized in any future year related to remaining performance obligations, excluding revenue pertaining to contracts that have an original expected duration of one year or less, contracts where revenue is recognized as invoiced and contracts with variable consideration related to undelivered performance obligations, totaled $15,578,000 as of June 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 $12,237,000 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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(Unaudited)

Agreement. The Company recognized revenue of approximately $0.6 million and $0.5 million for the three months ended June 30, 2018 and 2017, respectively, and $1.1 million for each of the six months ended June 30, 2018 and 2017, respectively .

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 $1.6 million and $1.7 million for the three months ended June 30, 2018 and 2017, respectively, and $3.2 million and $2.9 million for the six months ended June 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 six months ended June 30, 2018 and 2017, the Company recorded stock-based compensation expense on its options granted under the Company’s 2018 Long Term Incentive Plan (the “Plan”) to its directors and officers, and its employees. Stock-based compensation expense recorded for the Company’s stock options was $353,161 for the three months ended June 30, 2018 and $1,070,899 for the three months ended June 30, 2017. Stock-based compensation expense for restricted shares was $1,012,171 and $1,040,787 for the three months ended June 30, 2018 and 2017, respectively. For the six months ended June 30, 2018 and 2017, the Company recorded stock-based compensation of $539,433 and $2,203,686 respectively, related to its stock options. For the six months ended June 30, 2018 and 2017, the Company recorded stock-based compensation expense on its restricted stock awards granted to its directors and officers, employees and non-employee consultants of $1,271,902 and $2,186,386, respectively.

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 months ended June 30, 2018 and 2017 were options to purchase common stock of 6,881,001 and 7,706,501, respectively and 480,000 shares of unvested restricted stock for the three months ended June 30, 2018 and 2017, respectively, (excluding subsequent cancellations). For the six months ended June 30, 2018 and 2017 the options to purchase common stock were 6,806,001 and 7,706,501, respectively and unvested restricted shares totaled 480,000 for the six months ended June 30, 2018 and 2017, respectively (excluding subsequent cancellations).

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(Unaudited)

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 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) which supersedes FASB Topic 840, Leases (Topic 840) and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of classification. Leases with a term of twelve months or less will be accounted for similar to existing guidance for operating leases. In January 2018, the FASB issued ASU 2018-01, Leases (Topic 842) Land Easement Practical Expedient for Transition to Topic 842, which amends ASU 2016-02 to provide entities an optional transition practical expedient to not evaluate under Topic 842 existing or expired land easements that were not previously accounted for as leases under the current leases guidance in Topic 842. An entity that elects this practical expedient should evaluate new or modified land easements

under Topic 82 beginning at the date that the entity adopts Topic 842. The standard will be effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted upon issuance. The Company is currently evaluating the effect that the updated standard will have on its condensed consolidated financial statements and related disclosures.

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 $20,936,973 as of June 30, 2018. 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 June 30, 2018 was $142,454. There were no unrealized gains were for the three months ended June 30, 2018. Realized gains for the three months ended June 30, 2018 were $2,213 and realized losses were $124,208 for the same period. Gross unrealized losses for the six months ended June 30, 2018 were $151,057and gross unrealized gains were $103,515 as of June 30, 2018. There were realized gains of $128,625 and realized losses of $3,638 during the six months ended June 30, 2018.

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

5. Inventory

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

	June 30, 2018	December 31, 2017
Raw Materials	$ 4,356,766	$ 10,604,232
Work in Process	219,553	212,505
Finished Goods	1,809,322	2,807,399
Total	$ 6,385,641	$ 13,624,136

As of June 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 June 30, 2018, we had total Triferic finished goods inventory aggregating $11,916,193 against which we had reserved $9,382,958.

6. Property and Equipment

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

	June 30, 2018	December 31, 2017
Leasehold Improvements	$ 875,806	$ 824,087
Machinery and Equipment	8,083,260	7,893,566

Information Technology & Office Equipment	2,473,160	2,327,524
Laboratory Equipment	603,092	631,666
Transportation Equipment	—	242,277
	12,035,318	11,919,120
Accumulated Depreciation	(9,429,173)	(9,370,142)
Net Property and Equipment	$ 2,606,145	$ 2,548,978

Depreciation expense for the three months ended June 30, 2018 and 2017, totaled $152,162 and $128,781. Depreciation expense for the six months ended June 30, 2018 and 2017, totaled $281,150 and $258,907.

