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, 2021

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.)
30142 S. Wixom Road, Wixom, Michigan	**48393**
(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 13, 2021 was 93,888,881.

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
(Dollars in Thousands)

	June 30, 2021	December 31, 2020
	(Unaudited)	
ASSETS		
Cash and Cash Equivalents	$ 32,378	$ 48,682
Investments Available-for-Sale	8,574	9,997
Accounts Receivable, net	5,357	4,171
Inventory, net	4,677	3,913
Prepaid and Other Current Assets	1,413	2,706
Total Current Assets	**52,399**	**69,469**
Property and Equipment, net	2,529	2,642
Inventory, Non-Current	1,122	1,176
Right of Use Assets, net	6,085	2,911
Goodwill	921	921
Other Non-Current Assets	628	629
Total Assets	**$ 63,684**	**$ 77,748**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts Payable	$ 4,932	$ 4,155
Accrued Liabilities	3,993	5,013
Lease Liability - Current	1,674	1,167
Deferred License Revenue - Current	2,166	2,175
Term Loan - Net of Issuance Costs	21,133	—
Customer Deposits	140	152
Other Current Liability - Related Party	—	131
Total Current Liabilities	**34,038**	**12,793**
Lease Liability - Long-Term	4,506	1,821
Term Loan, Net of Issuance Costs	—	20,949
Deferred License Revenue - Long-Term	6,937	8,015
Total Liabilities	**45,481**	**43,578**
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, 2021 and December 31, 2020	—	—
Common Stock, $0.0001 par value; 170,000,000 shares authorized; 93,811,381 and 93,573,165 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	9	9
Additional Paid-in Capital	371,700	371,510
Accumulated Deficit	(353,558)	(337,406)
Accumulated Other Comprehensive Income	52	57
Total Stockholders' Equity	**18,203**	**34,170**
Total Liabilities and Stockholders' Equity	**$ 63,684**	**$ 77,748**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Dollars in Thousands, Except Per Share Amounts)

	Three Months Ended June 30, 2021	Three Months Ended June 30, 2020	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
Net Sales	$ 15,137	$ 15,896	$ 30,611	$ 31,753
Cost of Sales	15,399	15,015	30,471	29,759
Gross Profit	(262)	881	140	1,994
Research and Product Development	2,416	1,616	4,224	3,438
Selling and Marketing	1,468	1,997	3,319	4,069
General and Administrative	3,677	2,871	7,602	8,145
Operating Loss	(7,823)	(5,603)	(15,005)	(13,658)
Other (Expense) Income				
Realized (Loss) Gain on Investments	(1)	2	(1)	4
Warrant Modification Expense	—	(837)	—	(837)
Interest Expense	(583)	(521)	(1,164)	(623)
Interest Income	7	67	18	238
Total Other Expense	(577)	(1,289)	(1,147)	(1,218)
Net Loss	$ (8,400)	$ (6,892)	$ (16,152)	$ (14,876)
Basic and Diluted Net Loss per Share	$ (0.09)	$ (0.10)	$ (0.17)	$ (0.22)
Basic and Diluted Weighted Average Shares Outstanding	93,703,492	69,428,574	93,647,583	68,473,407

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Dollars in Thousands)

	Three Months Ended June 30, 2021	Three Months Ended June 30, 2020	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
Net Loss	**$ (8,400)**	**$ (6,892)**	**$ (16,152)**	**$ (14,876)**
Unrealized Loss on Available-for-Sale Debt Instrument Investments	(1)	(6)	(8)	(13)
Foreign Currency Translation Adjustments	—	1	3	7
Comprehensive Loss	**$ (8,401)**	**$ (6,897)**	**$ (16,157)**	**$ (14,882)**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(Dollars in Thousands)

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT				
Balance as of January 1, 2021	**93,573,165**	**$ 9**	**$ 371,510**	**$ (337,406)**	**$ 57**	**$ 34,170**
Net Loss	—	—	—	(7,752)	—	(7,752)
Unrealized Loss on Available-for-Sale Investments	—	—	—	—	(7)	(7)
Foreign Currency Translation Adjustments	—	—	—	—	3	3
Stock-based Compensation	26,354	—	(236)	—	—	(236)
Balance as of March 31, 2021	**93,599,519**	**$ 9**	**$ 371,274**	**$ (345,158)**	**$ 53**	**$ 26,178**
Net Loss	—	—	—	(8,400)	—	(8,400)
Unrealized Loss on Available-for-Sale Investments	—	—	—	—	(1)	(1)
Vesting of Restricted Stock Units Issued, net of taxes withheld	211,862	—	(7)	—	—	(7)
Stock-based Compensation expense	—	—	433	—	—	433
Balance as of June 30, 2021	**93,811,381**	**$ 9**	**$ 371,700**	**$ (353,558)**	**$ 52**	**$ 18,203**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(Dollars in Thousands)

	COMMON STOCK					
	SHARES	AMOUNT	ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME	TOTAL STOCKHOLDERS' EQUITY
Balance as of January 1, 2020	**65,378,890**	**$ 7**	**$ 326,777**	**$ (306,516)**	**$ 52**	**$ 20,320**
Net Loss	—	—	—	(7,984)	—	(7,984)
Unrealized Loss on Available-for-Sale Investments	—	—	—	—	(7)	(7)
Foreign Currency Translation Adjustments	—	—	—	—	6	6
Issuance of common stock, net of offering costs/Bought Deal	3,670,212	—	8,003	—	—	8,003
Issuance of Warrants related to Debt Financing	—	—	501	—	—	501
Stock-based Compensation	—	—	935	—	—	935
Balance as of March 31, 2020	**69,049,102**	**$ 7**	**$ 336,216**	**$ (314,500)**	**$ 51**	**$ 21,774**
Net Loss	—	—	—	(6,892)	—	(6,892)
Unrealized Loss on Available-for-Sale Investments	—	—	—	—	(6)	(6)
Foreign Currency Translation Adjustments	—	—	—	—	1	1
Issuance of common stock, net of offering costs/Public Offering	987,716	—	1,978	—	—	1,978
Vesting of Restricted Stock Units Issued, net of taxes withheld	120,104	—	(19)	—	—	(19)
Warrant Modification Expense	—	—	837	—	—	837
Stock-based Compensation	—	—	(1,461)	—	—	(1,461)
Balance as of June 30, 2020	**70,156,922**	**$ 7**	**$ 337,551**	**$ (321,392)**	**$ 46**	**$ 16,212**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Dollars in Thousands)

