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United States
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2019

or

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

For the transition period from to

Commission File Number: 000-23661

ROCKWELL MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware	**38-3317208**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
411 Hackensack Avenue, Suite 501, Hackensack , New Jersey	**07601**
(Address of principal executive offices)	(Zip Code)

(248) 960-9009
(Registrant's telephone number, including area code)

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

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

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

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

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☒
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

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

Title of each class:	Trading Symbol	Name of each exchange on which registered:
Common Stock, par value $.0001	RMTI	Nasdaq Global Market

The number of shares of common stock outstanding as of November 12, 2019 was 63,955,893.

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

	September 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
Cash and Cash Equivalents	$ 14,421,394	$ 22,713,980
Investments Available-for -Sale	14,575,589	10,818,059
Accounts Receivable, net	5,122,453	6,979,514
Insurance Receivable	—	371,217
Inventory	3,583,452	4,038,778
Prepaid and Other Current Assets	2,861,708	1,903,682
Total Current Assets	**40,564,596**	**46,825,230**
Property and Equipment, net	2,506,093	2,638,293
Inventory, Non-Current	528,000	1,637,000
Right of Use Assets, net	3,011,805	—
Goodwill	920,745	920,745
Other Non-current Assets	555,933	536,516
Total Assets	$ **48,087,172**	$ **52,557,784**
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts Payable	$ 3,194,039	$ 4,492,071
Accrued Liabilities	3,916,069	5,129,761
Settlement Payable	270,000	416,668
Lease Liability - Current	1,482,441	—
Deferred License Revenue - Current	2,238,450	2,252,868
Insurance Financing Note Payable	1,145,133	—
Customer Deposits	48,163	63,143
Other Current Liability - Related Party	100,000	850,000
Total Current Liabilities	**12,394,295**	**13,204,511**
Lease Liability - Long-Term	1,589,098	—
Deferred License Revenue - Long-Term	10,401,166	12,076,399
Total Liabilities	**24,384,559**	**25,280,910**
Commitments and Contingencies (See Note 16)		
Shareholders' Equity:		
Preferred Shares, $.0001 par value, no shares issued and outstanding at September 30, 2019 and December 31, 2018	—	—
Common Shares, $.0001 par value; 170,000,000 shares authorized; 63,887,384 and 57,034,154 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	6,389	5,703
Additional paid-in capital	322,837,353	299,596,257
Accumulated Deficit	(299,213,836)	(272,388,234)
Accumulated Other Comprehensive Income	72,707	63,148
Total Shareholders' Equity	**23,702,613**	**27,276,874**
Total Liabilities And Shareholders' Equity	$ **48,087,172**	$ **52,557,784**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Net Sales	$ 15,407,248	$ 16,672,416	$ 45,812,475	$ 46,534,358
Cost of Sales	15,423,612	14,703,606	44,085,298	49,303,048
Gross Profit (Loss)	(16,364)	1,968,810	1,727,177	(2,768,690)
Selling and Marketing	1,827,473	121,874	7,148,848	716,414
General and Administrative	4,623,503	6,037,267	16,340,672	14,465,634
Settlement Expense	—	—	430,000	1,030,000
Research and Product Development	1,474,735	808,192	4,930,287	4,033,494
Operating Loss	(7,942,075)	(4,998,523)	(27,122,630)	(23,014,232)
Other Income				
Realized Gain (Loss) on Investments	6,268	(97,027)	24,292	(222,014)
Interest Income, net	80,735	125,918	272,736	486,301
Total Other Income	87,003	28,891	297,028	264,287
Net Loss	$ (7,855,072)	$ (4,969,632)	$ (26,825,602)	$ (22,749,945)
Basic and Diluted Net Loss per Share	$ (0.12)	$ (0.10)	$ (0.45)	$ (0.44)
Basic and Diluted Weighted Average Shares Outstanding	63,796,723	51,288,537	59,728,446	51,288,462

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Net Loss	**$ (7,855,072)**	**$ (4,969,632)**	**$ (26,825,602)**	**$ (22,749,945)**
Unrealized Gain on Available-for-Sale Debt Instrument Investments	5,926	143,868	10,190	96,327
Foreign Currency Translation Adjustments	(776)	(6,402)	(631)	(13,791)
Comprehensive Loss	**$ (7,849,922)**	**$ (4,832,166)**	**$ (26,816,043)**	**$ (22,667,409)**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

For the three months ended September 30, 2019

(Unaudited)

	COMMON SHARES		ADDITIONAL PAID-IN	ACCUMULATED	ACCUMULATED OTHER COMPREHENSIVE	TOTAL SHAREHOLDER'S
	SHARES	AMOUNT	CAPITAL	DEFICIT	INCOME	EQUITY
Balance as of July 1, 2019	**63,398,704**	**$ 6,340**	**$ 320,876,606**	**$ (291,358,764)**	**$ 67,557**	**$ 29,591,739**
Net Loss	—	—	—	(7,855,072)	—	(7,855,072)
Unrealized Gain on Available-for-Sale Investments	—	—	—	—	5,926	5,926
Foreign Currency Translation Adjustments	—	—	—	—	(776)	(776)
Delivery of common stock underlying restricted stock units, net of tax	62,800	6	(84,866)	—	—	(84,860)
Issuance of common stock, net of offering costs/Public offering	425,880	43	1,169,199	—	—	1,169,242
Stock-based Compensation	—	—	876,414	—	—	876,414
Balance as of September 30, 2019	**63,887,384**	**$ 6,389**	**$ 322,837,353**	**$ (299,213,836)**	**$ 72,707**	**$ 23,702,613**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

For the three months ended September 30, 2018

(Unaudited)

	COMMON SHARES		ADDITIONAL PAID-IN	ACCUMULATED	ACCUMULATED OTHER COMPREHENSIVE	TOTAL SHAREHOLDER'S
	SHARES	AMOUNT	CAPITAL	DEFICIT	INCOME / (LOSS)	EQUITY
Balance as of July 1, 2018	**51,768,424**	**$ 5,177**	**$ 275,017,065**	**$ (258,042,689)**	**$ (90,313)**	**$ 16,889,240**
Net Loss	—	—	—	(4,969,632)	—	(4,969,632)
Unrealized Gain on Available-for-Sale Investments	—	—	—	—	143,868	143,868
Foreign Currency Translation Adjustments	—	—	—	—	(6,402)	(6,402)
Exercise of Employee Stock Options, Net of Tax	870	—	(1,978)	—	—	(1,978)
Stock-based Compensation	—	—	614,584	—	—	614,584
Balance as of September 30, 2018	**51,769,294**	**$ 5,177**	**$ 275,629,671**	**$ (263,012,321)**	**$ 47,153**	**$ 12,669,680**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

For the nine months ended September 30, 2019

(Unaudited)

	COMMON SHARES		ADDITIONAL PAID-IN	ACCUMULATED	ACCUMULATED OTHER COMPREHENSIVE	TOTAL SHAREHOLDER'S
	SHARES	AMOUNT	CAPITAL	DEFICIT	INCOME	EQUITY
Balance as of January 1, 2019	**57,034,154**	**$ 5,703**	**$ 299,596,257**	**$ (272,388,234)**	**$ 63,148**	**$ 27,276,874**
Net Loss	—	—	—	(26,825,602)	—	(26,825,602)
Unrealized Gain on Available-for-Sale Investments	—	—	—	—	10,190	10,190
Foreign Currency Translation Adjustments	—	—	—	—	(631)	(631)
Exercise of Employee Stock Options	30,000	3	147,897	—	—	147,900
Delivery of common stock underlying restricted stock units, net of tax	126,973	13	(180,302)	—	—	(180,289)
Issuance of common stock, net of offering costs/Public offering	6,259,214	626	17,289,296	—	—	17,289,921
Issuance of common stock, net of offering costs/At-the-market offering	437,043	44	2,089,164	—	—	2,089,208
Stock-based Compensation	—	—	3,895,041	—	—	3,895,041
Balance as of September 30, 2019	**63,887,384**	**$ 6,389**	**$ 322,837,353**	**$ (299,213,836)**	**$ 72,707**	**$ 23,702,613**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

For the nine months ended September 30, 2018

(Unaudited)

	COMMON SHARES		ADDITIONAL PAID-IN	ACCUMULATED	ACCUMULATED OTHER COMPREHENSIVE	TOTAL SHAREHOLDER'S
	SHARES	AMOUNT	CAPITAL	DEFICIT	(LOSS)	EQUITY
Balance as of January 1, 2018	**51,768,424**	**$ 5,177**	**$ 273,205,730**	**$ (240,262,376)**	**$ (35,383)**	**$ 32,913,148**
Net Loss	—	—	—	(22,749,945)	—	(22,749,945)
Unrealized Gain on Available-for-Sale Investments	—	—	—	—	96,327	96,327
Foreign Currency Translation Adjustments	—	—	—	—	(13,791)	(13,791)
Exercise of Employee Stock Options, Net of Tax	870	—	(1,978)	—	—	(1,978)
Stock-based Compensation	—	—	2,425,919	—	—	2,425,919
Balance as of September 30, 2018	**51,769,294**	**$ 5,177**	**$ 275,629,671**	**$ (263,012,321)**	**$ 47,153**	**$ 12,669,680**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

For the nine months ended September 30, 2019 and 2018

(Unaudited)

	2019	2018
Cash Flows From Operating Activities:		
Net Loss	**$ (26,825,602)**	**$ (22,749,945)**
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	581,982	466,994
Stock-based Compensation	3,895,041	2,425,919
Increase in Inventory Reserves	1,271,000	3,442,547
Amortization of Right of Use Asset	1,429,727	—
(Gain) Loss on Disposal of Assets	(620)	4,030
Realized (Gain) Loss on Sale of Investments Available-for-Sale	(24,292)	222,014
Foreign Currency Translation Adjustment	(631)	(13,791)
Changes in Assets and Liabilities:		
Decrease (Increase) in Accounts Receivable, net	1,857,061	(1,226,133)
Decrease (Increase) in Insurance Receivable	371,217	(500,000)
Decrease in Inventory	293,326	3,669,233
Decrease in Other Assets	930,847	75,570
(Decrease) Increase in Accounts Payable	(1,298,031)	2,709,133
(Decrease) Increase in Settlement Payable	(146,668)	666,667
Decrease in Lease Liability	(1,369,994)	—
Decrease in Other Liabilities	(1,228,671)	(2,109,802)
Decrease in Deferred License Revenue	(1,689,651)	(1,718,127)
Changes in Assets and Liabilities	(2,280,564)	1,566,541
Cash Used In Operating Activities	**(21,953,959)**	**(14,635,691)**
Cash Flows From Investing Activities:		
Purchase of Investments Available-for-Sale	(34,202,301)	(18,483,694)
Sale of Investments Available-for-Sale	30,479,252	29,596,315
Purchase of Equipment	(448,896)	(589,541)
Purchase of Research and Development Licenses (Related Party)	(750,000)	—
Cash (Used in) Provided By Investing Activities	**(4,921,945)**	**10,523,080**
Cash Flows From Financing Activities:		
Payments on Short Term Notes Payable	(763,422)	—
Proceeds from the Issuance of Common Stock / Public Offering	18,777,642	—
Offering Costs from the Issuance of Common Stock / Public Offering	(1,487,721)	—
Proceeds from the Issuance of Common Stock / At-the Market Offering	2,296,235	—
Offering Costs from the Issuance of Common Stock / At-the Market Offering	(207,027)	—
Proceeds from the Exercise of Employee Stock Options	147,900	—
Stock Retained in Satisfaction of Tax Liabilities	(180,289)	(1,978)
Cash Provided By (Used In) Financing Activities	**18,583,318**	**(1,978)**
Decrease In Cash and Cash Equivalents	(8,292,586)	(4,114,589)
Cash At Beginning Of Period	22,713,980	8,406,917
Cash At End Of Period	**$ 14,421,394**	**$ 4,292,328**
Supplemental Disclosure of Noncash Investing and Financing Activities:		
Insurance Financing Note Payable	$ 1,145,133	$ —

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

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

1. Description of Business

Rockwell Medical, Inc. and subsidiaries (collectively, "we", "our", "us", or the "Company"), is a biopharmaceutical company dedicated to improving outcomes for patients with anemia, with an initial focus on end-stage renal disease (ESRD). We are also a manufacturer of hemodialysis concentrates for dialysis providers and distributors in the United States and abroad. We supply the domestic market with dialysis concentrates and we also supply dialysis concentrates to distributors serving a number of foreign countries, primarily in the Americas and the Pacific Rim. Substantially, all of our sales have been concentrate products and ancillary items, though we initiated commercial sales of our proprietary therapeutic, Triferic, during the second quarter of 2019.

Our mission is to transform anemia management in a wide variety of disease states across the globe while improving patients' lives. Accordingly, we are building the foundation to become a leading medical and commercial organization in the field of dialysis.

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

2. Going Concern

As of September 30, 2019, the Company had approximately $14.4 million of cash and cash equivalents, $14.6 million of investments available-for-sale, working capital of $28.2 million and an accumulated deficit of $299.2 million. Net cash used in operating activities for the nine months ended September 30, 2019 was approximately $21.9 million.

The Company will require significant additional capital to sustain its 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 one year of the issuance of the accompanying condensed consolidated financial statements.

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.

On June 20, 2019, the Company closed a public offering of 5,833,334 shares of common stock at a price of $3.00 per share. The aggregate proceeds from this public offering (net of the underwriters' commissions and offering expenses) were approximately $16.1 million. On July 9, 2019, the underwriters of the public offering partially exercised their over-allotment option and purchased an additional 425,800 shares of common stock at a price of $3.00 per share, which closed on July 11, 2019. The aggregate proceeds from the exercise of the over-allotment option (net of the underwriters' discount and offering expenses) were approximately $1.2 million.

On March 22, 2019, the Company entered into a sales agreement with Cantor Fitzgerald & Co. (the "Agent"), pursuant to which the Company may offer and sell from time to time shares of the Company's common stock through the Agent up to $40,000,000. As of September 30, 2019, approximately $37.7 million remains available for issuance under this facility. We are not required to sell any shares at any time during the term of the facility. Our ability to sell common stock under the facility may be limited by several factors including, among other things, the trading volume of our common stock and certain black-out periods that we may impose upon the facility, among other things.

The Company will require additional capital to sustain its operations and make the investments it needs to execute upon its longer-term business plan, including the launch of Dialysate Triferic and I.V. Triferic. If the Company is unable to generate sufficient revenue from its existing long-term business plan, the Company will need to obtain additional equity

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

or debt financing. If the Company attempts to obtain additional debt or equity financing, the Company cannot assume that such financing will be available on favorable terms, if at all.

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

At the 2019 Annual Meeting, the Company's shareholders voted and approved to reincorporate the Company from the State of Michigan to the State of Delaware (the "Reincorporation"). The Reincorporation became effective on August 30, 2019 and was accomplished by the filing of (i) a certificate of conversion with the Bureau of Commercial Services of the Michigan Department of Labor & Economic Growth; (ii) a certificate of conversion with the Secretary of State of the State of Delaware; and (iii) a Certificate of Incorporation with the Secretary of State of the State of Delaware (the "Certificate of Incorporation").

The Company's new authorized capital stock consists of 170,000,000 shares of common stock, $0.0001 par value per share, and 2,000,000 shares of preferred stock, $0.0001 par value per share.

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

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

The results for the condensed consolidated statement of operations are not necessarily indicative of results to be expected for the year ending December 31, 2019 or for any future interim period. The condensed consolidated balance sheet at September 30, 2019 has been derived from unaudited financial statements; however, it does not include all of the information and notes required by U.S. GAAP for complete financial statements. The condensed consolidated balance sheet at December 31, 2018 has been derived from audited financial statements, however, it does not include all of the information and notes required by U.S. GAAP for complete financial statements. The accompanying condensed consolidated financial statements should be read in conjunction with the consolidated financial statements for the year ended December 31, 2018 and notes thereto included in the Company's annual report on Form 10-K filed on March 18, 2019.

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

Use of Estimates

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

Significant Accounting Policies

With the exception of the adoption of ASU 2016-02 relating to accounting for leases, there have been no material changes in the Company's significant accounting policies as previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

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

Leases

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

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

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

Loss Per Share

ASC 260, Earnings Per Share, requires dual presentation of basic and diluted earnings per share ("EPS"), with a reconciliation of the numerator and denominator of the basic EPS computation to the numerator and denominator of the diluted EPS computation. Basic EPS excludes dilution. Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that are then sharing 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 net income per share in the future that were not included in the computation of diluted loss per share were as follows:

	As of September 30,	
	2019	2018
Options to purchase common stock	8,170,382	8,048,105
Unvested restricted stock awards	146,800	146,800
Unvested restricted stock units	1,324,172	1,293,750
Warrants to purchase common stock	2,770,781	-
	12,412,135	9,488,655

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 review to determine the consequences of the change to its consolidated financial statements and assures that there are sufficient controls in place to ascertain that the Company's consolidated financial statements properly reflect the change.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which amended the guidance on accounting for leases. The FASB issued this update to increase transparency and comparability among organizations. This update requires the recognition of lease assets and lease liabilities on the balance sheet and the disclosure of key information about leasing arrangements. The Company adopted this ASU effective January 1, 2019 using the additional (optional) approach by recording a right-of-use asset and a lease liability of approximately $3.5 million. Our adoption of

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

this ASU had no effect on opening retained earnings, and the Company continues to account for leases in the prior period consolidated financial statements under ASC Topic 840. In adopting the new standard, the Company elected to apply the practical expedients regarding identification of leases, lease classification, indirect costs, and the combination of lease and non-lease components.