7. Shareholders' Equity

Preferred Stock

As of June 30, 2018 and December 31, 2017, there were no shares of the Company's 2,000,000 shares of authorized preferred stock outstanding.

Common Stock

There were no changes to common stock from January 1, 2018 through June 30, 2018.

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8. Stock-Based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Restricted stock awards	$ 1,012,171	$ 1,040,787	$ 1,271,902	$ 2,186,386
Stock option awards	353,161	1,070,899	539,433	2,203,686
	$ 1,365,332	$ 2,111,686	$ 1,811,335	$ 4,390,072

Restricted Stock Awards

A summary of the Company’s restricted stock activity during the six months ended June 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	-	-
Granted at June 30, 2018	1,380,000	$ 7.27

The fair value of restricted stock awards are measured based on their fair value on the date of grant and amortized over the vesting period.

Stock Options

A summary of the Company's stock option activity for the six months ended June 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	-	-	-	
Exercised	-	-	-	
Forfeited	(100,000)	6.93	-	
Outstanding at June 30, 2018	6,806,001	$ 7.93	4.6	$ 629,680
Exercisable at June 30, 2018	6,578,161	$ 7.93	4.5	$ 629,680

The aggregate intrinsic value in the table above represents the total intrinsic (the difference between the Company's closing stock price on June 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 June 30, 2018.

During the six months ended June 30, 2018, there were 100,000 options forfeited under the Plan. The vested options were exercisable at an average price of $7.93 per share and the unvested options were exercisable at an average of $8.02 per share.

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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 June 30, 2018, total stock-based compensation expense related to unvested options not yet recognized totaled approximately $98,000.

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 Notes 10 and 11. The Company accrued approximately $1.5 million related to this Settlement Agreement as of June 30, 2018. The Company is also entitled to a partial reimbursement for this accrual from the Company's insurance company of approximately $0.5 million (an increase to accounts receivable). This resulted in a net settlement expense of approximately $1.0 million for the three and six months ended June 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

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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

As a follow up to its prior inquiry letters, the Company received further correspondence and a subpoena from the SEC during the Company's third quarter requesting certain information generally with respect to the status of CMS's determination of separate reimbursement status for Triferic and the Company's prior decision not to actively market and sell Triferic without such separate reimbursement, as well as requests for information with respect to the Board's termination of our former CEO. The Company is actively cooperating and responding to these requests.

Whistleblower Complaint & Independent Investigation

On May 17, 2018, the Company's former CEO and former CFO filed a whistleblower complaint with the SEC alleging that certain of the Company's directors violated their fiduciary duties of loyalty and care to the Company, rules under Regulation FD and various federal securities laws. The Board's Audit Committee has engaged independent counsel to conduct an independent investigation into the allegations set forth in the whistleblower complaint, as well as a related shareholder demand. The Company's Board and management are actively cooperating with the investigation of the independent counsel.

11. Subsequent Events

Litigation

State Court and Federal Court Actions

As reported above under Note 10, 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. As of the date of this Quarterly Report, the Federal Court has not yet entered an order of dismissal in the Federal Court action.

Shareholder Class Action Lawsuits

As of the date of this Quarterly Report, the Company is aware of one purported class action lawsuit naming the Company and its former CEO and former CFO as defendants. The complaint, which was filed on July 27, 2018 in the United States District Court for the Eastern District of New York, alleges that, from that period of March 16, 2018 through June 26, 2018, the defendants violated certain federal securities laws by disseminating false and misleading information. The lawsuits seeks damages sustained by the class and an award of plaintiffs' costs and attorneys' fees. As of the date of this Quarterly Report, no lead plaintiff has been appointed, no class has been certified and the Company has not been served with the complaint.

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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 ability to maintain compliance with SEC and NASDAQ rules and requirements; our plans relating to the commercialization of Triferic and Calcitriol; our timing and ability to obtain add-on reimbursement for Triferic; our ability to obtain FDA and EMA approval of the intravenous formulation of Triferic; whether we can successfully execute on our new 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.

Risks Related To Our Drug Business

- There can be no assurance of if or when we might receive separate reimbursement status for Triferic from CMS given the recent communication that the Company's Triferic demonstration project submitted in October 2017 is no longer being considered by CMS' Center for Medicare & Medicaid Innovation.

