
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended September 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 No.: 001-36534

IRADIMED CORPORATION

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

73-1408526

(I.R.S. Employer
Identification Number)

**1025 Willa Springs Drive
Winter Springs, Florida**

(Address of principal executive offices)

32708

(Zip Code)

(407) 677-8022

(Registrant's telephone number, including area code)

N/A

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

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

<u>Title of each class:</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered:</u>
Common stock, par value \$0.0001	IRMD	NASDAQ Capital Market

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 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 or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" as defined in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐

Non-accelerated filer ☒

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. Yes ☐ No ☐

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

The registrant had 12,341,750 shares of common stock, par value \$0.0001 per share, outstanding as of November 1, 2021.

IRADIMED CORPORATION

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections entitled “Business,” “Risk Factors” and “Management’s Discussion and Analysis and Results of Operations.” In some cases, you can identify forward-looking statements by the following words: “may,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “ongoing” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements relate to future events or our future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. These forward-looking statements include, but are not limited to, statements about:

- our ability to respond and adapt to unexpected hospital, legal and regulatory changes resulting from the ongoing COVID-19 pandemic, such as changes in hospital treatment and financial practices, shelter-in-place orders, travel, social distancing and quarantine policies, curtailment of trade, and other business restrictions affecting our ability to assemble and sell our products;
- our ability to receive 510(k) clearance for our products and product candidates, complete inspections conducted by the U.S. Food & Drug Administration (“FDA”) or other regulatory bodies resulting in favorable outcomes, additional actions by or requests from the FDA, including a request to cease domestic distribution of products, or other regulatory bodies and unanticipated costs or delays associated with the resolution of these matters;
- the timing and likelihood of regulatory approvals or clearances from the FDA or other regulatory bodies and regulatory actions on our product candidates and product marketing activities;
- unexpected costs, expenses and diversion of management attention resulting from actions or requests posed to us by the FDA or other regulatory bodies;
- our primary reliance on a limited number of products;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our expectations regarding the sales and marketing of our products, product candidates and services;
- our expectations regarding the integrity of our supply chain for our products;
- the potential for adverse application of environmental, health and safety and other laws and regulations of any jurisdiction on our operations;
- our expectations for market acceptance of our new products;
- the potential for our marketed products to be withdrawn due to recalls, patient adverse events or deaths;
- our ability to establish and maintain intellectual property on our products and our ability to successfully defend these in cases of infringement;
- the implementation of our business strategies;
- the potential for exposure to product liability claims;
- our financial performance expectations and interpretations thereof by securities analysts and investors;
- our ability to compete in the development and marketing of our products and product candidates with other companies in our industry;

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- difficulties or delays in the development, production, manufacturing and marketing of new or existing products and services, including difficulties or delays associated with obtaining requisite regulatory approvals or clearances associated with those activities;
- changes in laws and regulations or in the interpretation or application of laws or regulations, as well as possible failures to comply with applicable laws or regulations as a result of possible misinterpretations or misapplications;
- cost-containment efforts of our customers, purchasing groups, third-party payers and governmental organizations;
- costs associated with protecting our trade secrets and enforcing our patent, copyright and trademark rights, and successful challenges to the validity of our patents, copyrights or trademarks;
- actions of regulatory bodies and other government authorities, including the FDA and foreign counterparts, that could delay, limit or suspend product development, manufacturing or sales or result in recalls, seizures, consent decrees, injunctions and monetary sanctions;
- costs or claims resulting from potential errors or defects in our manufacturing that may injure persons or damage property or operations, including costs from remediation efforts or recalls;
- the results, consequences, effects or timing of any commercial disputes, patent infringement claims or other legal proceedings or any government investigations;
- interruption in our ability to manufacture our products or an inability to obtain key components or raw materials or increased costs in such key components or raw materials;
- uncertainties in our industry due to the effects of government-driven or mandated healthcare reform;
- competitive pressures in the markets in which we operate;
- the loss of, or default by, one or more key customers or suppliers; and
- unfavorable changes to the terms of key customer or supplier relationships.

