

**United States  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Form 10-Q**

(Mark One)

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

For the quarterly period ended June 30, 2013

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 000-23661

**ROCKWELL MEDICAL, INC.**

(Exact name of registrant as specified in its charter)

**Michigan**  
(State or other jurisdiction of  
incorporation or organization)

**38-3317208**  
(I.R.S. Employer  
Identification No.)

**30142 Wixom Road, Wixom, Michigan**  
(Address of principal executive offices)

**48393**  
(Zip Code)

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  Yes  No

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

Large accelerated filer  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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

**APPLICABLE ONLY TO CORPORATE ISSUERS:**

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

Class	Outstanding as of July 24, 2013
Common Stock, no par value	39,916,961 shares

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**PART I — FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**ROCKWELL MEDICAL, INC. AND SUBSIDIARY**

**CONSOLIDATED BALANCE SHEETS**

**As of June 30, 2013 and December 31, 2012**

	June 30, 2013 (Unaudited)	December 31, 2012
<b>ASSETS</b>		
Cash and Cash Equivalents	\$ 40,952,067	\$ 4,711,730
Accounts Receivable, net of a reserve of \$32,500 in 2013 and \$26,000 in 2012	4,576,492	4,431,932
Inventory	2,916,599	2,649,639
Other Current Assets	814,765	1,356,131
Total Current Assets	49,259,923	13,149,432
Property and Equipment, net	1,740,379	1,858,442
Intangible Assets	583,229	666,744
Goodwill	920,745	920,745
Other Non-current Assets	1,523,502	429,723
Total Assets	\$ 54,027,778	\$ 17,025,086
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Capitalized Lease Obligations	\$ 592	\$ 2,280
Accounts Payable	8,303,965	14,833,565
Accrued Liabilities	8,455,508	12,015,978
Customer Deposits	29,007	135,133
Total Current Liabilities	16,789,072	26,986,956
Long Term Debt	20,000,000	—
Shareholders' Equity:		
Common Shares, no par value, 39,916,961 and 21,494,696 shares issued and outstanding	146,702,432	92,866,458
Common Share Purchase Warrants, 2,071,407 and 2,233,240 warrants issued and outstanding	7,786,474	7,178,929
Accumulated Deficit	(137,250,200)	(110,007,257)
Accumulated Other Comprehensive Loss	—	—
Total Shareholders' Equity (Deficit)	17,238,706	(9,961,870)

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED INCOME STATEMENTS

For the three and six months ended June 30, 2013 and June 30, 2012

(Unaudited)

	Three Months Ended June 30, 2013	Three Months Ended June 30, 2012	Six Months Ended June 30, 2013	Six Months Ended June 30, 2012
<b>Sales</b>	\$ 12,984,164	\$ 12,124,790	\$ 25,320,538	\$ 24,153,207
Cost of Sales	11,299,099	10,405,991	22,354,493	20,807,932
<b>Gross Profit</b>	<b>1,685,065</b>	<b>1,718,799</b>	<b>2,966,045</b>	<b>3,345,275</b>
Selling, General and Administrative	3,237,974	2,824,379	7,154,757	5,723,063
Research and Product Development	10,222,721	10,876,396	22,977,239	20,281,943
<b>Operating Income (Loss)</b>	<b>(11,775,630)</b>	<b>(11,981,976)</b>	<b>(27,165,951)</b>	<b>(22,659,731)</b>
Interest and Investment Income, net	4,566	77,091	15,238	188,188
Interest Expense	92,155	456	92,230	709
Income (Loss) Before Income Taxes	(11,863,219)	(11,905,341)	(27,242,943)	(22,472,252)
Income Tax Expense	—	—	—	—
<b>Net Income (Loss)</b>	<b>\$ (11,863,219)</b>	<b>\$ (11,905,341)</b>	<b>\$ (27,242,943)</b>	<b>\$ (22,472,252)</b>
<b>Basic Earnings (Loss) per Share</b>	<b>\$ (.38)</b>	<b>\$ (.58)</b>	<b>\$ (1.04)</b>	<b>\$ (1.12)</b>
<b>Diluted Earnings (Loss) per Share</b>	<b>\$ (.38)</b>	<b>\$ (.58)</b>	<b>\$ (1.04)</b>	<b>\$ (1.12)</b>

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

For the three and six months ended June 30, 2013 and June 30, 2012

(Unaudited)

	Three Months Ended June 30, 2013	Three Months Ended June 30, 2012	Six Months Ended June 30, 2013	Six Months Ended June 30, 2012
<b>Net Income (Loss)</b>	<b>\$ (11,863,219)</b>	<b>\$ (11,905,341)</b>	<b>\$ (27,242,943)</b>	<b>\$ (22,472,252)</b>
Unrealized Gain on Available-for-Sale Investments	—	4,453	—	105,162
<b>Comprehensive Income (Loss)</b>	<b>\$ (11,863,219)</b>	<b>\$ (11,900,888)</b>	<b>\$ (27,242,943)</b>	<b>\$ (22,367,090)</b>

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

For the six months ended June 30, 2013

(Unaudited)

	COMMON SHARES		PURCHASE WARRANTS		ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)	TOTAL SHAREHOLDER'S EQUITY
	SHARES	AMOUNT	WARRANTS	AMOUNT			
Balance as of December 31, 2012	21,494,696	\$ 92,866,458	2,233,240	\$ 7,178,929	\$ (110,007,257)	\$ —	\$ (9,961,870)