- We may not be able to commercialize Triferic successfully.
- If we are unable to use our Triferic inventory before its shelf life expires, we will have to recognize additional inventory obsolescence reserves which could have a material adverse effect on our results of operations, financial condition and cash flows and which has already resulted in a restatement of our first quarter financial results for the quarter ended March 31, 2018 and the incurrence of substantial inventory reserves during the first six months of 2018.
- Our ability to market Triferic and other FDA-approved drugs is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, which may limit our ability to market Triferic and our other drug products.
- We may experience technical challenges with certain Triferic applications which may lead some dialysis providers to prefer one Triferic application over another or choose not to use Triferic all-together.
- While we intend to file an NDA with the FDA prior to December 31, 2018 to allow for the intravenous application of Triferic, such application process is costly and there can be no assurance it will be successful.
- If we are unable to obtain and maintain adequate protection for our data, intellectual property and other proprietary rights, our business may be harmed.
- Defending our proprietary rights could be expensive, we may not always be successful in protecting our intellectual property, licenses and other proprietary rights and we could be prevented from selling products, forced to pay royalties and damages and compelled to defend against litigation if we infringe the rights of a third party.
- We depend on contract manufacturing organizations to manufacture our drug products. If these organizations are unable or unwilling to manufacture our drug products, or if these organizations fail to comply with FDA or other applicable regulations or otherwise fail to meet our requirements, our drug business will be harmed.

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- We rely on third party suppliers for raw materials and packaging components of our drug products. We may not be able to obtain the raw materials and proper components we need, or the cost of the materials or components may be higher than expected, any of which could impair our production or commercialization of drug products and have a material adverse effect on our business, results of operations and financial position.
- We may not be successful in obtaining foreign regulatory approvals or in arranging out-licensing partners capable of obtaining the approvals needed to effectively commercialize our drug products outside of the United States. Even if we are successful in out-licensing our drug products and obtaining the required regulatory approvals, the licensees or partners may not be effective at marketing our products in certain markets or at all.
- If our products are approved and marketed outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.
- We may not be successful in expanding our drug product portfolio or in our business development efforts related to in-licensing, acquisitions or other business collaborations. Even if we are able to enter into business development arrangements, they could have a negative impact on our business and our profitability.
- Expansion of our drug business in the United States may require FDA approval of new drug candidates or indications for use. The process of obtaining FDA approval is a long and expensive process with no guarantee of success.
- Our drug business depends on government funding of health care, and changes could impact our ability to be paid in full for our products, increase prices or cause consolidation in the dialysis provider market.
- It may be difficult for us to capture market share for Calcitriol in the highly competitive generic drug market.

Risks Related To Our Concentrate Business

- We may be required to repay a portion of the fees received from Baxter, which could materially and adversely affect our financial position and cash reserves.
- A few customers account for a substantial portion of the end user sales of our concentrate products. The loss of any of these customers could have a material adverse effect on our results of operations and cash flow from our concentrate business.
- The concentrate market is competitive and has a large competitor with substantial resources.
- We may be affected materially and adversely by increases in raw material costs.

Risks Related To Our Business As A Whole

- Our existing cash, liquidity and capital resources may not be adequate to finance our operating cash requirements for the length of time that we have estimated, particularly given the recent litigation and other events related to the termination of our former Chief Executive Officer and Chief Financial Officer. Our financial statements for the quarter ended June 30, 2018 include a footnote identifying a going concern risk.
- We will likely need to raise additional equity or debt capital in the near future to help ensure we have sufficient liquidity to fund our operations.
- We likely will be unable to obtain secured debt financing because of borrowing restrictions under the Baxter Agreement.
- Our potential inability to hire a new Chief Financial Officer.

- Our ongoing independent investigation of the whistleblower complaint filed with the SEC by our former Chief Executive Officer and Chief Financial Officer and other related allegations will be costly, time consuming and distracting to our Board and management team and could have an adverse effect on our business.
- Any adverse conclusions from our ongoing SEC inquiry could result in fines, criminal penalties and have an adverse effect on our business.
- Our ongoing defense of class action lawsuits will be costly, time consuming and distracting to our Board and management team and could have an adverse effect on our business.
- Our drug and concentrate businesses are highly regulated, resulting in additional expense and risk of noncompliance that can materially and adversely affect our business, results of operation, financial position and cash flows.
- Health care reform could adversely affect our business.
- We recently hired a new Chief Executive Officer and we are still actively seeking a new Chief Financial Officer; there can be no assurance that this management transition is successful.
- Defending our intellectual property rights could be expensive, we may not always be successful in protecting our exclusive rights and we could be prevented from selling products, forced to pay damages and compelled to defend against litigation if we infringe the rights of a third party.

