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, 2020

or

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

For the transition period from to

Commission File Number: 000-23661

ROCKWELL MEDICAL, INC.

(Exact name of registrant as specified in its charter)

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

(248) 960-9009
(Registrant's telephone number, including area code)
(Former name, former address and former fiscal year, if changed since last report)

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

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

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

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

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

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

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

Title of each class:	**Trading Symbol**	**Name of each exchange on which registered:**
Common Stock, par value $0.0001	RMTI	Nasdaq Global Market

The number of shares of common stock outstanding as of August 7, 2020 was 70,297,814.

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

Item 1. Financial Statements

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2020	December 31, 2019
	(Unaudited)	
ASSETS		
Cash and Cash Equivalents	$ 26,697,063	$ 11,794,526
Investments Available-for-Sale	13,258,197	14,250,176
Accounts Receivable, net	3,565,292	4,202,725
Inventory, net	4,557,177	3,646,906
Prepaid and Other Current Assets	3,458,104	2,979,504
Total Current Assets	**51,535,833**	**36,873,837**
Property and Equipment, net	2,306,462	2,433,405
Inventory, Non-Current	821,000	441,000
Right of Use Assets, net	2,440,115	3,212,530
Goodwill	920,745	920,745
Other Non-Current Assets	560,588	434,935
Total Assets	**$ 58,584,743**	**$ 44,316,452**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts Payable	$ 3,313,240	$ 3,018,424
Accrued Liabilities	4,437,080	4,517,732
Settlement Payable	—	104,000
Lease Liability - Current	1,342,228	1,493,394
Deferred License Revenue - Current	2,174,626	2,233,640
Insurance Financing Note Payable	—	763,422
Customer Deposits	38,273	55,100
Other Current Liability - Related Party	189,600	187,849
Total Current Liabilities	**11,495,047**	**12,373,561**
Lease Liability - Long-Term	1,204,210	1,780,626
Term Loan, Net of Issuance Costs	20,764,213	—
Deferred License Revenue - Long-Term	8,909,703	9,842,762
Total Liabilities	**42,373,173**	**23,996,949**
Commitments and Contingencies (See Note 14)		
Stockholders' Equity:		
Preferred Stock, $0.0001 par value, 2,000,000 shares authorized; no shares issued and outstanding at June 30, 2020 and December 31, 2019	—	—
Common Stock, $0.0001 par value; 170,000,000 shares authorized; 70,156,922 and 65,378,890 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	7,017	6,538
Additional Paid-in Capital	337,551,385	326,777,250
Accumulated Deficit	(321,392,548)	(306,516,265)
Accumulated Other Comprehensive Income	45,716	51,980
Total Stockholders' Equity	**16,211,570**	**20,319,503**
Total Liabilities and Stockholders' Equity	**$ 58,584,743**	**$ 44,316,452**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Net Sales	$ 15,895,971	$ 14,845,788	$ 31,752,510	$ 30,405,227
Cost of Sales	15,015,404	14,112,639	29,759,017	28,661,686
Gross Profit	880,567	733,149	1,993,493	1,743,541
Selling and Marketing	1,996,595	2,218,997	4,069,393	5,321,375
General and Administrative	2,871,013	5,496,670	8,144,445	11,717,169
Settlement Expense	—	430,000	—	430,000
Research and Product Development	1,616,393	2,958,276	3,437,881	3,455,552
Operating Loss	(5,603,434)	(10,370,794)	(13,658,226)	(19,180,555)
Other Income (Expense)				
Realized Gain on Investments	2,065	4,135	3,994	18,023
Warrant Modification Expense	(837,322)	—	(837,322)	—
Interest Expense	(520,604)	—	(622,556)	—
Interest Income	66,750	74,476	237,827	192,002
Total Other Income	(1,289,111)	78,611	(1,218,057)	210,025
Net Loss	$ (6,892,545)	$ (10,292,183)	$ (14,876,283)	$ (18,970,530)
Basic and Diluted Net Loss per Share	$ (0.10)	$ (0.18)	$ (0.22)	$ (0.33)
Basic and Diluted Weighted Average Shares Outstanding	69,428,574	58,216,066	68,473,407	57,660,947

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Net Loss	**$ (6,892,545)**	**$ (10,292,183)**	**$ (14,876,283)**	**$ (18,970,530)**
Unrealized Loss on Available-for-Sale Debt Instrument Investments	(5,701)	11,426	(12,411)	4,265
Foreign Currency Translation Adjustments	536	236	6,147	144
Comprehensive Loss	**$ (6,897,710)**	**$ (10,280,521)**	**$ (14,882,547)**	**$ (18,966,121)**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

For the three and six months ended June 30, 2020

(Unaudited)

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT				
Balance as of January 1, 2020	**65,378,890**	**$ 6,538**	**$ 326,777,250**	**$ (306,516,265)**	**$ 51,980**	**$ 20,319,503**
Net Loss	—	—	—	(7,983,738)	—	(7,983,738)
Unrealized Loss on Available-for-Sale Investments	—	—	—	—	(6,710)	(6,710)
Foreign Currency Translation Adjustments	—	—	—	—	5,611	5,611
Issuance of common stock, net of offering costs/Bought Deal	3,670,212	367	8,003,590	—	—	8,003,957
Issuance of Warrants related to Debt Financing	—	—	500,736	—	—	500,736
Stock-based Compensation	—	—	934,846	—	—	934,846
Balance as of March 31, 2020	**69,049,102**	**$ 6,905**	**$ 336,216,422**	**$ (314,500,003)**	**$ 50,881**	**$ 21,774,205**
Net Loss	—	—	—	(6,892,545)	—	(6,892,545)
Unrealized Loss on Available-for-Sale Investments	—	—	—	—	(5,701)	(5,701)
Foreign Currency Translation Adjustments	—	—	—	—	536	536
Issuance of common stock, net of offering costs/Public offering	987,716	99	1,977,531	—	—	1,977,630
Vesting of Restricted Stock Units Issued, net of taxes withheld	120,104	13	(18,876)	—	—	(18,863)
Warrant Modification Expense	—	—	837,322	—	—	837,322
Stock-based Compensation expense	—	—	(1,461,014)	—	—	(1,461,014)
Balance as of June 30, 2020	**70,156,922**	**$ 7,017**	**$ 337,551,385**	**$ (321,392,548)**	**$ 45,716**	**$ 16,211,570**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

For the three and six months ended June 30, 2019

(Unaudited)

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT				
Balance as of January 1, 2019	**57,034,154**	**$ 5,703**	**$ 299,596,257**	**$ (272,388,234)**	**$ 63,148**	**$ 27,276,874**
Net Loss	—	—	—	(8,678,347)	—	(8,678,347)
Unrealized Loss on Available-for-Sale Investments	—	—	—	—	(7,161)	(7,161)
Foreign Currency Translation Adjustments	—	—	—	—	(92)	(92)
Exercise of Employee Stock Options, Net of Tax	30,000	3	147,897	—	—	147,900
Delivery of common stock underlying restricted stock units, net of tax	64,173	7	(95,436)	—	—	(95,429)
Stock-based Compensation	—	—	1,517,302	—	—	1,517,302
Balance as of March 31, 2019	**57,128,327**	**$ 5,713**	**$ 301,166,020**	**$ (281,066,581)**	**$ 55,895**	**$ 20,161,047**
Net Loss	—	—	—	(10,292,183)	—	(10,292,183)
Unrealized Gain on Available-for-Sale Investments	—	—	—	—	11,426	11,426
Foreign Currency Translation Adjustments	—	—	—	—	236	236
Issuance of common stock, net of offering costs/Public offering	5,833,334	583	16,120,096	—	—	16,120,679
Issuance of common stock, net of offering costs/At-the-market offering	437,043	44	2,089,164	—	—	2,089,208
Stock-based Compensation	—	—	1,501,326	—	—	1,501,326
Balance as of June 30, 2019	**63,398,704**	**$ 6,340**	**$ 320,876,606**	**$ (291,358,764)**	**$ 67,557**	**$ 29,591,739**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

For the six months ended June 30, 2020 and 2019

(Unaudited)

	2020	2019
Cash Flows From Operating Activities:		
Net Loss	**$ (14,876,283)**	**$ (18,970,530)**
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	407,680	380,372
Stock-based Compensation	(526,168)	3,018,628
Warrant Modification Expense	837,322	—
Increase in Inventory Reserves	12,000	192,000
Amortization of Right of Use Asset	748,160	975,947
Amortization of Debt Financing Costs and Accretion of Debt Discount	107,527	—
Loss (Gain) on Disposal of Assets	6,048	(300)
Realized (Gain) on Sale of Investments Available-for-Sale	(3,996)	(18,023)
Foreign Currency Translation Adjustment	6,147	144
Changes in Assets and Liabilities:		
Decrease in Accounts Receivable, net	637,432	1,590,656
Decrease in Insurance Receivable	—	371,217
(Increase) Decrease in Inventory	(1,302,270)	66,141
(Increase) Decrease in Prepaid and Other Assets	(607,574)	125,750
Increase (Decrease) in Accounts Payable	294,816	(426,772)
Increase (Decrease) in Settlement Payable	(104,000)	13,332
Decrease in Lease Liability	(703,327)	(977,636)
Decrease in Other Liabilities	(95,728)	(992,909)
Decrease in Deferred License Revenue	(992,073)	(1,126,434)
Changes in Assets and Liabilities	(2,872,724)	(1,356,655)
Cash Used In Operating Activities	**(16,154,287)**	**(15,778,417)**
Cash Flows From Investing Activities:		
Purchase of Investments Available-for-Sale	(16,513,592)	(21,774,410)
Sale of Investments Available-for-Sale	17,497,153	18,798,678
Purchase of Equipment	(283,462)	(305,030)
Purchase of Research and Development Licenses (Related Party)	—	(500,000)
Cash Provided By (Used In) Investing Activities	**700,099**	**(3,780,762)**
Cash Flows From Financing Activities:		
Proceeds from Term Loan	22,500,000	—
Debt Issuance Costs	(1,342,578)	—
Payments on Short Term Note Payable	(763,421)	—
Proceeds from the Issuance of Common Stock / Public Offering	8,147,871	17,500,002
Offering Costs from the Issuance of Common Stock / Public Offering	(143,914)	(1,379,323)
Proceeds from the Issuance of Common Stock / At-the Market Offering	2,034,073	2,296,235
Offering Costs from the Issuance of Common Stock / At-the Market Offering	(56,443)	(207,027)

Proceeds from the Exercise of Employee Stock Options	—	147,900
Repurchase of Common Stock to Pay Employee Withholding Taxes	(18,863)	(95,429)
Cash Provided By Financing Activities	**30,356,725**	**18,262,358**
Increase (Decrease) In Cash and Cash Equivalents	14,902,537	(1,296,821)
Cash and cash equivalents At Beginning Of Period	11,794,526	22,713,980
Cash and cash equivalents At End Of Period	**$ 26,697,063**	**$ 21,417,159**
Supplemental Disclosure of Cash Flow Information:		
Cash Paid for Interest	$ 409,931	$ —
Supplemental Disclosure of Noncash Investing and Financing Activities:		
Change in Unrealized Loss on Marketable Securities Available-for-Sale	$ (12,411)	$ 4,265
Insurance Financing Note Payable	$ —	$ 1,908,554
Fair Value of Warrants issued related to Debt Financing	$ 500,736	$ —

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

1. Description of Business

Rockwell Medical, Inc. and subsidiaries (collectively, “we”, “our”, “us”, or the “Company”), is a biopharmaceutical company dedicated to improving outcomes for patients with iron deficiency and iron-deficiency anemia, with an initial focus on patients with end-stage kidney disease (ESKD) and on dialysis. The Company is focused on developing its proprietary ferric pyrophosphate citrate (“FPC”) therapeutic platform. The first product developed from this platform is Triferic, the first-FDA approved product for the replacement of iron and maintenance of hemoglobin in adult hemodialysis patients. We initiated commercial sales of Triferic Dialysate, during the second quarter of 2019 and received approval by the U.S. Food and Drug Administration ("FDA") for the intravenous formulation of Triferic, Triferic AVNU, on March 27, 2020. We plan to leverage our experience with Triferic to develop our FPC platform for iron deficiency and iron deficiency anemia in other disease states. We are also a manufacturer of hemodialysis concentrates for dialysis providers and distributors in the United States and abroad. We supply the domestic market with dialysis concentrates and we also supply dialysis concentrates to distributors serving a number of foreign countries, primarily in the Americas and the Pacific Rim.