For the six months ended June 30, 2021 and 2020

	2021	2020
Cash Flows From Operating Activities:		
Net Loss	**$ (16,152)**	**$ (14,876)**
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	385	408
Stock-based Compensation	197	(526)
Warrant Modification Expense	—	837
Increase in Inventory Reserves	89	12
Amortization of Right of Use Asset	857	748
Amortization of Debt Financing Costs and Accretion of Debt Discount	184	108
Loss on Disposal of Assets	8	6
Realized Loss (Gain) on Sale of Investments Available-for-Sale	1	(4)
Foreign Currency Translation Adjustment	3	6
Changes in Assets and Liabilities:		
(Increase) Decrease in Accounts Receivable, net	(1,186)	637
Increase in Inventory	(799)	(1,302)
Decrease (Increase) in Prepaid and Other Assets	1,293	(608)
Increase in Accounts Payable	777	295
Decrease in Settlement Payable	—	(104)
Decrease in Lease Liability	(839)	(703)
Decrease in Other Liabilities	(1,163)	(96)
Decrease in Deferred License Revenue	(1,088)	(992)
Changes in Assets and Liabilities	(3,005)	(2,873)
Cash Used In Operating Activities	**(17,433)**	**(16,154)**
Cash Flows From Investing Activities:		
Purchase of Investments Available-for-Sale	(13,765)	(16,514)
Sale of Investments Available-for-Sale	15,181	17,497
Purchase of Equipment	(281)	(283)
Cash Provided By Investing Activities	**1,135**	**700**
Cash Flows From Financing Activities:		
Proceeds from Term Loan	—	22,500
Debt Issuance Costs	—	(1,343)
Payments on Short Term Note Payable	—	(763)
Proceeds from the Issuance of Common Stock / Public Offering	—	8,148
Offering Costs from the Issuance of Common Stock / Public Offering	—	(144)
Proceeds from the Issuance of Common Stock / At-the-Market Offering	—	2,034
Offering Costs from the Issuance of Common Stock / At-the-Market Offering	—	(56)
Repurchase of Common Stock to Pay Employee Withholding Taxes	(6)	(19)
Cash (Used In) Provided By Financing Activities	**(6)**	**30,357**
(Decrease) Increase in Cash and Cash Equivalents	(16,304)	14,903
Cash and Cash Equivalents at Beginning of Period	48,682	11,794
Cash and Cash Equivalents at End of Period	**$ 32,378**	**$ 26,697**
Supplemental Disclosure of Cash Flow Information:		
Cash Paid for Interest	$ 982	$ 410
Supplemental Disclosure of Noncash Investing and Financing Activities:		
Change in Unrealized Loss on Marketable Securities Available-for-Sale	$ (7)	$ (12)
Fair Value of Warrants issued related to Debt Financing	$ —	$ 501

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

1. Description of Business

Rockwell Medical, Inc. ("Rockwell Medical," "Rockwell" or the "Company") is a commercial-stage, biopharmaceutical company developing and commercializing our next-generation parenteral iron technology platform, ferric pyrophosphate citrate (“FPC”), which we believe has the potential to lead to transformative treatments for iron deficiency in multiple disease states, that we believe could reduce healthcare costs and improve patients’ lives. We are also one of the two major suppliers of life saving hemodialysis concentrate products to kidney dialysis clinics in the United States.

We have two novel, FDA approved therapies, Triferic and Triferic AVNU, which are the first two products developed from our FPC platform. We are marketing both products to kidney dialysis centers for their patients receiving dialysis. In 2021, we intend to advance our FPC platform strategy outside of dialysis by starting a Phase II trial for the treatment of iron deficiency anemia in patients outside of dialysis, who are receiving long-term and or chronic intravenous medications for various therapeutic needs in the home infusion setting. In our R&D pipeline, we are also exploring FPC’s impact in the treatment of hospitalized patients with acute heart failure, with the potential to begin another Phase 2 trial in these patients in 2022.

We are the second largest supplier of hemodialysis concentrates in the United States generating approximately $60 million in annual revenue. The Company's reputation for excellent service, quality, and reliability is based on over 25 years of service to kidney dialysis centers. Our approximately 300 dedicated employees, as well as a management team with experience in manufacturing, logistics, pharmaceutical development and commercialization gives us a solid foundation upon which to grow.

2. Liquidity and Capital Resources

Since inception, Rockwell has incurred significant net losses and has funded its operations primarily through revenue from commercial products, proceeds from the issuance of debt and equity securities and payments from partnerships. At June 30, 2021, Rockwell had an accumulated deficit of approximately $353.6 million and stockholders' equity of $18.2 million. As of June 30, 2021, Rockwell had approximately $41.0 million of cash, cash equivalents and investments available-for-sale, and working capital of $18.4 million. Net cash used in operating activities for the six months ended June 30, 2021 was approximately $17.4 million.

The Company is subject to certain covenants and cure provisions under its Loan Agreement with Innovatus. As of the date of this report, the Company is in compliance with all covenants. As a result of the ongoing COVID-19 pandemic and its effect on the Company's sales activities, among other factors, the Company may not be able to satisfy such covenants over the next 12 months. However, based on the foregoing, the Company has classified amounts payable under the Loan Agreement as a current liability. If and when the Company reaches an agreement with Innovatus to avoid an event of default, the amounts payable under the Loan Agreement will be reclassified. The financial statements for June 30, 2021, have been prepared with the assumption that the Company will be able to agree to an appropriate remedy during the applicable cure period for any future breaches of operating covenants. If the Company is unable to comply with the covenants under the Loan Agreement, it would pursue all available cure options in order to regain compliance (See Note 15 for further detail).

The Company expects it will require additional capital to sustain its operations and make the investments it needs to execute its strategic plan, including the commercialization of Triferic (dialysate) and Triferic AVNU in dialysis, generating additional data for Triferic in dialysis, developing FPC for iron deficiency anemia in patients undergoing home infusion and for progressing our pipeline development program of new indications for its FPC platform. If the Company is unable to generate sufficient revenue from sales of its commercial products and from partnerships, 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.

Based on the currently available working capital and managements assumption that the Company will be able to agree to an appropriate remedy, 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 COVID-19 pandemic and resulting domestic and global disruptions have adversely affected Rockwell's business and operations, including, but not limited to, our sales and marketing efforts, research and development activities, and the operations of third parties upon whom the Company relies. Quarantines, shelter-in-place, executive and similar government orders and the recent surge in infections domestically may continue to negatively impact Rockwell's sales and marketing activities, particularly if its sales representatives are unable to interact with current and potential customers to the same extent as before onset of the COVID-19 pandemic. The Company's international business development activities may also continue to be negatively impacted by COVID-19, especially with the recent surge in infections internationally, ongoing international travel restrictions and quarantines or shelter-in-place orders.

The COVID-19 pandemic, the domestic and international surge in infections and resulting global disruptions have caused significant volatility in financial and credit markets. Rockwell has utilized a range of financing methods to fund its operations in the past; however, current conditions in the financial and credit markets may limit the availability of funding, refinancing 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 the Company's liquidity and capital resources in the future.

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

The accompanying condensed consolidated financial statements have been prepared in accordance with the accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim financial information and pursuant to the instructions to Form 10-Q and 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, 2021, condensed consolidated statements of operations for the three and six months ended June 30, 2021 and 2020, condensed consolidated statements of comprehensive loss for the three and six months ended June 30, 2021 and 2020, condensed consolidated statement of changes in stockholders' equity for the three and six months ended June 30, 2021 and 2020, and condensed consolidated statements of cash flows for the six months ended June 30, 2021 and 2020 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, 2021 are not necessarily indicative of results to be expected for the year ending December 31, 2021 or for any future interim period. The condensed consolidated balance sheet at December 31, 2020 has been derived from audited financial statements, however, it does not include all of the information and notes required by U.S. GAAP for complete financial statements. The accompanying condensed consolidated financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2020 and notes thereto included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2020 as filed with the SEC on March 31, 2021. 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.