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

4. Revenue Recognition

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

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

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

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

Nature of goods and services

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

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

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

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

Disaggregation of revenue

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

In thousands of US dollars ($)	Three Months Ended September 30, 2019			Nine Months Ended September 30, 2019		
Products By Geographic Area	Total	U.S.	Rest of World	Total	U.S.	Rest of World
Drug Revenues						
Product Sales – Point-in-time	$ 98	$ 98	$ -	$ 112	$ 112	$ -
License Fee – Over time	68	-	68	205	-	205
Total Drug Products	166	98	68	317	112	205
Concentrate Products						
Product Sales – Point-in-time	14,746	13,353	1,393	44,010	39,100	4,910
License Fee – Over time	495	495	-	1,485	1,485	-
Total Concentrate Products	15,241	13,848	1,393	45,495	40,585	4,910
Net Revenue	$ 15,407	$ 13,946	$ 1,461	$ 45,812	$ 40,697	$ 5,115

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

Contract balances

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

In thousands of US dollars ($)	September 30, 2019	December 31, 2018
Receivables, which are included in "Trade and other receivables"	$ 5,122	$ 6,980
Contract liabilities	$ 12,640	$ 14,329

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There were no impairment losses recognized related to any receivables arising from the Company's contracts with customers for the three and nine months ended September 30, 2019 and 2018.

For the three and nine months ended September 30, 2019 and September 30, 2018, the Company did not recognize material bad-debt expense and there were no material contract assets recorded on the condensed consolidated balance sheet as of September 30, 2019 and December 31, 2018. The Company does not generally accept returns of its concentrate products and no reserve for returns of concentrate products was established as of September 30, 2019 or December 31, 2018.

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

Transaction price allocated to remaining performance obligations

For the three and nine months ended September 30, 2019, revenue recognized from performance obligations related to prior periods was not material.

Revenue expected to be recognized in any future year related to remaining performance obligations, excluding revenue pertaining to contracts that have an original expected duration of one year or less, contracts where revenue is recognized as invoiced and contracts with variable consideration related to undelivered performance obligations, totaled $10.4 million as of September 30, 2019. The amount relates primarily to upfront payments and consideration received from customers that are received in advance of the customer assuming control of the related products. The Company applies the practical expedient in paragraph 606-10-50-14 and does not disclose information about remaining performance obligations that have original expected durations of one year or less. The Baxter Agreement includes minimum commitments of product sales over the duration of the agreement. Unfulfilled performance obligations related to the Baxter Agreement are product sales of $9.6 million, which will be amortized through expiration of the agreement on October 2, 2024.

5. Investments - Available-for-Sale

Investments available-for-sale consisted of the following as of September 30, 2019 and December 31, 2018:

	September 30, 2019			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Available-for-Sale Securities				
Bonds	$ 14,549,799	$ 26,401	$ (611)	$ 14,575,589

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

The fair value of investments available-for-sale are determined using quoted market prices from daily exchange-traded markets based on the closing price as of the balance sheet date and are classified as Level 1, as described in Note 3 on Form 10-K, Fair Value Measurement to our condensed consolidated financial statements.

As of September 30, 2019 and December 31, 2018, available-for-sale securities were due in one year or less.

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6. Inventory

Components of inventory, net of reserves as of September 30, 2019 and December 31, 2018 are as follows:

	September 30, 2019	December 31, 2018
Raw Materials	$ 2,390,179	$ 3,621,548
Work in Process	209,940	256,129
Finished Goods	1,511,333	1,798,101
Total	$ 4,111,452	$ 5,675,778

As of September 30, 2019 and December 31, 2018, we classified $0.5 million and $1.6 million, respectively, of inventory as non-current, all of which was related to Triferic or the active pharmaceutical ingredient (API) for Triferic. As of September 30, 2019 and December 31, 2018, we had total Triferic inventory aggregating $3.5 million and $8.0 million respectively, against which we had reserved $2.8 million and $5.8 million respectively.

The $0.7 million net value of Triferic inventory consisted of $0.1 million of Dialysate Triferic finished goods with expiration dates ranging from March 2020 to May 2021, and $0.6 million of Triferic API with estimated useful lives extending through 2023. The Company increased its inventory reserve for Triferic by $1.1 million as of September 30, 2019 due to, among other factors, the impact of the Centers for Medicare & Medicaid Services (“CMS”) Final Rule, which is discussed in Note 17 below, and its current volume forecasts for Triferic across the globe.

7. Property and Equipment

As of September 30, 2019 and December 31 2018, the Company’s property and equipment consisted of the following:

	September 30, 2019	December 31, 2018
Leasehold Improvements	$ 1,114,503	$ 929,849
Machinery and Equipment	4,719,132	4,800,774
Information Technology & Office Equipment	1,810,246	2,459,832
Laboratory Equipment	653,075	668,977
	8,296,956	8,859,432
Accumulated Depreciation	(5,790,863)	(6,221,139)
Net Property and Equipment	$ 2,506,093	$ 2,638,293

Depreciation expense for the three months ended September 30, 2019 and 2018, totaled $0.2 million and $0.2 million, respectively. Depreciation expense for the nine months ended September 30, 2019 and 2018, totaled $0.58 million and $0.47 million, respectively.

8. Accrued Liabilities

Accrued liabilities as of September 30, 2019 and December 31, 2018 consisted of the following:

	September 30, 2019	December 31, 2018
Accrued Research & Development Expense	$ 84,798	$ 86,820
Accrued Compensation and Benefits	1,334,563	1,525,599
Accrued Legal Expenses	392,869	170,334
Accrued Marketing Expenses	206,649	5,000
Other Accrued Liabilities	1,897,190	3,342,008
Total Accrued Liabilities	$ 3,916,069	$ 5,129,761

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9. Insurance Financing Note Payable

On June 3, 2019, the Company entered into a short-term note payable for $1.9 million, bearing interest at 4.65% per annum to finance various insurance policies. Principal and interest payments related to this note began on July 3, 2019 and are paid on a straight-line amortization over a 10-month period with the final payment due on April 3, 2020. As of September 30, 2019, the Company's insurance note payable balance was $1.15 million.

10. 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 Baxter Agreement. The Company recognized revenue of approximately $0.5 million and $1.5 million during the three and nine months ended September 30, 2019 and 2018, respectively. Deferred revenue related to the Baxter Agreement totaled $9.6 million as of September 30, 2019 and $11.1 million as of December 31, 2018.

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

During the year ended December 31, 2016, the Company entered into a distribution and license agreement with Wanbang and received an upfront fee of $4.0 million. The upfront fee was recorded as deferred revenue and is being recognized as revenue based on the agreement term. The Company recognized revenue of approximately $0.1 million and $0.2 million during the three and nine months ended September 30, 2019 and 2018, respectively. Deferred revenue related to the Wanbang agreement totaled $3.0 million as of September 30, 2019 and $3.2 million as of December 31, 2018.

11. Shareholders' Equity

At the 2019 Annual Meeting, the Company's shareholders voted and approved to reincorporate the Company from the State of Michigan to the State of Delaware (the "Reincorporation"). The Reincorporation became effective on August 30, 2019 and was accomplished by the filing of (i) a certificate of conversion with the Bureau of Commercial Services of the Michigan Department of Labor & Economic Growth; (ii) a certificate of conversion with the Secretary of State of the State of Delaware; and (iii) a Certificate of Incorporation with the Secretary of State of the State of Delaware (the "Certificate of Incorporation").

The Company's new authorized capital stock consists of 170,000,000 shares of common stock, $0.0001 par value per share, and 2,000,000 shares of preferred stock, $0.0001 par value per share.

Preferred Stock

As of September 30, 2019 and December 31, 2018, there were 2,000,000 shares of preferred stock authorized and no shares of preferred stock issued or outstanding.

Common Stock

As of September 30, 2019, the Company's authorized shares of common stock was 170 million shares. On June 6, 2019, the Company obtained shareholder approval to increase the number of authorized shares of the Company's

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common stock by 50 million shares from 120 million shares to 170 million shares. On July 30, 2019, the Company amended its Articles of Incorporation to reflect this increase in authorized shares from 120 million to 170 million shares.

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

Controlled Equity Offering

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

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

In April 2019, the Company sold 437,043 shares of its common stock pursuant to the Sales Agreement for gross proceeds of $2,296,235, at a weighted average selling price of approximately $5.25. The Company paid $207,027 in commissions and offering fees related to the sale of the common shares. As of September 30, 2019, approximately $37.7 million remains available for issuance under this facility.

We are not required to sell any shares at any time during the term of the facility. Our ability to sell common stock under the facility may be limited by several factors including, among other things, the trading volume of our common stock and certain black-out periods that we may impose upon the facility, among other things.

Public Offering of Common Stock

On June 17, 2019, the Company entered into a purchase agreement with Piper Jaffray & Co., and Cantor Fitzgerald & Co, pursuant to which the Company agreed to issue and sell up to 6,708,334 shares of common stock, which included 875,000 optional shares that may be sold pursuant to an option granted to the underwriters.

On June 20, 2019, the Company closed the sale of 5,833,334 shares of its common stock for gross proceeds of $17,500,002 at the public offering price of $3.00 per share (the "Offering"). The Company paid $1,379,323 in underwriters' commissions and fees related to the sale of the common shares. The Offering was made pursuant to the Company's effective registration statement on Form S-3 (File No. 333-227363), which was previously filed with the SEC. On July 9, 2019, the Underwriters exercised their over-allotment option to purchase an additional 425,800 shares of common stock at a price of $3.00 per share, which closed on July 11, 2019. The total proceeds to the Company (net of underwriting commissions and offering fees) from the exercise of the over-allotment option were approximately $1.2 million.

Restricted Common Stock

During the nine months ended September 30, 2019, 195,042 shares of common stock related to fully vested restricted stock units were delivered to an officer of the Company. The Company withheld 68,069 of these common shares at a fair value of $180,289 to cover the officer's withholding taxes related to the vesting of restricted stock units.

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12. Stock-Based Compensation

The Company recognized total stock-based compensation expense during the three and nine months ended September 30, 2019 and 2018 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Service based awards:				
Restricted stock awards	$ -	$ 20,222	$ -	$ 1,292,125
Restricted stock units	502,080	166,417	1,273,903	166,417
Stock option awards	596,657	427,944	1,795,819	967,377
	1,098,737	614,583	3,069,722	2,425,919
Performance based awards:				
Restricted stock units	(332,389)	-	468,814	-
Stock option awards	110,065	-	356,505	-
	(222,324)	-	825,319	-
Total	$ 876,413	$ 614,583	$ 3,895,041	$ 2,425,919

The decrease in stock-based compensation associated with performance based awards for restricted stock units is the result of a change in vesting criteria from probable to improbable based on the CMS Final Rule as described in Note 17 below. This change resulted in a reduction of stock-based compensation expense of $0.7 million for the three and nine months ended September 30, 2019.

Restricted Stock

A summary of the Company's restricted stock awards during the nine months ended September 30, 2019 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at December 31, 2018	146,800	$ 5.70
Unvested at September 30, 2019	146,800	$ 5.70

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

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at December 31, 2017	480,000	$ 7.27
Forfeited	(333,200)	5.70
Unvested at September 30, 2018	146,800	$ 5.70

The fair value of restricted stock awards are measured based on their fair value on the date of grant and amortized over the vesting period of 20 months. As of September 30, 2019 unvested restricted stock awards of 146,800 were related to performance based awards.

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Service Based Restricted Stock Units

A summary of the Company's service based restricted stock units during the nine months ended September 30, 2019 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at December 31, 2018	472,959	$ 4.32
Granted	222,497	4.26
Forfeited	(4,950)	4.81
Vested	(96,542)	4.70
Unvested at September 30, 2019	593,964	$ 4.23

The fair value of service based restricted stock units are measured based on their fair value on the date of grant and amortized over the vesting period. The vesting periods range from 1-3 years. Stock-based compensation expense of $0.5 million and $1.3 million was recognized during the three and nine months ended September 30, 2019. Stock-based compensation expense of $0.2 million was recognized for each of three and nine months ended September 30, 2018. As of September 30, 2019, the unrecognized stock-based compensation expense was $1.3 million.

Performance Based Restricted Stock Units

A summary of the Company's performance based restricted stock units during the nine months ended September 30, 2019 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at December 31, 2018	988,958	$ 4.48
Unvested at September 30, 2019	988,958	$ 4.48

Stock-based compensation expense recognized for performance based restricted stock units was ($0.3) million and $0.5 million during the three and nine months ended September 30, 2019. The Company did not record stock-based compensation expenses related to the performance-based grants as of September 30, 2018. As of September 30, 2019, the unrecognized stock-based compensation expense related to performance based restricted stock units was $1.0 million. The performance based restricted stock unit compensation was reduced by $0.7 million for the three and nine months ended September 30, 2019 due to a change in vesting criteria from probable to improbable for certain performance based awards. The Company will continue to review this performance award criteria and recognize compensation costs as it relates to the probability of vesting.

Service Based Stock Options

The fair value of the service based stock options granted for the nine months ended September 30, 2019 were based on the following assumptions:

	Nine Months Ended September 30,	
	2019	2018
Exercise price	$2.39 - $6.21	$4.52 - $5.75
Expected stock price volatility	67.5% - 70.3%	67.5%
Risk-free interest rate	1.4% - 2.6%	2.7% - 2.9%
Term (years)	5.25 - 6.5	5.0 - 6.5

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A summary of the Company's service based stock option activity for the nine months ended September 30, 2019 is as follows:

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2018	7,856,480	$ 7.50	5.2	$ -
Granted	576,477	4.17	9.2	12,074
Exercised	(30,000)	4.93	-	-
Forfeited	(620,700)	6.34	-	-
Outstanding at September 30, 2019	7,782,257	$ 7.35	5.1	$ 12,074
Exercisable at September 30, 2019	6,340,901	$ 8.07	4.2	$ -

A summary of the Company's service based stock option activity for the nine months ended September 30, 2018 is as follows:

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2017	6,906,001	$ 7.92	5.0	$ 976,335
Granted	1,337,271	4.96	9.4	
Exercised	(5,000)	6.59	-	
Forfeited	(190,167)	6.59	-	
Outstanding at September 30, 2018	8,048,105	$ 7.46	5.2	$ 365,135
Exercisable at September 30, 2018	6,248,160	$ 7.90	4.1	$ 365,135

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

During the nine months ended September 30, 2019, the Company granted to certain employees stock options to purchase up to 576,477 shares of common stock. During the nine months ended September 30, 2019, forfeitures were 620,700. Forfeitures are recorded in the period of occurrence; compensation expense is adjusted accordingly.

Stock-based compensation expense recognized for service based stock options was $0.6 million and $1.8 million for the three and nine months ended September 30, 2019 and $0.4 million and $1.0 million for the three and nine months ended September 30, 2018. As of September 30, 2019, total stock-based compensation expense related to unvested options not yet recognized totaled approximately $2.1 million.

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Performance Based Stock Options

A summary of the performance based stock options for the nine months ended September 30, 2019, is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2018	388,125	$ 4.70
Outstanding at September 30, 2019	388,125	$ 4.70
Exercisable at September 30, 2019	-	$ -

Stock-based compensation expense recognized for performance based stock options was $0.1 million and $0.4 million during the three and nine months ended September 30, 2019. Stock-based compensation expense recognized for performance based stock options was $51,000 for each of the three and nine months ended September 30, 2018. As of September 30, 2019, the unrecognized stock-based compensation expense related to performance based stock options was $0.6 million.

13. Related Party Transactions

Product License Agreements

The Company is a party to an in-license agreement for exclusive worldwide rights to certain patents and information related to our Triferic® product. On October 7, 2018, the Company entered into a Master Services and IP Agreement (the "Charak MSA") with Charak, LLC and Dr. Ajay Gupta (collectively "Charak"), who serves as Executive Vice President and Chief Scientific Officer of the Company. Pursuant to the MSA, the parties entered into three additional agreements described below related to the license of certain soluble ferric pyrophosphate ("SFP") intellectual property owned by Charak, as well as the Employment Agreement (defined below). The Charak MSA provides for a payment of $1.0 million to Dr. Gupta, payable in four quarterly installments of $250,000 each on October 15, 2018, January 15, 2019, April 15, 2019 and July 15, 2019, and reimbursement for certain legal fees incurred in connection with the Charak MSA. The Company recorded $1.1 million as Research and Development Expense – License Acquired (Related Party) for the twelve months ended December 31, 2018. As of September 30, 2019, the Company paid all four of the quarterly installments totaling $1.0 million and accrued $0.1 million for the reimbursement of certain legal expenses. As of September 30, 2019 and December 31, 2018, the Company accrued $0.1 million and $850,000, respectively, as a related party payable on the condensed consolidated balance sheet.