Forward-looking statements are not guarantees of future performance and are subject to substantial risks and uncertainties that could cause the actual results to differ materially from those that we predicted in the forward-looking statements. Investors should carefully review the information contained under the caption "Risk Factors" contained in Part II, Item 1A for a description of risks and uncertainties that could cause actual results to differ from those that we predicted. All forward-looking statements are based on information available to us on the date hereof, and we assume no obligation to update forward-looking statements, except as required by Federal Securities laws.

Unless expressly indicated or the context requires otherwise, references in this Quarterly Report to "IRADIMED," the "Company," "we," "our," and "us" refer to IRADIMED CORPORATION.

PART I. FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

IRADIMED CORPORATION CONDENSED BALANCE SHEETS

	September 30, 2021 (unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 58,371,572	\$ 50,068,728
Investments	945,066	1,909,368
Accounts receivable, net of allowance for doubtful accounts of \$45,891 as of September 30, 2021 and \$46,484 as of December 31, 2020	4,253,647	4,574,932
Inventory, net	4,433,389	3,933,987
Prepaid expenses and other current assets	685,449	771,666
Prepaid income taxes	2,899,939	2,477,211
Total current assets	71,589,062	63,735,892
Property and equipment, net	2,110,377	2,120,148
Intangible assets, net	1,054,641	960,885
Operating lease right-of-use asset, net	2,548,702	2,715,030
Deferred income taxes, net	870,028	1,272,672
Other assets	225,749	261,993
Total assets	\$ 78,398,559	\$ 71,066,620
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 842,660	\$ 657,054
Accrued payroll and benefits	2,413,986	1,714,782
Other accrued taxes	91,254	103,981
Warranty reserve	111,007	90,054
Deferred revenue	2,442,430	1,949,259
Current portion of operating lease liability	272,498	255,698
Other current liabilities	146,435	146,435
Total current liabilities	6,320,270	4,917,263
Deferred revenue	1,910,668	2,305,413
Operating lease liability, less current portion	2,276,204	2,459,332
Total liabilities	10,507,142	9,682,008
Stockholders' equity:		
Common stock; \$0.0001 par value; 31,500,000 shares authorized; 12,340,654 shares issued and outstanding as of September 30, 2021 and 12,308,432 shares issued and outstanding as of December 31, 2020	1,234	1,231
Additional paid-in capital	24,766,697	23,676,843
Retained earnings	43,102,255	37,669,451
Accumulated other comprehensive income	21,231	37,087
Total stockholders' equity	67,891,417	61,384,612
Total liabilities and stockholders' equity	\$ 78,398,559	\$ 71,066,620

See accompanying notes to unaudited condensed financial statements.

IRADIMED CORPORATION
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue	\$ 10,907,302	\$ 7,699,096	\$ 29,941,721	\$ 23,171,329
Cost of revenue	2,501,745	1,958,036	7,141,547	6,036,353
Gross profit	8,405,557	5,741,060	22,800,174	17,134,976
Operating expenses:				
General and administrative	2,252,274	2,196,935	7,247,262	10,062,089
Sales and marketing	2,585,702	2,282,491	7,434,603	7,090,192
Research and development	480,696	476,876	1,410,192	1,389,812
Total operating expenses	5,318,672	4,956,302	16,092,057	18,542,093
Income (loss) from operations	3,086,885	784,758	6,708,117	(1,407,117)
Other income, net	7,143	9,352	14,675	125,706
Income (loss) before provision for income taxes	3,094,028	794,110	6,722,792	(1,281,411)
Provision for income tax expense (benefit)	517,767	(280,536)	1,289,988	(2,012,998)
Net income	\$ 2,576,261	\$ 1,074,646	\$ 5,432,804	\$ 731,587
Net income per share:				
Basic	\$ 0.21	\$ 0.09	\$ 0.44	\$ 0.06
Diluted	\$ 0.20	\$ 0.09	\$ 0.43	\$ 0.06
Weighted average shares outstanding:				
Basic	12,331,062	12,243,362	12,318,476	12,071,027
Diluted	12,603,566	12,493,309	12,570,925	12,414,932

See accompanying notes to unaudited condensed financial statements.