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- Our products may have undesirable side effects and our product liability insurance may not be sufficient to protect us from material liability or harm to our business.
- Our business and operations would suffer in the event of a security breach, system failure, invasion, corruption, destruction or interruption of our or our business partners' critical information technology systems or infrastructure.
    - We use biological and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.
- Our distribution costs may increase as we and the industry experience a shortage of qualified transportation drivers, which shortage could have an effect on our costs to deliver goods as well as our costs to use third-party suppliers and delivery services.

Risks Related To Our Common Stock

- Any additional issuances of our common shares in order to raise equity capital would likely be dilutive to our existing shareholders.
- Shares eligible for future sale may affect the market price of our common shares.
- The market price for our common stock is volatile.
- Our ability to use our net operating loss carryforwards to offset potential taxable income and related income taxes that would otherwise be due may be limited.
- In addition to the material weakness in our internal control over financial reporting identified by our former independent registered public accounting firm, we have identified additional material weaknesses in our internal control over financial reporting, which, until remedied, could result in errors in our financial statements requiring restatement of our financial statements. As a result, investors may lose confidence in our reported financial information, which could lead to a decline in our stock price.
- Structural and anti-takeover provisions reduce the likelihood that you will receive a takeover premium.
- We do not anticipate paying dividends in the foreseeable future.

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. We do not undertake and 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. 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 (Ferric Pyrophosphate Citrate)

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

Until June 7, 2018, we focused mainly on obtaining separate add-on reimbursement status for Triferic and therefore refrained from a broad commercial launch of Triferic.

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On June 7, 2018, feedback received from the organization under CMS, Center for Medicare & Medicaid Innovation ("CMMI"), informed the view of our Board of Directors that the near-term prospects were unlikely for obtaining add-on reimbursement for Triferic. As a result, our Board of Directors believed that it would be in the best interests of the Company and dialysis patients to commercially launch Triferic with initial reimbursement within the bundle of payments to dialysis providers and we announced that we will move forward with the commercial planning and launch of Triferic. In parallel with the commercial launch of Triferic, we will continue our pursuit of obtaining separate reimbursement status for Triferic; however, we cannot predict the outcome or timing of the process to obtain separate reimbursement and there can be no assurance of if or when we might receive separate reimbursement for Triferic. We do not anticipate Triferic sales will have a material impact on our total revenue for 2018.

We have built and previously invested in significant inventory of Triferic in anticipation of receiving separate reimbursement status. However, as a result of the recent feedback received from CMMI, we wrote off a total of $2.0 million of our inventory investment in Triferic in the first quarter of 2018. As of June 30, 2018, we had $7.5 million of Triferic finished goods inventory that could expire within the next 12 months and against which we have reserved $7.3 million. In the second quarter of 2018, we reserved an additional $3.3 million (included within our $7.3 million reserve) resulting in a remaining net book value of $0.2 million of Triferic finished goods inventory as of June 30, 2018. As of June 30, 2018, we also had approximately $2.1 million of Triferic Active Pharmaceutical Ingredient ("API") and classified $1.9 million of Triferic API as non-current inventory. If CMS does not award us separate reimbursement for Triferic during 2018, further extends its review of Triferic for separate reimbursement or should we not realize commercial sales of Triferic during 2018 or 2019, additional amounts or all of our current investment in Triferic finished goods inventory and some or all of our 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.

While we intend to market and sell Triferic directly in the United States, our global strategy is to partner with and license to established companies in other regions of the world Triferic to assist in the further development of, and if necessary, commercialization of Triferic. We continue to pursue international licensing opportunities in a number of countries and specific regions.

Dialysis Concentrates

We manufacture, sell, deliver and distribute hemodialysis concentrates, along with a full line of ancillary 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 six months ended June 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 ("CMO"). On July 11, 2018, we received FDA approval of our Prior Approval Supplement for manufacturing Calcitriol. This approval allows us to now begin marketing and commercialization of Calcitriol in the United States; however, we do not anticipate Calcitriol sales 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 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 to be initiated in the third quarter of 2018.