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

Also pursuant to the Charak MSA, the Company and Charak entered into a Commercialization and Technology License Agreement I.V. Triferic®, dated as of October 7, 2018 (the "IV Agreement"), under which Charak granted the Company an exclusive, sublicensable, royalty-bearing license to SFP for the purpose of commercializing certain

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intravenous-delivered products incorporating SFP for the treatment of iron disorders worldwide for a term that expires on the later of February 1, 2034 or upon the expiration or termination of a valid claim of a licensed patent. The Company is liable to pay Charak royalties on net sales by the Company of products developed under the license at a specified rate until December 31, 2021. From January 1, 2022 until February 1, 2034, the Company is liable to pay Charak a base royalty at a reduced rate on net sales and an additional royalty on net sales while there exists a valid claim of a licensed patent, on a country-by-country basis. The Company shall also pay to Charak a percentage of any sublicense income received during the term of the IV Agreement, which amount shall not be less than a minimum specified percentage of net sales of the licensed products by the sub-licensee in jurisdictions where there exists a valid claim, on a country-by-country basis, and not be less than a lower rate of the net sales of the licensed products by the sub-licensee in jurisdictions where there exists no valid claim, on a country-by-country basis.

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

The transaction was accounted for as an asset acquisition pursuant to ASU 2017-01,*Business Combinations (Topic 805), Clarifying the Definition of a Business,* as the majority of the fair value of the assets acquired was concentrated in a group of similar assets, and the acquired assets did not have outputs or employees. The assets acquired under the MSA include a license of SFP. Because SFP has not yet received regulatory approval, the $1.1 million purchase price paid and accrued for these assets has been expensed in the Company's statement of operations for the year ended December 31, 2018. In addition, the potential milestone payments are not yet considered probable, and no milestone payments have been accrued at September 30, 2019.

14. Leases

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

At September 30, 2019, the Company had operating lease liabilities of $3.0 million and right-of-use assets of $3.0 million, which are included in the consolidated balance sheet.

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

	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019
Operating leases		
Operating lease cost	$ 531,709	$ 1,591,686
Variable lease cost	90,411	258,492
Operating lease expense	622,120	1,850,178
Short-term lease rent expense	4,157	12,470
Total rent expense	$ 626,277	$ 1,862,648
Other information		
Operating cash flows from operating leases	$ 493,872	$ 1,531,953
Right of use assets exchanged for operating lease liabilities	$ 136,124	$ 4,441,553
Weighted-average remaining lease term – operating leases	1.8	1.8
Weighted-average discount rate – operating leases	6.8%	6.8%

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

Three months ended December 31, 2019	$ 479,345
Year ending December 31, 2020	1,433,260
Year ending December 31, 2021	811,097
Year ending December 31, 2022	346,649
Year ending December 31, 2023	197,130
Year ending December 31, 2024	97,423
Total	$ 3,364,904
Less present value discount	(293,365)
Operating lease liabilities	$ 3,071,539

15. Settlement Agreements

On August 7, 2018, the Company entered into a confidential settlement agreement and mutual release (the "Settlement Agreement") with its former CEO, former CFO and a former and then current director. For more details see Note 10 in Form 10-K filed on March 18, 2019. This resulted in a net settlement expense of approximately $1.0 million for the nine month ended September 30, 2018.

On August 7, 2019, the Company entered into a settlement agreement relating to the class action lawsuits described below. This resulted in a settlement expense of approximately $0.4 million for the nine months ended September 30, 2019. See Note 16 below for further details. The settlement is subject to court review and approval, which is scheduled for February, 2020.

16. Commitments and Contingencies

Litigation

SEC Investigation

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

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Shareholder Class Action Lawsuits

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

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

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

On August 7, 2019, all parties to the class action entered into a settlement of the consolidated class action. Pursuant to the terms and conditions of the settlement agreement, the Company will pay the Plaintiffs $3.7 million (the "Settlement Amount') in exchange for a full release of all liability as to all defendants. Of the Settlement Amount, the Company will be contributing approximately $0.4 million, which represents the remaining retention amount under the Company's director and officer liability insurance policy. The remainder of the settlement amount will be funded by the Company's director and officer insurance policy. The settlement is subject to court review and approval, which is scheduled for February, 2020.

Shareholder Derivative Actions

Two verified stockholder derivative complaints (the "Derivative Complaints") entitled LeClair v Rockwell Medical, Inc., and Post v Rockwell Medical, Inc. were filed in the United States District Court in the Eastern District of New York, purportedly on behalf of the Company (as nominal defendant) and against certain of the Company's current and former directors (the "Individual Defendants"). The Derivative Complaints assert causes of actions against the Individual Defendants for breach of fiduciary duty, waste of corporate assets, and unjust enrichment. The Derivative Complaints allege the Individual Defendants breached duties by, among other things, permitting alleged misstatements to be made in public filings regarding the status of separate reimbursement for Triferic from CMS, the adequacy of Rockwell's reserves, and the adequacy of Rockwell's internal controls. Recently, the Plaintiffs have amended their derivative complaints. These cases are at an early stage, and the Company anticipates filing a motion to dismiss the action.

The Company has tendered the above shareholder derivative actions to its D&O insurance carrier(s) for defense and indemnity under its applicable insurance policies. The Company maintains a $1.0 million self-insured retention under

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the applicable insurance policies, which will be exhausted upon payment of the Company's share of the Settlement Amount from the settlement of the class action described above.

17. Subsequent Events

On October 31, 2019, CMS issued a final rule to update payment policies and rates under the ESRD Prospective Payment System for renal dialysis services furnished to beneficiaries on or after January 1, 2020 (the "2020 Final Rule"). The Final Rule contains certain revisions to the eligibility requirements for the CMS Transitional Drug Add-on Payment Adjustment ("TDAPA") program, which has the potential to provide two years of add-on reimbursement for certain qualifying new drugs. Under the revisions to the TDAPA rules, ESRD drugs approved by the FDA under the following types of New Drug Applications (an "NDA") are ineligible for TDAPA, effective as of January 1, 2020: (a) NDA Types 3, 5, 7 and 8, (b) NDA Type 3 in combination with NDA Type 2 or NDA Type 4, (c) NDA Type 5 in combination with NDA Type 2, or (d) NDA Type 9, when the "parent NDA" is NDA Type 3, 5, 7 or 8.

As previously disclosed, we have filed an NDA for the intravenous formulation of Triferic. The FDA has informed the Company that the NDA for I.V. Triferic will be classified as Type 3. As a result, the Company believes that I.V. Triferic will not be eligible for TDAPA.

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

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

Forward-Looking Statements

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

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

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

Overview and Recent Developments

We are a specialty pharmaceutical company targeting end-stage renal disease with products for the treatment of iron deficiency and hemodialysis. We are also a manufacturer of hemodialysis concentrates/dialysates to dialysis providers and distributors in the United States and abroad. We supply approximately 25% of the United States domestic market with dialysis concentrates and we also supply dialysis concentrates to distributors serving a number of foreign countries, primarily in the Americas and the Pacific Rim. To date, substantially all of our sales have been concentrate products and related ancillary items, though we initiated commercial sales of our proprietary therapeutic, Triferic, during the second quarter of 2019.

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

Triferic

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

Our objective for Triferic is to transform anemia management in a wide variety of disease states across the globe while improving patients' lives. Accordingly, we are building the foundation to become a leading medical and commercial organization in the field of dialysis, which we believe will enable Triferic to become the standard of care for ESRD patients. Specifically, we are investing in our medical capabilities to, among other things, generate real-world data, provide medical education to the dialysis community regarding the potentinal benefits of Triferic, and engage with key opinion leaders and centers of excellence to guide the delveopment and commercialization of Triferic.

Dialysate Triferic

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

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

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

While the Company was pursuing the earlier strategy of delaying commercialization until receipt of add-on reimbursement approval, we built up significant inventory of active pharmaceutical ingredient ("API") and Dialysate Triferic finished goods. However, due to the delays in launching Triferic and taking into account feedback received from CMMI in March 2018 regarding the prospects for near-term approval of add-on reimbursement for Triferic, we increased our inventory reserves for Triferic by a total of $8.1 million during 2018 from $3.5 million as of December 31, 2017 to $11.6 million as of December 31, 2018. For the nine months ended September 30, 2019, Triferic inventory reserves increased by approximately $0.9 million. After deducting inventory destroyed or used for samples, as of September 30, 2019 we had $0.5 million of Dialysate Triferic Finished Goods inventory with $0.4 million reserved leaving a net value of $0.1 million. As of September 30, 2019, we also had approximately $3.0 million of Triferic API against which we have reserved $2.0 million leaving a net value of $1.0 million. Depending on the timing and success of our commercial launch of Dialysate Triferic in 2019 and the degree of uptake of the drug commercially, additional amounts or all of our current investment in Dialysate Triferic finished goods inventory and some or all of our API inventory may need to be written off in future periods. Additional write-offs of existing Triferic inventory will not have a material negative impact on our cash flow, but could potentially have a material adverse impact on our reported results of operations and financial position.

I.V. Triferic

We are also developing an intravenous injection of Triferic ("I.V. Triferic") for use by hemodialysis patients in the United States as well as international markets. A clinical equivalence study of I.V. Triferic infusion presentation has been completed and, on the basis of the clinical and non-clinical data prepared by the Company, we submitted a New Drug Application ("NDA") seeking FDA approval to market I.V. Triferic in the United States for the clinical indication of replacing iron and maintaining hemoglobin in adult hemodialysis patients on May 28, 2019. The NDA for I.V. Triferic was accepted for filing by the FDA on August 2, 2019 with a Prescription Drug User Fee Act ("PDUFA") date of March 28, 2020.

In November 2018 CMS provided interpretative guidance ("CMS Guidance") regarding the TDAPA program and its potential application to I.V. Triferic. Based on the CMS Guidance, the Company believed that, if approved by the

FDA on or after January 1, 2020, I.V. Triferic would possibly be eligible for separate add-on reimbursement under CMS's TDAPA program for a period of two years On October 31, 2019, CMS issued its final rule to update payment policies and rates under the ESRD Prospective Payment System (PPS) for 2020 (the "2020 Final Rule"). The 2020 Final Rule included updates to TDAPA program eligibility, specifically excluding from eligibility for TDAPA, effective as of January 1, 2020: (a) NDA Types 3, 5, 7 and 8, (b) NDA Type 3 in combination with NDA Type 2 or NDA Type 4, (c) NDA Type 5 in combination with NDA Type 2, or (d) NDA Type 9, when the "parent NDA" is NDA Type 3, 5, 7 or 8.

As previously disclosed, the Company has submitted an NDA for the intravenous formulation of Triferic. The FDA has informed the Company that the classification for the I.V. Triferic NDA is Type 3. Accordingly, the Company believes that I.V. Triferic is adversely impacted by the 2020 Final Rule, because it is not eligible for TDAPA reimbursement under the 2020 Final Rule.

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

Dialysis Concentrates

We manufacture, sell, deliver and distribute hemodialysis concentrates, along with a line of ancillary dialysis products abroad. We use Baxter as our exclusive marketer and distributor in the United States and in select foreign markets. Dialysate concentrates accounted for approximately 97% of our revenues for the three months ended September 30, 2019, with ancillary products and Triferic 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. On August 1, 2019, we entered into a Products Purchase Agreement with DaVita (the "DaVita Agreement"). The Davita Agreement supersedes and replaces that certain First Amended and Restated Products Purchase Agreement, effective as of May 8, 2013 (as subsequently amended) by and between the Company and DaVita, which agreement expired effective as of July 31, 2019 (the "Prior Agreement"). The DaVita Agreement is effective from July 1, 2019 through December 31, 2023. Generally, the DaVita Agreement is similar to the Prior Agreement, except that it provides for an increase in the product sale prices relative to the prices charged for these products under the Prior Agreement.

Calcitriol (Active Vitamin D) Injection

Calcitriol, an active Vitamin D injection for the management of hypocalcemia in patients undergoing chronic hemodialysis, is FDA approved under an Abbreviated New Drug Application. To date, we have not commercially launched Calcitriol. Following a strategic review of this product, including pricing, commercial distribution and marketing, manufacturing efficiencies and capacity (including potential capital investment), we have determined commercialization of Calcitriol in the U.S. would not be viable at this time. The decision was based, in part, on the fact that prevailing market prices for similar Vitamin D products are lower than our cost to produce Calcitriol on a dose-equivalent basis, and as a result it would be difficult for us to market Calcitriol profitably. As a result of this decision, we recorded an inventory reserve reflecting the remainder of our Calcitriol inventory. As of December 31, 2018 and September 30, 2019, this reserve totaled $0.7 million.

Clinical Development

Although Dialysate Triferic is approved for commercial sale in the United States, Triferic is not approved for sale in other major markets globally. We have received regulatory guidance from the European Medicines Agency ("EMA") regarding the clinical studies that are needed to file for approval of I.V. Triferic in Europe. At the present time, we do not intend to commence these clinical studies, absent finding a development partner in Europe or raising additional capital. In conjunction with our licensee in the People's Republic of China, Wanbang Biopharmaceutical ("Wanbang"), two clinical pharmacology studies were completed earlier in 2019 and Wanbang has requested a meeting with the National Medical Products Administration (NMPA) (formerly, China Food and Drug Administration or CFDA) to review the results of these studies and discuss whether these studies are sufficient to support a submission for regulatory approval for Dialysate Triferic. Pursuant to our license agreement with Wanbang, we are entitled to up to $35 million of regulatory and sales-based milestones, including an $8 million milestone payment upon regulatory approval of Triferic in China. We will supply the finished dosage form of Triferic to Wanbang at a transfer price comprising cost of goods sold, a mark-up and a percentage of net sales in the low-to-mid 20% range.

As a post-approval requirement under the Pediatric Research Equity Act, we are required to conduct a further clinical study of the effectiveness of Triferic in a pediatric patient population. We have reached agreement with the FDA on the design of this study, which we intend to commence in 2019, assuming we have the liquidity and capital resources to do so. In April 2019, we entered into a contract with a CRO for the conduct of the pediatric study and prepaid approximately $0.8 million for future work under the contract. We expect to begin enrollment of patients in the pediatric study in the first half of 2020. We expect that the data from this study could be used as part of the overall clinical data package to support approval by the EMA, if and when we are able to complete the other clinical trials needed to support making such a filing.

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

Results of Operations for the three months ended September 30, 2019 and 2018

Net Sales

During the three months ended September 30, 2019, our net sales were $15.4 million compared to sales of $16.7 million during the three months ended September 30, 2018. Net sales of hemodialysis concentrates to dialysis providers and distributors in the U.S. and abroad were $15.2 million for the three months ended September 30, 2019 compared to $16.6 million for the three months ended September 30, 2018. The decrease of $1.4 million was primarily due to lower sales to international customers offset by an increase in sales pursuant to the Company's contract with DaVita Inc. Net sales of Triferic were $166,000 for the three months ended September 30, 2019 compared to $68,000 for the three months ended September 30, 2018. For each of the three months ended September 30, 2019 and September 30, 2018, Triferic net sales included approximately $68,000 of deferred revenue recognized under the Company's license in the People's Republic of China with Wanbang Biopharmaceutical. Triferic net sales for the three months ended September 30, 2019 also included approximately $98,000 of Triferic product sales to U.S. customers..

Gross Profit (Loss)

Cost of sales during the three months ended September 30, 2019 was $15.4 million, resulting in gross loss of $16,000 during the three months ended September 30, 2019, compared to cost of sales of $14.7 million and a gross profit of $2.0 million during the three months ended September 30, 2018. Cost of sales for the three months ended September 30, 2019 included $14.3 million of manufacturing and distribution costs associated with the Company's concentrates products and $1.1 million of inventory reserve expenses and product costs for Triferic, compared to $14.6 million and $0.1 million, respectively, for the three months ended September 30, 2018. Gross profit decreased by $2.0 million in the third quarter of 2019 compared to the third quarter of 2018, due primarily to a decrease in sales of $1.3 million; an increase in inventory reserve expense of $1.1 million; increase in labor, maintenance and recruiting of $0.4 million; offset by a decrease in distribution and materials and overhead of $0.7 million.

Selling and Marketing Expense

Selling and marketing expenses were $1.8 million during the three months ended September 30, 2019 compared with $0.1 million during the three months ended September 30, 2018. The increase of $1.7 million was due to the investments the Company made in developing a commercial platform to support the commercial launch of Triferic.

General and Administrative Expense

General and administrative expenses were $4.6 million during the three months ended September 30, 2019 compared with $6.0 million during the three months ended September 30, 2018. The decrease of $1.4 million is primarily due to a decrease in legal and related costs associated with various matters, including litigation activities, related to the departure of certain executives and directors during 2018, partially offset by increases in insurance premiums.

Settlement Expense

Settlement expense was nil for each of the three months ended September 30, 2019 and 2018, respectively.