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

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

2. Liquidity and Capital Resources

As of June 30, 2020, the Company had approximately $26.7 million of cash and cash equivalents, $13.3 million of investments available-for-sale, working capital of $40.0 million and an accumulated deficit of $321.4 million. Net cash used in operating activities for the six months ended June 30, 2020 was approximately $16.2 million. Management evaluated the Company’s ability to continue as going concern for at least the next 12 months from the filing of this report. Based on the currently available working capital, capital raise and debt financing described below, management believes the Company currently has sufficient funds to meet its operating requirements for at least the next twelve months from the date of the filing of this report.

In February 2020, the Company sold 3,670,212 shares of its common stock for proceeds of $8.0 million, net of issuance costs. On March 16, 2020, the Company closed a debt financing transaction with net proceeds at closing of approximately $21.2 million, net of fees and expenses (See Note 15 for further detail).

During the six months ended June 30, 2020, the Company sold 987,716 shares of its common stock as part of its sales agreement with Cantor Fitzgerald & Co. for proceeds of $2.0 million, net of issuance costs. Approximately $32.6 million remains available for sale under this facility. See Note 10 for further detail.

The Company will require additional capital to sustain its operations and make the investments it needs to execute upon its longer-term business plan, including the continued commercialization of Triferic Dialysate and Triferic AVNU, executing plans for enhancing its medical capabilities, generating additional data for Triferic and developing Triferic for new therapeutic indications. If the Company is unable to generate sufficient revenue from its existing long-term business plan, the Company will need to obtain additional equity or debt financing. If the Company attempts to obtain additional debt or equity financing, the Company cannot assume that such financing will be available on favorable terms, if at all.

The COVID-19 pandemic and resulting global disruptions have adversely affected our business and operations, including, but not limited to, our sales and marketing efforts and our research and development activities, and the operations of third parties upon whom we rely. As noted above, we intend to initiate a sample evaluation program for Triferic AVNU during the third quarter of 2020 in order to prepare for a commercial launch. Quarantines, shelter-in-place, executive and similar government orders may negatively impact our sales and marketing activities, particularly if our sales representatives are unable to interact with current and potential customers to the same extent as before onset of the COVID-19 pandemic. Depending on the severity of the impact on our sales and marketing efforts, the timing of our commercial launch of Triferic AVNU could be adjusted into the first quarter of 2021.

The COVID-19 pandemic and resulting global disruptions have caused significant volatility in financial and credit markets. We have utilized a range of financing methods to fund our operations in the past; however, current conditions in the financial and

credit markets may limit the availability of funding or increase the cost of funding. Due to the rapidly evolving nature of the global situation, it is not possible to predict the extent to which these conditions could adversely affect our liquidity and capital resources in the future.

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

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

The accompanying condensed consolidated financial statements have been prepared in accordance with the accounting principles generally accepted in the United States ("U.S.") of America ("GAAP") for interim financial information and pursuant to the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the U. S. Securities and Exchange Commission ("SEC") and on the same basis as the Company prepares its annual audited consolidated financial statements.

The condensed consolidated balance sheet at June 30, 2020, condensed consolidated statements of operations for the three and six months ended June 30, 2020 and 2019, condensed consolidated statements of cash flows for the six months ended June 30, 2020 and 2019, and condensed consolidated statement of changes in shareholder's equity for the three and six months ended June 30, 2020 and 2019 are unaudited, but include all adjustments, consisting of normal recurring adjustments, that the Company considers necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented. The results for the three and six months ended June 30, 2020 are not necessarily indicative of results to be expected for the year ending December 31, 2020 or for any future interim period. The condensed consolidated balance sheet at December 31, 2019 has been derived from audited financial statements, however, it does not include all of the information and notes required by GAAP for complete financial statements. The accompanying condensed consolidated financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2019 and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 as filed with the SEC on Form 10-K on March 17, 2020. The Company's consolidated subsidiaries consisted of its wholly-owned subsidiaries, Rockwell Transportation, Inc. and Rockwell Medical India Private Limited.

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

Certain reclassifications have been made to the 2019 financial statements and notes to conform to the 2020 presentation.

Use of Estimates

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

Leases

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

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

Loss Per Share

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

Basic net loss per share of common stock excludes dilution and is computed by dividing the net loss by the weighted average number of shares outstanding during the period. Diluted net loss per share of common stock reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the entity unless inclusion of such shares would be anti-dilutive. The Company has only incurred losses, therefore, basic and diluted net loss per share is the same. Securities that could potentially dilute net income per share in the future that were not included in the computation of diluted loss per share were as follows:

	As of June 30,	
	2020	**2019**
Options to purchase common stock	6,225,562	8,187,161
Unvested restricted stock awards	146,800	146,800
Unvested restricted stock units	503,395	1,658,205
Warrants to purchase common stock	3,248,054	2,770,781
	10,123,811	12,762,947

Adoption of Recent Accounting Pronouncements

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

4. Revenue Recognition

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

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

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

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

Nature of goods and services

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

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

services based on their stand-alone selling prices. The stand-alone selling prices are determined based on the cost plus margin approach.

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

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

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

Disaggregation of revenue

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

In thousands of US dollars ($)	Three Months Ended June 30, 2020			Six Months Ended June 30, 2020		
Products By Geographic Area	Total	U.S.	Rest of World	Total	U.S.	Rest of World
Drug Revenues						
Product Sales – Point-in-time	$ 182	$ 182	$ —	$ 381	$ 381	$ —
License Fee – Over time	56	—	56	112	—	112
Total Drug Products	238	182	56	493	381	112
Concentrate Products						
Product Sales – Point-in-time	15,168	13,319	1,849	30,280	26,826	3,454
License Fee – Over time	490	490	—	980	980	—
Total Concentrate Products	15,658	13,809	1,849	31,260	27,806	3,454
Net Revenue	$ 15,896	$ 13,991	$ 1,905	$ 31,753	$ 28,187	$ 3,566

In thousands of US dollars ($)	Three Months Ended June 30, 2019			Six Months Ended June 30, 2019		
Products By Geographic Area	Total	U.S.	Rest of World	Total	U.S.	Rest of World
Drug Revenues						
Product Sales – Point-in-time	$ 15	$ 15	$ —	$ 15	$ 15	$ —
License Fee – Over time	$ 68	$ —	68	136	—	136
Total Drug Products	83	15	68	151	15	136
Concentrate Products						
Product Sales – Point-in-time	14,268	12,822	1,446	29,264	25,746	3,518
License Fee – Over time	495	495	—	990	990	—
Total Concentrate Products	14,763	13,317	1,446	30,254	26,736	3,518
Net Revenue	$ 14,846	$ 13,332	$ 1,514	$ 30,405	$ 26,751	$ 3,654

Contract balances

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

In thousands of US dollars ($)	June 30, 2020	December 31, 2019
Receivables, which are included in "Trade and other receivables"	$ 3,565	$ 4,203
Contract liabilities	$ 11,084	$ 12,076

There were no material losses recognized related to any receivables arising from the Company's contracts with customers for the three and six months ended June 30, 2020 and 2019.

For the three and six months ended June 30, 2020 and June 30, 2019, the Company did not recognize any material bad-debt expense. There were no material contract assets recorded on the condensed consolidated balance sheet as of June 30, 2020 and December 31, 2019. The Company does not generally accept returns of its concentrate products and no material reserve for returns of concentrate products was established as of June 30, 2020 or December 31, 2019.

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

Transaction price allocated to remaining performance obligations

For the three and six months ended June 30, 2020, revenue recognized from performance obligations related to prior periods was not material.

Revenue expected to be recognized in any future year related to remaining performance obligations, excluding revenue pertaining to contracts that have an original expected duration of one year or less, contracts where revenue is recognized as invoiced and contracts with variable consideration related to undelivered performance obligations, totaled $11.1 million as of June 30, 2020. The amount relates primarily to upfront payments and consideration received from customers that are received in advance of the customer assuming control of the related products. The Company applies the practical expedient in paragraph 606-10-50-14 and does not disclose information about remaining performance obligations that have original expected durations of one year or less. The Baxter Agreement includes minimum commitments of product sales over the duration of the agreement. Unfulfilled performance obligations related to the Baxter Agreement are product sales of $8.2 million as of June 30, 2020, which is being amortized ratably through expiration of the Baxter Agreement on October 2, 2024.

5. Investments - Available-for-Sale

Investments available-for-sale consisted of the following as of June 30, 2020 and December 31, 2019:

	June 30, 2020				
	Amortized Cost	Unrealized Gain	Unrealized Loss	Accrued Interest Income	Fair Value
Available-for-Sale Securities					
Bonds	$ 13,172,049	$ 14,468	$ (447)	$ 72,127	$ 13,258,197

	December 31, 2019				
	Amortized Cost	Unrealized Gain	Unrealized Loss	Accrued Interest	Fair Value
Available-for-Sale Securities					
Bonds	$ 14,238,161	$ 13,321	$ (1,306)	$ —	$ 14,250,176

The fair value of investments available-for-sale are determined using quoted market prices from daily exchange-traded markets based on the closing price as of the balance sheet date and are classified as a Level 1 measurement under ASC 820 *Fair Value Measurements.*

As of June 30, 2020 and December 31, 2019, the amortized cost and estimated fair value of our available-for-sale securities were due within one year.

6. Inventory

Components of inventory, net of reserves, as of June 30, 2020 and December 31, 2019 are as follows:

	June 30, 2020	December 31, 2019
Raw Materials	$ 3,041,887	$ 2,471,234
Work in Process	303,545	184,382
Finished Goods	2,032,745	1,432,290
Total	$ 5,378,177	$ 4,087,906

As of June 30, 2020, we classified $0.8 million of inventory as non-current, all of which was related to Triferic or the active pharmaceutical ingredient and raw materials for Triferic. As of June 30, 2020, we had total Triferic inventory aggregating $3.7 million, against which we had reserved $2.5 million.

The $1.2 million net value of Triferic inventory consisted of $0.2 million of Triferic Dialysate finished goods with expiration dates ranging from December 2020 to May 2021, $0.5 million of Triferic API with estimated remaining shelf life extending through 2023, and $0.5 million of raw materials for Triferic with estimated remaining shelf life extending beyond 2025.