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,	
	2021	**2020**
Options to purchase common stock	6,070,801	6,225,562
Unvested restricted stock awards	78,300	146,800
Unvested restricted stock units	342,604	503,395
Warrants to purchase common stock	26,426,863	3,248,054
Total	32,918,568	10,123,811

Adoption of Recent Accounting Pronouncements

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

In April 2021, the Financial Accounting Standards Board ("FASB") recently issued Accounting Standards Update ("ASU") 2021-04 to codify the final consensus reached by the Emerging Issues Task Force (EITF) on how an issuer should account for modifications made to equity-classified written call options (hereafter referred to as a warrant to purchase the issuer's common stock). The guidance in the ASU requires the issuer to treat a modification of an equity-classified warrant that does not cause the warrant to become liability-classified as an exchange of the original warrant for a new warrant. This guidance applies whether the modification is structured as an amendment to the terms and conditions of the warrant or as termination of the original warrant and issuance of a new warrant. The Company is evaluating the impact of this guidance on its condensed consolidated financial statements.

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 five distribution and license agreements that have been deferred as a contract liability. The amounts received from Wanbang Biopharmaceuticals Co., Ltd. (“Wanbang”), Sun Pharmaceutical Industries Ltd. ("Sun Pharma"), Jeil Pharmaceutical Co., Ltd. ("Jeil Pharma") and Drogsan Pharmaceuticals ("Drogsan 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, India and South Korea, 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 U.S. dollars ($)	Three Months Ended June 30, 2021			Six Months Ended June 30, 2021		
Products By Geographic Area	Total	U.S.	Rest of World	Total	U.S.	Rest of World
Drug Revenues						
Product Sales – Point-in-time	$ 215	$ 215	$ —	$ 439	$ 439	$ —
License Fee – Over time	58	—	58	117	—	117
Total Drug Products	273	215	58	556	439	117
Concentrate Products						
Product Sales – Point-in-time	14,379	13,026	1,353	29,084	26,227	2,857
License Fee – Over time	485	485	—	971	971	—
Total Concentrate Products	14,864	13,511	1,353	30,055	27,198	2,857
Net Revenue	$ 15,137	$ 13,726	$ 1,411	$ 30,611	$ 27,637	$ 2,974

In thousands of U.S. 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

Contract balances

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

In thousands of U.S. dollars ($)	June 30, 2021	December 31, 2020
Receivables, which are included in "Trade and other receivables"	$ 5,357	$ 4,171
Contract liabilities	$ 9,103	$ 10,190

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, 2021 and 2020.

For the three and six months ended June 30, 2021 and June 30, 2020, 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, 2021 and December 31, 2020. 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, 2021 or December 31, 2020.

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, 2021, 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 $9.1 million as of June 30, 2021. 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 minimum commitments related to the Baxter Agreement are product sales of $6.2 million as of June 30, 2021, which is 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, 2021 and December 31, 2020 (table in thousands):

	June 30, 2021				
	Amortized Cost	Unrealized Gain	Unrealized Loss	Accrued Interest Income	Fair Value
Available-for-Sale Securities					
Bonds	$ 8,558	$ 1	$ —	$ 15	$ 8,574

	December 31, 2020				
	Amortized Cost	Unrealized Gain	Unrealized Loss	Accrued Interest	Fair Value
Available-for-Sale Securities					
Bonds	$ 9,987	$ 3	$ —	$ 7	$ 9,997

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, 2021 and December 31, 2020, 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, 2021 and December 31, 2020 are as follows (table in thousands):

	June 30, 2021	December 31, 2020
Raw Materials	$ 3,598	$ 3,112
Work in Process	265	172
Finished Goods	1,936	1,805
Total	$ 5,799	$ 5,089

As of June 30, 2021, the Company classified $1.1 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, 2021, the total Triferic inventory net of reserve was $1.7 million.

The $1.7 million net value of Triferic inventory consisted of $0.3 million of Triferic (dialysate) finished goods with expiration dates ranging from September 2021 to December 2023, $0.5 million of Triferic API with estimated remaining shelf life extending beyond 2021, and $0.9 million of raw materials for Triferic with estimated remaining shelf life extending beyond 2025.

7. Property and Equipment

As of June 30, 2021 and December 31, 2020, the Company's property and equipment consisted of the following (table in thousands):

	June 30, 2021	December 31, 2020
Leasehold Improvements	$ 1,196	$ 1,196
Machinery and Equipment	5,684	5,475
Information Technology & Office Equipment	1,847	1,831
Laboratory Equipment	676	676
	9,403	9,178
Accumulated Depreciation	(6,874)	(6,536)
Property and Equipment, net	$ 2,529	$ 2,642

Depreciation expense for each of the three and six months ended June 30, 2021 and 2020 totaled $0.2 million and $0.4 million.

8. Accrued Liabilities

Accrued liabilities as of June 30, 2021 and December 31, 2020 consisted of the following (table in thousands):

	June 30, 2021	December 31, 2020
Accrued Research & Development Expense	$ 315	$ 232
Accrued Compensation and Benefits	1,420	2,500
Accrued Unvouchered Receipts	647	755
Accrued Workers Compensation	531	395
Other Accrued Liabilities	1,080	1,131
Total Accrued Liabilities	$ 3,993	$ 5,013

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 each of the three and six months ended June 30, 2021 and 2020. Deferred revenue related to the Baxter Agreement totaled $6.2 million as of June 30, 2021 and $7.2 million as of December 31, 2020.

If a "Refund Trigger Event" occurs under the Baxter Agreement prior to December 31, 2021, Rockwell would be obligated to repay 25% of the upfront fee.

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 approximately $53,000 and $0.1 million revenue for each of the three and six months ended June 30, 2021 and 2020. Deferred revenue related to the Wanbang Agreement totaled $2.6 million as of June 30, 2021 and $2.7 million as of December 31, 2020.

In January 2020, the Company 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 the Company will supply the product to Sun Pharma. In consideration for the license, the Company 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 for each of the three and six months ended June 30, 2021 and 2020. Deferred revenue related to the Sun Pharma Agreement totaled $85,000 and $90,000 as of June 30, 2021 and December 31, 2020, respectively.

In September 2020, the Company entered into a license and supply agreements with Jeil Pharma (the "Jeil Pharma Agreements"), for the rights to commercialize Triferic (dialysate) (ferric pyrophosphate citrate) in South Korea. Under the terms of the Jeil Pharma Agreements, Jeil Pharma will be the exclusive development and commercialization partner for Triferic (dialysate) in South Korea, and the Company will supply the product to Jeil Pharma. In consideration for the license, the Company received an upfront fee of $0.2 million, and will be eligible for milestone payments and royalties on net sales. A Joint Alliance Committee, comprised of members from the Company and Jeil Pharma, will guide the development and execution for Triferic (dialysate) in South Korea. Jeil 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 $2,500 and nil for the three months ended June 30, 2021 and 2020, respectively, and $5,000 and nil for the six months ended June 30, 2021 and 2020, respectively. Deferred revenue related to the Jeil Pharma Agreement totaled approximately $0.2 million as of June 30, 2021 and December 31, 2020.