As part of the FDA's approval of Triferic in 2015, we committed to conduct a further clinical study of the effectiveness of Triferic in a pediatric patient population. We have reached agreement with the FDA on the design of this study, which we intend to commence by early 2019, assuming we have the liquidity and capital resources to do so. We expect that the

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data from this pediatric study could be used to support pediatric approval by the EMA, if and when we are able to complete the other clinical trials needed to support making such a filing.

We are also in the process of preparing a New Drug Application ("NDA") seeking FDA approval for an intravenous ("IV") formulation of Triferic. We believe that an IV formulation has the potential to be more commercially viable in the United States and abroad than the current application of Triferic. We plan to file the NDA before the end of 2018, assuming we have the liquidity and capital resources to do so, at which point we would expect an approximate 10-month review period by the FDA. Upon filing of the NDA, we will be required to pay a filing fee to the FDA of approximately $1.2 million.

Results of Operations for the three months ended June 30, 2018 and June 30, 2017

Sales

During the second quarter of 2018 our sales were $14.9 million, which is $1.7 million, or 12.6%, higher than the second quarter of 2017. The increase was primarily due to higher domestic concentrate sales of $13.4 million which was primarily due to increased pass through delivery costs billed to Baxter and the addition of ARA clinics brought on by Baxter. Our international sales increased 9.6% over the second quarter of 2017. Revenue recognized from licensing fees was $0.6 million and $0.5 million for the three months ended June 30, 2018 and 2017, respectively.

Gross Profit (Loss)

Cost of sales during the second quarter of 2018 was $18.9 million resulting in a negative gross profit of $(4.0) million as the gross profit from our concentrate business was offset by expenses related to our drug business. Gross profit was negatively impacted by $5.6 million in costs related to our drug business which included an increase in our Triferic inventory reserve of $5.4 million. Our concentrate gross profit was approximately $1.5 million and decreased by $0.1 million in the second quarter of 2018 compared to the second quarter of 2017. The decrease in our concentrate business gross profit was largely due to increased concentrate distribution costs and lower pricing under the Baxter Agreement, 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 costs in the near term.

Selling, General and Administrative Expense

Selling, general and administrative expenses were $5.7 million during the second quarter of 2018 compared with $6.5 million during the second quarter of 2017. The $0.9 million decrease was primarily due to lower stock-based compensation expense of $1.4 million recorded for the three months ended June 30, 2018, as compared to stock-based compensation expense of $2.1 million recorded for the three months ended June 30, 2017. Equity grants awarded to our independent directors and non-executive employees during the first quarter were made expressly contingent upon shareholder approval of our proposed Plan at our annual meeting of shareholders, which approval was obtained in July 2018. Since our shareholders approved the Plan at the annual meeting of shareholders, we will begin to amortize $1.5 million of equity compensation expense associated with these awards, with approximately $740,000 expected to be recognized during the remainder of 2018. We expect our selling, general and administrative expense will increase materially in the second half of the year to help support our expected increased Triferic commercialization efforts, as well as due to costs associated with the litigation with our former Chief Executive Officer and Chief Financial Officer. See Part II – Item 1 – Legal Proceedings.

Research and Product Development Expense

Research and product development expenses were $1.6 million for the second quarter 2018 compared with $1.7 million of expenses incurred during the second quarter of 2017. We incurred research and product development costs due to our investment in future product development, intellectual property, regulatory activities and patent approvals of new products, primarily Triferic. Research and product development expenses incurred in the second 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 our currently planned additional clinical development of Triferic Calcitriol and other products, assuming we have the liquidity and capital resources to do so.

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Interest and Investment Income, Net

Interest and investment income was $0.1 million for the three months ended June 30, 2018 and net interest and investment loss in the second quarter of 2017 totaled $0.4 million.

Results of Operations for the six months ended June 30, 2018 and June 30, 2017

Sales

Sales during the six months ended June 30, 2018 were $29.8 million compared to sales of $27.8 million during the six months ended June 30, 2017. The increase of $2.0 million was primarily due to higher domestic concentrate sales of $26.3 million which was primarily due to increased pass through delivery costs billed to Baxter. Our international sales increased 5% over the six months ended June 30, 2017. Revenue recognized from licensing fees was $1.1 million for each of the six months ended June 30, 2018 and 2017.