7. Property and Equipment

As of June 30, 2020 and December 31, 2019, the Company's property and equipment consisted of the following:

	June 30, 2020	December 31, 2019
Leasehold Improvements	$ 1,175,986	$ 1,162,328
Machinery and Equipment	4,869,771	4,672,724
Information Technology & Office Equipment	1,822,260	1,810,246
Laboratory Equipment	652,676	653,075
	8,520,693	8,298,373
Accumulated Depreciation	(6,214,231)	(5,864,968)
Property and Equipment, net	$ 2,306,462	$ 2,433,405

Depreciation expense for the three months ended June 30, 2020 and 2019 totaled $0.2 million. Depreciation expense for the six months ended June 30, 2020 and 2019 totaled $0.4 million.

8. Accrued Liabilities

Accrued liabilities as of June 30, 2020 and December 31, 2019 consisted of the following:

	June 30, 2020	December 31, 2019
Accrued Research & Development Expense	$ 268,677	$ 283,407
Accrued Compensation and Benefits	2,032,651	1,018,196
Accrued Legal Expenses	116,578	181,597
Accrued Marketing Expenses	191,797	61,164
Other Accrued Liabilities	1,827,377	2,973,368
Total Accrued Liabilities	$ 4,437,080	$ 4,517,732

9. Deferred Revenue

In October 2014, the Company entered into the Baxter Agreement with Baxter and received an upfront fee of $20 million. The upfront fee was recorded as deferred revenue and is being recognized based on the proportion of product shipments to Baxter in each period, compared with total expected sales volume over the term of the Baxter Agreement, which expires in October 2024. The Company recognized revenue of approximately $0.5 million and $1.0 million for the three and six months ended June 30,

2020 and 2019, respectively. Deferred revenue related to the Baxter Agreement totaled $8.2 million as of June 30, 2020 and $9.1 million as of December 31, 2019.

If a “Refund Trigger Event” occurs under the Baxter Agreement, we would be obligated to repay a portion of the upfront fee and any paid portion of the facility fee. In the event of a Refund Trigger Event occurring from April 1, 2020 to December 31, 2021, Baxter would be eligible for a 25% refund of the Baxter Agreement’s upfront fee. In addition, if Baxter terminates the Baxter Agreement because Baxter has been enjoined by a court of competent jurisdiction from selling in the United States any product covered by the Baxter Agreement due to a claim of intellectual property infringement or misappropriation relating to such product prior to the end of 2020, Baxter would be eligible for a partial refund of the upfront fee of $5.0 million. In no event does the Baxter Agreement require more than one refund be paid.

In 2016, the Company entered into a distribution and license agreement with Wanbang (the "Wanbang Agreement") and received an upfront fee of $4.0 million. The upfront fee was recorded as deferred revenue and is being recognized as revenue based on the agreement term. The Company recognized revenue of approximately $53,000 and $0.1 million for the three and six months ended June 30, 2020 and 2019, respectively. Deferred revenue related to the Wanbang Agreement totaled $2.9 million as of June 30, 2020 and $3.0 million as of December 31, 2019.

On January 14, 2020, we entered into license and supply agreements with Sun Pharma (the "Sun Pharma Agreements"), for the rights to commercialize Triferic Dialysate (ferric pyrophosphate citrate) in India. Under the terms of the Sun Pharma Agreements, Sun Pharma will be the exclusive development and commercialization partner for Triferic Dialysate in India, and we will supply the product to Sun Pharma. In consideration for the license, we received an upfront fee of $0.1 million, and will be eligible for milestone payments and royalties on net sales. A Joint Alliance Committee, comprised of members from the Company and Sun Pharma, will guide the development and execution for Triferic Dialysate in India. Sun Pharma will be responsible for all clinical and regulatory approval, as well as commercialization activities. The upfront fee was recorded as deferred revenue and is being recognized as revenue based on the agreement term. The Company recognized revenue of approximately $2,500 and $5,000 during the three and six months ended June 30, 2020, respectively.

10. Stockholders’ Equity

The Company held its annual meeting of stockholders on May 18, 2020 (the “Annual Meeting”). At the Annual Meeting, the Company’s stockholders approved the amendment and restatement of the Rockwell Medical, Inc. 2018 Long Term Incentive Plan to increase the number of shares of common stock issuable thereunder by 2,900,000 shares (the “Amended 2018 Plan”).

Preferred Stock

As of June 30, 2020 and December 31, 2019, there were 2,000,000 shares of preferred stock, $0.0001 par value per share, authorized and no shares of preferred stock issued or outstanding.

Common Stock

As of June 30, 2020 and December 31, 2019, there were 170,000,000 shares of common stock, $0.0001 par value per share, authorized and 70,156,922 and 65,378,890 shares issued and outstanding, respectively.

Controlled Equity Offering (or "At the Market" Offering)

On March 22, 2019, the Company entered into a sales agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co. (the “Agent”), pursuant to which the Company may offer and sell from time to time shares of the Company’s common stock through the Agent. The offering and sale of up to $40.0 million of the shares has been registered under the Securities Act of 1933, as amended (the "Securities Act"), pursuant to the Company’s registration statement on Form S-3 (File No. 333-227363), which was originally filed with the SEC on September 14, 2018 and declared effective by the SEC on October 1, 2018, the base prospectus contained within the registration statement, and a prospectus supplement that was filed with the SEC on March 22, 2019.

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

During the year ended December 31, 2019, the Company sold 1,840,443 of shares of its common stock pursuant to the Sales Agreement for gross proceeds of $5,383,079, at a weighted average selling price of approximately $2.92. The Company paid $309,479 in commissions and offering fees related to the sale of the common stock. For the six months ended June 30, 2020, the Company sold 987,716 of shares of its common stock pursuant to the Sales Agreement for gross proceeds of $2,034,073, at a weighted average selling price of approximately $2.06. The Company paid $56,443 in commissions and offering fees related to the sale of common stock. Approximately $32.6 million remains available for sale under this facility.

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

Public Offering of Common Stock

On February 4, 2020, the Company entered into an underwriting agreement with Cantor Fitzgerald & Co., as underwriter, pursuant to which the Company agreed to issue and sell an aggregate of up to 3,670,212 shares of its common stock, which included 478,723 optional shares that may be sold pursuant to an over-allotment option granted to the underwriters. On February 6, 2020, the Company closed the sale of 3,191,489 shares of its common stock at the public offering price of $2.22 per share (the "Offering").

On February 19, 2020, the underwriter exercised its over-allotment option to purchase an additional 478,723 shares at a price of $2.22 per share, which closed on February 21, 2020. The Company raised a total of $8.0 million, net of issuance costs of $0.1 million, relating to the sale of the common stock in the Offering. The Offering was made pursuant to the Company's effective Registration Statement on Form S-3 (File No. 333-227363), which was previously filed with the SEC.

11. Stock-Based Compensation

The Company recognized total stock-based compensation expense during the three and six months ended June 30, 2020 and 2019 as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Service-based awards:				
Restricted stock units	$ (4,127)	$ 427,472	$ 233,987	$ 771,823
Stock option awards	336,513	547,139	776,138	1,199,163
	332,386	974,611	1,010,125	1,970,986
Performance-based awards:				
Restricted stock units	(1,196,713)	402,814	(1,025,502)	801,202
Stock option awards	(596,687)	123,901	(510,791)	246,440
	(1,793,400)	526,715	(1,536,293)	1,047,642
Total	$ (1,461,014)	$ 1,501,326	$ (526,168)	$ 3,018,628

Restricted Stock

A summary of the Company's restricted stock awards during the six months ended June 30, 2020 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2020	146,800	$ 5.70
Unvested at June 30, 2020	146,800	$ 5.70

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

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2019	146,800	$ 5.70
Unvested at June 30, 2019	146,800	$ 5.70

The fair value of restricted stock awards are measured based on their fair value on the date of grant and amortized over the vesting period of 20 months. As of June 30, 2020, unvested restricted stock awards of 146,800 were related to performance-based awards.

Service-Based Restricted Stock Units

A summary of the Company's service-based restricted stock units during the six months ended June 30, 2020 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2020	463,786	$ 4.26
Granted	188,904	2.09
Vested	(128,460)	4.30
Forfeited	(104,168)	4.66
Unvested at June 30, 2020	420,062	$ 3.27

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

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2019	472,959	$ 4.32
Granted	199,938	4.45
Forfeited	(3,650)	4.81
Unvested at June 30, 2019	669,247	$ 4.36

The fair value of service based restricted stock units are measured based on their fair value on the date of grant and amortized over the vesting period. The vesting periods range from 1 to 3 years. Stock-based compensation expense of nil and $0.2 million was recognized during the three and six months ended June 30, 2020, respectively. Stock-based compensation expense of $0.4 million and $0.8 million was recognized during the three and six months ended June 30, 2019, respectively. As of June 30, 2020, the unrecognized stock-based compensation expense was $0.6 million, which is expected to be recognized over an estimated weighted average remaining term of 1 year. Included in the forfeited service-based restricted stock units are 96,541 units related to the resignation of the Company's former President and Chief Executive Officer on April 17, 2020. These forfeited awards reduced stock-based compensation expense by $0.2 million.

Performance-Based Restricted Stock Units

A summary of the Company's performance-based restricted stock units during the six months ended June 30, 2020 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2020	988,958	$ 4.48
Forfeited	(905,625)	4.61
Unvested at June 30, 2020	83,333	$ 3.09

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

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2019	988,958	$ 4.48
Unvested at June 30, 2019	988,958	$ 4.48

Stock-based compensation expense recognized for performance-based restricted stock units was ($1.2) million and ($1.0) million during the three and six months ended June 30, 2020 and $0.4 million and $0.8 million for the three and six months ended June 30, 2019, respectively. As of June 30, 2020, the unrecognized stock-based compensation expense related to performance-based restricted stock units was $0.1 million, which is expected to be recognized over an estimated weighted average remaining term of 2 years. The forfeited performance-based restricted stock awards of 905,625 is due to the resignation of the Company's former President and Chief Executive Officer on April 17, 2020. These forfeited awards reduced stock-based compensation expense by $1.3 million.

Service-Based Stock Options

The fair value of the service-based stock options granted for the six months ended June 30, 2020 were based on the following assumptions:

	June 30, 2020
Exercise price	$1.77 - $2.45
Expected stock price volatility	68.2% - 74.4%
Risk-free interest rate	0.35% - 1.65%
Term (years)	5.5 -6.5

A summary of the Company's service-based stock option activity for the six months ended June 30, 2020 is as follows:

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2020	8,210,024	$ 7.06	5.1	$ 107,150
Granted	1,610,344	2.24	5.9	—
Forfeited	(211,471)	4.41	—	—
Expired	(3,983,335)	8.30	—	—
Outstanding at June 30, 2020	5,625,562	$ 4.90	6.7	$ 1,100
Exercisable at June 30, 2020	2,809,954	$ 7.09	4.3	$ —

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

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2019	7,856,480	$ 7.50	5.2	$ —
Granted	523,105	4.33	9.7	—
Exercised	(30,000)	4.93	—	—
Forfeited	(550,549)	6.67	—	—
Outstanding at June 30	7,799,036	$ 7.36	5.4	$ 2,500
Exercisable at June 30, 2019	6,183,193	$ 8.16	4.3	$ —

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

During the six months ended June 30, 2020, the Company granted stock options to purchase up to 1,610,344 shares of common stock to certain employees. During the six months ended June 30, 2020, 211,471 shares were forfeited. Forfeitures are recorded in the period of occurrence; compensation expense is adjusted accordingly.