In June 2021, the Company entered into license and supply agreements with Drogsan Pharma (the "Drogsan Agreements"), for the rights to commercialize Triferic (dialysate) and Triferic AVNU in Turkey. Under the terms of the Drogsan Agreements, Drogsan Pharma will be the exclusive commercialization partner for Triferic (dialysate) and Triferic AVNU in Turkey. In consideration for the license, the Company is due to receive an upfront fee of $0.2 million, and will be eligible for milestone payment and royalties on net sales. A Joint Alliance Committee, comprised of members from the Company and Drogsan Pharma, will guide the execution for Triferic (dialysate) and Triferic AVNU in Turkey. Drogsan Pharma will be responsible for all regulatory approval and commercialization activities, and the Company will supply the product to Drogsan Pharma for Turkey. The upfront fee will be recorded as deferred revenue and will be recognized as revenue based on the agreement term.

10. Stockholders’ Equity

Preferred Stock

As of June 30, 2021 and December 31, 2020, 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, 2021 and December 31, 2020, there were 170,000,000 shares of common stock, $0.0001 par value per share, authorized and 93,811,381 and 93,573,165 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 three and six months ended June 30, 2021, the Company has not sold shares of its common stock pursuant to the Sales Agreement. Approximately $32.3 million remains available for sale under this facility.

The Company is not required to sell any shares at any time during the term of the facility. The Company's ability to sell common stock under the facility may be limited by several factors including, among other things, the trading volume of its common stock and certain black-out periods that the Company may impose upon the facility, among other things.

11. Stock-Based Compensation

The Company recognized total stock-based compensation expense during the three and six months ended June 30, 2021 and 2020 as follows (table in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Service-based awards:				
Restricted stock units	$ 78	$ (4)	$ 182	$ 234
Stock option awards	344	336	735	776
	422	332	917	1,010
Performance-based awards:				
Restricted stock awards	—	—	(390)	—
Restricted stock units	—	(1,197)	—	(1,025)
Stock option awards	11	(596)	(330)	(511)
	11	(1,793)	(720)	(1,536)
Total	$ 433	$ (1,461)	$ 197	$ (526)

Restricted Stock

A summary of the Company’s restricted stock awards during the six months ended June 30, 2021 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2021	146,800	$ 5.70
Forfeited	(68,500)	$ 5.70
Unvested at June 30, 2021	78,300	$ 5.70

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

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, 2021, unvested restricted stock awards of 78,300 were related to performance-based awards. The forfeited performance-based restricted stock awards of 68,500 was due to the termination of the Company's former Chief Science Officer on January 19, 2021. These forfeited awards reduced stock-based compensation expense by $0.4 million.

Service-Based Restricted Stock Units

A summary of the Company's service-based restricted stock units during the six months ended June 30, 2021 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2021	265,494	$ 2.60
Granted	310,050	0.90
Vested	(221,474)	2.38
Forfeited	(11,466)	4.81
Unvested at June 30, 2021	342,604	$ 1.17

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	(104,168)	4.66
Forfeited	(128,460)	4.30
Unvested at June 30, 2020	420,062	$ 3.27

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 $0.1 million and $0.2 million was recognized for the three and six months ended June 30, 2021, respectively. Stock-based compensation expense of nil and $0.2 million was recognized for the three and six months ended June 30, 2020, respectively. As of June 30, 2021, the unrecognized stock-based compensation expense was $0.3 million, which is expected to be recognized over an estimated weighted average remaining term of less than 1 year.

Performance-Based Restricted Stock Units

As of June 30, 2021, there were no outstanding 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

Service-Based Stock Options

The fair value of the service-based stock options granted for the six months ended June 30, 2021 were based on the following assumptions:

	June 30, 2021
Exercise price	$0.90 - $0.94
Expected stock price volatility	75.8% - 77.7%
Risk-free interest rate	0.47% - 1.06%
Term (years)	5.5 - 6

A summary of the Company's service-based stock option activity for the six months ended June 30, 2021 is as follows:

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2021	5,717,956	$ 4.55	6.6	$ —
Granted	1,522,162	0.96	6.0	—
Forfeited	(277,764)	2.52	—	—
Expired	(1,266,553)	7.35	—	—
Outstanding at June 30, 2021	5,695,801	$ 3.07	7.8	$ 5,000
Exercisable at June 30, 2021	2,387,440	$ 5.25	5.8	$ —

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	$ 107,000
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	$ 1,000
Exercisable at June 30, 2020	2,809,954	$ 7.09	4.3	$ —

The aggregate intrinsic value in the table above is calculated as the difference between the closing price of the Company's 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, 2021, the Company granted stock options to purchase up to 1,522,162 shares of common stock to certain employees. During the six months ended June 30, 2021, 277,764 shares were forfeited and 1,266,553 shares expired. 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 $0.7 million for the three and six months ended June 30, 2021, respectively. 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. As of June 30, 2021, total stock-based compensation expense related to unvested options not yet recognized totaled approximately $2.0 million, which is expected to be recognized over an estimated weighted average remaining term of 3.0 years.

Performance-Based Stock Options

A summary of the performance-based stock options for the six months ended June 30, 2021 is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding at January 1, 2021	750,000	$ 2.20
Expired	(375,000)	2.20
Outstanding at June 30, 2021	375,000	$ 2.20
Exercisable at June 30, 2021	—	$ —

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	—	$ —

Stock-based compensation expense recognized for performance-based stock options was nil and $(0.3) million for the three and six months ended June 30, 2021, respectively. 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, respectively. The reduction in stock-based compensation expense was due to the performance criteria of certain performance-based options granted to officers of the Company becoming non-probable as of March 31, 2021. The Company will continue to assess the probability of the performance criteria until such time the criteria becomes probable and the performance-based stock option vests or continues to be non-probable and the performance-based stock option expires. As of June 30, 2021, there was no unrecognized stock-based compensation expense related to unvested performance-based stock options.

12. Licensing Agreements

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, a former 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. 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 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 December 31, 2020, the Company had fulfilled its reimbursement obligation of certain legal expenses. As of June 30, 2021, the Company accrued $0.2 million relating to certain IP reimbursement expenses and certain sublicense royalty fees within accrued liabilities 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.

13. Leases

The Company leases its production facilities and administrative offices as well as certain equipment used in our operations including leases on transportation equipment used in the delivery of its products. The lease terms range from monthly to five years. The Company occupies a 51,000 square foot facility and a 17,500 square foot facility in Wixom, Michigan under a lease expiring in August 2024. The Company also occupies two other manufacturing facilities, a 51,000 square foot facility in Grapevine, Texas under a lease expiring in December 2025, and a 57,000 square foot facility in Greer, South Carolina under a lease expiring February 2023. In addition, the Company occupies 4,100 square feet of office space in Hackensack, New Jersey under a lease expiring on July 1, 2024. This lease is currently being offered for sublease.

At June 30, 2021, the Company had operating and finance lease liabilities of $6.2 million and right-of-use assets of $6.1 million, which are included in the consolidated balance sheet.

At December 31, 2020, the Company had operating lease liabilities of $3.0 million and right-of-use assets of $2.9 million, which are included in the consolidated balance sheet.