IRADIMED CORPORATION
CONDENSED STATEMENTS OF COMPREHENSIVE INCOME
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Net income	\$ 2,576,261	\$ 1,074,646	\$ 5,432,804	\$ 731,587
Other comprehensive (loss) income:				
Change in fair value of available-for-sale securities, net of tax (benefit) expense of \$(944) and \$(1,402) for the three months ended September 30, 2021 and 2020, respectively, and \$(8,275) and \$9,071 for the nine months ended September 30, 2021 and 2020, respectively	(2,948)	(7,181)	(6,027)	23,049
Realized gain on available-for-sale securities reclassified to net income, net of tax expense of \$3,176 and \$2,199 for the nine months ended September 30, 2021 and 2020, respectively	—	—	(9,829)	(6,662)
Other comprehensive (loss) income	(2,948)	(7,181)	(15,856)	16,387
Comprehensive income	<u>\$ 2,573,313</u>	<u>\$ 1,067,465</u>	<u>\$ 5,416,948</u>	<u>\$ 747,974</u>

See accompanying notes to unaudited condensed financial statements.

IRADIMED CORPORATION
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)

	Common Stock		Additional	Retained	Accumulated	Stockholders'
	Shares	Amount	Paid-in	Earnings	Other	Equity
			Capital		Comprehensive	
					Income	
Balances, December 31, 2020	12,308,432	\$ 1,231	\$ 23,676,843	\$ 37,669,451	\$ 37,087	\$ 61,384,612
Net income	—	—	—	1,386,849	—	1,386,849
Other comprehensive loss	—	—	—	—	(4,869)	(4,869)
Stock-based compensation expense	—	—	347,741	—	—	347,741
Net share settlement of restricted stock units	3,502	—	(38,707)	—	—	(38,707)
Exercise of stock options	250	—	2,460	—	—	2,460
Balances, March 31, 2021	12,312,184	\$ 1,231	\$ 23,988,337	\$ 39,056,300	\$ 32,218	\$ 63,078,086
Net income	—	—	—	1,469,694	—	1,469,694
Other comprehensive loss	—	—	—	—	(8,039)	(8,039)
Stock-based compensation expense	—	—	358,012	—	—	358,012
Net share settlement of restricted stock units	2,727	1	(15,875)	—	—	(15,874)
Exercise of stock options	2,125	—	20,235	—	—	20,235
Balances, June 30, 2021	12,317,036	\$ 1,232	\$ 24,350,709	\$ 40,525,994	\$ 24,179	\$ 64,902,114
Net income	—	—	—	2,576,261	—	2,576,261
Other comprehensive loss	—	—	—	—	(2,948)	(2,948)
Stock-based compensation expense	—	—	361,836	—	—	361,836
Net share settlement of restricted stock units	618	—	(8,766)	—	—	(8,766)
Exercise of stock options	23,000	2	62,918	—	—	62,920
Balances, September 30, 2021	12,340,654	\$ 1,234	\$ 24,766,697	\$ 43,102,255	\$ 21,231	\$ 67,891,417

See accompanying notes to unaudited condensed financial statements.

IRADIMED CORPORATION
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (continued)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income	Stockholders' Equity
	Shares	Amount				
Balances, December 31, 2019	11,765,875	\$ 1,177	\$ 19,192,394	\$ 36,300,450	\$ 30,374	\$ 55,524,395
Net income	—	—	—	1,769,211	—	1,769,211
Other comprehensive income	—	—	—	—	10,433	10,433
Stock-based compensation expense	—	—	568,958	—	—	568,958
Net share settlement of restricted stock units	14,521	1	(133,873)	—	—	(133,872)
Exercise of stock options	190,541	19	322,160	—	—	322,179
Balances, March 31, 2020	11,970,937	\$ 1,197	\$ 19,949,639	\$ 38,069,661	\$ 40,807	\$ 58,061,304
Net loss	—	—	—	(2,112,270)	—	(2,112,270)
Other comprehensive income	—	—	—	—	13,135	13,135
Stock-based compensation expense	—	—	2,658,632	—	—	2,658,632
Net share settlement of restricted stock units	76,381	8	(725,393)	—	—	(725,385)
Exercise of stock options	150,519	15	468,795	—	—	468,810
Balances, June 30, 2020	12,197,837	\$ 1,220	\$ 22,351,673	\$ 35,957,391	\$ 53,942	\$ 58,364,226
Net income	—	—	—	1,074,646	—	1,074,646
Other comprehensive loss	—	—	—	—	(7,181)	(7,181)
Stock-based compensation expense	—	—	416,525	—	—	416,525
Net share settlement of restricted stock units	8,245	1	(63,491)	—	—	(63,490)
Exercise of stock options	63,041	6	931,726	—	—	931,732
Balances, September 30, 2020	12,269,123	\$ 1,227	\$ 23,636,433	\$ 37,032,037	\$ 46,761	\$ 60,716,458

See accompanying notes to unaudited condensed financial statements.