Stock-based compensation expense recognized for service-based stock options was $0.3 million and $0.8 million for the three and six months ended June 30, 2020, respectively. Stock-based compensation expense recognized for service-based stock options was $0.5 million and $1.2 million for the three and six months ended June 30, 2019, respectively. As of June 30, 2020, total stock-based compensation expense related to unvested options not yet recognized totaled approximately $3.1 million, which is expected to be recognized over an estimated weighted average remaining term of 1.4 years. Included in the forfeited service-based stock options are 129,375 unvested options related to the resignation of the Company's former President and Chief Executive Officer on April 17, 2020. These forfeited awards reduced stock-based compensation expense by $0.2 million. Included in the expired service-based stock options are 3,783,335 options related to the settlement with the former Chief Executive Officer, Robert Chioini, former Chief Financial Officer, Thomas Klema, and a former and then current director. See Note 14 for further details.

Performance-Based Stock Options

A summary of the performance-based stock options for the six months ended June 30, 2020 is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding at January 1, 2020	388,125	$ 4.70
Granted	600,000	2.45
Forfeited	(388,125)	4.70
Outstanding at June 30, 2020	600,000	$ 2.45
Exercisable at June 30, 2020	—	$ —

A summary of the performance-based stock options for the six months ended June 30, 2019 is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding at January 1, 2019	388,125	$ 4.70
Outstanding at June 30, 2019	388,125	$ 4.70
Exercisable at June 30, 2019	—	$ —

Stock-based compensation expense recognized for performance-based stock options was ($0.6) million and ($0.5) million for the three and six months ended June 30, 2020. Stock-based compensation expense recognized for performance-based stock options was $0.1 million and $0.2 million during the three and six months ended June 30, 2019. As of June 30, 2020, the unrecognized stock-based compensation expense related to unvested performance-based stock options was $0.1 million. The forfeited unvested performance-based stock options of 388,125 is due to the resignation of the Company's former President and Chief Executive Officer on April 17, 2020. These forfeited options reduced stock-based compensation expense by $0.7 million.

12. Related Party Transactions

Product License Agreements

The Company is a party to a Licensing Agreement with Charak, LLC ("Charak") dated January 7, 2002 (the "2002 Agreement") that grants the Company exclusive worldwide rights to certain patents and information related to our Triferic® product. On October 7, 2018, the Company entered into a Master Services and IP Agreement (the “Charak MSA”) with Charak and Dr. Ajay Gupta, who serves as Executive Vice President and Chief Scientific Officer of the Company. Pursuant to the MSA, the parties entered into three additional agreements described below related to the license of certain soluble ferric pyrophosphate (“SFP”) intellectual property owned by Charak, as well as the Employment Agreement (defined below). The Charak MSA provided for a payment of $1.0 million to Dr. Gupta, payable in four quarterly installments of $250,000 each on October 15, 2018, January 15, 2019, April 15, 2019 and July 15, 2019, and reimbursement for certain legal fees incurred in connection with the Charak MSA. The Company recorded $1.1 million as Research and Development Expense - License Acquired (Related Party) for the twelve months ended December 31, 2018. The Company paid all four of the quarterly installments totaling $1.0 million and accrued $0.1 million for the reimbursement of certain legal expenses during the year ended December 31, 2019. As of June 30, 2020, and December 31, 2019, the Company accrued $27,500 and $0.1 million, respectively, as a related party payable on the condensed consolidated balance sheet. In addition, the Company accrued $0.2 million relating to certain IP reimbursement expenses as a related party payable on the condensed consolidated balance sheet.

Pursuant to the Charak MSA, the aforementioned parties entered into an Amendment, dated as of October 7, 2018 (the “Charak Amendment”), to the 2002 Agreement, under which Charak granted the Company an exclusive, worldwide, non-transferable license to commercialize SFP for the treatment of patients with renal failure. The Charak Amendment amends the royalty payments due to Charak under the 2002 Agreement such that the Company is liable to pay Charak royalties on net sales by the Company of products developed under the license, which includes the Company’s Triferic® product, at a specified rate until December 31, 2021 and thereafter at a reduced rate from January 1, 2022 until February 1, 2034. Additionally, the Company

shall pay Charak a percentage of any sublicense income during the term of the agreement, which amount shall not be less than a minimum specified percentage of net sales of the licensed products by the sub-licensee in jurisdictions where there exists a valid claim, on a country-by-country basis, and be no less than a lower rate of the net sales of the licensed products by the sub-licensee in jurisdictions where there exists no valid claim, on a country-by-country basis.

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

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

The transaction was accounted for as an asset acquisition pursuant to ASU 2017-1, *Business Combinations* (Topic 805), *Clarifying the Definition of a Business*, as the majority of the fair value of the assets acquired was concentrated in a group of similar assets, and the acquired assets did not have outputs or employees. The assets acquired under the Charak MSA include a license of SFP. Because SFP has not yet received regulatory approval, the $1.1 million purchase price paid and accrued for these assets has been expensed in the Company’s statement of operations for the year ended December 31, 2018. In addition, because the potential milestone payments are not yet considered probable, no milestone payments have been accrued at June 30, 2020.

13. Leases

We lease our production facilities and administrative offices as well as certain equipment used in our operations including leases on transportation equipment used in the delivery of our products. The lease terms range from monthly to five years. We occupy a 51,000 square foot facility and a 17,500 square foot facility in Wixom, Michigan under a lease expiring in August 2021. We also occupy two other manufacturing facilities, a 51,000 square foot facility in Grapevine, Texas under a lease expiring in December 2020, and a 57,000 square foot facility in Greer, South Carolina under a lease expiring February 2023. In addition, we occupy a 1,408 square foot office space in Greer, South Carolina under a lease expiring April 2021. In addition, we executed a lease for 4,100 square feet of office space in Hackensack, New Jersey with a lease term beginning on April 1, 2019 and expiring on July 1, 2024.

At June 30, 2020, the Company had operating lease liabilities of $2.5 million and right-of-use assets of $2.4 million, which are included in the consolidated balance sheet.

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

	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Operating leases				
Operating lease cost	$ 403,077	$ 554,921	$ 845,905	$ 1,089,888
Variable lease cost	122,865	78,237	312,149	168,081
Operating lease expense	525,942	633,158	1,158,054	1,257,969
Short-term lease rent expense	4,157	4,122	8,313	8,313
Total rent expense	$ 530,099	$ 637,280	$ 1,166,367	$ 1,266,282
Other information				
Operating cash flows from operating leases	$ 410,092	$ 514,116	$ 854,785	$ 1,038,081
Right of use assets exchanged for operating lease liabilities	$ —	$ 821,195	$ —	$ 4,305,428
Weighted-average remaining lease term – operating leases	2.4	2.6	2.4	2.6
Weighted-average discount rate – operating leases	6.8%	6.8%	6.8%	6.8%

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

Year ending December 31, 2020 (remaining)	$ 780,038
Year ending December 31, 2021	1,054,873
Year ending December 31, 2022	591,925
Year ending December 31, 2023	234,327
Year ending December 31, 2024	97,423
Total	$ 2,758,586
Less present value discount	(212,148)
Operating lease liabilities	$ 2,546,438

14. Commitments and Contingencies

Demand Notice

In February 2020, the Company received a letter from a supplier relating to a supply agreement entered into with the Company in 2015. The supplier alleged the Company did not meet certain annual minimums under the supply agreement, and has requested $3.0 million in penalties, plus payment of the cost for certain raw materials. No lawsuit was filed. While the Company believed it had several defenses to the supplier's claim, the Company and the supplier negotiated an amicable resolution of the dispute. On July 31, 2020, the Company and the supplier entered into a settlement agreement, which released the Company from any penalties relating to annual minimums under the 2015 agreement, established new minimums under an amended supply agreement and required the Company to pay for certain raw materials with 50% of the cost to be paid upon execution of the settlement agreement and the remaining 50% to be paid no later than December 31, 2020.

Litigation

SEC Investigation

As a follow up to certain prior inquiries, the Company received a subpoena from the SEC during the Company's quarter ended September 30, 2019 requesting, among other things, certain information and documents relating to the status of the Company's request to the Centers for Medicare & Medicaid Services (the "CMS") for separate reimbursement status for Triferic Dialysate, the Company's reserving methodology for expiring Triferic inventory, and the basis for the Board's termination of the former Chief

Executive Officer, Robert Chioini, and former Chief Financial Officer, Thomas Klema, in 2018. The Company is cooperating with the SEC and is responding to the SEC's requests for documents and information.

Shareholder Class Action Lawsuits

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

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

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

On August 7, 2019, all parties to the class action entered into a settlement of the consolidated class action. Pursuant to the terms and conditions of the settlement agreement, the Company will pay the Plaintiffs $3.7 million (the "Settlement Amount") in exchange for a full release of all liability as to all defendants. This resulted in a settlement expense of approximately $0.4 million for the year ended December 31, 2019. Of the Settlement Amount, the Company contributed approximately $0.1 million, which represented the remaining retention amount under the Company's director and officer liability insurance policy as of June 30, 2020. The remainder of the settlement amount has been funded by the Company's director and officer insurance policy. The settlement was approved by the court on February 26, 2020.

Shareholder Derivative Actions

Plaintiff Bill Le Clair filed a Verified Stockholder Derivative Complaint on April 23, 2019 in Case No. 1:19-cv-02373, and Plaintiff John Post filed a Verified Stockholder Derivative Complaint on May 10, 2019 in Case No. 1:19-cv-02774 (the "Derivative Complaints") in the United States District Court in the Eastern District of New York, purportedly on behalf of the Company (as nominal defendant) and against certain of the Company's current and former directors (the "Individual Defendants"). The Derivative Complaints assert causes of actions against the Individual Defendants for breach of fiduciary duty, waste of corporate assets, and unjust enrichment. The Derivative Complaints allege the Individual Defendants breached duties by, among other things, permitting alleged misstatements to be made in public filings regarding the status of separate reimbursement for Triferic from CMS, the adequacy of the Company's reserves and internal controls. The Derivative Complaints demand a jury trial, seeking monetary damages, corporate governance and internal procedure reform, injunctive relief on the Individual Directors' trading activities, restitution, and attorneys' fees. The cases have been consolidated and the parties are in advanced settlement discussions. If a settlement is not reached, the Defendants anticipate filing motions to dismiss.

The Company tendered the above shareholder derivative actions to its director and officer insurance carrier(s) for defense and indemnity under its applicable insurance policies. On May 18, 2020, the Company, the Individual Defendants and the Plaintiffs (the "Settling Parties") entered into a formal Stipulation of Settlement, which memorializes the terms of the Settling Parties'

settlement of the Derivative Complaints. On June 2, 2020, the court issued an order preliminarily approving the settlement. A hearing is set for August 10, 2020 to determine if the court should issue a final order approving the final settlement. The Company has exhausted self-insured retention under the above insurance policies. The Company's director and officer insurance company has funded the settlement amount on behalf of the Company.

Termination of our former CEO and CFO

On August 7, 2018, the Company entered into a confidential settlement agreement and mutual release with Robert Chioini, its former Chief Executive Officer, Thomas Klema, its former Chief Financial Officer and a former and then current director. For more details see Note 15 in the Company's Annual Report on Form 10-K filed on March 17, 2020.

15. Loan and Security Agreement

On March 16, 2020, Rockwell Medical, Inc. and Rockwell Transportation, Inc., as Borrowers, entered into a Loan and Security Agreement (the "Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP ("Innovatus"), as collateral agent and the lenders party thereto, pursuant to which Innovatus, as a lender, agreed to make certain term loans to the Company in the aggregate principal amount of up to $35.0 million (the "Term Loans"). Funding of the first $22.5 million tranche was completed on March 16, 2020. The Company will be eligible to draw on a second tranche of $5.0 million upon achievement of certain milestones, including the FDA approval of the Company's New Drug Application for Triferic AVNU. The Company will be eligible to draw on a third tranche of $7.5 million upon the achievement of certain additional milestones, including the achievement of certain Triferic sales thresholds. Net draw down proceeds were $21.2 million with closing costs of $1.3 million.