The following summarizes quantitative information about the Company's operating leases (table in thousands):

	Three Months Ended June 30, 2021	Three Months Ended June 30, 2020	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
Operating leases				
Operating lease cost	$ 432	$ 403	$ 851	$ 846
Variable lease cost	90	123	192	312
Operating lease expense	522	526	1,043	1,158
Finance leases				
Amortization of right-of-use assets	67	—	112	—
Interest on lease obligations	20	—	33	—
Finance lease expense	87	—	145	—
Short-term lease rent expense	4	4	8	8
Total rent expense	$ 613	$ 530	$ 1,196	$ 1,166
Other information				
Operating cash flows from operating leases	$ 428	$ 410	$ 853	$ 855
Operating cash flows from finance leases	$ 21	$ —	$ 34	$ —
Financing cash flows from finance leases	$ 56	$ —	$ 93	$ —
Right of use assets exchanged for operating lease liabilities	$ 1,476	$ —	$ 3,371	$ —
Right of use assets exchanged for finance lease liabilities	$ 316	$ —	$ 777	$ —
Weighted-average remaining lease term – operating leases	3.5	2.4	3.5	2.4
Weighted-average remaining lease term – finance leases	5.5	0.0	5.5	0
Weighted-average discount rate – operating leases	6.2 %	6.8 %	6.2 %	6.8 %
Weighted-average discount rate – finance leases	5.5 %	— %	5.5 %	— %

Future minimum rental payments under operating lease agreements are as follows (in thousands):

	Operating	Finance
Year ending December 31, 2021 (remaining)	$ 865	$ 148
Year ending December 31, 2022	1,603	300
Year ending December 31, 2023	1,285	305
Year ending December 31, 2024	930	305
Year ending December 31, 2025	468	305
Remaining future payments	97	319
Total	$ 5,248	$ 1,682
Less present value discount	(522)	(228)
Operating and finance lease liabilities	$ 4,726	$ 1,454

14. Commitments and Contingencies

Litigation

SEC Investigation

As a follow up to certain prior inquiries, the Company received a subpoena from the SEC during the Company's quarter ended September 30, 2018 requesting, among other things, certain information and documents relating to the status of the Company's request to the 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.

15. Loan and Security Agreement

In March 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 is no longer eligible to draw on a second tranche of $5.0 million, which was tied to the achievement of certain milestones by a specific date. The Company may 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 each of the three months ended June 30, 2021 interest expense amounted to $0.6 million. For the six months ended June 30, 2021 and 2020, interest expense amounted to $1.2 million and $0.6 million, respectively.

The Loan Agreement is secured by all assets of the Company and Rockwell Transportation, Inc. Proceeds are being 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. The Company cannot assure you that we can maintain compliance with the covenants under our Loan Agreement, which may result in an event of default. The Company's ability to comply with these covenants may be adversely affected by events beyond its control. For example, the Loan Agreement contains certain financial covenants relating to sales and, as a result of the ongoing COVID-19 pandemic and its effect on the Company's sales activities, among other factors, the Company may not be able to satisfy such covenants in the future. If the Company is unable to comply with the covenants under the Loan Agreement, it would pursue all available cure options in order to regain compliance. The Company previously failed to satisfy a revenue covenant for the period ended December 31, 2020 and then subsequently agreed to an appropriate remedy during the applicable cure period. However, the Company may not be able to mutually agree with Innovatus on appropriate remedies to cure a future breach of a covenant, which could give rise to an event of default. If the Company is unable to avoid an event of default, any required repayments could have an adverse effect on its liquidity. As of June 30, 2021, the Company is in compliance with all the reporting and financial covenants. The financial statements for June 30, 2021 have been prepared with the assumption that the Company will be able to agree to an appropriate remedy during the applicable cure period for any future breaches of operating covenants. Based on the foregoing, the Company has classified amounts payable under the Loan Agreement as a current liability. If and when the Company reaches an agreement with Innovatus to avoid an event of default, the amounts payable under the Loan Agreement will be reevaluated for its classification and presentation.

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. The Company evaluated the warrant under ASC 470, Debt, and recognized an additional debt discount of approximately $0.5 million based on the relative fair value of the base instruments and warrants. The Company calculated the fair value of the warrant using the Black-Scholes model.

As of June 30, 2021, the outstanding balance of the Term Loan was $21.1 million, net of unamortized issuance costs and unaccreted discount of $1.4 million.

The following table reflects the schedule of principal payments on the Term Loan as of June 30, 2021 (in thousands):

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

16. Subsequent Events

On July 3, 2021, the Company entered into a short-term note payable for $2.0 million, bearing interest at 3.925% per annum to finance various insurance policies. Principal and interest payments related to this note will begin on July 3, 2021 and are paid on a straight-line amortization over a 9-month period with the final payment due on March 3, 2022.

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 "Rockwell," 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 ability to successfully launch FDA-approved Triferic AVNU; our ability to develop FPC for other indications; our ability to 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, 2020 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

Rockwell is a commercial-stage, biopharmaceutical company developing and commercializing our next-generation parenteral iron technology platform, Ferric Pyrophosphate Citrate ("FPC"), which we believe has the potential to lead to transformative treatments for iron deficiency in multiple disease states, that we believe could reduce healthcare costs and improve patients' lives. We are also one of the two major suppliers of life-saving hemodialysis concentrate products to kidney dialysis clinics in the United States.

We have two novel, FDA approved therapies, Triferic and Triferic AVNU, which are the first two products developed from our FPC platform. We are marketing both products to kidney dialysis centers for their patients receiving dialysis. In 2021, we intend to advance our FPC platform strategy outside of dialysis by starting a Phase 2 trial for the treatment of iron deficiency anemia in patients who are receiving long-term and or chronic intravenous ("IV") medications for various therapeutic needs in the home infusion setting.. The trend toward providing medical care, including the delivery of medicines, at home make the home infusion market a rapidly growing area of healthcare. We believe that the home infusion setting is a natural path for expansion of our platform as many of the patients suffer from chronic diseases that are associated with iron deficiency and anemia. We are currently seeking additional FDA feedback and clarification regarding the clinical development plan for FPC in the home-infusion setting. Our expectations regarding the commencement of a Phase 2 trial in 2021 is based on the assumption that the FDA agrees with the development plan as we have proposed. In our R&D pipeline, we are also investigating FPC's impact on iron deficiency in the treatment of hospitalized patients with acute heart failure, with the potential to begin another Phase 2 trial in these patients in 2022.

We are the second largest supplier of hemodialysis concentrates in the United States, with a reputation for excellent service, quality, and reliability. We believe that this reputation, which is based on over 25 years of service to the kidney

dialysis centers, combined with about $60 million in annual revenue, approximately 300 dedicated employees, expertise in manufacturing and logistics and the added expertise in pharmaceutical development and commercialization brought to the Company by recent additions to our management team, gives us a solid foundation on which to grow.

At Rockwell Medical, we are dedicated to replacing the currently inadequate standard of care for treatment of iron deficiency in acute and chronic disease by leveraging our proprietary FPC platform technology. We believe that our proprietary drug platform, FPC, is a next-generation parenteral iron therapeutic that has several advantages over other parenteral iron therapies. Importantly, it provides iron that is immediately bioavailable for critical body processes once it is administered. It has been demonstrated to be safe and well-tolerated, with a safety profile similar to placebo.

Iron deficiency, which is often overlooked and undertreated in several illnesses because of the difficulty in treating them, can develop into a serious medical condition when left untreated. It is a common comorbidity in many disease states, such as end-stage kidney disease, chronic kidney disease, acute heart failure, cancer and multiple chronic gastrointestinal conditions. Iron deficiency impacts patients' health in many ways, including anemia, organ dysfunction, slower recovery, diminished energy and reduced quality of life.