Research and Product Development Expense

Research and product development expenses were $1.5 million for the three months ended September 30, 2019 compared with $0.8 million during the three months ended September 30, 2018. The increase of $0.7 million was due to the Company's commitment to investing in and building its medical capabilities mentioned above, including generating data from studies and real-world use of Triferic to support medical education and development efforts for Triferic, as well as the expansion of the Company's internal medical affairs staff. The Company expects its research and product development expenses to increase in the future due to additional clinical development of Dialysate and I.V. Triferic, including the pediatric clinical trial for Triferic, and investments we are making in our medical platform to support medical education efforts and the collection and analysis of real-world data for Triferic

Other Income, Net

Other income for the three months ended September 30, 2019 was $0.1 million, consisting primarily of interest income. Other income for the three months ended September 30, 2018 was $29,000, consisting of $0.13 million of interest income, offset by $0.1 million of realized gains on investments.

Results of Operations for the nine months ended September 30, 2019 and 2018

Net Sales

During the nine months ended September 30, 2019, our net sales were $45.8 million compared to sales of $46.5 million during the nine months ended September 30, 2018. Net sales of hemodialysis concentrates to dialysis providers and distributors in the U.S. and abroad were $45.5 million for the nine months ended September 30, 2019 compared to $46.3 million for the nine months ended September 30, 2019. The decrease of $0.7 million was primarily due to lower sales to international customers offset by an increase in sales pursuant to the Company's contract with DaVita Inc. Net sales of Triferic were $0.3 million for the nine months ended September 30, 2019 compared to $0.2 million for the nine months ended September 30, 2018. For each of the nine months ended September 30, 2019 and September 30, 2018, Triferic net sales included approximately $0.2 million of deferred revenue recognized under the Company's license in the People's Republic of China with Wanbang Biopharmaceutical. Triferic net sales for the nine months ended September 30, 2019 also included approximately $112,000 of Triferic product sales to U.S. customers.

Gross Profit (Loss)

Cost of sales during the nine months ended September 30, 2019 was $44.1 million, resulting in gross profit of $1.7 million during the nine months ended September 30, 2019, compared to cost of sales of $49.3 million and a gross loss of $2.8 million during the nine months ended September 30, 2018. Gross profit increased by $4.5 million during the nine months ended September 30, 2019 compared to the nine months ended September 30, 2018, due primarily to a non-cash charge taken for an inventory reserve for Triferic of $8.3 million for the nine months ended September 30, 2018, partially offset by a gross profit decrease of $1.2 million in our dialysis concentrates products. The decrease in gross profit for our dialysis concentrates products was primarily attributable to increased labor, materials and overhead costs.

Selling and Marketing Expense

Selling and Marketing Expenses were $7.2 million during the nine months ended September 30, 2019 compared with $0.7 million during the nine months ended September 30, 2018. The increase of $6.5 million was due to the investments the Company made in developing a commercial platform to support the commercial launch of Triferic, which included $3.4 million in marketing costs and $2.8 million in hiring, training and educating new employees.

General and Administrative Expense

General and administrative expenses were $16.3 million during the nine months ended September 30, 2019 compared with $14.5 million during the nine months ended September 30, 2018. The $1.8 million increase was driven primarily by increases to stock compensation, insurance premium expense, annual reporting and consulting fees; offset by a decrease legal and related costs associated with various matters, including litigation activities, related to the departure of certain executives and directors during 2018.

Research and Product Development Expense

Research and product development expenses were $4.9 million for the nine months ended September 30, 2019 compared with $4.0 million during the nine months ended September 30, 2018. The increase of $0.9 million was due to the Company's commitment to investing in and building its medical capabilities mentioned above, including generating data from studies and real-world use of Triferic to support medical education and development efforts for Triferic, as well as the expansion of the Company's internal medical affairs staff. The Company expects its research and product development expenses to increase in the future due to additional clinical development of Dialysate and I.V. Triferic, including the pediatric clinical trial for Triferic, and investments we are making in our medical platform to support medical education efforts and the collection and analysis of real-world data for Triferic.

Settlement Expense

Settlement Expense was $0.4 million for the nine months ended September 30, 2019, compared to $1.0 million in for the nine months ended September 30, 2018. Settlement Expense for the nine months ended September 30, 2018 reflected the terms of the confidential settlement agreement and mutual release entered into with the Company's former CEO, former CFO and a former and then current director. Settlement Expense for the third quarter of 2019 reflected the Company's contribution of the Settlement Amount relating to the consolidated class action. See Note 16 on the condensed consolidated financial statements herein for more detail.

Other Income, Net

Other income for each of the nine months ended September 30, 2019 and 2018 was $0.3 million, respectively. The amounts consist primarily of interest income.

Liquidity and Capital Resources

As of September 30, 2019, we had approximately $29.0 million of cash, cash equivalents and investments available-for-sale, and working capital of $28.2 million. Net cash used in operating activities for the nine months ended September 30, 2019 was approximately $21.9 million. On June 20, 2019, the Company closed a public offering of 5,833,334 shares of common stock at a price of $3.00 per share. On July 9, 2019, the underwriters of the public offering partially exercised their over-allotment option to purchase an additional 425,800 shares of common stock at a price of $3.00 per share, which closed on July 11, 2019.

On March 22, 2019, the Company entered into a sales agreement with Cantor Fitzgerald & Co. (the "Agent"), pursuant to which the Company may offer and sell from time to time shares of the Company's common stock through the Agent up to $40,000,000. In April 2019, the Company sold 437,043 shares of its common stock pursuant to the Sales Agreement for gross proceeds of $2,296,235, at a weighted average selling price of approximately $5.25. The Company did not issue an shares of common stock pursuant to the Sales Agreement during the third quarter of 2019. As of September 30, 2019, approximately $37.7 million was available for issuance under the Sales Agreement. We are not required to sell any shares at any time during the term of the facility. Our ability to sell common stock under the facility may be limited by several factors, including, among other things, the trading volume of our common stock and certain black-out periods that we may impose upon the facility, among other things.

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

The Company will require additional capital to sustain its operations and make the investments it needs to execute upon its longer-term business plan, including the commercialization of Dialysate Triferic and I.V. Triferic, if approved, and executing plans for enhancing its medical capabilities and generating additional data for Triferic. If the Company is unable to generate sufficient revenue from its existing long-term business plan, the Company will need to obtain additional

equity or debt financing. If the Company attempts to obtain additional debt or equity financing, the Company cannot assume that such financing will be available on favorable terms, if at all.

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 commercialization and investments we are making in our medical capabilities to support Dialysate Triferic and I.V. Triferic, if approved, in the United States; the timing and magnitude of cash received from drug product sales; and the timing and expenditures associated with the development of Triferic for international markets; and the costs associated with ongoing litigation and investigatory matters.

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

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

Cash Used in Operating Activities

Net cash used in operating activities was $21.9 million for the nine months ended September 30, 2019. The net loss for this period was higher than net cash used in operating activities by $4.9 million, which was primarily attributable to non-cash expenses of $7.2 million, consisting primarily of $3.9 million of stock-based compensation, $1.4 million of amortization of the right to use assets, $1.3 million of inventory reserves, $0.6 million of depreciation and amortization, and a $2.3 million net change in assets and liabilities.

Net cash used in operating activities was $14.6 million for the nine months ended September 30, 2018. The net loss for this period was higher than net cash used in operating activities by $8.1 million, which was primarily attributable to non-cash expenses of $6.6 million, consisting of $3.4 million of inventory reserves, $2.4 million of stock-based compensation, $0.5 million of depreciation and amortization, and $0.2 million of realized losses on sale of investments available-for-sale, offset by a decrease of $3.7 million in inventory related to the destruction of Triferic finished goods inventory, a decrease of $2.1 million in other liabilities related to the reduction in bonus and other payroll accruals, a decrease of $1.7 million in deferred revenue relating to the recognition of revenue from our licensing agreements, an increase of $1.2 million in accounts receivable related to increases in revenue related to our international sales, an increase in accounts payable of $2.7 million, as well as increased legal fee accrued, an increase of $0.7 million related to settlement payable, comprised of the $1.5 million accrued in the third quarter of 2018 for the settlement fee related to the Settlement Agreement between the Company and its former directors and officers, offset by settlement payments of $0.8 million, and a $0.5 million increase due to an insurance settlement receivable related to the Settlement Agreement.

Cash (Used in) Provided by Investing Activities

Net cash used in investing activities was $4.9 million during the nine months ended September 30, 2019. The net cash used was primarily due to the purchase of investments available-for-sale of $34.2 million, offset by $30.5 million sale of our available-for-sale investments, $0.4 million for the purchase of equipment and $0.8 million for the purchase of research and development licenses acquired from a related party.

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

Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities was $18.5 million during the nine months ended September 30, 2019. The net cash provided was primarily due to net proceeds of $17.3 million and $2.1 million from the sale of our common stock, related to our public offering and our at-the market offering, respectively. Net cash used in financing activities was $1,978 during the nine months ended September 30, 2018, for the repurchase of common stock to pay the employee withholding taxes on a stock option exercise in September 2018.

Critical Accounting Policies and Significant Judgements and Estimates

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

Recently issued and adopted accounting pronouncements.

We have evaluated all recently issued accounting pronouncements and believe such pronouncements do not have a material effect our financial statements. See Note 3 of the condensed consolidated financial statements at September 30, 2019.

Item 3.

Not applicable.

Item 4. Disclosure Controls and Procedures

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

Under the supervision of and with the participation of our management, including the Company's Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2019. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, because of the material weaknesses in our internal controls over financial reporting described in our December 31, 2018 Annual Report, our disclosure controls and procedures were not effective. Notwithstanding the material weaknesses, the Company's management, including the Chief Executive Officer and Chief Financial Officer, have concluded that the condensed consolidated financial statements as of September 30, 2019, are fairly stated, in all material respects, in accordance with generally accepted accounting principles in the United States for each of the periods presented herein.

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

Changes in Internal Control over Financial Reporting

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

We continue to make further improvements to our internal controls over financial reporting, in addition to the improvements developed in 2018. During nine months ended September 30, 2019 and through the date of this report, we implemented the following:

- Hired staff required to address and improve financial and information technology capabilities, including (i) a Vice President, Corporate Controller and Principal Accounting Officer; (ii) an internal audit consultant; and (iii) a Manager of Information Technology.
- Developed our preliminary 2019 audit program, which includes an in-house audit of entity level and IT general controls.
- Implemented new programs and policies to provide improved control over the accounting for discretionary bonuses and stock-based compensation.
- Updated our process of obtaining information for calculation of our inventory reserves, including a comprehensive sales and operations planning process.
- Migrated the hosting of our ERP system and performed testing of the system before and after the completion of the migration.
- Preparation of our SEC reporting on Form 10-Q for the quarter ended September 30, 2019, was completed by our Principal Accounting Officer, supported by internal and external resources.

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

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

The disclosure set forth above in Note 16 (*Commitments and Contingencies – Litigation*) to our unaudited condensed consolidated financial statements is incorporated herein by reference.

Additionally, we are involved in certain other legal proceedings from time to time before various courts and governmental agencies. We cannot predict the final disposition of such proceedings. We regularly review legal matters and record provisions for claims that are considered probable of loss. The resolution of these pending proceedings is not expected to have a material effect on our operations or consolidated financial statements in the period in which they are resolved.

Item 1A. Risk Factors

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

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

We have limited capital resources, a cumulative deficit of approximately $299.2 million since inception and expect to incur further losses for the foreseeable future. As of September 30, 2019, we had approximately $29.0 million of cash, cash equivalents and investments available-for-sale, and working capital of $28.2 million. Net cash used in operating activities for the nine months ended September 30, 2019 was approximately $21.9 million. On June 20, 2019, the company closed a public offering of 5,833,334 shares of common stock at a price of $3.00 per share. On July 9, 2019, the underwriters of the public offering partially exercised their over-allotment option to purchase an additional 425,800 shares of common stock at a price of $3.00 per share, which closed on July 11, 2019.

On March 22, 2019, the Company entered into a sales agreement with Cantor Fitzgerald & Co. (the "Agent"), pursuant to which the Company may offer and sell from time to time shares of the Company's common stock through the Agent up to $40,000,000. We are not required to sell any shares at any time during the term of the facility. Our ability to sell common stock under the facility may be limited by several factors, including, among other things, the trading volume of our common stock and certain black-out periods that we may impose upon the facility, among other things.

The Company's recurring operating losses, net operating cash flow deficits, and an accumulated deficit, raise substantial doubt about the Company's ability to continue as a going concern for one year from the issuance of the accompanying consolidated financial statements. The consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company has not made any adjustments to the accompanying consolidated financial statements related to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company will require additional capital to sustain its operations and make the investments it needs to execute upon its longer-term business plan, including the launch of dialysate Triferic and I.V. Triferic. If the Company is unable to generate sufficient revenue from its existing long-term business plan, the Company will need to obtain additional equity or debt financing. If the Company attempts to obtain additional debt or equity financing, the Company cannot assume that such financing will be available on favorable terms, if at all.

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

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

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

We cannot commercialize I.V. Triferic unless and until we receive FDA approval of our planned NDA submission for this drug. Even if the FDA approves I.V. Triferic for commercialization, the degree of success in

commercializing this drug will depend upon our ability to receive add-on reimbursement status, such as through the TDAPA program. Under the 2020 Final Rule published by CMS in October 2019, it appears that I.V. Triferic is not be eligible for add-on reimbursement, meaning I.V. Triferic would be required to be sold within the bundled payment for dialysis treatment, if approved. This could significantly limit the overall commercial opportunity in the United States for I.V. Triferic.

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

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.

In the ordinary course of business, we and our business partners store sensitive data, including intellectual property and proprietary information related to our business, our customers and our business partners, on our information technology systems. Despite the implementation of security measures, these systems are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, natural disasters, terrorism, war and telecommunication, electrical and other system failures due to employee error, malfeasance or other disruptions. We could experience a business interruption, intentional theft of confidential information or reputational damage, including damage to key customer and partner relationships, from system failures, espionage attacks, malware, ransomware or other cyber-attacks. Such cyber-security breaches may compromise our system infrastructure or lead to data leakage, either internally or at our contractors or consultants. In particular, system failures or cyber-security breaches could result in the loss of nonclinical or clinical trial data from completed, ongoing or planned trials, which could cause delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

The risk of a security breach or disruption, particularly through cyber-attacks, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We have experienced cyber-security attacks in the past, including attacks targeting our e-mail systems, which to date have not had a material impact on our operations or development programs; however; there is no assurance that such impacts will not be material in the future.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, including protected health information or personal data of employees or former employees, we could be subject to legal claims or proceedings, liability under laws and regulations governing the protection of health and other personally identifiable information and related regulatory penalties. In any such event, our business, results of operations, financial position and cash flows could be materially adversely affected.

Item 6. Exhibits

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

EXHIBIT INDEX

Exhibit No.	Description
3.1	Restated Articles of Incorporation, as amended as of August 28, 2019 (Company's Form 8-K filed August 30, 2019)
3.2	Amended and Restated Bylaws (Company's Form 8-K filed August 30, 2019)
10.1§	Davita Agreement
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1	Certification pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(b) of the Securities Exchange Act of 1934
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Database
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

§ Certain confidential portions of this exhibit were omitted by means of marking such portions with asterisks because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ROCKWELL MEDICAL, INC.
(Registrant)

Date: November 12, 2019

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

Date: November 12, 2019

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

Exhibit 10.1

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

EXECUTION COPY

PRODUCTS PURCHASE AGREEMENT

THIS PRODUCTS PURCHASE AGREEMENT (this "Agreement"), is entered into and effective as of the 1st day of July, 2019 (the "Effective Date"), by and between Rockwell Medical, Inc., a Michigan corporation ("Rockwell"), and DaVita Inc., f/k/a DaVita Healthcare Partners Inc., a Delaware corporation ("DaVita") on behalf of itself and for the benefit of the DaVita Facilities (as defined in Recital B). Capitalized terms used herein and not otherwise defined herein shall have the meaning set forth in Article XVIII.

RECITALS

A. Rockwell is in the business of manufacturing and selling dialysis products and supplies, including the dialysis products and supplies set forth on Exhibit A attached hereto and incorporated herein by this reference (each, a "Product", and collectively, the "Products").

B. DaVita owns (in whole or in part) or manages dialysis and vascular access facilities, clinics, and units located throughout the United States and its territories (each, a "DaVita Facility", and collectively, the "DaVita Facilities").

C. Rockwell and DaVita entered into that certain First Amended and Restated Products Purchase Agreement, effective as of March 8, 2013, as amended (the "Original Agreement"), whereby Rockwell agreed to sell certain products to DaVita and the DaVita Facilities, subject to all of the terms and conditions of the Original Agreement.

D. Rockwell and DaVita desire to enter into this Agreement in order to (i) supersede and replace the Original Agreement, effective as of the Effective Date, and (ii) set forth the terms and conditions on which: (A) DaVita, on behalf of itself and the DaVita Facilities, will purchase and acquire the Products from Rockwell, and (B) Rockwell will supply and sell the Products to DaVita and the DaVita Facilities.

In consideration of the foregoing premises and mutual covenants, agreements, representations, and warranties contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, agree as follows:

ARTICLE I

PURCHASE AND SALE OF PRODUCTS AND REPORTS

1.1 Sale and Purchase. During the Term (as defined in Section 2.2) and subject to the terms and conditions of this Agreement, Rockwell will sell, supply, convey, transfer, assign, and deliver the Products to DaVita and the DaVita Facilities in such quantities as DaVita or the DaVita Facilities may order from time to time.