The Company is entitled to make interest-only payments for thirty months, or up to thirty-six months if certain conditions are met. The Term Loans will mature on March 16, 2025, and will bear interest at the greater of (i) Prime Rate (as defined in the Loan Agreement) and (ii) 4.75%, plus 4.00% with an initial interest rate of 8.75% per annum and an effective interest rate of 10.9%. The Company has the option, under certain circumstances, to add 1.00% of such interest rate amount to the then outstanding principal balance in lieu of paying such amount in cash. For the three months ended June 30, 2020 and 2019, interest expense amounted to $0.5 million and nil, respectively. For the six months ended June 30, 2020 and 2019, interest expense amounted to $0.6 million and nil, respectively.

The Loan Agreement is secured by all assets of the Company and Rockwell Transportation, Inc. Proceeds will be used for working capital purposes. The Loan Agreement contains customary representations and warranties and covenants, subject to customary carve outs, and includes financial covenants related to liquidity and trailing twelve months sales of Triferic, with the latter beginning with the period ending December 31, 2020, or September 30, 2020 if the Company draws the second tranche of $5.0 million. As of June 30, 2020, the Company was in compliance with all the reporting and financial covenants.

In connection with each funding of the Term Loans, the Company is required to issue to Innovatus a warrant (the "Warrants") to purchase a number of shares of the Company's common stock equal to 3.5% of the principal amount of the relevant Term Loan funded divided by the exercise price, which will be based on the lower of (i) the volume weighted average closing price of the Company's stock for the 5-trading day period ending on the last trading day immediately preceding the execution of the Loan Agreement or (ii) the closing price on the last trading day immediately preceding the execution of the Loan Agreement (or for the second and third tranches only at the lower of (i) $1.65 per share or (ii) the volume weighted average closing price of the Company's stock for the 5-trading day period ending on the last trading day immediately preceding the relevant Term Loan funding). The Warrants may be exercised on a cashless basis and are immediately exercisable through the seventh anniversary of the applicable funding date. The number of shares of common stock for which each Warrant is exercisable and the associated exercise price are subject to certain proportional adjustments as set forth in such Warrant. In connection with the first tranche of the Term Loans, the Company issued a Warrant to Innovatus, exercisable for an aggregate of 477,273 shares of the Company's common stock at an exercise price of $1.65 per share.

As of June 30, 2020, the outstanding balance of the Term Loan was $20.8 million, net of unamortized issuance costs and unaccreted discount of $1.7 million.

The following table reflects the schedule of principal payments on the Term Loan as of June 30, 2020:

	Principal Payments
2020	$ —
2021	—
2022	2,250,000
2023	9,000,000
2024	9,000,000
2025	2,250,000
	$ 22,500,000

16. Subsequent Events

Resignation of Chief Financial Officer

On June 5, 2020, Angus Smith, the Company's Chief Financial Officer, notified the Company of his intent to resign from the Company effective July 3, 2020. As a result of Mr. Smith's resignation, certain of his time-based, all of his performance-based and market-based stock awards previously granted to Mr. Smith will be forfeited. Such forfeitures will be reflected in the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2020. The estimated expense the forfeited stock awards is approximately $0.7 million.

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

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

Forward-Looking Statements

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

While we believe that our forward-looking statements are reasonable, you should not place undue reliance on any such forward-looking statements, which are based on information available to us on the date of this report or, if made elsewhere, as of the date made. Because these forward-looking statements are based on estimates and assumptions that are subject to significant business, economic and competitive uncertainties, many of which are beyond our control or are subject to change, actual results could be materially different. Factors that might cause such a difference include, without limitation, the risks and uncertainties discussed in this report, "Item 1A — Risk Factors" in our Form 10-K for the year ended December 31, 2019 and from time to time in our other reports filed with the SEC, including in this Form 10-Q.

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

Overview and Recent Developments

We are a biopharmaceutical company dedicated to transforming iron deficiency and iron deficiency anemia and improving outcomes for patients across the globe, with an initial focus on ESKD. We are also a manufacturer of hemodialysis concentrates for dialysis providers and distributors in the United States and abroad. We supply the domestic market with dialysis concentrates and we also supply dialysis concentrates to distributors serving a number of foreign countries, primarily in the Americas and the Pacific Rim. Substantially, all of our sales have been concentrate products and ancillary items, though we initiated commercial sales of our proprietary therapeutic, Triferic Dialysate, during the second quarter of 2019.

We are focused on developing our proprietary ferric pyrophosphate ("FPC") therapeutic platform, and the first product developed from this platform is Triferic, the first-FDA approved product for the replacement of iron and maintenance of hemoglobin in adult hemodialysis patients. Our mission is to develop and commercialize the FPC platform to transform the treatment of iron deficiency and iron deficiency anemia in a wide variety of disease states across the globe while improving patients' lives. Accordingly, as an initial step, we are building the foundation to become a leading medical and commercial organization in the field of dialysis.

Triferic

Triferic is the Company's first proprietary iron therapy from the FPC therapeutic platform that replaces iron and maintains hemoglobin in dialysis patients without increasing iron stores. Triferic Dialysate was the first FDA approved product indicated to replace iron and maintain hemoglobin concentration in adult HDD-CKD hemodialysis patients. On March 27, 2020, the FDA approved Triferic AVNU, a novel intravenous formulation of Triferic that would be used for the same indication. Descriptions of Triferic Dialysate and Triferic AVNU are set forth below.

Triferic Dialysate

Triferic Dialysate, our dialysate formulation of Triferic, received FDA approval in 2015 and remains the first FDA-approved therapy indicated to replace iron and maintain hemoglobin in adult hemodialysis patients. Triferic Dialysate received a reimbursement J-code on January 1, 2016 from the Centers for Medicare & Medicaid Services (the "CMS"), providing that Triferic Dialysate would be reimbursed for administration to dialysis patients within the existing fixed-price “bundle” of payments that CMS provides to dialysis providers. On April 26, 2019, pursuant to a request we submitted earlier in 2019, we were notified of a preliminary recommendation by CMS to grant our powder packet formulation of Triferic Dialysate a separate J-Code, which became effective on July 1, 2019.

In June 2018, the Company determined, based on feedback provided from CMMI, that Triferic Dialysate was unlikely to obtain add-on reimbursement in the near term. As a result, the Company changed its commercialization strategy to plan for the commercial launch of Triferic Dialysate with reimbursement within the bundle of payments to dialysis providers, while continuing to develop Triferic AVNU (discussed below). We commercially launched Triferic Dialysate in May 2019.

Triferic AVNU (formerly I.V. Triferic)

We are also developing Triferic AVNU, an intravenous injection formulation of Triferic, for use by hemodialysis clinics in the United States as well as international markets. On March 27, 2020, we received FDA approval for Triferic AVNU, and we intend to initiate a sample evaluation program for Triferic AVNU during the third quarter of 2020 with commercialization expected to follow in the fourth quarter of 2020. Triferic AVNU will be reimbursed within the existing fixed-price bundle of payments that CMS provides to dialysis providers.

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

Dialysis Concentrates

We manufacture, sell, deliver and distribute hemodialysis concentrates, along with a line of ancillary dialysis products abroad. We use Baxter as our exclusive marketer and distributor in the United States and in select foreign markets. Dialysate concentrates accounted for approximately 96% of our revenues for the year ended December 31, 2019, with ancillary products and Triferic accounting for most of the remainder. We receive a pre-defined gross profit margin on our concentrate products sold pursuant to the Baxter Agreement, subject to an annual true-up of costs.

Calcitriol (Active Vitamin D) Injection

Calcitriol, an active Vitamin D injection for the management of hypocalcemia in patients undergoing chronic hemodialysis, is FDA approved under an Abbreviated New Drug Application ("ANDA"). To date, we have not commercially launched Calcitriol. Following a strategic review of this product, including pricing, commercial distribution and marketing, manufacturing efficiencies and capacity (including potential capital investment), we have determined commercialization of Calcitriol in the United States would not be viable at this time. The decision was based, in part, on the fact that prevailing market prices for similar Vitamin D products are lower than our cost to produce Calcitriol on a dose-equivalent basis, and as a result, it would be difficult for us to market Calcitriol profitably. As a result of this decision, we recorded an inventory reserve reflecting the remainder of our Calcitriol inventory. As of June 30, 2020, this reserve totaled $0.7 million. We are in the process of disposing of all inventory and in March 2020, we notified the FDA of our intention to withdraw the ANDA. On May 4, 2020, the ANDA was withdrawn.

Clinical Development

Although Triferic is approved for commercial sale in the United States, it is not approved for sale in other major markets globally. We have received regulatory guidance from the European Medicines Agency ("EMA") regarding the clinical studies that are needed to file for approval of Triferic AVNU in Europe. At the present time, we do not intend to commence these clinical studies, absent finding a development partner in Europe or raising additional capital. In conjunction with our licensee in China, Wanbang Biopharmaceutical, Co., Ltd. ("Wanbang"), we completed two clinical pharmacology studies in China during 2019. We expect Wanbang to initiate an additional clinical study during 2020 that is required to support a submission for regulatory approval

in China. In addition, pursuant to the licensing agreement with Sun Pharmaceutical Industries Ltd. ("Sun Pharma"), our licensee in India, meetings between Sun Pharma and the regulatory authorities in India have been initiated. Sun Pharma continues to follow up with the Indian regulatory authorities to determine the requirements for approval of Triferic in India. See "Item 1A - Risk Factors" below for a discussion of the potential impact of COVID-19 on such clinical studies.

As a post-approval requirement under the Pediatric Research Equity Act, we are required to conduct a further clinical study of the effectiveness of Triferic in a pediatric patient population. We have reached agreement with the FDA and EMA on the design of this study. We have engaged a contract research organization and are in process of selecting sites in the United States and selected EU countries. We expect to initiate enrollment in the study during the third quarter of 2020. We expect that the data from this study could be used as part of the overall clinical data package to support approval by the EMA, if and when we are able to complete the other clinical trials needed to support making such a filing. See "Item 1A - Risk Factors" below for a discussion of the potential impact of COVID-19 on such clinical studies.

Additionally, we plan to leverage our development and regulatory experience with Triferic and believe that our FPC technology has the potential to be developed for use in other indications, in which iron replacement is required. In addition, we are assessing potential investments to evaluate other product presentations of Triferic within ESKD.

Results of Operations for the three months ended June 30, 2020 and 2019

The following table summarizes our operating results for the periods presented below (dollars in thousands):

	For the Three Months Ended June 30,				
	2020	**% of Revenue**	**2019**	**% of Revenue**	**% Change**
Net Sales	**$ 15,896**		**$ 14,846**		**7.1 %**
Cost of Sales	15,015	94.5 %	14,113	95.1 %	6.4
Gross Profit	881	5.5	733	4.9	20.1
Selling and Marketing	1,997	12.6	2,219	14.9	(10.0)
General and Administrative	2,871	18.1	5,497	37.0	(47.8)
Settlement Expense, net of Reimbursement	—	—	430	2.9	—
Research and Product Development	1,616	10.2	2,958	19.9	(45.4)
Operating Loss	**$ (5,603)**	**(35.3)%**	**$ (10,371)**	**(69.9)%**	**(46.0)%**

Net Sales

During the three months ended June 30, 2020, our net sales were $15.9 million compared to sales of $14.8 million during the three months ended June 30, 2019. The increase of $1.1 million was primarily due to increased sales in our dialysis concentrates products. Triferic Dialysate net sales for the three months ended June 30, 2020 included approximately $0.2 million of Triferic Dialysate product sales to United States customers. Triferic was launched in Q2 2019 via the sample evaluation program and there were nominal revenues for the same period in 2019.