Net Loss	—	—	—	—	(27,242,943)	—	(27,242,943)
Issuance of Common Shares	17,861,432	50,098,632	—	—	—	—	50,098,632
Shares Issued in Exchange for Services	200,000	196,000	—	—	—	—	196,000
Purchase Warrant Expense	—	—	—	1,004,786	—	—	1,004,786
Exercise of Purchase Warrants	50,833	762,222	(161,833)	(397,241)	—	—	364,981
Stock Option Based Expense	—	1,950,359	—	—	—	—	1,950,359
Restricted Stock Issuance	310,000	—	—	—	—	—	—
Restricted Stock Amortization	—	828,761	—	—	—	—	828,761
Balance as of June 30, 2013	<u>39,916,961</u>	<u>\$ 146,702,432</u>	<u>2,071,407</u>	<u>\$ 7,786,474</u>	<u>\$ (137,250,200)</u>	<u>\$ —</u>	<u>\$ 17,238,706</u>

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the six months ended June 30, 2013 and June 30, 2012

(Unaudited)

	2013	2012
<b>Cash Flows From Operating Activities:</b>		
<b>Net (Loss)</b>	<b>\$ (27,242,943)</b>	<b>\$ (22,472,252)</b>
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	502,178	555,182
Share Based Compensation — Non-employee	1,200,785	614,762
Share Based Compensation- Employees	2,779,121	2,393,609
Loss (Gain) on Disposal of Assets	5,516	25,340
Changes in Assets and Liabilities:		
(Increase) in Accounts Receivable	(144,560)	(133,189)
(Increase) in Inventory	(266,960)	(257,962)
Decrease in Other Assets	528,866	759,966
Increase (Decrease) in Accounts Payable	(6,529,600)	1,046,470
Increase (Decrease) in Other Liabilities	(3,666,596)	2,682,643
Changes in Assets and Liabilities	<u>(10,078,850)</u>	<u>4,097,928</u>
<b>Cash Provided By (Used In) Operating Activities</b>	<b>(32,834,193)</b>	<b>(14,785,431)</b>
<b>Cash Flows From Investing Activities:</b>		
Purchase of Equipment	(313,014)	(242,495)
Proceeds on Sale of Assets	6,898	1,578
(Purchase) of Investments Available for Sale	<u>—</u>	<u>(2,000,000)</u>
<b>Cash (Used In) Investing Activities</b>	<b>(306,116)</b>	<b>(2,240,917)</b>
<b>Cash Flows From Financing Activities:</b>		
Proceeds from the Issuance of Common Shares and Purchase Warrants	50,463,613	17,785,640
Proceeds from the Issuance of Notes Payable	20,000,000	—
Debt Issuance Costs	(1,081,279)	—
Payments on Capital Lease Obligations	(1,688)	(4,626)
<b>Cash Provided By Financing Activities</b>	<b>69,380,646</b>	<b>17,781,014</b>
<b>Increase (Decrease) In Cash</b>	<b>36,240,337</b>	<b>754,666</b>
Cash At Beginning Of Period	4,711,730	5,715,246
<b>Cash At End Of Period</b>	<b>\$ 40,952,067</b>	<b>\$ 6,469,912</b>

Supplemental Cash Flow disclosure

	2013	2012
Interest Paid	\$ 1,877	\$ 709

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

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## Notes to Consolidated Financial Statements

### 1. Description of Business

Rockwell Medical, Inc. and Subsidiary (collectively, “we”, “our”, “us”, or the “Company”) is a fully-integrated pharmaceutical company targeting end-stage renal disease (“ESRD”) and chronic kidney disease (“CKD”) with innovative products and services for the treatment of iron deficiency, secondary hyperparathyroidism and hemodialysis.

Rockwell’s lead drug candidate, Soluble Ferric Pyrophosphate (SFP), in late-stage clinical development, is an iron replacement therapy for dialysis patients. The Company has completed the efficacy portion of its SFP Phase 3 clinical studies (CRUISE-1 and CRUISE-2).

Rockwell is preparing to launch its FDA approved generic drug called Calcitriol to treat secondary hyperparathyroidism in dialysis patients. Calcitriol active vitamin D injection is indicated in the management of hypocalcemia in patients undergoing chronic renal dialysis. Rockwell intends to launch Calcitriol as soon as it receives FDA manufacturing approval.

Rockwell is also an established manufacturer and leader in delivering high-quality hemodialysis concentrates/dialysates to dialysis providers and distributors in the U.S. and abroad. Rockwell’s products are used to maintain human life, by removing toxins and replacing critical nutrients in the dialysis patient’s bloodstream. Rockwell has three manufacturing and distribution facilities located in the U.S. and its operating infrastructure is a ready-made sales and distribution channel that is able to provide seamless integration into the commercial market for its drug products, Calcitriol and SFP upon FDA market approval.

We are regulated by the Federal Food and Drug Administration under the Federal Drug and Cosmetics Act, as well as by other federal, state and local agencies. We have received 510(k) approval from the FDA to market hemodialysis solutions and powders and related equipment.

We have obtained global licenses for certain dialysis related drugs which we are developing and are seeking FDA approval to market. We plan to devote substantial resources to the development, testing and FDA approval of our lead drug candidate.