IRADIMED CORPORATION
CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2021	2020
Operating activities:		
Net income	\$ 5,432,804	\$ 731,587
Adjustments to reconcile net income to net cash provided by operating activities:		
Change in allowance for doubtful accounts	(567)	41,786
Change in provision for excess and obsolete inventory	51,731	29,209
Depreciation and amortization	1,020,223	999,812
Loss on disposal of property and equipment	1,066	—
Stock-based compensation	1,067,589	3,644,115
Deferred income taxes, net	414,095	310,329
Gain on maturities of investments	(13,005)	(8,861)
Changes in operating assets and liabilities:		
Accounts receivable	321,852	2,999,188
Inventory	(344,721)	(1,062,455)
Prepaid expenses and other current assets	(663,408)	(642,982)
Other assets	23,447	(40,899)
Accounts payable	(17,076)	(468,615)
Accrued payroll and benefits	699,204	(523,437)
Other accrued taxes	(12,727)	(473,380)
Warranty reserve	20,953	5,298
Deferred revenue	313,381	119,658
Other current liability	—	(2,335,105)
Prepaid income taxes	(422,728)	(3,820)
Net cash provided by operating activities	7,892,113	3,321,428
Investing activities:		
Proceeds from maturity of investments	950,000	480,000
Purchases of property and equipment	(391,303)	(349,283)
Capitalized intangible assets	(170,234)	(184,281)
Net cash provided by (used in) investing activities	388,463	(53,564)
Financing activities:		
Proceeds from exercises of stock options	85,615	1,722,721
Taxes paid related to the net share settlement of equity awards	(63,347)	(922,747)
Net cash provided by financing activities	22,268	799,974
Net increase in cash and cash equivalents	8,302,844	4,067,838
Cash and cash equivalents, beginning of period	50,068,728	43,481,781
Cash and cash equivalents, end of period	\$ 58,371,572	\$ 47,549,619
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	\$ 1,283,722	\$ —
Right-of-use asset recognized in exchange for a new lease obligation	\$ 27,713	\$ —
Operating and short-term lease payments recorded within cash flow provided by operating activities	\$ 364,545	\$ 321,856

See accompanying notes to unaudited condensed financial statements.

IRADIMED CORPORATION
Notes to Unaudited Condensed Financial Statements

1 — Basis of Presentation

The accompanying interim condensed financial statements of IRADIMED CORPORATION (“IRADIMED”, the “Company”, “we”, “our”) have been prepared pursuant to the rules and regulations of the SEC. Certain information and footnote disclosures normally presented in annual financial statements prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) have been condensed or omitted pursuant to such rules and regulations. The interim financial information is unaudited, but reflects all normal adjustments that are, in the opinion of management, necessary for the fair presentation of our financial position, results of operations and cash flows for the interim periods presented. Operating results for the three and nine months ended September 30, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021.

These accompanying interim condensed financial statements should be read with the financial statements and related footnotes to financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2020. The accounting policies followed in the preparation of these interim condensed financial statements, except as described in Note 1, are consistent in all material respects with those described in Note 1 of our Form 10-K.

We operate in one reportable segment which is the development, manufacture and sale of MRI compatible medical devices, related accessories, disposables and service for use by hospitals and acute care facilities during MRI procedures.

Certain Significant Risks and Uncertainties

We market our products to end users in the U.S. and to distributors internationally. Sales to end users in the U.S. are generally made on open credit terms. Management maintains an allowance for potential credit losses.

We have deposited our cash and cash equivalents with various financial institutions. Our cash and cash equivalents balances exceed federally insured limits throughout the year. We have not incurred any losses related to these balances.

Our products require clearance from the Food and Drug Administration and international regulatory agencies prior to commercialized sales. Our future products may not receive required approvals. If we were denied such approvals, or if such approvals were revoked or delayed or if we were unable to timely renew certain approvals for existing products, it would have a materially adverse impact on our business, results of operations and financial condition.