Gross Profit

Cost of sales during the three months ended June 30, 2020 was $15.0 million, resulting in gross profit of $0.9 million during the three months ended June 30, 2020, compared to cost of sales of a $14.1 million and a gross profit of $0.7 million during the three months ended June 30, 2019. Gross profit increased by $0.2 million in the second quarter of 2020 compared to the second quarter of 2019, due primarily to the increase in sales of $1.0 million; offset by an increase in labor and material costs $0.8 million to address requirements to support demand arising from the ongoing COVID-19 pandemic. Gross profits are primarily related to our concentrates business at this time. The Company anticipates that potential future sales of Triferic will impact the mix on our future gross profits.

Selling and Marketing Expense

Selling and marketing expenses were $2.0 million during the three months ended June 30, 2020, compared with $2.2 million during the three months ended June 30, 2019. The decrease of $0.2 million is primarily due to a decrease in marketing costs associated with the initial investment in a specialty commercial team and marketing programs to support the launch of Triferic in Q2 2019.

General and Administrative Expense

General and administrative expenses were $2.9 million during the three months ended June 30, 2020, compared with $5.5 million during the three months ended June 30, 2019. The decrease of $2.6 million is due primarily to a decrease in stock compensation of $2.0 million, relating to a decrease in incentive compensation from forfeited equity awards associated with the departure of our former President and Chief Executive Officer in April 2020; a decrease in legal expense of $0.7 million, relating to previous litigation that has since been resolved; partially offset by an increase of $1.2 million for severance pay related to the same former President and Chief Executive Officer.

Research and Product Development Expense

Research and product development expenses were $1.6 million for the three months ended June 30, 2020, compared with $3.0 million during the three months ended June 30, 2019. The decrease of $1.4 million was due primarily to the payment for the Triferic AVNU NDA application fee of $1.3 million in Q2 2019. The Company is continuing to invest in its medical and scientific programs to support the global launch of Triferic and the advancement of our FPC technology platform.

Other Income (Expense)

Other income for the three months ended June 30, 2020 was $68,815, consisting of interest income of $66,750 and $2,065 of realized gains on investments. Other income for the three months ended June 30, 2019 was $78,611, consisting of $74,476 of interest income and $4,135 of realized gains on investments. Other expense for the three months ended June 30, 2020 was $1.4 million, consisting of interest expense of $0.5 million related to our debt facility (see Note 15 for more information on our debt facility) and warrant modification expense of $0.8 million. No interest expense was recorded for the three months ended June 30, 2019.

Results of Operations for the six months ended June 30, 2020 and 2019

The following table summarizes our operating results for the periods presented below (dollars in thousands):

	For the Six Months Ended June 30,				
	2020	**% of Revenue**	**2019**	**% of Revenue**	**% Change**
Net Sales	**$ 31,753**		**$ 30,405**		**4.4 %**
Cost of Sales	29,759	93.7 %	28,662	94.3 %	3.8
Gross Profit	1,994	6.3	1,744	5.7	14.4
Selling and Marketing	4,069	12.8	5,321	17.5	(23.5)
General and Administrative	8,144	25.6	11,717	38.5	(30.5)
Settlement Expense, net of Reimbursement	—	—	430	1.4	(100.0)
Research and Product Development	3,438	10.8	3,456	11.4	(0.5)
Operating Loss	**$ (13,657)**	**(43.0)%**	**$ (19,181)**	**(63.1)%**	**(28.8)%**

Net Sales

During the six months ended June 30, 2020, our net sales were $31.8 million compared to sales of $30.4 million during the six months ended June 30, 2019. The increase of $1.4 million was primarily due to higher domestic dialysis concentrate sales of $1.0 million and an increase in Triferic Dialysate sales of approximately $0.4 million compared to the six months ended June 30, 2019. Triferic was launched in the second quarter of 2019 via the sample evaluation program and there were nominal revenues for the same period in 2019.

Gross Profit (Loss)

Cost of sales during the six months ended June 30, 2020 was $29.8 million, resulting in gross profit of $2.0 million during the six months ended June 30, 2020, compared to cost of sales of $28.7 million and a gross profit of $1.7 million during the six months ended June 30, 2019. Gross profit increased by $0.3 million during the six months ended June 30, 2020 compared to the six months ended June 30, 2019. The increase was due primarily to a gross margin increase of $0.3 million in our Triferic Dialysate product in 2020. In comparison, the launch and sales of Triferic Dialysate occurred in the second quarter of 2019 and had no to minimal impact during the six months ended June 30, 2019. Gross profits are primarily related to our concentrates business at this time. The Company anticipates that potential future sales of Triferic will impact the mix on our future gross profits.

Selling and Marketing Expense

Selling and marketing expenses were $4.1 million during the six months ended June 30, 2020, compared with $5.3 million during the six months ended June 30, 2019. The decrease of $1.2 million is due primarily to the decrease in marketing costs of $2.0 million, partially offset by an increase in costs associated with hiring, training and educating new employees of $0.8 million. The fluctuation in these costs are mainly due to the timing of the Triferic Dialysate launch in the second quarter of 2019. We expect those costs to level off quarter over quarter going forward.

General and Administrative Expense

General and administrative expenses were $8.1 million during the six months ended June 30, 2020, compared with $11.7 million during the six months ended June 30, 2019. The $3.6 million decrease was driven primarily by decreases to stock compensation, legal, recruiting and consulting fees, partially offset by an increase in labor costs. The increase in labor costs and decrease in stock compensation primarily relate to the resignation of our former President and Chief Executive Officer in April 2020.

Research and Product Development Expense

Research and product development expenses was $3.4 million for both the six months ended June 30, 2020 and 2019. Research and development expenses for the six months ended June 30, 2020 included clinical trials and other product development expenses of $1.2 million for Triferic, compared to $0.7 million during the six months ended June 30, 2019. The Company is continuing to invest in its medical and scientific programs to support the global launch of Triferic and the advancement of our FPC technology platform.

Settlement Expense, net of Reimbursement

Settlement expense was nil for the six months ended June 30, 2020, compared to $0.4 million in for the six months ended June 30, 2019. Settlement expense for the six months ended June 30, 2019 reflected the terms of the confidential settlement agreement and mutual release entered into in August 2018 relating to the Company’s former Chief Executive Officer, Robert Chioini, former Chief Financial Officer, Thomas Klema, and a former and then current director.

Other Income (Expense)

Other income for the six months ended June 30, 2020 was $241,821, consisting of interest income of $237,827 and $3,994 of realized gains on investments. Other income for the six months ended June 30, 2019 was $210,025, consisting of $192,002 of interest income and $18,023 of realized gains on investments. Other expense for the six months ended June 30, 2020 was $1.5 million, consisting of warrant modification expense of $0.8 million and interest expense of $0.6 million related to our debt facility (see Note 15 for more information on our debt facility). No interest expense was recorded for the six months ended June 30, 2019.

Liquidity and Capital Resources

As of June 30, 2020, we had approximately $40.0 million of cash, cash equivalents and investments available-for-sale, and working capital of $40.0 million. Net cash used in operating activities for the six months ended June 30, 2020 was approximately $16.2 million.

On March 22, 2019, the Company entered into a sales agreement with Cantor Fitzgerald & Co. (the “Agent”), pursuant to which the Company may offer and sell from time to time shares of the Company’s common stock through the Agent up to $40.0 million. As of December 31, 2019, the Company sold 1,840,443 shares of its common stock pursuant to the Sales Agreement for gross proceeds of approximately $5.4 million, at a weighted average selling price of approximately $2.92. The Company paid approximately $0.3 million in commissions and offering fees related to the sale of the common stock.

During the six months ended June 30, 2020, the Company sold 987,716 of shares of its common stock pursuant to the Sales Agreement with the Agent for proceeds of $2.0 million, net of issuance costs. As of June 30, 2020, approximately $32.6 million remains available for sale under this facility.

On February 4, 2020, the Company entered into an underwriting agreement with Cantor Fitzgerald & Co., as underwriter, pursuant to which the Company agreed to issue and sell up to 3,670,212 shares of its common stock, which included 478,723 shares optional shares that may be sold pursuant to an over-allotment option granted to the underwriters. On February 6, 2020, the Company closed the sale of 3,191,489 shares of its common stock at the public offering price of $2.22 per share (the “Offering”). On February 19, 2020, the underwriter exercised its over-allotment option to purchase an additional 478,723 shares at a price of $2.22 per share, which closed on February 21, 2020. The Company raised a total of $8.0 million, net of issuance costs of $0.1 million, relating to the sale of the common stock in the Offering. The Offering was made pursuant to the Company’s effective Registration Statement on Form S-3 (File No. 333-227363), which was previously filed with the SEC.

On March 16, 2020, Rockwell Medical, Inc. and Rockwell Transportation, Inc., as Borrowers, entered into a Loan and Security Agreement (the "Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP (“Innovatus”), as collateral agent and the lenders party thereto, pursuant to which Innovatus, as a lender, agreed to make certain term loans to the Company in the aggregate principal amount of up to $35.0 million (the “Term Loans”). Funding of the first $22.5 million tranche was completed on March 16, 2020. The Company will be eligible to draw on a second tranche of $5.0 million upon achievement of certain milestones, including the FDA approval of the Company’s New Drug Application for Triferic AVNU. The Company will be eligible to draw on a third tranche of $7.5 million upon the achievement of certain additional milestones, including the achievement of certain Triferic sales thresholds. Net draw down proceeds were $21.2 million with closing costs of $1.3 million.

The Company is entitled to make interest-only payments for thirty months, or up to thirty-six months if certain conditions are met. The Term Loans will mature on March 16, 2025 and will bear interest at the greater of (i) Prime Rate (as defined in the Loan Agreement) and (ii) 4.75%, plus 4.00%, with an initial interest rate of 8.75% per annum. The Company has the option, under certain circumstances, to add 1.00% of such interest rate amount to the then outstanding principal balance in lieu of paying such amount in cash. For the six months ended June 30, 2020 and 2019, interest expense amounted to $0.6 million.

The Loan Agreement is secured by all assets of the Company and Rockwell Transportation, Inc. Proceeds will be used for working capital purposes. The Loan Agreement contains customary representations and warranties and covenants, subject to customary carve outs, and includes financial covenants related to liquidity and trailing twelve months sales of Triferic, with the latter beginning with the period ending December 31, 2020, or September 30, 2020 if the Company draws the second tranche of $5.0 million. As of June 30, 2020, we were in compliance with all the reporting and financial covenants. However, if the Company is unable to maintain compliance with the reporting and financial covenants in the future, the Company could experience an event of default under the Loan Agreement, which would negatively impact the Company’s liquidity. For more information, see the risk factor entitled “Our Loan Agreement with Innovatus contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay the outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation. The occurrence of any of these events could cause a significant adverse impact on our business, prospects and share price.” in “Item 1A-Risk Factors.”

Based on the capital raise and debt financing noted above, management believes the Company currently has sufficient funds to meet its operating requirements for at least the next twelve months from the date of the filing of this report.