### 2. Summary of Significant Accounting Policies

#### Basis of Presentation

Our consolidated financial statements include our accounts and the accounts for our wholly owned subsidiary, Rockwell Transportation, Inc. All intercompany balances and transactions have been eliminated in consolidation. The accompanying consolidated financial statements have been prepared using accounting principles generally accepted in the United States of America, or “GAAP,” and with the instructions to Form 10-Q and Securities and Exchange Commission Regulation S-X as they apply to interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. The balance sheet at December 31, 2012 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by GAAP for complete financial statements.

In the opinion of our management, all adjustments have been included which are necessary to make the financial statements not misleading. All of these adjustments that are material are of a normal and recurring nature. Our operating results for the three and six months ended June 30, 2013 are not necessarily indicative of the results to be expected for the year ending December 31, 2013. You should read our unaudited interim

financial statements together with the financial statements and related footnotes for the year ended December 31, 2012 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2012 includes a description of our significant accounting policies.

#### Revenue Recognition

We recognize revenue at the time we transfer title to our products to our customers consistent with generally accepted accounting principles. Generally, we recognize revenue when our products are delivered to our customer’s location consistent with our terms of sale. We recognize revenue for international shipments when title has transferred consistent with standard terms of sale.

We require certain customers, mostly international customers, to pay for product prior to the transfer of title to the customer. Deposits received from customers and payments in advance for orders are recorded as liabilities under Customer Deposits until such time as orders are filled and title transfers to the customer consistent with our terms of sale.

#### Cash and Cash Equivalents

We consider cash on hand, money market funds, unrestricted certificates of deposit and short term marketable securities with an original maturity of 90 days or less as cash and cash equivalents.

#### Research and Product Development

We recognize research and product development expenses as incurred. We incurred product development and research costs related to the commercial development, patent approval and regulatory approval of new products, including our anemia related iron maintenance drug candidate, Soluble Ferric Pyrophosphate, or SFP, aggregating approximately \$23.0 million and \$20.3 million for the six months ended June 30, 2013 and 2012, respectively. We are

conducting human clinical trials on SFP. We recognize the costs of the human clinical trials as the costs are incurred and services performed over the duration of the trials.

### Net Earnings Per Share

We computed our basic earnings (loss) per share using weighted average shares outstanding for each respective period. Diluted earnings per share also reflect the weighted average impact from the date of issuance of all potentially dilutive securities, consisting of stock options and common share purchase warrants, unless inclusion would have had an anti-dilutive effect. The calculation of basic weighted average shares outstanding excludes unvested restricted stock. Actual weighted average shares outstanding used in calculating basic and diluted earnings per share were:

	Three Months Ended June 30, 2013	Three Months Ended June 30, 2012	Six Months Ended June 30, 2013	Six Months Ended June 30, 2012
Basic Weighted Average Shares Outstanding	31,191,079	20,568,133	26,243,526	20,001,975
Effect of Dilutive Securities	—	—	—	—
Diluted Weighted Average Shares Outstanding	<u>31,191,079</u>	<u>20,568,133</u>	<u>26,243,526</u>	<u>20,001,975</u>

### 3. Inventory

Components of inventory as of June 30, 2013 and December 31, 2012 are as follows:

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	June 30, 2013	December 31, 2012
Raw Materials	\$ 1,257,690	\$ 1,018,648
Work in Process	226,102	179,922
Finished Goods	1,432,807	1,451,069
Total	<u>\$ 2,916,599</u>	<u>\$ 2,649,639</u>

### 4. Other Current Assets

Other current assets includes amounts advanced to contract services providers. These advances will offset future liabilities incurred with contract services providers for services and travel related to our clinical trials. As of June 30, 2013, the amount included in other current assets was \$0.3 million.

### 5. Loans Payable

As of June 14, 2013, the Company entered into a loan and security agreement (the "Loan Agreement") with Hercules Technology III, L.P. ("Hercules") pursuant to which the Company received a loan in the aggregate principal amount of \$20.0 million. The Company is required to repay the aggregate principal balance under the Loan Agreement in 30 equal monthly installments of principal and interest commencing on September 1, 2014.

The loan will mature and become due on March 1, 2017, subject to adjustment as provided below, and will bear interest at the greater of (i) 12.50% plus the prime rate as reported in The Wall Street Journal minus 3.25%, or (ii) 12.50%. The Company will be required to make monthly interest only payments through August 31, 2014 (or May 31, 2014 if we fail to meet primary end points for both Phase 3 trials for our SFP drug prior to December 15, 2013). The Company met the primary endpoint on its first clinical trial, Cruise 1, and anticipates a confirmatory result on the Cruise 2 trial. If the interest only period is not extended, the maturity date for the loan would be December 1, 2016. Monthly principal and interest payments will be due on the loan following the interest only period through the maturity date. The loan may be prepaid at any time after June 14, 2014 without penalty and will mature and become due upon any change in control of the Company. The Company paid debt issuance costs totaling \$1.1 million, including a fee of \$0.2 million at closing to the Lender, which are recorded as a noncurrent asset, and is required to pay a fee of \$1.1 million upon any prepayment or at maturity. The \$1.1 million fee due upon any prepayment or at maturity is accrued using the effective interest rate method over the life of the loan. The effective interest rate of the loan is 14.5%.