Strategy Evolution and Overview

Rockwell Medical has evolved its strategy over the past year to develop into a more medically-, scientifically- and data-driven company. We believe future clinical, regulatory and commercial success require the right people with the right experience to navigate us to the right data. There has been an evolution of both our management and board, providing us with greater relevant experience. In particular, we have added board members and employees with significant medical and commercial experience in iron deficiency anemia and the dialysis sector, drug development and commercialization, small-cap public company finance and management and clinical nurse educator patient support. We believe these changes support an improved execution of our strategy to generate data that will support future commercial growth, fair reimbursement and regulatory approvals.

Our strategy is to accelerate Rockwell's growth by creating and developing pharmaceutical products based on our FPC technology for disease states where patients can benefit the most from an effective treatment for iron deficiency or iron deficiency anemia, while concurrently refining our dialysis business to drive incremental growth and efficiencies. We plan to leverage and build on the foundation provided by our current dialysis business serving kidney dialysis centers by developing a pipeline of additional potential drug therapies in multiple disease states outside of nephrology. We have preliminarily identified three disease states where we believe FPC may have the biggest impact.

Dialysis Business: We are the second largest supplier, and one of the two major suppliers of hemodialysis concentrates in the United States. We manufacture, sell and deliver hemodialysis concentrates, which are used to maintain human life by removing toxins and balancing electrolytes in the dialysis patient's bloodstream. We have core capabilities in manufacturing hemodialysis concentrates in three facilities, totaling 159,000 square feet, located in Michigan, Texas and South Carolina. We also have core capabilities in the logistics of delivering these products to dialysis clinics throughout most of the United States.

Our first two branded products from our FPC platform, Triferic® (dialysate) and Triferic AVNU® (IV), are used to maintain hemoglobin in patients undergoing hemodialysis. We are building on our reputation and industry presence by commercializing then to medium and small dialysis organizations. We began commercializing Triferic and Triferic AVNU in the United States in the second half of 2019 and in early 2021, respectively. In April 2021, we received marketing approval for Triferic AVNU from Health Canada for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease, which is the first international regulatory approval for our intravenous therapy. We expect Triferic AVNU to become commercially available in Canada during 2022. Our strategy for increasing Triferic adoption is to continue to generate data in clinics showing the benefits of Triferic in real world protocols. In addition, we expect to study Triferic use with the innovations that we believe have the potential to change future medical practices (e.g. introduction and adoption of HIF-PHIs), subject to FDA approval. We believe that positive data from these studies would better position Triferic for long-term growth. We are developing strategic alliance partners for development, regulatory approval and commercialization of Triferic outside of the United States.

Home Infusion Program: We plan to initiate a clinical trial program of FPC for the treatment of iron deficiency anemia in the home-infusion setting. Many patient groups requiring home infusion therapies suffer from chronic diseases that

are associated with a high incidence of iron deficiency and anemia. Home infusion represents a large and rapidly-growing segment of healthcare where we believe FPC may have distinct advantages over currently available iron replacement therapy options.

Pipeline Development: We are investigating the use of our FPC platform for the treatment of iron deficiency in hospitalized patients with acute heart failure. We believe that FPC may deliver rapidly bioavailable iron to the heart and improve cardiac energetics. This effect could help patients recover faster, resulting in shorter hospital stays and fewer 30-day re-admissions, which would be a meaningful reduction healthcare costs and human suffering.

Our Growth Strategy

We plan to accelerate our growth by combining the solid foundation, strength and reputation of our dialysis business with the high-growth potential from therapeutics derived (or generated) from our FPC platform in multiple disease states where patients can benefit the most from an effective treatment for iron deficiency. In parallel with continually seeking to drive incremental growth and efficiencies in our dialysis business unit, our strategy is to accelerate the growth of our business in large, higher-margin markets by creating and developing pharmaceutical products based on our proprietary FPC technology that address iron deficiency in patients who are currently under-treated.

Dialysis Business

We are one of the two major suppliers of hemodialysis concentrates in the United States. Over the past 25 years we have developed a core expertise in manufacturing and delivering hemodialysis concentrates. Because these concentrates are used to maintain human life by removing toxins and balancing electrolytes in the dialysis patient's bloodstream, we manufacture them under cGMP regulations as described below. Our concentrates are manufactured in three facilities, totaling 159,000 square feet, located in Michigan, Texas and South Carolina, from which we deliver these products to dialysis clinics throughout most of the United States. We utilize our own delivery fleet as well as third parties. We employ approximately 300 people in the concentrates unit of our dialysis business.

The "Rockwell Medical" name has earned a reputation for dependability, quality and service within our customer base. This reputation was further strengthened during the recent challenges presented, not only by the COVID-19 pandemic, but also by the multitude of recent natural disasters where our team has been challenged by hurricanes, flooding and freezing, while still meeting production demands.

Our dialysis business in concentrates and our growth opportunities with FPC technology are synergistic. We are leveraging our leadership position in the dialysis sector to commercialize our first two FPC-based products, Triferic and Triferic AVNU, which are indicated for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease. We commercialize the Triferic products ourselves in the United States, and are partnering with established local pharmaceutical companies for the regulatory approval and commercialization outside of the United States.

Although we have an excellent reputation for dependability and service within the dialysis sector, with concentrates and Triferic, our growth opportunities for both in the United States dialysis market are challenged by the consolidated ownership of dialysis clinics, a capitated reimbursement model and the demographics of the patient population. The two largest dialysis organizations treat approximately 73% of the patients in the United States. One manufactures its own concentrates and IV iron and we already supply concentrates to the other. Through our partnership with Baxter International, we currently supply concentrates to a significant percentage of the small and medium sized dialysis organizations. In a sector, such as kidney dialysis, with capitated reimbursement for the dialysis procedure and all included inputs, new product success depends on compelling data demonstrating improved patient outcomes and/or pharmacoeconomics versus the current standard of care in practice in the clinics. Once Medicare determined that Triferic and Triferic AVNU would be reimbursed under the fixed bundled rate, market adoption became more dependent on the generation of these data, which were not required for the drug's approval from the FDA.

Notwithstanding the growth limitations mentioned above, we have made progress and continue to be confident that Triferic has the potential to be the treatment of choice for the maintenance of hemoglobin in dialysis patients. Toward this end, we have increased our efforts in generating real world data in clinics with current protocols, which we believe will help with the adoption of Triferic and Triferic AVNU as these results are developed and disseminated over time. In addition, we believe the hemodialysis industry may experience a great deal of change over the next several years. We plan to take the steps necessary to

generate the data necessary to potentially allow Triferic and Triferic AVNU to benefit from these new innovations, such as the potential approval of a class of drugs, known as hypoxia-inducible factor prolyl hydroxylase inhibitors ("HIF-PHIs"), as well as the new, solid-state dialysis equipment in development. We are planning to study Triferic in combination with these potential new innovations as they become available.

A key element of our dialysis business strategy is to also improve the strength of our concentrates business by creating efficiencies and enhancing our manufacturing and transportation operations. We have launched projects to identify ways to improve the overall profitability of these core operations. Specifically, we are reviewing our entire supply chain to identify opportunities for improvement, prioritizing initiatives that will have the largest impact on long-term efficiency, profitability and growth.