Certain key components of our products essential to their functionality are sole-sourced. Any disruption in the availability of these components would have a materially adverse impact on our business, results of operations and financial condition.

COVID-19 Considerations

The COVID-19 pandemic, and related governmental and societal responses thereto, continue to cause disruption in global supply and distribution channels and significantly change the way companies manage their business. From the beginning of this global health crisis, our priority has been the safety and well-being of our employees and continuing to supply our customers with access to our therapeutic and diagnostic device solutions.

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We continue to monitor the developments associated with the COVID-19 pandemic and its effects on our employees, customers, supply chain and distribution channels. The ongoing impact of the pandemic depends on several factors including the severity and duration of the pandemic and the extent and severity of the impact on our customers, which is uncertain and unpredictable. Our future results of operations and cash flows may suffer adverse effects from disruptions in our supply chain and manufacturing operations, delays in payments on outstanding accounts receivable, uncertain demand for our products, and effects of any actions we may take to address financial and operational challenges our customers may face. Our future results may potentially be heavily determined by global vaccination rates, duration of the pandemic, its geographic spread, further business disruptions and the overall impact on the global economy. Other risks and uncertainties that we face include, but are not limited to:

- disruptions in our supply chain that may limit our ability to procure materials necessary to manufacture our products or procuring materials at elevated costs resulting in diminished financial results;
- postponement or cancellation of MRI medical procedures and their uncertain return which adversely impacts our business;
- potential temporary or prolonged closure of our office and production facility;
- the health of our employees and ability to meet our staffing needs;
- potential new or continued governmental actions that may limit employees' ability to work;
- civil unrest relating to government, corporate and societal responses to the pandemic;
- volatility in economic conditions and the financial markets, and
- other unanticipated effects that remain unknown.

We are actively managing our response to the COVID-19 pandemic and working with our customers, distributors, vendors, and suppliers and assessing the potential effects to our financial position, results of operations and cash flows. As of the date of the issuance of these financial statements, the extent to which COVID-19, or its variants, may materially impact our financial condition, liquidity, or results of operations in future periods remains uncertain.

Recent Accounting Pronouncements

Recently Issued Accounting Pronouncements to be Implemented

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires the Company to measure and recognize expected credit losses for financial assets held and not accounted for at fair value through net income. In November 2018, April 2019 and May 2019, the FASB issued ASU 2018-19, *Codification Improvements to Topic 326, Financial Instruments - Credit Losses*, ASU 2019-04, *Codification Improvements to Topic 326, Financial Instruments - Credit Losses* and ASU 2019-05, *Financial Instruments - Credit Losses (Topic 326): Targeted Transition Relief*, which provided additional implementation guidance on ASU 2016-03. The previously mentioned ASUs are effective for fiscal years beginning after December 15, 2022, with early adoption permitted. We do not expect the adoption of these ASUs to have a material impact on our financial condition, results of operations or cash flows.

Accounting Pronouncements Implemented in 2021

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. ASU 2019-12 will be effective for fiscal years, and interim periods within those years, beginning after December 15, 2020. We adopted ASU 2019-12 on January 1, 2021, and the adoption did not have an impact on our financial condition, results of operations or cash flows.

2 — Revenue Recognition

Disaggregation of Revenue

We disaggregate revenue from contracts with customers by geographic region and revenue type as we believe it best depicts the nature, amount, timing and uncertainty of our revenue and cash flow.

Revenue information by geographic region is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(unaudited)		(unaudited)	
United States	\$ 8,676,488	\$ 6,465,184	\$ 23,992,474	\$ 17,430,206
International	2,230,814	1,233,912	5,949,247	5,741,123
Total revenue	<u>\$ 10,907,302</u>	<u>\$ 7,699,096</u>	<u>\$ 29,941,721</u>	<u>\$ 23,171,329</u>