In connection with the loan, the Company granted Hercules a security interest in substantially all of the Company's assets other than motor vehicles, real property and certain intellectual property and other interests. The Loan Agreement provides for standard indemnification of Hercules and contains representations, warranties and non-financial covenants of the Company. The Loan Agreement contains covenants that, among other things, limit the Company's ability to incur additional indebtedness, transfer assets, acquire assets of or merge with another entity and pay dividends to the Company's shareholders. The Loan Agreement defines event of default, to include, among other events, the occurrence of an event that results in a material adverse effect upon the Company's business operations, properties, assets or condition (financial or otherwise), the collateral or the perfection of the security interest, or the Company's ability to perform its obligations under the Loan Agreement. The Company was in compliance with the terms of the Loan Agreement and there was no event of default as of June 30, 2013.

The balance of the above debt matures as follows assuming the Company meets primary end points for both Phase 3 trials for its SFP drug prior to December 15, 2013:

2013	\$ —
2014	1,731,981
2015	7,492,371
2016	8,484,481
2017	<u>2,291,167</u>
Total Principal Payable	<u>\$ 20,000,000</u>

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Interest accrued on the loan payable through June 30, 2013 was \$90,278.

## **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 the Consolidated Financial Statements and the Notes thereto included elsewhere in this report. References in this report to “we,” “our” and “us” are references to Rockwell Medical, Inc. and its subsidiary.

### **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,” “predict,” “forecast,” “projected,” “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 competitors, statements regarding the timing and costs of obtaining FDA approval of our new Soluble Ferric Pyrophosphate or SFP product and statements regarding our anticipated future financial condition, operating results, cash flows and business plans.

We claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 for all of our forward-looking statements. 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 below and elsewhere in this report, and from time to time in our other reports filed with the SEC, including, without limitation, in “Item 1A — Risk Factors” in our Form 10-K for the year ended December 31, 2012.

- The dialysis provider market is highly concentrated in national and regional dialysis chains that account for the majority of our domestic revenue. Our business is substantially dependent on a few customers that account for a substantial portion of our sales. The loss of any of these customers would have a material adverse effect on our results of operations and cash flow.
- We operate in a very competitive market against a substantially larger competitor with greater resources.
- Our lead drug candidate requires FDA approval and expensive clinical trials before it can be marketed.
- Even if we receive FDA approval to manufacture and market our new drug products, we may not be able to market them successfully.

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- We may require additional financing to achieve our goals, and such financing may result in dilution to shareholders or restrictions on our ability to operate our business. A failure to obtain capital if needed, could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- We may not be successful in maintaining our gross profit margins.
- We depend on government funding of health care.
- Health care reform could adversely affect our business.
- We depend on key personnel.
- Our business is highly regulated.
- We depend on contract research organizations and independent clinicians to manage and conduct our clinical trials and if they fail to follow our protocol or meet FDA regulatory requirements our clinical trial data and results could be compromised delaying our development plans or causing us to do more testing than planned.
- Foreign approvals to market our new drug products may be difficult to obtain.
- We could be prevented from selling products, forced to pay damages and compelled to defend against litigation if we infringe the rights of a third party.
- We may not have sufficient products liability insurance.
- Our Board of Directors is subject to potential deadlock.
- Shares eligible for future sale may affect the market price of our common shares.
- We could have a material weakness in our internal control over financial reporting, which, until remedied, could result in errors in our financial statements requiring restatement of our financial statements. As a result, investors may lose confidence in our reported financial information, which could lead to a decline in our stock price.

- The market price of our securities may be volatile.
- Voting control and anti-takeover provisions reduce the likelihood that you will receive a takeover premium.
- We do not anticipate paying dividends in the foreseeable future.

Other factors not currently anticipated may also materially and adversely affect our results of operations, cash flow and financial position. There can be no assurance that future results will meet expectations. We do not undertake, and expressly disclaim, any obligation 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

Rockwell Medical, Inc. is a fully-integrated pharmaceutical company targeting end-stage renal disease and chronic kidney disease with innovative products and services for the treatment of iron deficiency, secondary hyperparathyroidism and hemodialysis. We are also an established manufacturer and leader in delivering high-quality hemodialysis concentrates/dialysates to dialysis providers and distributors in the U.S. and abroad.

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We are developing unique, proprietary renal drug therapies. These novel 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.

Our strategy is to develop high potential drugs while expanding our dialysis products business. Our dialysis products business has been cash flow positive, excluding research and development expenses, and provides a ready-made sales and distribution infrastructure to market our drugs and other related products used in dialysis.

Our product development costs were primarily related to SFP, our lead drug which is nearing completion of its Phase 3 clinical studies. The first efficacy study, Cruise-1, reported successful top line results in July 2013 having met its primary efficacy end point, all key secondary endpoints and demonstrated a very good safety profile. Cruise-2 results will be reported during the third quarter of 2013 and are anticipated to be confirmatory results to the identically designed Cruise-1 study.

Based upon clinical data to date, we believe SFP has unique and substantive benefits compared to current treatment options. Obtaining regulatory approval for a drug in the United States is expensive and can take several years. We expect to incur substantial costs related to product testing and development in 2013 and to a lesser extent for regulatory approval in 2014. We expect to incur losses from operations in 2013 largely as a result of the cost of the SFP program.

We completed a multi-year extension of the supply agreement with our largest customer during the second quarter of 2013 and anticipate future volume and revenue growth from this agreement due to an increase in the minimum number of committed clinics, but do not expect a material change in gross profit margins.