Home Infusion

Our growth strategy is to go beyond our foundational business in dialysis by leveraging the pre-clinical, clinical pharmacology and safety data from Triferic. We are planning to develop an FPC-based therapeutic for iron deficiency to be given in the home infusion setting. According to the National Home Infusion Association, the number of patients served by home infusion therapy has grown from approximately 800,000 in 2010 to over 3,000,000 in 2019. The home infusion setting is expected to continue to expand, which has been further accelerated by the COVID-19 pandemic and the desire to reduce or eliminate hospital and or clinic exposure. Many patient groups requiring home infusion therapies suffer from diseases that are associated with an incidence of iron deficiency and anemia. For example, it is estimated that 40% to 55% of all home parenteral nutrition patients are iron deficient. We believe, based on our data with hemodialysis patients, FPC as a home infusion therapy for iron deficiency anemia may have distinct advantages over currently available iron replacement therapy options.

We plan on initiating a Phase 2 clinical study in home infusion patients with iron deficient anemia during the second half of 2021 to confirm the dose and duration of FPC treatment. We expect data from the trial in the second half of 2022. Prior to commencing this study, the company is planning to further review and discuss this clinical plan with the FDA. After reviewing the development plan with the FDA, and subject to clarifying expected clinical development requirements, we expect to initiate the trial in the second half of 2021.

Pipeline Development

In our R&D pipeline, we are also exploring FPC’s impact in the treatment of iron deficiency in hospitalized heart failure patients. More than one million people in the United States are hospitalized each year for acute heart failure. Clinical improvement in heart failure has already been demonstrated with older first-generation forms of IV iron in clinical trials in the outpatient setting. We believe that FPC may deliver rapidly bioavailable iron to the heart and improve cardiac energetics during hospitalization. This effect could help patients recover faster resulting in improved function, shorter hospital stays and fewer 30-day re-admissions. If so, these outcomes would translate into a meaningful reduction in healthcare costs and human suffering. We expect to communicate with the FDA in 2021 regarding a development pathway for this indication.

We continue exploring other potential patient populations for application of our technology. We are considering disease states where patients can benefit the most from an effective treatment for iron deficiency, and where the development path, cost estimates and reimbursement are the most favorable.

Results of Operations for the Three Months Ended June 30, 2021 and 2020

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

	For the Three Months Ended June 30,				
	2021	**% of Revenue**	**2020**	**% of Revenue**	**% Change**
Net Sales	**$ 15,137**		**$ 15,896**		**(4.8)%**
Cost of Sales	15,399	101.7 %	15,015	94.5 %	2.6
Gross (Loss) Profit	(262)	(1.7)	881	5.5	(129.7)
Research and Product Development	2,416	16.0	1,616	10.2	49.5
Selling and Marketing	1,468	9.7	1,997	12.6	(26.5)
General and Administrative	3,677	24.3	2,871	18.1	28.1
Operating Loss	**$ (7,823)**	**(51.7)%**	**$ (5,603)**	**(35.2)%**	**39.6 %**

Net Sales

During the three months ended June 30, 2021, our net sales were $15.1 million compared to net sales of $15.9 million during the three months ended June 30, 2020. The decrease of $0.8 million was primarily due to a decrease in sales of dialysis concentrates products.

Gross Profit

Cost of sales during the three months ended June 30, 2021 was $15.4 million, resulting in gross loss of $0.3 million during the three months ended June 30, 2021, compared to cost of sales of a $15.0 million and a gross profit of $0.9 million during the three months ended June 30, 2020. Gross profit decreased by $1.2 million mainly due to a decrease in concentrate sales and an increase in costs related to protocols implemented because of the ongoing COVID-19 pandemic, shipping, fuel and labor.

Research and Product Development Expense

Research and product development expenses were $2.4 million for the three months ended June 30, 2021, compared with $1.6 million during the three months ended June 30, 2020. The increase of $0.8 million was primarily due to the Company continuing to invest in its medical and scientific programs to support the continued advancement of our FPC technology platform.

Selling and Marketing Expense

Selling and marketing expenses were $1.5 million during the three months ended June 30, 2021, compared with $2.0 million during the three months ended June 30, 2020. The decrease of $0.5 million is primarily due to a decrease in marketing costs related to Triferic (dialysate) partially offset by a slight increase in costs associated with the launch of Triferic AVNU.

General and Administrative Expense

General and administrative expenses were $3.7 million during the three months ended June 30, 2021, compared with $2.9 million during the three months ended June 30, 2020. The increase of $0.8 million is due primarily to an increase in stock compensation of $1.9 million, which was a decrease in incentive compensation in Q2 2020 of $1.5 million from forfeited equity awards of the former President and Chief Executive Officer; partially offset by a decrease of $0.8 million for the reduction of severance costs related to our former President and Chief Executive Officer.

Other Income (Expense)

Other income for the three months ended June 30, 2021 was $7,000, consisting primarily of interest income. Other income for the three months ended June 30, 2020 was $0.1 million, consisting primarily of interest income. Other expense for the three months ended June 30, 2021 was $0.6 million of interest expense related to our debt facility (see Note 15 for more

information on our debt facility). 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 and warrant modification expense of $0.8 million.

Results of Operations for the Six Months Ended June 30, 2021 and 2020

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

	For the Six Months Ended June 30,				
	2021	**% of Revenue**	**2020**	**% of Revenue**	**% Change**
Net Sales	**$ 30,611**		**$ 31,753**		**(3.6)%**
Cost of Sales	30,471	99.5 %	29,759	93.7 %	2.4
Gross Profit	140	0.5	1,994	6.3	(93.0)
Research and Product Development	4,224	13.8	3,438	10.8	22.9
Selling and Marketing	3,319	10.8	4,069	12.8	(18.4)
General and Administrative	7,602	24.8	8,145	25.7	(6.7)
Operating Loss	**$ (15,005)**	**(49.0)%**	**$ (13,658)**	**(43.0)%**	**9.9 %**

Net Sales

During the six months ended June 30, 2021, our net sales were $30.6 million compared to net sales of $31.8 million during the six months ended June 30, 2020. The decrease of $1.2 million was primarily due to a decrease in sales of dialysis concentrates products.

Gross Profit

Cost of sales during the six months ended June 30, 2021 was $30.5 million, resulting in gross profit of $0.1 million during the six months ended June 30, 2021, compared to cost of sales of a $29.8 million and a gross profit of $2.0 million during the six months ended June 30, 2020. Gross profit decreased by $1.9 million mainly due to a decrease in concentrate sales and an increase in costs related to protocols implemented because of the ongoing COVID-19 pandemic, shipping and fuel costs and labor.

Research and Product Development Expense

Research and product development expenses were $4.2 million for the six months ended June 30, 2021, compared with $3.4 million during the six months ended June 30, 2020. This increase of $0.8 million is primarily due to continued investments the Company is making in its medical and scientific programs to support the continued advancement of our FPC technology platform.

Selling and Marketing Expense

Selling and marketing expenses were $3.3 million during the six months ended June 30, 2021, compared with $4.1 million during the six months ended June 30, 2020. The decrease of $0.8 million is primarily due to a decrease in marketing costs related to Triferic (dialysate) partially offset by a slight increase in costs associated with the launch of Triferic AVNU.