Gross Profit (Loss)

Cost of sales during the six months ended June 30, 2018 was $34.6 million resulting in a negative gross profit of $(4.7) million as the gross profit from our concentrate business was offset by expenses related to our drug business. Gross profit was negatively impacted by $8.0 million in costs related to our drug business which included an increase in our Triferic inventory reserve of $7.6 million. Our concentrate gross profit was approximately $3.1 million and decreased by $0.9 million in the six months ended June 30, 2018 compared to the six months ended June 30, 2017. The decrease in our concentrate business gross profit was largely due to increased concentrate distribution costs and lower pricing under the Baxter Agreement, 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 costs in the near term.

Selling, General and Administrative Expense

Selling, general and administrative expenses during the six months ended June 30, 2018 were $9.0 million compared to $12.6 million during the six months ended June 30, 2017. The $3.6 million decrease was primarily due to lower stock-based compensation expense of $1.8 million recorded during the six months ended June 30, 2018, compared to stock-based compensation expense of $4.4 million recorded during the six months ended June 30, 2017. Equity grants awarded to our independent directors and non-executive employees during the first quarter were made expressly contingent upon shareholder approval of our proposed Plan at our annual meeting of shareholders, which approval was obtained in July 2018. Since our shareholders approved the Plan at the annual meeting of shareholders, we will begin to amortize $1.5 million of equity compensation expense associated with these awards, with approximately $740,000 expected to be recognized during the remainder of 2018. We expect our selling, general and administrative expense will increase materially in the second half of the year to help support our expected increased Triferic commercialization efforts, as well as due to costs associated with the litigation with our former Chief Executive Officer and Chief Financial Officer. See Part II – Item 1 – Legal Proceedings.

Research and Product Development Expense

Research and product development expense increased $0.3 million. Research and product development expenses were $3.2 million for the six months ended June 30, 2018 compared with $2.9 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, regulatory activities and patent approvals of new products, primarily Triferic. Research and product development expenses incurred during the six months ended June 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 Triferic, Calcitriol and other products, assuming we have the liquidity and capital resources to do so.

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Interest and Investment Income, Net

Interest and investment income in the six months ended June 30, 2018 was $0.2 million as compared to $0.1 million of loss during the six months ended June 30, 2017.

Liquidity and Capital Resources

Going Concern

As of June 30, 2018, we had approximate balances of $1.7 million of cash and cash equivalents, $20.9 million of investments available-for-sale, working capital of $24.3 million and an accumulated deficit of $258 million. Net cash used in operating activities for the six months ended June 30, 2018 was approximately $9.8 million.

We will require significant additional capital to sustain our short-term operations and make the investments we need to execute our longer-term business plan. Our existing liquidity is not sufficient to fund our operations and anticipated capital expenditures within the next 12 months. As a result, we intend to seek additional debt or equity financing; however, there are currently no commitments in place for further financing nor is there any assurance that such financing will be available to us on favorable terms, if at all.

Our recurring operating losses, net operating cash flow deficits, and accumulated deficit, raise substantial doubt about our ability to continue as a going concern for one year from the date of this Quarterly Report. Our condensed consolidated financial statements have prepared assuming we will continue as a going concern. We have not made adjustments to our accompanying condensed consolidated financial statements related to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

General

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

Our uses of cash have primarily been for operating expenses and research and product development expenses. Cash used in operating activities was $9.8 million in the six months ended June 30, 2018, which included research and development expenses of $3.2 million. A settlement payment to an activist group of $428,000 was paid in the first quarter of 2018 and we incurred $2.5 million in legal expenditures in the second quarter of 2018 as a result of our litigation with our former Chief Executive Officer and Chief Financial Officer. In August 2018, we also paid $780,000 as part of the total $1,530,000 in settlement payments that we agreed to pay to resolve claims with our former Chief Executive Officer and Chief Financial Officer.