As of June 30, 2013 we had \$41.0 million in cash and cash equivalents. In May 2013, we completed a common stock offering for \$40.3 million in gross proceeds and approximately \$37.7 million in net proceeds. In June 2013 we entered into a loan agreement and borrowed \$20,000,000. We believe these cash resources are adequate for the Company to complete the regulatory approval for SFP and through its commercialization. The Company expects to launch SFP immediately following FDA approval and to largely use its existing sales, marketing and business infrastructure in support of the SFP commercial development.

In 2011, we acquired an FDA approved generic vitamin D injection, Calcitriol, indicated in the treatment of secondary hyperparathyroidism, which is common in ESRD patients. We have submitted the necessary manufacturing data to the FDA to obtain commercial marketing approval and intend to begin marketing Calcitriol following regulatory approval from the FDA which we expect later this year. We anticipate that our gross profit margins will be favorably impacted by revenue from Calcitriol once we obtain FDA approval for manufacturing changes.

We may experience changes in our customer and product mix in future quarters that could impact gross profit, since we sell a wide range of products with varying profit margins and to customers with varying order patterns. These changes in mix may cause our gross profit and our gross profit margins to vary period to period.

The majority of our business is with domestic clinics who order routinely. From time to time, we have experienced volatility in international orders.

## Results of Operations for the Three and Six Months Ended June 30, 2013 and June 30, 2012

### Sales

Sales in the second quarter of 2013 were \$13.0 million compared to \$12.1 million in the second quarter of 2012. Sales increased

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due to growth in our CitraPure® product lines, which increased significantly in the second quarter, reflective of increased market adoption and to a lesser extent, as a result of the multi-year supply agreement executed with our largest customer in May 2013. Domestic sales accounted for about half of the increase.

Sales in the first six months of 2013 were \$25.3 million compared to \$24.2 million in the first six months of 2012 an increase of \$1.1 million or 4.8%. The increase was due to growth in CitraPure sales and, to a lesser extent, the execution of the multi-year supply agreement. Domestic sales accounted for

nearly all of the increase.

## **Gross Profit**

Gross profit dollars in the second quarter of 2013 and 2012 were \$1.7 million while gross profit margins in the second quarter of 2013 were 13.0% compared to 14.2 % in the second quarter of 2012, a decrease of 1.2 percentage points which was due to inflationary cost increases for our raw materials.

Gross profit margins for the first six months of 2013 were 11.7 % compared to 13.9 % in the first six months of 2012. Gross profit dollars year to date were \$3.0 million compared to \$3.3 million in the first six months of 2012. The decrease in gross profit was primarily due to higher material costs coupled with increased operating costs compared to the first half of 2012. Operating costs increased due to inflation and increased costs due to government regulations.

## **Selling, General and Administrative Expense**

Selling, general and administrative expense during the second quarter of 2013 was \$3.2 million compared to \$2.8 million in the second quarter of 2012. Non-cash equity compensation was \$1.7 million in the second quarter of 2013 compared to \$1.5 million in the second quarter of 2012. We recognized an increase of \$0.2 million related to the mandated medical device tax in the second quarter of 2013.

Selling, general and administrative expense in the first half of 2013 was \$7.2 million compared to \$5.7 million in the first half of 2012. We incurred a non-cash charge of \$0.9 million related to the extension of certain expiring common stock purchase warrants in 2013. We also recognized an increase in cost related to the recently mandated medical device tax of \$0.5 million in the first half of 2013.

## **Research and Development**

Research and development cost was \$10.2 million in the second quarter of 2013 compared to \$10.9 million in the second quarter of 2012. Research and development costs in the first six months of 2013 were \$23.0 million compared to \$20.3 million in the first six months of 2012. Spending in both years was primarily for clinical testing and development of SFP with the increase in 2013 due to increased testing associated with the SFP Phase 3 clinical program. We anticipate substantial spending for clinical development and regulatory approval for SFP to continue into 2014 until the new drug application for SFP is submitted to the FDA.

## **Interest Expense, Net**

Our net interest expense was \$88,000 in the second quarter of 2013 compared to net interest and investment income of \$77,000 in the second quarter of 2012. Year to date net interest expense was \$77,000 compared to net interest and investment income of \$188,000 in the first half of 2012. The increase in interest expense was due to the loan obligation entered into in June 2013. Reduced net interest and investment income was due to lower funds available for investment in 2013 compared to 2012.

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## **Liquidity and Capital Resources**

We expect to expend substantial amounts in support of our clinical development plan and regulatory approval of SFP. SFP will require the expenditure of substantial cash resources over the next year as we execute our clinical program and complete the process of seeking regulatory approval for SFP in the United States. Once completed, we expect these costs to decrease substantially. Costs for research and development were \$23.0 million in the first half of 2013 compared to \$20.3 million in the first half of 2012. We also reduced our accounts payable by \$6.3 million and other accrued liabilities by \$3.3 million in the first half of 2013.

Our cash resources include cash generated from the proceeds of equity offerings, including the receipt of \$12.0 million in net proceeds from an equity offering completed in March 2013 and \$37.7 million in an equity offering completed in May of 2013. We also borrowed \$20.0 million in June 2013. The repayment and other terms of the loan are described in Note 5 to the accompanying consolidated financial statements.

We had \$41.0 million in cash as of June 30, 2013. Our current assets were \$49.3 million and our current liabilities were \$16.8 million as of June 30, 2013. In the first six months of 2013, our cash position increased by \$36 million as a result of \$69.7 million in capital raised in financing activities offset by our clinical development program for which we incurred \$23 million in R&D expenses in the first half of 2013.