General and Administrative Expense

General and administrative expenses were $7.6 million during the six months ended June 30, 2021, compared with $8.1 million during the six months ended June 30, 2020. The decrease of $0.5 million is due primarily to a decrease of $0.8 million from the completion of severance pay related to our former President and Chief Executive Officer (CEO); a decrease in legal costs of $0.3 million, relating to previous litigation that has since been resolved; and a decrease in insurance and accounting costs of $0.2 million, relating to reduced premiums; partially offset by an increase of $0.7 million for stock compensation, relating to a decrease in Q2 2020 incentive compensation from forfeited equity awards related to our former President and CEO.

Other Income (Expense)

Other income for the six months ended June 30, 2021 was $18,000, consisting primarily of interest income. Other income for the six months ended June 30, 2020 was $0.2 million, consisting primarily of interest income. Other expense for the six months ended June 30, 2021 was $1.2 million of interest expense related to our debt facility (see Note 15 for more information on our debt facility). 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.

Liquidity and Capital Resources

Since inception, Rockwell has incurred significant net losses and has funded its operations primarily through revenue from commercial products, proceeds from the issuance of debt and equity securities and payments from partnerships. At June 30, 2021, Rockwell had an accumulated deficit of approximately $353.6 million and stockholders' equity of $18.2 million. As of June 30, 2021, Rockwell had approximately $41.0 million of cash, cash equivalents and investments available-for-sale, and working capital of $18.4 million. Net cash used in operating activities for the six months ended June 30, 2021 was approximately $17.4 million.

The Company is subject to certain covenants and cure provisions under its Loan Agreement with Innovatus. As of the date of this report, the Company is in compliance with all covenants. As a result of the ongoing COVID-19 pandemic and its effect on the Company's sales activities, among other factors, the Company may not be able to satisfy such covenants over the next 12 months. However, based on the foregoing, the Company has classified amounts payable under the Loan Agreement as a current liability. If and when the Company reaches an agreement with Innovatus to avoid an event of default, the amounts payable under the Loan Agreement will be reclassified. The financial statements for June 30, 2021, have been prepared with the assumption that the Company will be able to agree to an appropriate remedy during the applicable cure period for any future breaches of operating covenants. If the Company is unable to comply with the covenants under the Loan Agreement, it would pursue all available cure options in order to regain compliance (See Note 15 for further detail).

The Company expects it will require additional capital to sustain its operations and make the investments it needs to execute its strategic plan, including the commercialization of Triferic (dialysate) and Triferic AVNU in dialysis, generating additional data for Triferic in dialysis, developing FPC for iron deficiency anemia in patients undergoing home infusion and for progressing our pipeline development program of new indications for its FPC platform. If the Company is unable to generate sufficient revenue from sales of its commercial products and from partnerships, 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.

Based on the currently available working capital and managements assumption that the Company will be able to agree to an appropriate remedy, 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.

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 operations in the United States and internationally (with partners); the timing and magnitude of cash received from drug product sales; the timing and expenditures associated with the development programs including our FPC technology for home infusion and potentially acute heart failure; the costs associated with our manufacturing and transportation operations related to our concentrate business; any potential accelerated amortization under the Loan Agreement in the event of a failure to satisfy operating covenants..

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, or if at all; and (ii) strategic transactions, including potential alliances and collaborations focused on markets outside the United States, as well as potential combinations (including by merger or acquisition) or other corporate transactions. In particular, our Baxter Agreement prohibits us from entering into a contract that would encumber the assets used in our concentrate business without the prior written consent of Baxter. Due to the fact that the assets used in our concentrate business currently constitute a substantial portion of the tangible assets we own other than our drug inventory, we may not be able to, or we may find it difficult, to obtain secured debt financing without the consent of Baxter.

We believe that our ability to fund our activities in the long term will be highly dependent upon 1) our ability to execute on the development of the FPC platform for new therapies, and 2) our ability to commercialize and increase adaptation of Triferic (dialysate) and Triferic AVNU. Both of these strategies is subject to significant risks and uncertainties such that there can be no assurance that we will be successful is achieving approval of FPC in a new therapeutic area or that we will be able to have sustained commercial success with Triferic (dialysate) and Triferic AVNU. If our planned clinical program is delayed or fails or if our commercialization of Triferic (dialysate) and/or Triferic AVNU should fail to increase sales, we may be forced to implement cost-saving measures that may potentially have a negative impact on our activities and potentially the results of our research and development programs. Even though we began commercialization of Triferic (dialysate) and Triferic AVNU as planned, if the results are unsuccessful, we may be unable to secure the additional capital that we will require to continue our

research and development activities and operations, which could have a material adverse effect on our business. If we are unable to raise the required capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to raise sufficient capital, such financings may only be available on unattractive terms, or result in significant dilution of 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 $17.4 million for the six months ended June 30, 2021 compared to net cash used in operating activities of $16.2 million for the six months ended June 30, 2020. The increase in cash used from operating activities during the current period was primarily due to changes in current balance sheet accounts in the ordinary course of business of approximately $3.0 million, including an increase in net accounts receivable of $1.2 million and a reduction in accounts payable and accrued expense of approximately $0.4 million. Overall, our cash burn for the six months ended June 30, 2021 was in line with our expectations, and we continue to expect, in aggregate, 2021 cash burn to be lower than 2020 cash burn.

Cash Provided by Investing Activities

Net cash provided by investing activities was $1.1 million during the six months ended June 30, 2021 compared to net cash provided by investing activities of $0.7 million for the six months ended June 30, 2020. The net cash provided by investing activities during the six months ended June 30, 2021 was primarily due to sales and purchase of available-for-sale investments during the quarter.

Cash (Used in) Provided by Financing Activities

Net cash used in financing activities was $6,000 during the six months ended June 30, 2021 compared to the net cash provided by financing activities of $30.4 million for the six months ended June 30, 2020. The net cash provided during the six months ended June 30, 2020 was primarily due to net proceeds of $21.2 million related to proceeds from the debt facility and $8.0 million from the sale of our common stock, related to our public offering, offset by $0.8 million for payments on short term notes.

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. 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. The Company's international business development activities may also continue to be negatively impacted by COVID-19, especially with the recent surge in infections internationally, ongoing international travel restrictions and quarantines or shelter-in-place orders.

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, 2020. 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, 2020.

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, 2021.

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

Evaluation of Disclosure Controls and Procedures

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

Under the supervision of and with the participation of our management, including the Company's Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2021. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2021.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting in connection with the evaluation required by Rule 13a-15(d) of the Exchange Act that occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our 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 may be involved in certain routine 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

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, 2020 under "Item 1A — Risk Factors."

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
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1**	Certification pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(b) of the Securities Exchange Act of 1934
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase
101.DEF*	XBRL Taxonomy Extension Definition Database
101.LAB*	XBRL Taxonomy Extension Label Linkbase
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase
104*	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, 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

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 16, 2021 /s/ Russell Ellison

Russell Ellison
Chief Executive Officer (Principal Executive Officer)

Date: August 16, 2021 /s/ Russell Skibsted

Russell Skibsted
Chief Financial Officer (Principal Financial 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 16, 2021

/s/ Russell Ellison
Russell Ellison
Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a)

I, Russell Skibsted, 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 16, 2021

/s/ Russell Skibsted
Russell Skibsted
Chief Financial 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, 2021 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 16, 2021 /s/ Russell Ellison

Russell Ellison
Chief Executive Officer

Date: August 16, 2021 /s/ Russell Skibsted

Russell Skibsted
Chief Financial Officer