As we have limited capital resources, expect to continue to incur significant losses and will require significant additional capital to commercially launch Triferic and support our operations, including our research and development projects and our plans to submit an NDA prior to the end of 2018 seeking FDA approval for Triferic IV (filing fee for NDA is approximately $1.2 million, in addition to substantial additional related research and development costs), we will likely seek to raise additional capital through one or more of the following: (i) equity and debt raises through the equity and capital markets, though there can be no assurance that we will be able to secure additional capital or funding on acceptable terms, of if at all; and (ii) strategic transactions, including potential alliances and collaborations focused on markets outside the U.S., as well as potential combinations (including by merger or acquisition) or other corporate transactions. In particular, our Baxter Agreement prohibits us from entering into a contract that would encumber the assets used in our concentrate business without the prior written consent of Baxter. Due to the fact that the assets used in our concentrate business currently constitute a substantial portion of the tangible assets we own other than our drug inventory, we may not be able to, or we may find it difficult, to obtain secured debt financing without the consent of Baxter.

We believe that our ability to fund our activities in the long term will be highly dependent upon our ability to successfully launch Triferic and achieve results that are sufficiently positive to attract investor interest and support. Our

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commercialization of Triferic 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 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 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.

Operating Activities

Net cash used in operating activities was $9.8 million for the six months ended June 30, 2018. The net loss for this period was higher than net cash used in operating activities by $8.3 million, which was primarily attributable to non-cash expenses of $8.1 million, consisting of $5.9 million of inventory reserves, $1.8 million of stock-based compensation, $0.3 million of depreciation and amortization, and $0.1 million of realized losses on sale of investments available-for-sale, offset by a decrease of $1.3 million in inventory caused by the destruction of Triferic finished goods inventory, a decrease of $1.0 million in accounts receivable, a decrease of $1.1 million related to the recognition of revenue from our licensing agreements, a decrease in accounts payable of $1.0 million, an increase of $1.5 million due to an accrual for a settlement fee related to the Settlement Agreement between the Company and its former directors and officers, a $0.7 million increase in other assets and a $0.5 million increase due to an insurance settlement receivable related to the Settlement Agreement.

Net cash used in operating activities was $12.1 million for the six months ended June 30, 2017. The net loss for this period was lower than the net cash used in operating activities by $0.5 million which is primarily attributable to non-cash expenses of $5.0 million, consisting of $4.4 million of stock-based compensation, $0.4 million of realized losses on investments available-for-sale and depreciation and amortization of $0.3 million, primarily offset by increases in inventory of $2.5 million, a decrease in accounts payable of $2.0 million, a decrease of $1.0 million related to license revenue from our licensing agreements.

Investing Activities

Net cash provided by investing activities was $3.2 million during the six months ended June 30, 2018. The cash provided was primarily due to the sale of our available-for-sale investments of $6.1 million, offset by $2.6 million used for the purchase of investments available-for-sale and $0.3 million for the purchase of equipment.

Net cash provided by investing activities was $5.7 million during the six months ended June 30, 2017. The cash provided was primarily due to the sale of our available-for-sale investments of $33.4 million, offset by $27.3 million used for the purchase of investments available-for-sale and $0.4 million for the purchase of equipment.

Financing Activities

During the six months ended June 30, 2018, the Company did not engage in any cash based financing activities.

Net cash used in financing activities was $2.3 million during the six months ended June 30, 2017. The net cash used was related to restricted stock retained in satisfaction of tax liabilities.

Critical Accounting Policies and Significant Judgements and Estimates

Our critical accounting policies and significant estimates are detailed in our 2017 Annual Report. 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.

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 June 30, 2018.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We have invested $20.9 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 principal 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 Interim Principal 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 June 30, 2018. Based upon that evaluation, our Interim Principal 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 Interim Principal 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 first half of 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 June 30, 2018, our material weaknesses in internal control over financial reporting are:

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

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- 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

Circuit Court for Oakland County, Michigan

Following the Board's termination of our 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, we filed a complaint in the State Court seeking declaratory relief and a temporary restraining order. Following the State Court-ordered mediation, we and the other parties agreed to a 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 us to withdraw our 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, our former CEO and CFO filed a complaint in the Federal Court against us and certain of our directors. The complaint requested that the Federal Court reinstate our former CEO and CFO to their former positions and order us and 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 our 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, we filed an answer

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and counterclaim against our 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. As of the date of this Quarterly Report, the Federal Court has not yet entered an order of dismissal in the Federal Court action.

Settlement Agreement

On August 7, 2018, we and the various other parties, 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. We agreed to: (i) pay the settling parties a t