1.2 Product Commitment. DaVita covenants and agrees that [***] of the DaVita Facilities (the "Committed DaVita Facilities") will use their reasonable efforts to purchase all of their requirements for acid concentrate (i.e., CitraPure®(Liquid and Dry Acid) Dri-Sate® Dry Acid or RenalPure® Liquid Acid) and bicarbonate (i.e., RenalPure® Bicarbonate Powder or Sterilyte® Liquid Bicarbonate) from Rockwell each calendar year during the Term (the "Product Commitment"). [***] Rockwell's sole and exclusive remedy against DaVita and the DaVita Facilities for any breach by the DaVita Committed Facilities of the

Product Commitment shall be to terminate this Agreement, and in such event Rockwell shall not be entitled to any other relief or remedy whatsoever, including any monetary damages, against DaVita or any of the DaVita Facilities. Rockwell understands and acknowledges that the DaVita Facilities not included in the Committed DaVita Facilities (the "Non-Committed DaVita Facilities") have not promised or committed to purchase any particular quantity of any of the Products or any particular percentage of their requirements for items such as the Products, and that each of the Non-Committed DaVita Facilities may purchase other products from other vendors and suppliers performing some or all of the same functions as the Products.

1.3 Notice of Changes to Product Labeling. If, at any time during the Term, Rockwell or any applicable Governmental Authority determines that there must be an amendment, change, revision, or modification to the product labeling, safety information, or any other information relating to any particular Product (a "Product Labeling Event"), Rockwell shall within ten (10) Business Days of any such Product Labeling Event, deliver a written notice to DaVita which: (a) describes in reasonable detail any such Product Labeling Event, (b) explains in reasonable detail the reasons and the causes for any such Product Labeling Event, (c) includes a copy of such amendment, change, revision, or modification to the product labeling, safety information, or any other information relating to any such particular Product, (d) describes the potential effects of such Product Labeling Event on DaVita's or any DaVita Facilities' use of such Product, and (e) describes the effects of such Product Labeling Event on the inventory reserved by Rockwell for use by DaVita and the DaVita Facilities pursuant to Article VII of this Agreement, together with Rockwell's plan and timeline for ensuring that such reserved inventory is properly labeled (the "Product Label Change Notice"). Rockwell shall respond to any questions, inquiries, or requests for additional information that DaVita or any DaVita Facility may have with respect to any Product Label Change Notice and shall assist DaVita and the DaVita Facilities in understanding how, if at all, any Product Labeling Event may affect or have an impact on DaVita's or any DaVita Facilities' use of the Products.

ARTICLE II

TERM AND TERMINATION

2.1 Term. This Agreement shall commence on the Effective Date, and shall continue in effect until December 31, 2023 (the "Initial Term"), unless sooner terminated in accordance with the provisions of this Article II.

2.2 Renewal. If, upon the expiration of the Initial Term, the parties hereto have not negotiated, executed, and delivered (a) a new agreement relating to the subject matter hereof or (b) an extension of this Agreement, this Agreement shall continue until the earlier of: (i) either party hereto providing ninety (90) days prior written notice of termination to the other party hereto or (ii) the parties hereto entering into a new agreement relating to the subject matter hereof or an extension of this Agreement (the Initial Term, together with any such extension shall be referred to as the "Term").

2.3 DaVita Termination Rights. This Agreement may be terminated by DaVita as follows:

(a) Immediately in the event of a breach by Rockwell of any of its covenants or obligations set forth in Article VI or Article IX; or

(b) Upon thirty (30) days prior written notice to Rockwell, in the event of a breach by Rockwell of any representation, warranty, covenant, or obligation of Rockwell contained in this Agreement (other than the covenants or obligations set forth in Article VI or Article IX), and Rockwell fails to cure such breach within thirty (30) days following the date of such notice; or

(c) Immediately upon the occurrence of any of the following: (i) Rockwell files a voluntary petition in bankruptcy seeking protection from creditors (a "Bankruptcy Filing"); or (ii) Rockwell fails to contest an involuntary Bankruptcy Filing made against it or, despite contesting such involuntary Bankruptcy Filing, fails to obtain its dismissal within one hundred twenty (120) days from its filing; or (iii) a trustee or custodian is appointed for a substantial portion of or all of the assets of Rockwell; or (iv) Rockwell fails to pay its debts as they become due or admits its inability to do so (each of the foregoing, an "Insolvency Event"); or

(d) Immediately in the event there is a change in Rockwell's status which excludes it from participation in any Federal health care program, as defined under 42 U.S.C. § 1320a-7b(f).

2.4 Rockwell Termination Rights. This Agreement may be terminated by Rockwell as follows:

(a) Immediately in the event of a knowing and willful breach by DaVita of any of its covenants or obligations set forth in Article IX; or

(b) Upon thirty (30) days prior written notice to DaVita, in the event of a material breach by DaVita of any representation, warranty, covenant, or obligation of DaVita contained in this Agreement (other than the covenants or obligations set forth in Article IX or Section 17.1) that would reasonably be expected to result in a material negative effect on Rockwell's ability to perform its obligations under this Agreement or amounts received by Rockwell under this Agreement, and DaVita fails to cure such breach within thirty (30) days following the date of such notice; or

(c) Immediately upon the occurrence of an Insolvency Event with respect to DaVita; or

(d) Upon at least fourteen (14) months prior written notice to DaVita in the event that Rockwell decides to either: [***]; or

(e) Immediately in the event there is a change in DaVita's status which excludes it from participation in any Federal health care program, as defined under 42 U.S.C. § 1320a-7b(f).

2.5 Effect of Termination. The expiration of this Agreement or the earlier termination of this Agreement for any reason will not release either party hereto from any liability or obligation which, at the time of the expiration of this Agreement or the earlier termination of this Agreement for any reason, has already accrued or which thereafter may accrue in respect to any act or omission prior to the expiration of this Agreement or the earlier termination of this Agreement for any reason.

ARTICLE III

PURCHASE PRICE AND OTHER PRICING COVENANTS

3 . 1 Purchase Price. The purchase price(s) for the period July 1, 2019 through December 31, 2021 for each Product are set forth on Exhibit A (each, a "Purchase Price" and collectively, the " Purchase Prices"), subject to Section 3.4 below. The Purchase Price includes [***] to the states set forth on Exhibit B attached hereto (the "Territory"). In the event that DaVita or any DaVita Facility requires any Product to be shipped outside of the Territory, DaVita and Rockwell shall [***]. All orders for each Product by DaVita or any DaVita Facility shall be subject to [***] set forth on Exhibit C attached hereto. In the event that DaVita or any DaVita Facility desires to order an amount of any Product [***].

3 . 2 Taxes. Rockwell covenants and agrees that neither DaVita nor any DaVita Facility shall be liable for any taxes including any excise, gross receipts, gross earnings, gross value, property, income

taxes measured on Rockwell's income, or other taxes, other than applicable sales taxes, with respect to the purchase and sale of the Products. [***].

3.3 Pricing Covenant. Rockwell represents and warrants to DaVita that the Purchase Price for each Product and all other terms of sale offered to DaVita and the DaVita Facilities for each Product [***].

3.4 Price Increase.

(a) Commencing on [***], and no more than [***] each calendar year during the remaining Term, if (a) Rockwell's costs for raw materials, freight, and packaging relating to the manufacture, sale, and distribution ("Costs") for a Product for the remainder of any applicable calendar year are at least [***] percent higher than Rockwell's Costs for the most recent calendar year, or (b) an applicable Governmental Authority during any applicable contract year after [***] has changed the designation of such Product from a medical device to a drug and such change has increased Rockwell's manufacturing costs with respect to such Product ("Regulatory Costs") by at least [***] percent over the manufacturing costs with respect to such Product for the most recent calendar year for such Product, the Purchase Price for such Product shall be increased by the amount of such Costs or Regulatory Costs, as applicable, provided that in no event will the Purchase Price for any Product exceed [***] in any calendar year.

(b) If Rockwell believes the Costs or Regulatory Costs for a Product would result in an increase to the Purchase Price of such Product, Rockwell may submit a written notice to DaVita requesting an increase in the Purchase Price of such Product, together with reasonably detailed documentation showing Rockwell's calculation of the Costs and/or Regulatory Costs for the applicable calendar year for such Product and Rockwell's Costs and/or Regulatory Costs for the most recent calendar year in which there was a Purchase Price increase for such Product. DaVita will have thirty (30) days after receipt by DaVita of such notice to review the documentation of Rockwell's calculation of the Costs and/or Regulatory Costs for such Product. Rockwell agrees to reasonably cooperate with DaVita's review and will provide DaVita with reasonable access to Rockwell's books and records relating to such Costs and Regulatory Costs during normal business hours. If DaVita disagrees with Rockwell's calculation of the Costs and/or Regulatory Costs for such Product, DaVita may deliver a notice setting forth its objections to Rockwell's calculation of the Costs and/or Regulatory Costs. DaVita and Rockwell will use commercially reasonable efforts to reach an agreement on the calculation of the Costs and/or Regulatory Costs for such Product for a period of thirty (30) days after receipt by Rockwell of such notice. If DaVita and Rockwell are not able to agree on the calculation of the Costs and/or Regulatory Costs for such Product, the parties will retain a mutually acceptable independent accounting firm to determine the Costs and/or Regulatory Costs for such Product, during which time the Purchase Price for the Product(s) shall remain unchanged. The cost of such accountant will be borne equally by the parties.

ARTICLE IV

PURCHASE ORDERS; DELIVERY; DEDICATED CUSTOMER SERVICE REPRESENTATIVE

4.1 Purchase Orders and Delivery. Each Product shall be delivered by Rockwell to DaVita or any DaVita Facility, as applicable, pursuant to the terms of each purchase order submitted by DaVita or any such DaVita Facility, as applicable. DaVita or any DaVita Facility may submit an order for the purchase of any of the Products via facsimile at [***]. Rockwell shall provide accurate and on-time deliveries of all orders placed, in accordance with any reasonable special instructions that may be included in the purchase order [***]. Each DaVita Facility shall establish a delivery schedule with Rockwell's Customer Service

Department, and shall designate a specific day of the week for deliveries of the Products. All orders that a DaVita Facility places by [***] will be received by such DaVita Facility no later than its designated delivery day. Freight costs shall [***] in the pricing for the Product(s) set forth in Exhibit A to this Agreement. For the purposes of this Agreement, title to the Product(s) shall transfer from Rockwell to DaVita upon [***]. Risk of loss for the Product; [***]. Returns are subject to Rockwell Return Goods Policy (Section 4.3). Rockwell shall be responsible for providing inside delivery of the Products to DaVita or any DaVita Facility's designated storage area.

4.2 Dedicated Customer Service Representatives. Rockwell hereby agrees and covenants that it shall provide DaVita with reasonable access to one or more dedicated customer service representatives (each, a "Service Representative") who shall be available to promptly respond to and address any issues that DaVita or any DaVita Facility may have with respect to any of the Products or any of Rockwell's obligations set forth in this Agreement (the "Customer Services"). Rockwell further agrees and covenants that each Service Representative shall perform the Customer Services in a professional manner.

4.3 Return Goods Policy. Rockwell hereby represents and warrants to DaVita that attached hereto as Exhibit D is a true, correct, and complete copy of Rockwell's "Return Goods Policy" (the "Return Goods Policy"). Notwithstanding anything to the contrary set forth in the Return Goods Policy, DaVita or a DaVita Facility, as applicable, reserves the right to inspect all Products and to reject any or all of the Products which are, in DaVita's or a DaVita Facility's, as applicable, reasonable discretion, incorrectly shipped by Rockwell, defective, damaged, contaminated, or otherwise not in compliance with the warranties granted or assigned hereunder. Any return pursuant to this Section 4.3 by DaVita or any DaVita Facility, as applicable, shall be sent back to Rockwell, [***]. Upon the return of any Product by DaVita or any DaVita Facility, as applicable, to Rockwell pursuant to this Section 4.3, [***]. Rockwell shall provide DaVita with at least thirty (30) days prior written notice of any changes to the Return Goods Policy.

ARTICLE V

PAYMENT TERMS

All purchases by DaVita or any DaVita Facility of Products pursuant to this Agreement shall be paid on terms [***]. DaVita or any DaVita Facility, as applicable, may withhold payment on the portion of any invoice for which DaVita or any such DaVita Facility, as applicable, has a bona fide dispute if it: (a) pays all undisputed amounts, (b) notifies Rockwell of such invoice dispute within [***] of receipt of the invoice, and (c) provides to Rockwell a reconciliation of charges and any documentation necessary to support its claimed adjustment. The parties hereto agree to use their commercially reasonable efforts to resolve any invoice dispute within thirty (30) days of Rockwell's receipt of any such invoice dispute notice from DaVita or any DaVita Facility, as applicable.

ARTICLE VI

FAILURE TO SUPPLY

In the event of Rockwell's failure or inability to supply any Product(s) within and for the time period required by DaVita or any DaVita Facility, as applicable, including as a result of a force majeure event (e.g., act of God, fire, casualty, flood, war, act of terrorism, strike, lockout, labor trouble, failure of public utilities, injunction, epidemic, riot, insurrection, or any other circumstances beyond the reasonable control of Rockwell) (a "Failure to Supply Event"), Rockwell covenants and agrees, subject to any conflicting terms and conditions of any other distribution agreement of Rockwell entered into prior to the Effective Date of this Agreement, that it shall (a) give notice as promptly as is practicable under the circumstances, but in no event more than [***], to DaVita of such Failure to Supply Event, unless an order

of a regulatory agency or other action arising out of patient safety concerns requires the giving of shorter notice; (b) allocate any available quantities of any such Product(s) affected by such Failure to Supply Event (exclusive of the inventory of such Product(s) reserved by Rockwell for use by DaVita and the DaVita Facilities pursuant to Article VII, which inventory shall be solely for the use of DaVita and the DaVita Facilities) to DaVita and the DaVita Facilities, in accordance with the percentage of purchases of any such Product(s) made by DaVita and the DaVita Facilities from Rockwell during the [***] period immediately preceding such Failure to Supply Event in proportion to the percentage of purchases made by all other purchasers of any such Product(s) from Rockwell during the [***] period immediately preceding such Failure to Supply Event; (c) not intentionally discriminate against DaVita and the DaVita Facilities in its allocation of the available quantities of any such Product(s) affected by such Failure to Supply Event by making its allocation decisions, in whole or in part, on the basis of the prices, discounts, or other financial terms offered to DaVita and the DaVita Facilities pursuant to the terms and conditions of this Agreement; (d) compensate DaVita and the DaVita Facilities for (i) the difference between (A) the net price that DaVita and the DaVita Facilities have to pay for any alternative product(s) that DaVita and the DaVita Facilities purchase and (B) the Purchase Price that DaVita and the DaVita Facilities would have paid under this Agreement if Rockwell had been able to supply any such Product(s) affected by such Failure to Supply Event and (ii) all additional freight, handling, shipping, or service costs incurred by DaVita or the DaVita Facilities in acquiring an alternative product(s) in connection with such Failure to Supply Event; and (e) continue to perform its other obligations hereunder that are not affected by such Failure to Supply Event. Rockwell agrees to use commercially reasonable efforts to negotiate an amendment to any distribution agreement that may conflict with the terms of ARTICLE VI of this Agreement. Rockwell further covenants and agrees that during the period that a Failure to Supply Event is occurring, none of the Committed DaVita Facilities shall be subject to the Product Commitment.

ARTICLE VII

INVENTORY RESERVE COVENANTS

Rockwell agrees and covenants to DaVita that it shall, at all times during the Term, to allow for the continuous and uninterrupted supply of each of the Products to DaVita and the DaVita Facilities: (a) maintain and reserve for use exclusively by DaVita and the DaVita Facilities an amount of total inventory of each Product equal [***] and (b) have outstanding purchase orders with its suppliers for raw materials and products in amount sufficient to allow Rockwell to manufacture an amount of each such Product equal to [***]. At any time during the Term at DaVita's request, a responsible officer of Rockwell will deliver a written certification to DaVita that Rockwell is in compliance with its obligations under this Article VII. No more frequently than once in any [***] period, DaVita may arrange to conduct an inventory of the Products during normal business hours and at a mutually agreeable time. If, at any time during the Term, Rockwell does not have the outstanding purchase orders described above for a period in excess of [***] Business Days, Rockwell will deliver a written notice to DaVita which describes the reasons for Rockwell's failure to have such outstanding purchase orders, together with Rockwell's plan and timeline, which timeline shall not exceed [***] from the date of the notice, for entering into and such purchase orders. For the avoidance of doubt, any failure by Rockwell to meet the obligations in this Article VII shall constitute a material breach of the Agreement.