We believe we have adequate cash resources to fund our current development and commercialization plans for SFP. We are evaluating various business development and strategic partnering options which may provide additional financial resources.

Our contractual obligations are described in our Form 10-K for the year ended December 31, 2012. There have been no material changes to that information since December 31, 2012, other than the \$20 million loan described in Note 5 to the accompanying consolidated financial statements.

## **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

### **Foreign Currency Exchange Rate Risk**

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

## **Item 4. Controls and Procedures**

### **Disclosure Controls and Procedures**

Management is responsible for establishing and maintaining effective disclosure controls and procedures, as defined under Rule 13a-15 of the Securities Exchange Act of 1934, as amended, that are designed to ensure that 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 Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for 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

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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.

As of the end of the period covered by this report, we carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, as of the end of the period covered by this report.

### Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rule 13a-15 under the Exchange Act) during the most recently completed fiscal quarter that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II — OTHER INFORMATION

### Item 1A. Risk Factors

For information regarding risk factors affecting us, see "Risk Factors" in Item 1A of Part I of our 2012 Annual Report on Form 10-K. There have been no material changes to the risk factors described in such Form 10-K, except as described below.

The 2012 Form 10-K included a risk factor entitled "There is substantial doubt as to our ability to continue as a going concern." Because of our recurring losses and the need for us to raise additional working capital, the report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2012 contains an explanatory paragraph stating that our recurring losses and need for additional working capital raise substantial doubt about our ability to continue as a going concern. Our losses have resulted principally from expenses incurred in research and development of our technology and products and we expect to continue to incur operating losses as we complete the clinical trial process and pursue regulatory approval of SFP. As of December 31, 2012, our cash and investments were \$4.7 million and our current liabilities exceeded our current assets by \$13.8 million. However, in the first six months of 2013, we have raised approximately \$70 million in additional equity and debt capital, our current assets exceed our current liabilities by \$32.5 million at June 30, 2013 and we believe we now have sufficient financing to execute our clinical program and complete the process of seeking regulatory approval for SFP in the United States. As a result, we believe our potential inability to continue as a going concern is no longer a material risk.

In addition, as a result of the capital raised during the last six months, the risk factor entitled "We require substantial additional financing to achieve our goals, and such financing may result in substantial dilution to shareholders or restrictions on our ability to operate our business. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts." is modified to read as follows:

**We may require additional financing to achieve our goals, and such financing may result in dilution to shareholders or restrictions on our ability to operate our business. A failure to obtain capital, if needed, could force us to delay, limit, reduce or terminate our product development or commercialization efforts.**

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Over the last several years, we have dedicated a significant portion of our resources to the preclinical and clinical development of SFP. In particular, we are currently conducting a Phase 3 clinical program for SFP, which will require substantial funds to complete. We believe that we will continue to expend substantial resources for the foreseeable future developing SFP. These expenditures will include costs associated with research and development, conducting clinical trials, obtaining regulatory approvals and manufacturing products, as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

We may seek additional funds through public or private equity or debt financings or other sources, such as strategic partnerships. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we raise additional funds by issuing equity securities, substantial dilution to existing shareholders could result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may not be able to continue as a going concern or may be required to:

· delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates;

delay, limit, reduce or terminate our research and development activities; or

delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

The following risk factor is hereby added.

**We could be prevented from selling products, forced to pay damages and compelled to defend against litigation if we infringe the rights of a third party.**

Our success, competitive position and future revenues will depend in part on our ability to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties.

We could incur substantial costs in seeking enforcement of our patent rights against infringement, and we cannot guarantee that such patents will successfully preclude others from using technology that we rely upon. We have no knowledge of any infringement or patent litigation, threatened or filed at this time. It is possible that we may infringe on intellectual property rights of others without being aware of the infringement. If a third party believes that one of our products infringes on the third party's patent, it may sue us even if we have received our own patent protection for the technology. If we infringe the rights of a third party, we could be prevented from selling products, forced to pay damages and compelled to defend against litigation.

**Item 6. Exhibits**

See Exhibit Index following the signature page, which is incorporated herein by reference.

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**SIGNATURES**

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

ROCKWELL MEDICAL, INC.

(Registrant)

Date: August 1, 2013

/s/ ROBERT L. CHIOINI

Robert L. Chioini  
President and Chief Executive  
Officer (principal  
executive officer) (duly authorized  
officer)

Date: August 1, 2013

/s/ THOMAS E. KLEMA

Thomas E. Klema  
Vice President and Chief  
Financial Officer  
(principal financial  
officer and principal accounting  
officer)

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**10-Q EXHIBIT INDEX**

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.

<u>Exhibit No.</u>	<u>Description</u>
3.1	Restated Articles of Incorporation, as amended as of May 1, 2013. (Company's Form 10-Q filed May 8, 2013).
4.18	Loan and Security Agreement dated as of June 14, 2013, among Rockwell Medical, Inc., Rockwell Transportation, Inc. and Hercules Technology III, L.P. (Company's Form 8-K filed June 20, 2013).
10.53	Rockwell Medical, Inc. Amended and Restated 2007 Long Term Incentive Plan, as amended effective April 30, 2013 (appendix to Company's Proxy Statement for the 2013 Annual Meeting of Shareholders filed March 29, 2013).