The Company will require additional capital to sustain its operations and make the investments it needs to execute upon its longer-term business plan, including the commercial launch and medical education programs of Triferic Dialysate and Triferic AVNU, and the further development of our FPC pipeline programs. If the Company is unable to generate sufficient revenue from its existing long-term business plan, the Company will need to obtain additional equity or debt financing. If the Company attempts to obtain additional debt or equity financing, the Company cannot assume that such financing will be available on favorable terms, if at all.

General

The actual amount of cash that we will need to execute our business strategy is subject to many factors, including, but not limited to, the expenses and revenue associated with the commercial launch of Triferic Dialysate and Triferic AVNU; the timing and magnitude of cash received from drug product sales; and the timing and expenditures associated with the development of Triferic for international markets; the timing and expenditures associated with the development of further innovative administration techniques of Triferic for dialysis patients; the timing and expenditures associated with the development of our FPC technology for patients with iron-deficiency anemia in other disease states; and the costs associated with ongoing litigation and investigatory matters.

We may elect to raise capital in the future through one or more of the following: (i) equity and debt raises through the equity and capital markets, though there can be no assurance that we will be able to secure additional capital or funding on acceptable terms, of if at all; and (ii) strategic transactions, including potential alliances and collaborations focused on markets outside the U.S., as well as potential combinations (including by merger or acquisition) or other corporate transactions.

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

Cash Used in Operating Activities

Net cash used in operating activities was $16.2 million for the six months ended June 30, 2020. The net loss for this period was lower than net cash used in operating activities by $1.3 million, which was primarily attributable to non-cash expenses of $1.6 million, consisting primarily of $0.8 million of warrant modification expense, $0.7 million of amortization of the right to use assets, $0.4 million of depreciation and amortization, ($0.5) million of stock-based compensation and a ($2.9) million net change in assets and liabilities.

Net cash used in operating activities was $15.8 million for the six months ended June 30, 2019. The net loss for this period was higher than net cash used in operating activities by $3.2 million, which was primarily attributable to non-cash expenses of $4.5 million, consisting of $3.0 million of stock-based compensation, $1.0 million of amortization of the right to use assets, $0.4 million of depreciation and amortization, and a ($1.4) million net change in assets and liabilities.

Cash Provided by (Used In) Investing Activities

Net cash provided by investing activities was $0.7 million during the six months ended June 30, 2020. The net cash provided was primarily due to the sales of our available-for-sale investments of $17.5 million, offset by $16.5 million used for the purchase of investments available-for-sale and $0.3 million for the purchase of equipment.

Net used in investing activities was $3.8 million during the six months ended June 30, 2019. The cash used was primarily due to the purchase of our available-for-sale investments of $21.8 million, offset by $18.8 million provided by the sale of investments

available-for-sale, $0.5 million for the purchase of research and development licenses acquired from a related party and $0.3 million for the purchase of equipment.

Cash Provided by Financing Activities

Net cash provided by financing activities was $30.4 million during the six months ended June 30, 2020. The net cash provided was primarily due to net proceeds of $21.2 million related to the Loan Agreement and $8.0 million and $2.0 million from the sale of our common stock, related to our public offering and our at-the market offering, respectively.

Net cash provided by financing activities was $18.3 million during the six months ended June 30, 2019. The net cash provided was primarily due to net proceeds of $16.1 million and $2.1 million from the sale of our common stock, related to our public offering and our at-the market offering, respectively.

COVID-19 Impact

The COVID-19 pandemic and resulting global disruptions have adversely affected our business and operations, including, but not limited to, our sales and marketing efforts and our research and development activities, and the operations of third parties upon whom we rely. As noted above, we intend to initiate a sample evaluation program for Triferic AVNU during the third quarter of 2020 in order to prepare for a commercial launch. Quarantines, shelter-in-place, executive and similar government orders may negatively impact our sales and marketing activities, particularly if our sales representatives are unable to interact with current and potential customers to the same extent as before onset of the COVID-19 pandemic. Depending on the severity of the impact on our sales and marketing efforts, the timing of our commercial launch of Triferic AVNU could be adjusted into the first quarter of 2021.

The COVID-19 pandemic and resulting global disruptions have caused significant volatility in financial and credit markets. We have utilized a range of financing methods to fund our operations in the past; however, current conditions in the financial and credit markets may limit the availability of funding or increase the cost of funding. Due to the rapidly evolving nature of the global situation, it is not possible to predict the extent to which these conditions could adversely affect our liquidity and capital resources in the future.

Critical Accounting Policies and Significant Judgments and Estimates

Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2019. Our critical accounting policies and significant estimates have not changed from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019, except for those subjects mentioned in the section of the notes to the condensed consolidated financial statements titled Adoption of Recent Accounting Pronouncements.

Recently issued and adopted accounting pronouncements:

We have evaluated all recently issued accounting pronouncements and believe such pronouncements do not have a material effect our financial statements. See Note 3 of the condensed consolidated financial statements at June 30, 2020.

Item 3. **Quantitative and Qualitative Disclosures about Market Risk**

Per §229.305 of Regulation S-K, the Company, designated a Smaller Reporting Company as defined in §229.10(f)(1) of Regulation S-K, is not required to provide the disclosure required by this Item.

Item 4. Controls and Procedures

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

Under the supervision of and with the participation of our management, including the Company's Chief Executive Officer and Controller and Principal Accounting Officer, we evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2020. Based upon that evaluation, our Chief Executive Officer and Controller and Principal Accounting Officer concluded that our disclosure controls and procedures were not effective as of June 30, 2020.

The material weaknesses related to change management and third-party management controls in our Information Technology General Controls ("ITGC") which had a pervasive impact on other ITGC dependent business activity level controls in our internal controls over financial reporting, described in our Annual Report on Form 10-K for the year ended December 31, 2019, has been remediated. The Company is still evaluating the design, implementation and operating effectiveness of ITGC user access security, segregation of duties as it relates to user access controls and the pervasive effect on other ITGC dependent business activity level internal control cycles. Notwithstanding the material weaknesses, the Company's management, including the Chief Executive Officer and Controller and Principal Accounting Officer, have concluded that the condensed consolidated financial statements as of June 30, 2020, are fairly stated, in all material respects, in accordance with generally accepted accounting principles in the United States for each of the periods presented herein.

In connection with the user access security, segregation of duties as it relates to user access controls and the pervasive effect of the ITGC material weaknesses, management has taken a number of steps with the intention of remediating the above control deficiencies. We continue to implement enhanced procedures and controls to remediate our material weaknesses in internal control over financial reporting.

Changes in Internal Control over Financial Reporting

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

We continue to make further improvements to our internal controls over financial reporting, in addition to the improvements developed in 2019. During the quarter ended June 30, 2020, we implemented the following:

- Remediated the ITGC control deficiencies in connection with change management and third-party management controls.
- Implemented and started our 2020 audit program, utilizing a National Audit firm as our internal audit partner, which includes in-house remediation testing of our user access security, segregation of duties as it relates to user access controls and other ITGC dependent business activity level internal control cycles.
- Enhanced evidentiary review and documentation of key ITGC controls and implemented new programs and policies to provide improved control over change management and third-party management controls to the ERP system.

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

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

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

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

Item 1A. Risk Factors

Other than those set forth below, there have been no material changes to the risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2019 under “Item 1A — Risk Factors”.

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

We have limited capital resources, a cumulative deficit of approximately $321.4 million since inception and expect to incur further losses for the foreseeable future. As of June 30, 2020, we had approximately $40.0 million of cash, cash equivalents and investments available-for-sale, and working capital of $40.0 million. Net cash used in operating activities for the six months ended June 30, 2020 was approximately $16.2 million.

On March 22, 2019, the Company entered into a sales agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co. (the “Agent”), pursuant to which the Company may offer and sell from time to time up to $40.0 million of shares of the Company’s common stock through the Agent. As of December 31, 2019, the Company sold 1,840,443 shares of its common stock pursuant to the Sales Agreement for gross proceeds of $5.4 million, at a weighted average selling price of approximately $2.92. The Company paid $0.3 million in commissions and offering fees related to the sales. During the six months ended June 30, 2020, the Company sold 987,716 of shares of its common stock pursuant to the Sales Agreement with the Agent for proceeds of $2.0 million, net of issuance costs. As of June 30, 2020, approximately $32.6 million remains available for sale under this facility.

On February 4, 2020, the Company entered into an underwriting agreement with Cantor Fitzgerald & Co., as underwriter, pursuant to which the Company agreed to issue and sell an aggregate of up to 3,670,212 shares of its common stock, which included 478,723 optional shares that may be sold pursuant to an over-allotment option granted to the underwriters. On February 6, 2020, the Company closed the sale of 3,191,489 shares of its common stock at the public offering price of $2.22 per share (the “Offering”). On February 19, 2020, the underwriter exercised its over-allotment option to purchase an additional 478,723 shares at a price of $2.22 per share, which closed on February 21, 2020. The Company raised a total of $8.0 million, net of issuance costs of $0.1 million, relating to the sale of the common stock in the Offering.

On March 16, 2020, Rockwell Medical, Inc. and Rockwell Transportation, Inc., as Borrowers, entered into a Loan and Security Agreement (the "Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP, as collateral agent and the lenders party thereto, pursuant to which Innovatus, as a lender, agreed to make certain term loans to the Company in the aggregate principal amount of up to $35.0 million (the "Term Loans"). Funding of the first $22.5 million tranche was completed on March 16, 2020. The Company will be eligible to draw on a second tranche of $5.0 million upon achievement of certain milestones, including the FDA approval of the Company’s New Drug Application for Triferic AVNU. The Company will be eligible to draw on a third tranche of $7.5 million upon the achievement of certain additional milestones, including the achievement of certain Triferic sales thresholds. Net draw down proceeds were $21.2 million with closing costs of $1.3 million.

The Company is entitled to make interest-only payments for thirty months, or up to thirty-six months if certain conditions are met. The Term Loans will mature on March 16, 2025, and will bear interest at the greater of (i) Prime Rate (as defined in the Loan Agreement) and (ii) 4.75%, plus 4.00% with an initial interest rate of 8.75% per annum. The Company has the option, under certain circumstances, to add 1.00% of such interest rate amount to the then outstanding principal balance in lieu of paying such amount in cash. The Loan Agreement is secured by all assets of the Company and Rockwell Transportation, Inc. and contains customary representations and warranties and covenants, subject to customary carve outs, and includes financial covenants related to liquidity and trailing twelve months sales of Triferic, with the latter beginning with the period ending December 31, 2020, or September 30, 2020 if the Company draws the second tranche of $5.0 million.

Based on the equity offerings and the Loan Agreement described above, management believes the Company currently has sufficient funds to meet its operating requirements for at least the next twelve months from the date of the filing of this report.

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

Our near-term success depends substantially on the commercialization of Triferic Dialysate and Triferic AVNU. Although Triferic Dialysate and Triferic AVNU have been approved by the FDA, we may not be able to commercialize either product successfully.

Triferic Dialysate launched commercially in the United States in May 2019 and Triferic AVNU was approved by the FDA in March 2020; however, it is possible that either version of Triferic will not gain market acceptance and that we will not be successful in the commercialization of these products. We do not know whether we will be able to successfully implement our commercialization strategy for Triferic Dialysate and Triferic AVNU or whether our new business strategy will ultimately be successful.

Both formulations of Triferic will be reimbursed "within the bundle," which means that dialysis providers will not receive any additional amount of reimbursement from Medicare or Medicaid to compensate them for the cost of purchasing and administering Triferic. This reimbursement status may result in a slower rate of commercial adoption, as we must work to show dialysis providers that improved patient outcomes, the reduction of utilization in other therapies and the resulting savings offset the costs associated with Triferic. Additionally, Triferic competes against current anemia therapies (including intravenous iron and the ESA class of drugs) and possibly other future products. Additionally, it may be difficult to gain market acceptance from dialysis chains, anemia managers and nephrologists and such acceptance may be slower than expected, if at all.