Revenue information by type is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(unaudited)		(unaudited)	
Devices:				
MRI Compatible IV Infusion Pump Systems	\$ 3,369,068	\$ 2,153,699	\$ 9,329,182	\$ 6,693,692
MRI Compatible Patient Vital Signs Monitoring Systems	3,779,442	2,282,943	9,760,991	6,829,932
Total Devices revenue	7,148,510	4,436,642	19,090,173	13,523,624
Disposables, services and other	3,285,656	2,802,039	9,412,091	8,269,487
Amortization of extended warranty agreements	473,136	460,415	1,439,457	1,378,218
Total revenue	<u>\$ 10,907,302</u>	<u>\$ 7,699,096</u>	<u>\$ 29,941,721</u>	<u>\$ 23,171,329</u>

Contract Liabilities

Our contract liabilities consist of:

	September 30, 2021 (unaudited)	December 31, 2020
Advance payments from customers	\$ 427,442	\$ 85,590
Shipments in-transit	214,955	35,013
Extended warranty agreements	3,710,701	4,134,069
Total	<u>\$ 4,353,098</u>	<u>\$ 4,254,672</u>

Changes in the contract liabilities during the periods presented are as follows:

	Deferred Revenue
Contract liabilities, December 31, 2020	\$ 4,254,672
Increases due to cash received from customers	3,617,619
Decreases due to recognition of revenue	(3,519,193)
Contract liabilities, September 30, 2021	<u>\$ 4,353,098</u>

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	Deferred Revenue
Contract liabilities, December 31, 2019	\$ 4,301,887
Increases due to cash received from customers	1,655,021
Decreases due to recognition of revenue	(1,576,995)
Contract liabilities, September 30, 2020	<u>\$ 4,379,913</u>

Capitalized Contract Costs

Our capitalized contract costs totaled \$360,920 and \$384,367 as of September 30, 2021 and December 31, 2020, respectively.

3 — Basic and Diluted Net Income per Share

Basic net income per share is based upon the weighted-average number of common shares outstanding during the period. Diluted net income per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Stock options, restricted stock units and performance-based restricted stock units granted by us represent the only dilutive effect reflected in diluted weighted-average shares outstanding.

The following table presents the computation of basic and diluted net income per share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Net income	\$ 2,576,261	\$ 1,074,646	\$ 5,432,804	\$ 731,587
Weighted-average shares outstanding — Basic	12,331,062	12,243,362	12,318,476	12,071,027
Effect of dilutive securities:				
Stock options	187,737	204,108	191,439	294,202
Restricted stock units	72,327	45,839	50,201	49,703
Performance-based restricted stock units	12,440	—	10,809	—
Weighted-average shares outstanding — Diluted	12,603,566	12,493,309	12,570,925	12,414,932
Basic net income per share	\$ 0.21	\$ 0.09	\$ 0.44	\$ 0.06
Diluted net income per share	<u>\$ 0.20</u>	<u>\$ 0.09</u>	<u>\$ 0.43</u>	<u>\$ 0.06</u>

Stock options and restricted stock units excluded from the calculation of diluted net income per share because the effect would have been anti-dilutive are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Anti-dilutive stock options and restricted stock units	164	10,024	2,644	48,706

4 — Inventory

Inventory consists of:

	September 30, 2021	December 31, 2020
	(unaudited)	(unaudited)
Raw materials	\$ 3,408,311	\$ 3,210,815
Work in process	244,081	207,807
Finished goods	970,401	653,038
Inventory before allowance for excess and obsolete	4,622,793	4,071,660
Allowance for excess and obsolete	(189,404)	(137,673)
Total	<u>\$ 4,433,389</u>	<u>\$ 3,933,987</u>

5 — Property and Equipment

Property and equipment consist of:

	September 30, 2021 (unaudited)	December 31, 2020
Computer software and hardware	\$ 793,272	\$ 705,811
Furniture and fixtures	1,248,460	1,226,113
Leasehold improvements	236,036	230,351
Machinery and equipment	2,057,436	1,823,835
Tooling in-process	500,192	470,446
	4,835,396	4,456,556
Accumulated depreciation	(2,725,019)	(2,336,408)
Total	<u>\$ 2,110,377</u>	<u>\$ 2,120,148</u>

Depreciation expense of property and equipment was \$131,541 and \$128,513 for the three months ended September 30, 2021 and 2020, respectively, and \$396,278 and \$382,766 for the nine months ended September 30, 2021 and 2020, respectively.