10.54	Form of Restricted Stock Award Agreement June 2013 (Executive Version) (Company's Form 8-K filed June 19, 2013).
10.55	First Amended and Restated Products Purchase Agreement dated May 8, 2013, by and between Rockwell Medical, Inc. and DaVita Healthcare Partners, Inc. (with certain portions deleted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934).
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

[\* \*] Portions of this exhibit have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

## FIRST AMENDED AND RESTATED PRODUCTS PURCHASE AGREEMENT

THIS FIRST AMENDED AND RESTATED PRODUCTS PURCHASE AGREEMENT (this "Agreement"), is entered into and effective as of the 8<sup>th</sup> day of May, 2013 (the "Effective Date"), by and between Rockwell Medical, Inc., a Michigan corporation ("Rockwell"), and DaVita Healthcare Partners Inc., a Delaware corporation ("DaVita") on behalf of itself and 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 Products Purchase Agreement, effective as of February 16, 2011 (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) amend and restate (and 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 at [\* \*] of the DaVita Facilities (the "Committed DaVita Facilities") will use their best efforts to purchase all of their requirements for acid concentrate (i.e., CitraPure<sup>®</sup>, Dri-Sate<sup>®</sup> Dry Acid or RenalPure<sup>®</sup> Liquid Acid) and bicarbonate (i.e., RenalPure<sup>®</sup> Bicarbonate Powder or Sterilyte<sup>®</sup> 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 Monthly Reports. Each month during the Term, Rockwell shall deliver a report to DaVita in accordance with DaVita's specifications, which specifications will be given to Rockwell by DaVita. Each monthly report, at a minimum, shall (a) show all purchases of the Products made by each DaVita Facility by Product or Product categories, (b) include year-to-date purchase figures for each DaVita Facility, and (c) include any other information reasonably requested by DaVita relating to each DaVita Facility's purchases of the Products pursuant to this Agreement.

1.4 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 five (5) 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, and (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 (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, 2018 (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 Articles VI or IX; or

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(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 Articles VI or 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 sixty (60) 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 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 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), 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 nine (9) months prior written notice to DaVita in the event that Rockwell decides to either: [\* \*]; or

(e) Upon sixty (60) days advance written notice to DaVita in the event of a breach by DaVita of Section 17.1, and DaVita fails to cure such with breach within sixty (60) days following the date of such notice; or

(f) 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 for each Product is set forth on Exhibit A (each, a “Purchase Price” and collectively, the “Purchase Prices”). The Purchase Price includes [\* \*] to the states

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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. At any time on or after [\* \*], Rockwell may [\* \*] submit a written notice to DaVita requesting a meeting with DaVita to discuss and negotiate in good faith possible adjustments to the Purchase Price of any of the Products [\* \*]. The parties shall meet at a mutually agreeable time and location within fifteen (15) days of such meeting request. During such meeting, if Rockwell requests an increase to the Purchase Price of a Product, it shall deliver to DaVita within five (5) days of such meeting or at such meeting, reasonably detailed documentation which documents and indicates that [\* \*]. In the event the parties are not able to reach a mutually agreeable adjustment to the Purchase Price of any Product for which Rockwell requested an

adjustment within thirty (30) days of the meeting, then either party hereto shall have the right to terminate this Agreement upon ninety (90) days' prior written notice to the other party hereto.

#### 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 [\* \*].

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 the highest 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

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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**, [\* \*]. DaVita and each DaVita Facility shall also have the right to return any Product pursuant to the terms and conditions set forth in the Return Goods Policy which do not conflict with 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, 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 that it shall (a) give notice as promptly as is practicable under the circumstances 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; [\* \*]. 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 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 [\* \*].

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#### 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, 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 determined by 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.

## 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) 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)

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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. Notwithstanding anything to the contrary herein, the Non-Disclosing Party shall have the right to disclose any of the terms or provisions of this Agreement upon any determination by the Non-Disclosing Party 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 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.

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(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 may, in addition to other rights and remedies existing in its favor, apply to any court of competent jurisdiction for 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.

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

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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 at Rockwell's sole cost and expense.

10.8 Health Care Programs. Rockwell 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 Rockwell being excluded from participation in any Federal health care program, as defined under 42 U.S.C. §1320a-7b(f).

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.

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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).

## 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

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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 suit 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 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"). If the applicable Indemnifying Party does not notify the applicable Indemnified Party in writing within thirty (30) days from its receipt of the Direct Indemnification Notice 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) commercial general liability insurance, which includes contractual liability coverage, product liability (only in the case of Rockwell) and workers' compensation insurance, to cover any claims or liabilities arising from this Agreement. Such commercial general liability insurance shall be in an amount reasonably satisfactory to the other party 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 commercial general liability insurance policy 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

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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

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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 twenty (20) 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 twenty (20) 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 five (5) 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 agree 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. [\* \*].

17.4 Bicarbonate Mixer. Upon mutual written agreement between the parties hereto, Rockwell will [\* \*].

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## 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.

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18.8 “FDCA” 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, securityholder 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, securityholder 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

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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 Healthcare Partners Inc., 1111 Bayhill Drive, Suite 285, San Bruno, California 94066, Attention: Group Vice-President with a copy to DaVita Healthcare Partners Inc., 2000 16<sup>th</sup> 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. 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

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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; 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: (A) any newly formed Affiliate of Rockwell in connection with a corporate reorganization of Rockwell that does not involve a Sale of Rockwell to any Person that is not a party hereto or (B) any lenders of Rockwell as collateral for borrowings; provided that any such lenders or any of its Affiliates are not engaged in the business of manufacturing, selling, or distributing products used in the provision of dialysis services.