Market acceptance will depend on a number of factors, such as demonstration of Triferic Dialysate's safety and efficacy, cost-effectiveness, and advantages over existing products. Other factors that may impact the commercial success and ultimate profitability of Triferic include:

- the rate of adoption of Triferic Dialysate and Triferic AVNU relative to the shelf life of the existing inventory that we have on hand and whether we can sell our existing inventory before it expires;
- our ability to manage inventory available for commercial sale;
- the effectiveness of our marketing, sales and distribution strategies and operations for development and commercialization;
- the impact of Triferic Dialysate and Triferic AVNU on established customer protocols, formularies and operational practices;
- The ability and willingness of dialysis centers to adopt their protocols and utilize the drugs in a manner consistent with state regulatory agencies.
- reimbursement of either formulation of Triferic by government and commercial payors;
- our ability to execute our marketing strategy without significant additional expenditures;
- our competitors' activities, including aggressive marketing and pricing practices and other tactics to retain their market share;

- our ability to successfully assert our patents against potential competitors who may seek to introduce generic versions of either formulation of Triferic;
- our ability to comply with ongoing regulatory requirements applicable to either formulation of Triferic and the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping applicable to Triferic;
- the impact of certain royalties related to our sale of either formulation of Triferic paid by us based on the profitability of either formulation of Triferic;
- our ability to avoid third party patent interference or patent infringement claims;
- our ability to maintain a continued acceptable safety profile of either formulation of Triferic;
- the discovery of previously unknown problems with either formulation of Triferic or with any third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements; and
- the ability to successfully manufacture enough commercial product and successfully complete our commercialization planning to enable a launch of Triferic AVNU in 2020.

An adverse development with respect to any of the foregoing may have a material adverse effect on our ability to manufacture and market either formulation of Triferic. We cannot assure you that we will be able to generate meaningful and sustained revenues through the sale of either formulation of Triferic. If we are not successful in commercializing either formulation of Triferic, or are significantly delayed in doing so, our entire investment in Triferic may be of no value, our inventory of finished product may expire or become obsolete (resulting in write-offs of such inventory), our licensing rights could be materially adversely affected and the price of our common stock could substantially decline. Even if we are successful in commercializing either formulation of Triferic, since the market is highly concentrated with two significant suppliers, our continued success may depend on adoption of Triferic Dialysate by the limited number of existing dialysis providers.

The ongoing COVID-19 pandemic may result in significant disruptions to our business operations, including the commercial launch of our Triferic products and our clinical trials, which could have a material adverse effect on our business.

Our business and its operations, including but not limited to our sales and marketing efforts and our research and development activities, could be adversely affected by health epidemics in regions where we have business operations, and such health epidemics could cause significant disruption in the operations of third parties upon whom we rely. In December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread to other countries, including the United States, and has been declared a pandemic by the World Health Organization. In response to public health directives and orders related to COVID-19, we have implemented work-from-home policies for substantially all employees, excluding our essential manufacturing and distribution employees. The effects of executive and similar government orders, shelter-in-place orders and our work-from-home policies may negatively impact our growth and productivity, disrupt our business, including our sales and marketing activities, and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place, executive and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases, may impact personnel at our manufacturing facilities and third-party manufacturing facilities in the United States, Europe and other countries, or the availability or cost of materials we use or require to conduct our business, including product development, which would disrupt our supply chain. If the COVID-19 pandemic were to negatively affect our manufacturing facilities, the costs related to such manufacturing may increase and the productivity of our facilities may decrease. Furthermore, some of our manufacturers and suppliers are in Europe and may be impacted by port closures and other restrictions resulting from the COVID-19 pandemic, which may disrupt our supply chain or limit our ability to obtain sufficient materials for our drug products.

We commercially launched Triferic Dialysate in the United States in May 2019 and we intend to initiate a sample evaluation program for Triferic AVNU during the third quarter of 2020 in order to prepare for a commercial launch. Quarantines, shelter-in-place, executive and similar government orders, or changes in prospective customer practices in response to the COVID-19 outbreak, may negatively impact our sales and marketing activities, particularly if our sales representatives are unable to interact with current and potential customers to the same extent as before onset of the COVID-19 pandemic. Depending on the severity of the impact on our sales and marketing efforts, the commercial launch of Triferic AVNU could be delayed.

In addition, we may face decreased demand if our dialysis patients are unable to travel to dialysis clinics or if dialysis clinics are unable to make additional protocol changes that are required for Triferic. In order to ensure the safety of patients and staff at the dialysis clinics that use our Triferic products, we expect the dialysis clinics will implement a number of changes to their safety procedures. In addition, the dialysis clinics may face challenges related to decreased staffing, if staff members are affected by COVID-19. Changes to safety procedures and/or staffing issues may impede the clinics' ability to make additional protocol changes that are required for Triferic.

In addition, our clinical trials and our partners' clinical trials have been and may continue to be affected by the COVID-19 pandemic. For example, Wanbang is our commercialization partner for both Triferic Dialysate and Triferic AVNU in China and we currently expect Wanbang to initiate additional clinical studies during 2020 that are necessary to support a submission for regulatory approval in China. Such clinical studies may be delayed to later in 2020 than previously expected. In addition, meetings between Sun Pharma and the regulatory authorities in India related to our Triferic products have been postponed due to government restrictions in India. If COVID-19 continues to spread in the United States and elsewhere, we or our partners may experience additional disruptions that could severely impact our business and clinical trials, including:

- delays in receiving authorization from local regulatory authorities to initiate our planned clinical trials;
- delays in receiving legalization documents from foreign embassies, which are required to allow our partners to direct activities on behalf of the Company in local markets;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring and data entry and verification, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the completeness and integrity of clinical trial data and, as a result, determine the outcomes of the trial;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- risk that participants enrolled in our clinical trials will not be able to travel to our clinical trial sites as a result of quarantines or other restrictions resulting from COVID-19;
- risk that participants enrolled in our clinical trials will not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services;

- interruptions or delays in preclinical studies due to restricted or limited operations at our research and development laboratory facilities;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- refusal of the FDA to accept data from clinical trials in affected geographies; and
- interruption or delays to our clinical activities.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by COVID-19, and the duration of such impact, may be difficult to assess or predict, the widespread pandemic has resulted in significant disruption of global financial markets, which could reduce our ability to access capital and negatively affect our future liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 and related government orders and restrictions could materially affect our business and the value of our common stock.

The COVID-19 pandemic continues to evolve rapidly. The ultimate impact of the COVID-19 pandemic or a similar public health emergency is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems, or the global economy as a whole. However, any one or a combination of these events could have an adverse effect on the operation of and results from our clinical trials and on our other business operations, which could negatively impact our business, operating results and financial condition.

The risks related to the ongoing COVID-19 pandemic may amplify the other risk factors described in this “Item 1A.-Risk Factors” and in the risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2019.

Our Loan Agreement with Innovatus contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay the outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation. The occurrence of any of these events could cause a significant adverse impact on our business, prospects and share price.

Pursuant to the Loan Agreement, we have pledged substantially all of our assets and the assets of our subsidiary, Rockwell Transportation, Inc., and have agreed that we may not sell or assign rights to our patents and other intellectual property without the prior consent of Innovatus. Additionally, the Loan Agreement contains affirmative, including financial covenants related to liquidity and trailing twelve months sales of Triferic, and negative covenants that, among other things, restrict our ability to:

- incur additional indebtedness;
- grant liens;
- make distributions, including dividends;
- enter into a merger or consolidation;
- alter the business of the Company; or
- sell all or a portion of the Company’s property, business or assets.

These terms of the Loan Agreement could prevent us from taking certain actions without the consent of our lenders, which may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our stockholders, placing us at a competitive disadvantage compared to our competitors who have less leverage and who therefore may be able to take advantage of opportunities that our leverage prevents us from exploiting. Our ability to comply with these covenants may be adversely affected by events beyond our control, and we cannot assure you that we can maintain compliance

with these covenants, which may result in an event of default. These covenants could limit our ability to make needed capital expenditures or otherwise conduct necessary or desirable business activities.

The Loan Agreement also includes customary events of default, including, among other things, a change of control or a failure to comply with certain of the covenants in the Loan Agreement. Upon the occurrence and continuation of an event of default, all amounts due under the Loan Agreement become (in the case of a bankruptcy event), or may become (in the case of all other events of default and at the option of Innovatus), immediately due and payable.

If an event of default under the Loan Agreement should occur, we could be required to immediately repay the outstanding indebtedness. If we are unable to repay this debt, the lenders would be able to foreclose on the secured collateral, including our cash accounts, and take other remedies permitted under the Loan Agreement. Even if we are able to repay the indebtedness on an event of default, the repayment of these sums may significantly reduce our working capital and impair our ability to operate as planned. The occurrence of any of these events could cause a significant adverse impact on our business and financial condition.

We do not anticipate paying dividends in the foreseeable future.

Since inception, we have not paid any cash dividends on our common stock and do not anticipate paying such dividends in the foreseeable future. In addition, the terms of our Loan Agreement with Innovatus restrict our ability to pay dividends to limited circumstances. As a result, investors in our common stock may only receive a return if the market price of our common stock increases.

The payment of dividends is within the discretion of our Board of Directors, subject to the restrictions in the Loan Agreement, and depends upon our earnings, capital requirements, financial condition and requirements, future prospects, restrictions in future financing agreements, business conditions and other factors deemed relevant by the Board. We intend to retain earnings and any cash resources to finance our operations. Therefore, it is highly unlikely we will pay cash dividends.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

EXHIBIT INDEX

Exhibit No.	Description
10.1#	Russell Ellison Employment Agreement, dated April 17, 2020 (filed with the SEC as Exhibit 10.1 to the Company's Form 8-K filed on April 20, 2020)
10.2#	Rockwell Medical, Inc. Amended and Restated 2018 Long Term Incentive plan (filed with the SEC as Exhibit 10.1 to the Company's Form 8-K filed on May 21, 2020)
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2*	Certification of Principal Accounting Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1#**	Certification pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(b) of the Securities Exchange Act of 1934
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase
101.DEF*	XBRL Taxonomy Extension Definition Database
101.LAB*	XBRL Taxonomy Extension Label Linkbase
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase
104*	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, formatted in Inline XBRL (included as Exhibit 101)

* Filed herewith

#** Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act.

# Indicates management contracts or compensatory plans or arrangements.

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 10, 2020

/s/ Russell Ellison

Russell Ellison
Chief Executive Officer (Principal Executive Officer)

Date: August 10, 2020

/s/ Paul E. McGarry

Paul E. McGarry
Controller and Principal Accounting Officer

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a)

I, Russell Ellison, certify that:

1. 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) 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 10, 2020

/s/ Russell Ellison
Russell Ellison
Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a)

I, Paul E. McGarry, 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 10, 2020

/s/ Paul E. McGarry
Paul E. McGarry
Controller and Principal Accounting Officer

EXHIBIT 32.1

CERTIFICATION 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, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Periodic Report"), each of the undersigned, in the capacities and on the dates indicated below, hereby certifies pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that based on my knowledge:

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

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

Date: August 10, 2020

/s/ Russell Ellison

Russell Ellison
Chief Executive Officer

Date: August 10, 2020

/s/ Paul E. McGarry

Paul E. McGarry
Controller and Principal Accounting Officer