ARTICLE VIII

ADDITIONAL PRODUCTS AND REPLACEMENT PRODUCTS

8.1 Additional Products. Throughout the Term, Rockwell shall provide to DaVita and the DaVita Facilities the right to purchase or lease all current or new products manufactured, utilized, licensed, sold, or distributed by Rockwell or any of its Affiliates (including products and product lines acquired by

Rockwell or any of its Affiliates as a result of an acquisition, merger, or other transaction involving Rockwell or any of its Affiliates) that are or that become Commercially Available and which are not already covered by this Agreement or by any other agreement, whether written or oral, between the parties hereto (such products are collectively referred to as "Additional Products" and individually as an "Additional Product"). Rockwell agrees to include DaVita in all of its and its Affiliates distributions of customer announcements regarding Rockwell's or its Affiliates' Additional Products. The purchase price for any Additional Product(s) shall be negotiated by the parties hereto in good faith and the agreed upon purchase price shall be memorialized in writing as a supplement or amendment to this Agreement. Rockwell covenants and agrees that it shall only make an offer for the sale of any Additional Product(s) to DaVita's Vice-President of Clinical Operations, Chief Medical Officer, or Group Vice-President Purchasing, and not to any DaVita Facility directly; provided that the purchase of any Additional Product(s) by DaVita or any DaVita Facility through a Rockwell product catalog made generally available to the dialysis community shall not be a breach by Rockwell of this Section 8.1. If Rockwell or any of its Affiliates acquires any Additional Product(s) as a result of an acquisition, merger, or other transaction involving Rockwell or any of its Affiliates with a Person with which DaVita or a DaVita Facility, as applicable, already has a purchase or rebate arrangement whether written or oral (a "Prior Agreement"), Rockwell or such Affiliate covenants and agrees that it shall continue to abide by all of the terms and conditions of such Prior Agreement or if DaVita requests, any such Additional Product(s) shall be included in this Agreement on terms to be negotiated and mutually acceptable to the parties hereto as provided in this Section 8.1.

8.2 Replacement Products. If at anytime during the Term, Rockwell or any of its Affiliates introduces a product or offering that is a replacement for an existing Product covered by this Agreement, whether developed by Rockwell or any of its Affiliates or acquired by Rockwell or any of its Affiliates in connection with any transaction (a "Replacement Product"), Rockwell will allow (or will cause its Affiliate to allow) DaVita or any DaVita Facility, as applicable, to purchase such Replacement Product at the same price as the Product it is replacing or is ultimately intended to replace.

8.3. Modified Products. Unless required by a Governmental Authority, Rockwell shall not remove, discontinue, replace or change any Product unless Rockwell (i) provides DaVita with at least ninety (90) days' prior written notice of its intent to remove, discontinue, replace or materially change such Product, (ii) simultaneously notifies all of its customers who purchase such Product of Rockwell's intent to remove, discontinue, replace or materially change the Product, and (iii) replaces such Product with a substitute product that (a) in DaVita's reasonable discretion is clinically and functionally superior or equivalent to the Product being removed, discontinued, replaced or materially changed (the "Modified Product") and (b) is provided by Rockwell at a price equal to the Product. If DaVita determines that the proposed substitute product does not substantially match the clinical efficacy or functionality of the Modified Product, introduction of such substitute product shall in no way relieve Rockwell of any of its requirements and obligations in relation to the Modified Product under this Agreement.

ARTICLE IX

CONFIDENTIAL INFORMATION COVENANTS

9.1 Confidential Information.

(a) No Disclosure of Confidential Information. The Non-Disclosing Party (as defined in Section 18.5) agrees that in connection with the transactions contemplated by this Agreement and the relationship of the parties hereto, it will have access to Confidential Information of the Disclosing Party (as defined in Section 18.5) and that such Confidential Information is vital, sensitive, confidential, and proprietary to the Disclosing Party. Therefore, the Non-Disclosing Party agrees that during the Term and for the longest time permitted under applicable law after the expiration of this Agreement or the earlier

termination of this Agreement for any reason, that it will (i) use the Confidential Information solely for the purposes of performing its obligations or exercising its rights under this Agreement or for the purposes of using the Products, Additional Products or Replacement Products supplied pursuant to this Agreement (the "Purpose"), (ii) hold any Confidential Information delivered or communicated to it by the Disclosing Party in the strictest confidence, including taking all reasonable precautions to prevent the inadvertent disclosure of any such Confidential Information to any unauthorized third party or parties and (ii) not, at any time without the Disclosing Party's express written consent, which consent may be withheld by the Disclosing Party in its sole and absolute discretion (A) disclose, reproduce, display, perform, record, broadcast, transmit, distribute, modify, translate, combine with other information or materials, create derivative works based on, exploit commercially, or otherwise use any such Confidential Information in any manner or medium whatsoever, (B) disclose or publicize any such Confidential Information or the terms of this Agreement to any third party or parties, or (C) discuss with or otherwise disclose or reveal to any third party or parties any information relating to the Disclosing Party's business or the Non-Disclosing Party's duties or responsibilities to the Disclosing Party, regardless of whether such information constitutes Confidential Information, except, in each case, that the Non-Disclosing Party may disclose the Confidential Information to its contractors, agents or employees who have a need to know the Confidential Information in connection with the Purpose and who are bound by an obligation of confidentiality. Notwithstanding anything to the contrary herein, the Non-Disclosing Party shall have the right to disclose (to the minimum extent necessary) any of the terms or provisions of this Agreement upon any determination by the Non-Disclosing Party's legal counsel in consultation with Disclosing Party's counsel that such disclosure is necessary in connection with the compliance by the Non-Disclosing Party with any legal requirement, including applicable obligations and requirements pursuant to federal and state securities laws and listing standards.

(b) Retention and Destruction of Confidential Information. The Non-Disclosing Party shall not use, take or retain any Confidential Information that is in written, email, computerized, model, sample, or other form capable of physical delivery, upon or after the expiration of this Agreement or the earlier termination of this Agreement for any reason without the prior written consent of the Disclosing Party, which consent may be withheld by the Disclosing Party in its sole and absolute discretion. At any time upon the request of the Disclosing Party, the Non-Disclosing Party shall promptly redeliver to the Disclosing Party or destroy all written materials containing or reflecting any information contained in the Confidential Information (including all copies, extracts, or other reproductions) and agree to destroy all documents, memoranda, notes, and other writings whatsoever (including all copies, extracts, or other reproductions), prepared by the Non-Disclosing Party based on the information contained in the Confidential Information. Notwithstanding the return or destruction of the Confidential Information, the Non-Disclosing Party will continue to abide by its obligations of confidentiality and other obligations hereunder.

(c) Exceptions to Confidential Information. Notwithstanding anything to the contrary herein, Confidential Information shall not include any information that (i) was already known to the Non-Disclosing Party at the time of disclosure by the Disclosing Party free of any restriction, (ii) is generally available to the public or becomes publicly known through no wrongful act of the Non-Disclosing Party, or (iii) is received by the Non-Disclosing Party from a third-party who has a legal right to provide such information to the Non-Disclosing Party.

(d) Use of Trademarks and Other Intellectual Property. Each party hereto agrees not to internally or externally use, release, publish, or distribute any materials or information (including advertising and promotional materials) containing the names, tradenames, trademarks, or other intellectual property right of the other party hereto without the express prior written consent of such other party hereto.

(e) Disclosures of Confidential Information Required By Law. In the event that the Non-Disclosing Party is required by law (e.g., by oral questions, interrogatories, request for information or documents, subpoena, civil investigative demand, or any other similar process) to disclose any Confidential Information, the Non-Disclosing Party agrees that it shall provide the Disclosing Party with prompt written notice of any such disclosure of any such Confidential Information that is required by law (prior to making such disclosure and in no event later than five (5) days after the receipt of such request(s)) and shall consult with the Disclosing Party as to the advisability of taking legally advisable steps to resist or narrow any such disclosure of any such Confidential Information that is required by law. If disclosure of any Confidential Information is required by law, the Non-Disclosing Party will (i) furnish only that portion of any such Confidential Information which, in the reasonable opinion of the Non-Disclosing Party's counsel, after consultation with the Disclosing Party's counsel, it is legally obligated to disclose and (ii) use its best efforts to obtain an order or other reliable assurances that confidential and non-public treatment will be accorded to any such Confidential Information that is required to be disclosed by law.

(f) Employees, Agents, Representatives, Etc. For purposes of this Section 9.1, any Confidential Information received by any director, officer, member, manager, partner, employee, agent, subcontractor, advisor, or representative of the Non-Disclosing Party pursuant to the terms and conditions of this Agreement shall be deemed received by the Non-Disclosing Party and any breach by such persons of this Section 9.1 shall be deemed a breach by the Non-Disclosing Party of this Agreement.

9.2 Enforcement. The Non-Disclosing Party agrees that money damages would not be an adequate remedy for any breach of this Article IX. Therefore, in the event of a breach or threatened breach of the provisions of this Article IX by the Non-Disclosing Party, the Disclosing Party shall, in addition to other rights and remedies existing in its favor, be entitled to specific performance, injunctive relief, or any other relief in order to enforce or prevent any violation of the provisions of this Article IX (without proving monetary damages, posting a bond, or other security).

ARTICLE X

REPRESENTATIONS AND WARRANTIES OF ROCKWELL

Rockwell hereby represents and warrants to DaVita as follows:

10.1 Standing and Authority. Rockwell has the requisite corporate power, right, and authority to enter into this Agreement and to consummate the transactions contemplated hereby. Rockwell's execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly and validly authorized by all necessary corporate action on the part of Rockwell.

10.2 Execution; Delivery; Binding Effect. This Agreement has been duly executed and delivered by Rockwell, and constitutes the legal, valid, and binding obligation of Rockwell, enforceable against Rockwell in accordance with its terms.

10.3 No Conflicts. Neither the execution, delivery, or performance of this Agreement by Rockwell nor the consummation of the transactions contemplated in this Agreement, shall (a) conflict with, contravene, or result in a breach of any statute or administrative regulation, or of any law, rule, regulation, ordinance, order, writ, injunction, judgment, or decree of any Governmental Authority or of any arbitration award to which Rockwell is a party or by which any of the properties or assets of Rockwell are or may be bound or (b) conflict with, contravene, or violate any agreement, understanding, or arrangement to which Rockwell is a party or by which any of the properties or assets of Rockwell are or may be bound.

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

10.4 Title. Rockwell possesses good and marketable title to all of the Products free and clear of any and all liens, mortgages, charges, security interests, pledges, or other encumbrances or adverse claims of any nature, whether arising by agreement, operation of law, or otherwise (collectively, "Liens"). Rockwell has the right to convey and in connection with the transactions contemplated by this Agreement will convey to DaVita and the DaVita Facilities, as applicable, good and marketable title to all of the Products acquired hereunder, free and clear of any and all Liens.

10.5 Licenses, Permits, and Compliance with Laws. Rockwell has all rights, licenses, permits, and consents necessary to sell the Products to DaVita and the DaVita Facilities and to perform its obligations hereunder during the Term. Rockwell is and has at all times been in and during the Term shall be in compliance with all federal, state, and local laws, statutes, rules, and regulations applicable to its business and the performance of its obligations under this Agreement. No Product delivered hereunder during the Term is or will be adulterated or misbranded within the meaning of the FFDCA, or within the meaning of any applicable state or municipal law, or is or will be a product which may not be introduced into interstate commerce. During the Term, Rockwell shall immediately inform DaVita following its receipt of any information which states that the integrity or legal status of any Product provided hereunder has been called into question by any retailer, wholesaler, or state or federal authority, or that any such Product sold to DaVita or any DaVita Facility hereunder is suspected of being counterfeit, stolen, adulterated, misbranded, or otherwise an unlawful product and shall provide DaVita with prompt written confirmation of any such event, including copies of any and all documents related thereto. DaVita's and the DaVita Facilities' use of the Products in accordance with their intended use shall not infringe upon any ownership rights of any other Person or upon any patent, copyright, trademark, or other intellectual property or proprietary right or trade secret of any third party.

10.6 Products. Each Product purchased during the Term (a) is and shall be manufactured in accordance with its packaging, (b) is and shall be manufactured, handled, stored, and transported in accordance with all applicable United States, state, and local laws and regulations pertaining thereto, including to the extent applicable, the FFDCA and implementing regulations and FDA approved Good Manufacturing Practices, (c) meets all specifications for effectiveness and safety as required by the FDA, (d) is fit for the indications described in its labeling, and (e) is labeled in compliance with all applicable laws. Each Product is and will (i) be of the kind and quantity specified herein, (ii) be of safe and merchantable quality, (iii) be free of defects in design, materials, manufacture, or workmanship when delivered, (iv) [***], and (v) conform to its specifications as written or published, unless otherwise agreed to by the parties hereto. In the event any Product or any component of a Product is not manufactured by Rockwell, Rockwell hereby assigns or agrees to assign (to the extent assignable) to DaVita all such manufacturer warranties, copies of which shall be provided by Rockwell to DaVita upon request.

10.7 Expired Product. Rockwell will use its best efforts not to ship to DaVita or any DaVita Facility expired Product [***], unless agreed to in writing by DaVita. In the event that Rockwell ships to DaVita or any DaVita Facility expired Product [***], DaVita shall have the right to return such Product to Rockwell and Rockwell shall replace such Product with [***], all at Rockwell's sole cost and expense.

10.8 Health Care Programs. Neither Rockwell nor any of its Affiliates is currently (a) named on any of the following lists (i) HHS/OIG List of Excluded Individuals/Entities, (ii) GSA List of Parties Excluded from Federal Programs, or (iii) OFAC "SDN and Blocked Individuals" or (b) under investigation or otherwise aware of any circumstances which would result in Rockwell being excluded from participation in any Federal health care program, as defined under 42 U.S.C. §1320a-7b(f). Neither Rockwell nor any of its Affiliates or personnel has ever been either convicted of a criminal offense, assessed civil monetary penalties pursuant to the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, 42 U.S.C. § 1320a-7(b)(1)-(3) or excluded from the Medicare program or any state health care program. Further, neither Rockwell nor any of its Affiliates or personnel is subject to an action or investigation that could lead to the conviction

of a criminal offense, the assessment of civil monetary penalties, or exclusion from the Medicare program or any state health care program. Rockwell shall notify DaVita, immediately, if an action or investigation arises that could result in the conviction of a criminal offense, or the exclusion of it, or any of its Affiliates or personnel from the Medicare program, any state health care program or would otherwise result in it, its Affiliates or personnel being excluded as set forth in this Section 10.8. Failure to timely notify DaVita of any action or investigation shall give DaVita the right to terminate this Agreement effective immediately upon written notice. In the event that Rockwell becomes excluded, for any reason, during the Term of this Agreement, DaVita shall be entitled to terminate this Agreement, effective immediately upon written notice. Rockwell certifies that this Agreement is not intended to generate referrals for services or supplies for which payment may be made in whole or in part under any federal health care program.

All warranties granted or assigned under this Article X will continue in full force and effect notwithstanding transfer of title to any Product to or by DaVita or any DaVita Facility to any other DaVita Facility. All warranties granted under this Agreement shall survive inspection, acceptance, and payment of the Products.

ARTICLE XI

REPRESENTATIONS AND WARRANTIES OF DAVITA

DaVita hereby represents and warrants to Rockwell as follows:

11.1 Standing and Authority. DaVita has the requisite corporate power, right, and authority to enter into this Agreement and to consummate the transactions contemplated hereby. DaVita's execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly and validly authorized by all necessary corporate action on the part of DaVita.

11.2 Execution; Delivery; Binding Effect. This Agreement has been duly executed and delivered by DaVita, and constitutes the legal, valid, and binding obligation of DaVita, enforceable against DaVita in accordance with its terms.

11.3 No Conflicts. Neither the execution, delivery, or performance of this Agreement by DaVita nor the consummation of the transactions contemplated in this Agreement, shall (a) conflict with, contravene, or result in a breach of any statute or administrative regulation, or of any law, rule, regulation, ordinance, order, writ, injunction, judgment, decree of any Governmental Authority, or of any arbitration award to which DaVita is a party or by which any of the properties or assets of DaVita are or may be bound or (b) conflict with, contravene, or violate any provision of any agreement, understanding, or arrangement to which DaVita is a party or by which any of the properties or assets of DaVita are or may be bound.

11.4 Compliance with Laws. DaVita has all rights, licenses, permits, and consents necessary to perform its obligations hereunder during the Term. DaVita is and has at all times been in and during the Term shall be in compliance with all federal, state, and local laws, statutes, rules, and regulations applicable to its business and the performance of its obligations under this Agreement.

11.5 Health Care Programs. DaVita is not currently (a) named on any of the following lists (i) HHS/OIG List of Excluded Individuals/Entities, (ii) GSA List of Parties Excluded from Federal Programs, or (iii) OFAC "SDN and Blocked Individuals" or (b) under investigation or otherwise aware of any circumstances which would result in DaVita being excluded from participation in any Federal health care program, as defined under 42 U.S.C. §1320a-7b(f). DaVita shall promptly notify Rockwell if an action or investigation arises that results in a criminal conviction, or the exclusion of it, any of its Affiliates, or personnel from the Medicare program, or any state healthcare program or would otherwise result in it, its Affiliates or personnel being excluded as set forth in this Section 11.5.