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

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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.

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

**ROCKWELL:**

**DAVITA:**

**ROCKWELL MEDICAL, INC.**

**DAVITA  
HEALTHCARE  
PARTNERS  
INC.**

By: /s/ Robert Chioini

By: /s/ LeAnne  
Zumwalt

Print Name: Robert Chioini

Print LeAnne  
Name: Zumwalt

Title: CEO

Title: Group VP

Approved as to  
form:

**DAVITA  
HEALTHCARE  
PARTNERS  
INC.**

By: \_\_\_\_\_

Print  
Name: \_\_\_\_\_

Title: \_\_\_\_\_

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

EXHIBIT A

**PRODUCTS AND PURCHASE PRICE**

**Price Quote Standard Formulas**

<u>CATALOG #</u>	<u>DESCRIPTION</u>	<u>PACKAGING</u>	<u>UNIT PRICE</u>
[* *]			
[* *]		25 Gallon Case	Case [* *]
[* *]			
[* *]		55 Gallon Drum	Drum [* *]
[* *]		4 Gal/cs 3.785lt/gal	Case [* *]
[* *]			
[* *]		25 Gallon Case	Case [* *]
[* *]			
[* *]		55 Gallon Drum	Drum [* *]
[* *]		4 Gal/cs 3.785lt/gal	Case [* *]
[* *]			
[* *]		2.1 Gallon Bag 20/cs	Case [* *]

[* *]	15 Gallon Bag 4/cs	Case	[* *]
[* *]	25 Gallon Bag 2/cs	Case	[* *]
[* *]			
[* *]			
[* *]	4 Gallon Case	Case	[* *]
[* *]			
[* *]	4 Gallon Case	Case	[* *]
[* *]	50lb Bag	Bag	[* *]
[* *]	25lb Bag	Bag	[* *]

**NOTES:**

· **Dry Acid Mixers for Dri-Sate® and CitraPure® Dry Acid:**

<b>DSMIX-50</b>	<b>Dry Acid Mixer, 50 Gal</b>	[* *]
<b>DSMIX-100</b>	<b>Dry Acid Mixer, 100 Gal</b>	[* *]

· **Drum prices include [\* \*].**

[\* \*].

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EXHIBIT B

TERRITORY

The purchase price for the Products as set forth on Exhibit A is applicable in the following [\* \*]:

[\* \*]

[\* \*]

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EXHIBIT C

**ROCKWELL SHIPPING AND ORDER REQUIREMENTS**

GENERAL GUIDELINES APPLICABLE TO ALL PRODUCTS (DRI-SATE® DRY ACID CONCENTRATE, RENALPURE® LIQUID ACID CONCENTRATE, RENALPURE® BICARBONATE POWDER, STERILYTE® LIQUID BICARBONATE, CITRAPURE® DRY ACID and LIQUID ACID CONCENTRATE and CLEANING AGENTS)

1. Lead time from the initial order from a DAVITA dialysis clinic to the first delivery is [\* \*].
2. If DAVITA fails to maintain adequate inventory of a particular Product [\* \*], resulting in ROCKWELL shipping the Products via a third party carrier, [\* \*].
3. [\* \*] shall pay all return freight costs due to Products shipped in error and/or Products damaged prior to receipt by DAVITA; otherwise, [\* \*] shall pay [\* \*].
4. Orders for Products must be received via facsimile at [\* \*], otherwise a charge of [\* \*] will be applied [\* \*]. Each of DAVITA's dialysis clinics shall [\* \*].
5. ROCKWELL shall [\* \*].
6. ROCKWELL shall [\* \*].

**NOTE:** The minimum order requirement in the aggregate for all Products combined (liquid and dry acid concentrate, bicarbonate powder, SteriLyte and cleaning agents) is [\* \*].

SPECIFIC ADDITIONAL GUIDELINES FOR CERTAIN PRODUCTS

***DRY ACID CONCENTRATE***

1. Special formulas of Dry Acid Concentrate, if approved, [\* \*].

***LIQUID ACID CONCENTRATE***

1. Special formulas of Liquid Acid Concentrate, if approved, [\* \*].
2. With respect to Liquid Acid Concentrate, DAVITA will be responsible for a [\* \*].

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EXHIBIT D

RETURN GOODS POLICY

See Item 3 of Exhibit C.

## CERTIFICATION PURSUANT TO RULE 13a-14(a)

I, Robert L. Chioini, 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: August 1, 2013

/s/ Robert L. Chioini  
Robert L. Chioini  
President and Chief Executive Officer

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## CERTIFICATION PURSUANT TO RULE 13a-14(a)

I, Thomas E. Klema, 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: August 1, 2013

/s/ Thomas E. Klema  
Thomas E. Klema

Vice President and Chief Financial Officer

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**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
AND CHIEF FINANCIAL 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 June 30, 2013 as filed with the Securities and Exchange Commission on the date hereof (the "Periodic Report"), I, Robert L. Chioini, Chief Executive Officer of the Company and I, Thomas E. Klema, 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:

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: August 1, 2013

/s/ Robert L. Chioini  
\_\_\_\_\_  
Robert L. Chioini  
President and Chief Executive Officer

Dated: August 1, 2013

/s/ Thomas E. Klema  
\_\_\_\_\_  
Thomas E. Klema  
Vice President and Chief Financial Officer

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