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

ARTICLE XII

INDEMNIFICATION AND INSURANCE

12.1 Indemnification of DaVita. Rockwell agrees to defend, indemnify, and hold DaVita, its Affiliates, and the DaVita Facilities and each of their respective directors, officers, members, managers, partners, employees, and agents (collectively, the "DaVita Indemnitees") harmless from and against any and all causes of action (at law or in equity), actions, claims, costs, suits, liabilities, judgments, settlements, demands, losses, damages, proceedings, or expenses of all kinds (including reasonable attorneys' fees, witnesses' fees, investigation expenses, and any other expenses incident thereto) (collectively, "Losses") that the DaVita Indemnitees may sustain or incur as a result of: (a) any breach of any representation or warranty made by Rockwell in this Agreement or in materials furnished by Rockwell for DaVita's and the DaVita Facilities' use; (b) any breach by Rockwell of any of its covenants or obligations in this Agreement; (c) the use of any Product by DaVita or any DaVita Facility in accordance with any such Products' labeling and instructions for use; (d) any defect in the design or manufacture of any Product (including claims for property damage, loss of life, and bodily injury); (e) any Recall (as defined in Article XIII) with respect to any Product; or (f) any negligent, reckless, wanton, malicious, or other tortious conduct by Rockwell in connection with the transactions contemplated by this Agreement. Notwithstanding the foregoing, in no event shall Rockwell have an obligation to defend, indemnify, or hold any of the DaVita Indemnitees harmless hereunder to the extent any Losses were caused by the sole negligence or willful misconduct of any such DaVita Indemnitees.

12.2 Indemnification of Rockwell. DaVita agrees to defend, indemnify, and hold Rockwell and its Affiliates and each of their respective directors, officers, members, managers, partners, employees, and agents (collectively, the "Rockwell Indemnitees") harmless from and against any and all Losses that the Rockwell Indemnitees may sustain or incur as a result of: (a) any breach of any representation or warranty made by DaVita in this Agreement; (b) any breach by DaVita of any of its covenants or obligations in this Agreement; (c) the use of any Product by DaVita or any DaVita Facility not in accordance with any such Products' labeling and instructions for use; (d) any DaVita Facilities' negligence or misconduct in the "Administration" of a Product to its patients; or (e) any negligent, reckless, wanton, malicious, or other tortious conduct by DaVita in connection with the transactions contemplated by this Agreement. For purposes of this Section 12.2, the "Administration" of a Product by a DaVita Facility shall mean the dispensing and handling by such DaVita Facility and its employees of such Product and the actual administration of such Product to patients by such DaVita Facility and its employees, but shall exclude physician prescriptions of such Product to patients. Notwithstanding the foregoing, in no event shall DaVita have an obligation to defend, indemnify, or hold any of the Rockwell Indemnitees harmless hereunder to the extent any Losses were caused by the sole negligence or willful misconduct of any such Rockwell Indemnitees.

12.3 Indemnification Procedure for Third Party Claims. If any DaVita Indemnitee or any Rockwell Indemnitee entitled to indemnification under this Article XII (the "Indemnified Party") receives notice of the assertion of any claim, or the commencement of any suit, action, or proceeding by any Person who is not a party hereto or an Affiliate of a party hereto (a "Third Party Claim") against such Indemnified Party, the Indemnified Party shall give written notice regarding such Third Party Claim to the party hereto that is required to provide indemnification under this Article XII (the "Indemnifying Party") within thirty (30) days after learning of such Third Party Claim. The Indemnifying Party shall have the right, upon written notice to the Indemnified Party (the "Defense Notice") within thirty (30) days after receipt from the Indemnified Party of notice of such Third Party Claim, which Defense Notice by the Indemnifying Party shall specify the counsel it will appoint to defend such Third Party Claim (the "Defense Counsel"), to conduct at its expense the defense against such Third Party Claim in its own name, or if necessary in the name of the Indemnified Party; provided, however, that: (a) the Indemnified Party shall have the right to

approve the Defense Counsel, which approval shall not be unreasonably withheld, conditioned, or delayed by the Indemnified Party and (b) as a condition precedent to the Indemnifying Party's right to assume control of such defense, the Indemnifying Party must first enter into an agreement with the Indemnified Party (in form and substance reasonably satisfactory to the Indemnified Party) pursuant to which the Indemnifying Party agrees to be fully responsible for any and all Losses relating to such Third Party Claim and unconditionally guarantees the payment and performance of any and all Losses which may arise with respect to such Third Party Claim, subject to the terms and conditions set forth in this Section 12. The Indemnifying Party shall not have the right to assume control of, but may participate in, and the Indemnified Party shall have the sole right to assume control of any Third Party Claim, at its own expense which: (i) seeks a temporary restraining order, a preliminary or permanent injunction, or specific performance against the Indemnified Party, (ii) involves criminal or quasi-criminal allegations against the Indemnified Party, (iii) if unsuccessful would set a precedent that would materially interfere with, or have a material adverse effect on, the business or financial condition of the Indemnified Party, or (iv) imposes liability in the part of the Indemnified Party for substantially all of which the Indemnified Party is not entitled to indemnification under this Article XII. If the Indemnifying Party is permitted to assume and control the defense of any Third Party Claim and elects to do so, the Indemnified Party shall have the right to employ counsel separate from counsel employed by the Indemnifying Party in any such Third Party Claim and to participate in the defense thereof, but the fees and expenses of such counsel employed by the Indemnified Party shall be at the expense of the Indemnified Party unless (A) the employment thereof has been specifically authorized by the Indemnifying Party in writing, (B) the Indemnified Party has been advised by counsel that a conflict of interest exists between the Indemnifying Party and the Indemnified Party, or (C) the Indemnifying Party has failed to assume the defense and employ counsel, in which case the fees and expenses of the Indemnified Party's counsel shall be paid by the Indemnifying Party. No Indemnifying Party shall consent to the entry of any judgment or enter into any settlement of any Third Party Claim without the prior written consent of the Indemnified Party if (w) such judgment or settlement would lead to liability or create any financial or other obligation on the part of the Indemnified Party for which the Indemnified Party is not entitled to indemnification hereunder, (x) such judgment or settlement would result in the finding or admission of any violation of any federal, state, or local law, statute, ordinance, or regulation, (y) such judgment or settlement does not include as an unconditional term thereof the giving by each claimant or plaintiff to each Indemnified Party of a release from all liability in respect to such Third Party Claim, or (z) as a result of such judgment or settlement, injunctive or other equitable relief would be imposed against the Indemnified Party. In the event that the Indemnifying Party fails to give the Defense Notice within thirty (30) days of receiving notice of a Third Party Claim from the Indemnified Party, it shall be deemed to have elected not to conduct the defense of such Third Party Claim, or in the event the Indemnifying Party does deliver a Defense Notice within thirty (30) days of receiving notice of such Third Party Claim from the Indemnified Party and thereby elects to not conduct the defense of such Third Party Claim, then in either such event the Indemnified Party shall have the right to conduct and control the defense of such Third Party Claim in good faith and to compromise and settle such Third Party Claim or consent to the entry of a judgment of such Third Party Claim in good faith without the prior consent of the Indemnifying Party. A failure by the Indemnified Party to give timely, complete, or accurate notice as provided in this Section 12.3 will not affect the rights or obligations of the Indemnifying Party except and only to the extent that, as a result of such failure, the Indemnifying Party entitled to receive such notice was deprived of its right to recover any payment under its applicable insurance coverage or was otherwise directly and materially damaged as a result of such failure to give timely notice.

12.4 Indemnification Procedure for Direct Claims. In the event an applicable Indemnified Party should have an indemnification claim against an applicable Indemnifying Party hereunder which does not involve a Third Party Claim (a "Direct Claim"), the applicable Indemnified Party shall transmit to the applicable Indemnifying Party a written notice containing an estimate of the Losses attributable to such Direct Claim and the basis of the applicable Indemnified Party's request for indemnification under this Agreement within thirty (30) days after learning of such Direct Claim (the "Direct Indemnification

Notice"). Following transmission of the Direct Indemnification Notice, the applicable Indemnified Party shall host a meeting or telephone conference (the "Direct Indemnification Meeting") with the Indemnifying Party to ensure the Indemnifying Party received the Direct Indemnification Notice and to discuss or dispute the Direct Claim. If the applicable Indemnifying Party does not notify the applicable Indemnified Party in writing within thirty (30) days from the date of the Direct Indemnification Meeting that the applicable Indemnifying Party disputes a Direct Claim(s) specified by the applicable Indemnified Party in the Direct Indemnification Notice, such Direct Claim(s) specified by the applicable Indemnified Party in the Direct Indemnification Notice shall be deemed a liability of the applicable Indemnifying Party hereunder and the applicable Indemnifying Party shall be liable for any and all Losses in connection with such Direct Claim(s) specified by the applicable Indemnified Party in the Direct Indemnification Notice. If the applicable Indemnifying Party has timely disputed a Direct Claim(s) specified by the applicable Indemnified Party in the Direct Indemnification Notice as provided in this Section 12.4, such dispute shall be resolved by litigation in accordance with the terms and conditions of Sections 19.3, 19.4, and 19.5. A failure by the applicable Indemnified Party to give timely, complete, or accurate notice as provided in this Section 12.4 will not affect the rights or obligations of the applicable Indemnifying Party except and only to the extent that, as a result of such failure, the applicable Indemnifying Party entitled to receive such notice was deprived of its right to recover any payment under its applicable insurance coverage or was otherwise directly and materially damaged as a result of such failure to give timely notice.

12.5 Insurance. Each party hereto agrees that it shall secure and maintain in full force and effect throughout the Term (and following the expiration of this Agreement or the earlier termination of this Agreement for any reason, to cover any claims or liabilities arising from this Agreement) the insurance coverage set forth in Exhibit E attached hereto. Any limits on either party's insurance coverage shall not be construed to create a limit on its liability with respect to any of its obligations hereunder. Each party hereto shall name the other party as an additional insured on such party's commercial general liability insurance policy. Such insurance policies shall provide at least thirty (30) days prior written notice to the other party hereto of the cancellation, non-renewal, or substantial modification thereof. Each party hereto shall supply certificates of insurance to the other party hereto upon the other party's request.

ARTICLE XIII

RECALL

In the event the FDA initiates a mandatory recall (i.e., the correction or removal of a Product) or Rockwell believes in its sole discretion that it may be necessary to conduct a recall (i.e., the correction or removal of a Product), field market withdrawal, stock recovery, or other similar action with respect to any of the Products (a "Recall"), Rockwell shall immediately notify DaVita of such Recall. The parties hereto agree that the final decision as to and control of the handling of any Recall shall be in Rockwell's sole discretion; provided that Rockwell conducts any such Recall in accordance with any and all applicable legal requirements and general guidance issued by the FDA. In the event that Rockwell does not conduct a Recall, clearly and without dispute, in accordance with all applicable legal requirements and general guidance issued by the FDA, DaVita shall have the right to take any and all actions it determines necessary to comply with such applicable legal requirements and general guidance issued by the FDA, [***]. DaVita shall provide all reasonable assistance requested by Rockwell in connection with a Recall. In the event of a Recall with respect to any Product(s), Rockwell shall reimburse DaVita for: [***]. DaVita and Rockwell shall maintain records of all sales of the Products and customers who received such Products so as to enable Rockwell to adequately administer a Recall with respect to any of the Products in accordance with applicable legal requirements and general guidance issued by the FDA. In the event of a Recall, neither party hereto shall make any statement to the press or public concerning such Recall without first notifying the other party hereto and obtaining such other party's prior written approval of any such statement, which

approval shall not be unreasonably withheld, conditioned, or delayed. Any return by DaVita or any DaVita Facility pursuant to this Article XIII shall be sent back to Rockwell, [***].

ARTICLE XIV

OPEN RECORDS AND DISCOUNTS

14.1 Open Records. To the extent required by §1861(v)(1)(I) of the Social Security Act, the parties hereto will allow the U.S. Department of Health and Human Services, the U.S. Comptroller General, and their duly authorized representatives, access to this Agreement and any records necessary to verify the nature and extent of costs incurred pursuant to this Agreement during the Term and for four (4) years following the last date any Products are furnished by Rockwell to DaVita or any DaVita Facility under this Agreement. If Rockwell carries out its obligations under this Agreement through a subcontract worth Ten Thousand Dollars ($10,000) or more over a twelve (12) month period with a related organization, the subcontract shall also contain an access clause to permit access by the U.S. Department of Health and Human Services, the U.S. Comptroller General, and their duly authorized representatives to the related organization's books and records. Nothing in this Section 14.1 is intended to waive any right either party hereto may have under any applicable laws or regulations to retain in confidence information included in records so requested.

14.2 Discounts. Any discounts, rebates, incentives, or other reductions in price issued by Rockwell to DaVita or any DaVita Facility under this Agreement may constitute a discount within the meaning of 42 U.S.C. §1320a-7b(b)(3)(A). DaVita and the DaVita Facilities may have an obligation to properly disclose and appropriately reflect any such discounts, rebates, incentives, or other reductions in price to any state or federal program that provides cost or charge based reimbursement to DaVita or any such DaVita Facility for the items to which such discounts, rebates, incentives, or other reductions in price apply. In order to assist DaVita's and the DaVita Facilities' compliance with any such obligations, Rockwell agrees that it shall fully and accurately report all discounts, rebates, incentives, or other reductions in price on the invoices, coupons, or statements submitted to DaVita or any DaVita Facility and inform DaVita or any such DaVita Facility of their obligations to report such discounts, rebates, incentives, or other reductions in price. In the event the value of any discounts, rebates, incentives, or other reductions in price are not known at the time of sale, Rockwell shall fully and accurately report the existence of such discounts, rebates, incentives, or other reductions in price on the invoices, coupons, or statements submitted to DaVita or any DaVita Facility, inform DaVita or any DaVita Facility of their obligations to report such discounts, rebates, incentives, or other reductions in price, and when the value of such discounts, rebates, incentives, or other reductions in price becomes known, provide DaVita or any DaVita Facility with documentation of the calculation of such discounts, rebates, incentives, or other reductions in price and identifying the specific Products purchased to which such discounts, rebates, incentives, or other reductions in price will be applied. Rockwell shall also provide to DaVita or any DaVita Facility any other information that DaVita or any DaVita Facility may request that is necessary for them to obtain in order to comply with any such obligations, and Rockwell shall refrain from doing anything which would impede DaVita or any DaVita Facility from meeting its obligations under this Section 14.2 or any Medicare regulation.

ARTICLE XV

ACCESS AND POLICIES AND PROCEDURES

Rockwell acknowledges, agrees, and covenants that: (a) all of DaVita's applicable vendor relations policies and procedures and any updates thereto (the "Policies and Procedures") that will be in effect during the Term will be available for viewing by Rockwell during the Term by going to http://www.davita.com/about/vendor-policies and (b) Rockwell shall abide by the Policies and Procedures

during the Term. Rockwell further acknowledges, agrees, and covenants that it must obtain DaVita's prior written approval of: (i) all proposed educational, marketing, presentation, and promotional materials and (ii) all presentations that are in the case of subparagraphs (i) or (ii) related to any of the products or services offered by Rockwell, including the Products (the "Materials"), that are to be given or made by Rockwell to: (A) DaVita or any DaVita Facility or (B) any patient of DaVita or any DaVita Facility, which approval may only be given in writing by DaVita's Vice President, Clinical Operations or his or her authorized representative. DaVita's Vice President, Clinical Operations or his or her authorized representative agrees to use his or her commercially reasonable efforts to notify Rockwell of his or her decision with respect to the approval of the Materials within ten (10) Business Days following the receipt of a request by Rockwell to approve the Materials; provided that if DaVita's Vice President, Clinical Operations or his or her authorized representative fails to notify Rockwell of his or her decision with respect to the approval of the Materials within such ten (10) Business Day period, such request to approve the Materials will be deemed denied. Rockwell further acknowledges, agrees, and covenants that absent a specific request from DaVita or any DaVita Facility, none of Rockwell's agents, representatives, or employees shall: (x) contact any patient of DaVita or any DaVita Facility or (y) be permitted access at any time to DaVita or any DaVita Facility; provided that nothing in this Article XV shall prohibit Rockwell from contacting any patient of DaVita or any patient of a DaVita Facility in a manner that is consistent with the Policies and Procedures or as required by any applicable federal, state, or local law.

ARTICLE XVI

AUDIT

If DaVita disagrees with any computation or statement delivered by Rockwell to DaVita or any DaVita Facility under this Agreement, DaVita may, within thirty (30) days after the receipt of such computation or statement, audit any such computation or statement. DaVita shall conduct any such audit during such times as may be mutually agreed to by the parties hereto. In the event that DaVita's audit results in a number different from that set forth in the computation or statement delivered by Rockwell to DaVita or any DaVita Facility, DaVita shall deliver a written notice (an " Objection Notice") to Rockwell setting forth in reasonable detail any and all items of disagreement related to such computation or statement. If DaVita does not deliver an Objection Notice within such thirty (30) day period, the calculations set forth in any such computation or statement shall be deemed final, conclusive, and binding on the parties hereto. Rockwell and DaVita will use their commercially reasonable efforts to resolve any disagreements relating to any computation or statement, but if they do not obtain a final resolution within thirty (30) days after Rockwell has received the Objection Notice, then either Rockwell or DaVita may refer the items in dispute to a nationally recognized firm of independent public accounts as to which DaVita and Rockwell mutually agree (the "Firm"), to resolve any remaining disagreements. Rockwell and DaVita will direct the Firm to render a determination within forty five (45) days of its retention, and Rockwell and DaVita and their respective agents and employees will cooperate with the Firm during its engagement. The determination of the Firm will be conclusive and binding upon DaVita and Rockwell, and DaVita or Rockwell, as applicable, will make any payment owed to other party hereto within ten (10) Business Days of the Firm's determination. The Firm shall execute a confidentiality agreement in a form reasonably acceptable to Rockwell and DaVita. [***].

ARTICLE XVII

ADDITIONAL ACKNOWLEDGEMENTS AND AGREEMENTS OF THE PARTIES

17.1 Discontinuation Event. DaVita agrees that: (a) in the event a Committed DaVita Facility intends on discontinuing its purchase of the Products from Rockwell (a "Discontinuation Event"), it shall [***]. DaVita further agrees that in the event a Discontinuation Event occurs as to multiple Committed

DaVita Facilities in a geographic county, group of nearby counties, or subdivisions of a county (a " Market"), it shall use its commercially reasonable efforts to implement such Discontinuation Event as to such Committed DaVita Facilities in such Market in a manner which assists Rockwell in minimizing the negative effect it would experience as a result of such Discontinuation Event. In the event of a breach by DaVita of the provisions of this Section 17.1, Rockwell's sole and exclusive remedy shall be to terminate this Agreement pursuant to Section 2.4(e).

17.2 Business Model Change. Rockwell agrees to [***] and to use commercially reasonable efforts to [***]. DaVita acknowledges that in the event Rockwell wishes to [***], it will use its commercially reasonable efforts to [***]; provided that if DaVita uses its commercially reasonable efforts to [***], DaVita shall have no liability whatsoever to Rockwell, including any direct, indirect, consequential, exemplary, or punitive damages, [***].

17.3 Mixer Training. Rockwell agrees to furnish, [***], complete and appropriate training regarding the use and maintenance of the Dri-Sate® Acid Mixer used for mixing Dri-Sate® Dry Acid and CitraPure® Dry Acid, to such number of personnel of DaVita and the DaVita Facilities as DaVita shall designate. [***].

ARTICLE XVIII

CERTAIN DEFINED TERMS

The following terms as used herein have the following meaning:

18.1 "Affiliate" means, with respect to a Person, any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such Person. The term "control", including the terms "controlling", "controlled by", and "under common control with" for the purposes of the definition of "Affiliate", means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract, or otherwise.

18.2 [***].

18.3 "Business Day" means a day other than Saturday, Sunday, or a public holiday on which banks are authorized or required to be closed under the laws of the State of Colorado.

18.4 "Commercially Available" means any product that is approved by the FDA and manufactured, utilized, sold, or distributed anywhere in the United States by Rockwell or any of its Affiliates.

18.5 "Confidential Information" means information not generally known outside the disclosing party or any of its Affiliates (collectively, the "Disclosing Party") (unless as a result of a breach of any of the non-disclosing party's or any of its Affiliates'(collectively, the "Non-Disclosing Party's") obligations imposed by this Agreement) or which is identified as confidential by the Disclosing Party to the Non-Disclosing Party concerning the Disclosing Party's business and technical information, whether in written, computerized, oral, tangible or intangible, or other form, including: (a) the terms and provisions of this Agreement, (b) any and all trade secrets concerning the business, customers, and affairs of the Disclosing Party, product specifications, data, know-how, formulae, compositions, processes, designs, sketches, photographs, graphs, drawings, samples, inventions and ideas, past, current, and planned research and

development, current and planned manufacturing and distribution methods and processes, customer lists, current and anticipated customer requirements, price lists, market studies, business plans, clinical practices and patient protocols, computer software and programs (including object code and source code), database technologies, systems, improvements, devices, discoveries, concepts, methods, and information of the Disclosing Party and any other information of the Disclosing Party, however documented, that is a trade secret under applicable law, (c) any and all information concerning the business and affairs of the Disclosing Party, including historical financial statements, financial projections and budgets, rebates, discounts, payment terms, pricing, historical and projected sales, capital spending budgets and plans, contractual arrangements, the names and background of key personnel, contractors, agents, customers, suppliers, and potential suppliers, personnel training and techniques and materials, purchasing methods and techniques, however documented, (d) the names and addresses, records and charts, and any other information concerning the Disclosing Party's patients, and (e) any and all notes, analysis compilations, studies, summaries, and other materials prepared by or for the Disclosing Party containing or based, in whole or in part, upon any information included in the foregoing.

18.6 [***].

18.7 "FDA" means the United States Food and Drug Administration and any successor thereto.

18.8 "FFDCA" means the United States Federal Food, Drug and Cosmetic Act of 1938 and all regulations promulgated thereunder.

18.9 "Governmental Authority" means any multi-national, national, state, provincial, local, governmental, judicial, public, quasi-public, administrative, regulatory or self-regulatory authority, agency, commission, board, organization, or instrumentality.

18.10 "Person" means any individual or any group of individuals or any general partnership, limited partnership, limited liability partnership, limited liability company, professional limited liability company, corporation, joint venture, trust, business trust, cooperative or association or any other organization that is not a natural person and any combination of any such entity or organization and any natural persons acting in concert, and the heirs, executors, administrators, legal representatives, successors and assigns of any "person" where the context so permits.

18.11 "Sale of DaVita" means any transaction or series of transactions pursuant to which any Person or group of related Persons in the aggregate acquire(s): (a) securities of DaVita possessing the voting power to elect a majority of DaVita's board of directors (whether by merger, consolidation, reorganization, combination, sale or transfer of DaVita's securities, security holder or voting agreement, power of attorney, or otherwise) or (b) all or substantially all of DaVita's assets.

18.12 "Sale of Rockwell" means any transaction or series of transactions pursuant to which any Person or group of related Persons in the aggregate acquire(s): (a) securities of Rockwell possessing the voting power to elect a majority of Rockwell's board of directors (whether by merger, consolidation, reorganization, combination, sale or transfer of Rockwell's securities, security holder or voting agreement, proxy, power of attorney, or otherwise) or (b) all or substantially all of Rockwell's assets.

18.13 "Transfer" means (a) any Sale of Rockwell, (b) Sale of DaVita, or (c) any sale, transfer, assignment, pledge, mortgage, exchange, hypothecation, grant of a security interest, or other direct or

indirect disposition or encumbrance of an interest (including by operation of law) or the rights thereof. The term "Transferred," and other forms of the word "Transfer" shall have correlative meanings.

ARTICLE XIX

MISCELLANEOUS

19.1 Entire Agreement; Amendments. This Agreement, including its recitals and exhibits, constitutes the entire agreement between the parties hereto and supersedes any and all prior representations, warranties, statements, promises, agreements, and understandings between the parties hereto, whether oral or written, relating to the subject matter hereof, and no party hereto shall be bound by nor charged with any written or oral representations, warranties, statements, promises, agreements, or understandings not specifically set forth in this Agreement. No amendments or modifications of the terms of this Agreement, including any conflicting or additional terms contained in any sales order, purchase order, acknowledgment form, or other written document submitted by either party hereto, shall be binding on either party hereto unless reduced to writing and signed by a duly authorized representative of each party hereto.

19.2 Notices. All notices given pursuant to this Agreement shall be sent by: (a) certified mail, return receipt requested, in which case notice will be deemed delivered three (3) Business Days after deposit, postage prepaid in the United States mail; (b) a nationally recognized overnight courier, in which case notice will be deemed delivered one (1) Business Day after deposit with such courier; or (c) personal delivery, in which case notice will be deemed delivered upon delivery. The address of Rockwell is Rockwell Medical, Inc., 30142 Wixom Road, Wixom, Michigan 48383, Attention: Chief Executive Officer and the address of DaVita is DaVita Inc., 2000 16th Street, Denver, CO 80202, Attention: Group Vice-President – Procurement and Logistics with a copy to DaVita Inc., 2000 16th St., Denver, Colorado 80202, Attention: Chief Legal Officer. The addresses in this Section 19.2 may be changed by written notice to the other party hereto, provided that no notice of a change of address will be effective until actual receipt of such notice.

19.3 Choice of Law. All issues and questions concerning the construction, validity, enforcement, and interpretation of this Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to any choice of law or conflict of law rules or provisions (whether of the State of Delaware or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the laws of the State of Delaware.

19.4 **WAIVER OF JURY TRIAL. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY OF ANY CLAIM OR CAUSE OF ACTION IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE TRANSACTIONS OR EVENTS CONTEMPLATED HEREBY OR ANY COURSE OF CONDUCT, COURSE OF DEALING, STATEMENTS (WHETHER ORAL OR WRITTEN), OR ACTIONS OF ANY PARTY HERETO. THE PARTIES HERETO EACH AGREE THAT ANY AND ALL SUCH CLAIMS AND CAUSES OF ACTION SHALL BE TRIED BY THE COURT WITHOUT A JURY. EACH OF THE PARTIES HERETO FURTHER WAIVES ANY RIGHT TO SEEK TO CONSOLIDATE ANY SUCH LEGAL PROCEEDING IN WHICH A JURY TRIAL HAS BEEN WAIVED WITH ANY OTHER LEGAL PROCEEDINGS IN WHICH A JURY TRIAL CANNOT OR HAS NOT BEEN WAIVED.**

19.5 Attorneys Fees. In the event of any legal proceeding between the parties hereto with respect to this Agreement, the enforceability of any of its provisions, or any alleged or actual breach of this Agreement by any party hereto, the prevailing party shall be entitled to recover reasonable attorney's fees and all other costs and expenses incurred in connection with pursuing any action with respect thereto, in

addition to any other relief to which such party may be entitled. The term "prevailing party" shall mean with respect to each claim asserted in a complaint the party in whose favor final judgment after appeal (if any) is rendered with respect to each such claim asserted in the complaint.

19.6 Non-Limitation of Rights and Remedies. Except as otherwise expressly provided herein, the various rights and remedies provided herein shall be cumulative and in addition to any other rights and remedies the parties hereto may be entitled to pursue at law or equity, including specific performance. The exercise of one or more of such rights or remedies shall not impair the right of either party hereto to exercise any other right or remedy at law or equity.

19.7 Waiver. No waiver by any party hereto, whether express or implied, of its rights under any provision hereto shall constitute a waiver of the party's rights under such provisions at any other time or a waiver of the party's rights under any other provision hereto. No failure by any party hereto to take any action against any breach of this Agreement or default by another party hereto shall constitute a waiver of the former party's right to enforce any provision of this Agreement or to take action against any such breach or default or any subsequent breach or default by the other party hereto. To be effective any waiver must be in writing and signed by the waiving party.

19.8 Severability. In the event that any provision of this Agreement shall be held to be invalid or unenforceable in any respect, such provision shall be enforced to the fullest extent permitted by law and the remaining provisions of this Agreement shall remain in full force and effect. If any such invalid portion constitutes a material term of this Agreement, the parties hereto shall meet and in good faith seek to mutually agree to modify this Agreement so as to retain, if possible, the overall essential terms of this Agreement.

19.9 Conflicts. To the extent that any provision of any sales order, purchase order, invoice, or any other document, or the terms of any of Rockwell's general policies, terms and conditions, procedures or catalogs, conflict with or alter any term of this Agreement, this Agreement shall govern and control.

19.10 Assignment and Transfer. This Agreement will be binding upon and inure to the benefit of the parties hereto. This Agreement may not be Transferred by any party hereto without the prior written consent of the other party hereto which consent shall not be unreasonably withheld, conditioned, or delayed, except as provided below; provided however that nothing in this Agreement shall or is intended to limit the ability of: (a) DaVita to Transfer this Agreement, in whole or in part, without the consent of Rockwell to: (i) any Affiliate of DaVita; (ii) any buyer in connection with a Sale of DaVita; or (iii) any lenders of DaVita as collateral for borrowings or (b) Rockwell to Transfer this Agreement, in whole or in part, without the consent of DaVita to: (i) any Affiliate of Rockwell or (ii) any lenders of Rockwell as collateral for borrowings. Notwithstanding the above, in the event a Change in Control of Rockwell occurs, the parties agree that DaVita's consent to a transfer of this Agreement may be conditioned upon a two (2) year extension of the Term of this Agreement effective from the closing date of the transaction.

19.11 Relationship of the Parties. This Agreement is not intended to create and shall not be construed as creating between Rockwell and DaVita the relationship of Affiliate, principal and agent, joint venture, partnership, or any other similar relationship, the existence of which is hereby expressly denied. Neither party hereto shall have (nor shall it hold itself out as having) any right, power, or authority to make or incur any legally binding agreement, obligation, representation, warranty, or commitment on behalf of the other party hereto or to direct any action of, or activity by the other party hereto or any of its officers, directors, members, managers, employees, or agents.

19.12 Counterparts; Facsimile/PDF Signatures. This Agreement may be executed in any number of counterparts and any party hereto may execute any such counterpart, each of which when executed and

delivered shall be deemed to be an original and all of which counterparts taken together shall constitute but one and the same instrument. This Agreement shall become binding when one or more counterparts taken together shall have been executed and delivered by each of the parties hereto. It shall not be necessary in making proof of this Agreement or any counterpart hereof to produce or account for any of the other counterparts. The parties hereto agree that facsimile transmission or PDF of original signatures shall constitute and be accepted as original signatures.

19.13 Headings and Interpretation. All Section and Article headings contained in this Agreement are for convenience of reference only, do not form a part of this Agreement, and shall not affect in any way the meaning or interpretation of this Agreement. Words used herein, regardless of the number and gender specifically used, shall be deemed and construed to include any other number, singular or plural, and any other gender, masculine, feminine, or neuter as the context requires. The words "include", "includes", and "including", and words of similar import, shall be deemed to be followed by the phrase "without limitation". Unless the context expressly by its terms requires otherwise, (a) any reference to any law herein shall be construed as referring to such law as from time to time enacted, repealed, or amended, (b) any reference herein to any Person shall be construed to include such Person's permitted successors and assigns, (c) the words "herein", "hereof", and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, and (d) all references herein to Sections, Articles, or Exhibits shall be construed to refer to Sections, Articles, or Exhibits of this Agreement.

19.14 Joint Preparation. Each party hereto: (a) has participated in the preparation of this Agreement; (b) has read and understands this Agreement; and (c) has been represented by counsel of its own choice in the negotiation and preparation of this Agreement. Each party hereto represents that this Agreement is executed voluntarily and should not be construed against any party hereto solely because it drafted all or a portion hereof.

19.15 Time of Essence. Rockwell's obligation to meet the delivery dates or any other time periods set forth herein is of the essence.

19.16 Survival. Notwithstanding anything to the contrary that may be contained elsewhere in this Agreement, this Article XIX and Articles II, VI, IX, X, XI, XII, and XIII shall survive, and remain in full force and effect, following the expiration of this Agreement or the earlier termination of this Agreement for any reason.

19.17 Business Day. If any payment is due or any time period for giving notice or taking action expires on a day that is not a Business Day, the payment shall be due and payable on and the time period for giving such notice or taking such action shall automatically be extended to the next succeeding Business Day.

19.18 Public Announcements. Except as otherwise required pursuant to any applicable federal or state securities laws or stock listing requirements, no party hereto shall make any public announcement of any kind or any filing with respect to the other party hereto or any of the transactions provided for herein without the prior written consent of the other party hereto. Except as otherwise required pursuant to any applicable federal or state securities laws or stock listing requirements, any press release or other announcement or notice regarding the other party hereto or any of the transactions contemplated by this Agreement shall be by joint press release mutually agreed to in writing by the parties hereto.

19.19 [***].

[SIGNATURE PAGE FOLLOWS]

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be effective as of the Effective Date.

ROCKWELL:		**DAVITA:**	
ROCKWELL MEDICAL, INC.		**DAVITA INC.**	
By:	/s/ Stuart Paul	By:	/s/ LeAnne Zumwalt
Print Name:	Stuart Paul	Print Name:	LeAnne Zumwalt
Title:	Chief Executive Officer	Title:	Group Vice President

Approved as to form:

DAVITA INC.

By: /s/ Christy Crase

Print Name: Christy Crase

Title: Associate General Counsel for DaVita Inc.

[SIGNATURE PAGE TO FIRST AMENDED AND RESTATED PRODUCTS PURCHASE AGREEMENT]

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a)

I, Stuart Paul, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 12, 2019

/s/ Stuart Paul
Stuart Paul
Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a)

I, Angus Smith, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 12, 2019

/s/ Angus Smith
Angus Smith
Chief Financial Officer

EXHIBIT 32.1

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

In connection with the Quarterly Report of Rockwell Medical, Inc. (the "Company") on Form 10-Q for the quarter ending September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Periodic Report"), I, Stuart Paul, Chief Executive Officer of the Company, and I, Angus Smith, Chief Financial Officer of the Company, each certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that based on my knowledge:

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

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

Dated: November 12, 2019

/s/ Stuart Paul
Stuart Paul
Chief Executive Officer

Dated: November 12, 2019

/s/ Angus Smith
Angus Smith
Chief Financial Officer