Property and equipment, net, information by geographic region is as follows:

	September 30, 2021 (unaudited)	December 31, 2020
United States	\$ 1,879,040	\$ 1,832,894
International	231,337	287,254
Total property and equipment, net	<u>\$ 2,110,377</u>	<u>\$ 2,120,148</u>

Long-lived assets held outside of the United States consist principally of tooling and machinery and equipment, which are components of property and equipment, net.

6 — Intangible Assets

The following table summarizes the components of intangible asset balances:

	September 30, 2021 (unaudited)	December 31, 2020
Patents — in use	\$ 372,502	\$ 362,162
Patents — in process	94,826	69,733
Internally developed software — in use	872,218	872,253
Internally developed software — in process	396,008	261,622
Trademarks	27,697	27,247
	1,763,251	1,593,017
Accumulated amortization	(708,610)	(632,132)
Total	<u>\$ 1,054,641</u>	<u>\$ 960,885</u>

Amortization expense of intangible assets was \$25,256 and \$22,999 for the three months ended September 30, 2021 and 2020, respectively, and \$76,478 and \$68,489 for the nine months ended September 30, 2021 and 2020, respectively.

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Expected annual amortization expense for the remaining portion of 2021 and the next five years related to intangible assets is as follows (excludes in process intangible assets):

Three months ending December 31, 2021	\$ 25,257
2022	\$ 100,308
2023	\$ 99,797
2024	\$ 99,395
2025	\$ 96,225
2026	\$ 84,508

7 — Investments

Our investments consist of bonds that we have classified as available-for-sale and are summarized in the following tables:

	September 30, 2021			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. corporate bonds	\$ 926,387	\$ 18,679	\$ —	\$ 945,066

	December 31, 2020			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. corporate bonds	\$ 1,863,382	\$ 45,986	\$ —	\$ 1,909,368

8 — Fair Value Measurements

The fair values of cash equivalents, accounts receivables, net and accounts payable approximate their carrying amounts due to their short duration.

The fair value of our assets and liabilities subject to recurring fair value measurements are as follows:

	Fair Value at September 30, 2021			
	Fair Value	Quoted Prices in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
U.S. corporate bonds	\$ 945,066	\$ —	\$ 945,066	\$ —

	Fair Value at December 31, 2020			
	Fair Value	Quoted Prices in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
U.S. corporate bonds	\$ 1,909,368	\$ —	\$ 1,909,368	\$ —

Our corporate bonds are valued by a third-party custodian at closing prices from secondary exchanges or pricing vendors on the valuation date.

There were no transfers into or out of any Levels during the nine months ended September 30, 2021 or the year ended December 31, 2020.

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9 — Accumulated Other Comprehensive Income

The components of accumulated other comprehensive income, net of tax, for the three months ended September 30, 2021 and 2020 are as follows:

	Unrealized (Losses) Gains on Available-For-Sale Securities
Balance at June 30, 2021	\$ 24,179
Losses on available-for-sale securities, net	(2,948)
Reclassification realized in net earnings	—
Balance at September 30, 2021	\$ 21,231
Balance at June 30, 2020	\$ 53,942
Gains on available-for-sale securities, net	(7,181)
Reclassification realized in net earnings	—
Balance at September 30, 2020	\$ 46,761

The components of accumulated other comprehensive income, net of tax, for the nine months ended September 30, 2021 and 2020 are as follows:

	Unrealized (Losses) Gains on Available-For-Sale Securities
Balance at December 31, 2020	\$ 37,087
Losses on available-for-sale securities, net	(6,027)
Reclassification realized in net earnings	(9,829)
Balance at September 30, 2021	\$ 21,231
Balance at December 31, 2019	\$ 30,374
Gains on available-for-sale securities, net	23,049
Reclassification realized in net earnings	(6,662)
Balance at September 30, 2020	\$ 46,761

10 — Stock-Based Compensation

Stock-based compensation was recognized as follows in the Condensed Statements of Operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(unaudited)		(unaudited)	
Cost of revenue	\$ 68,227	\$ 28,751	\$ 177,375	\$ 145,258
General and administrative	152,261	291,100	513,319	3,153,886
Sales and marketing	96,210	77,607	269,505	286,134
Research and development	45,138	19,067	107,390	58,837
Total	\$ 361,836	\$ 416,525	\$ 1,067,589	\$ 3,644,115

As of September 30, 2021, we had \$2,449,679 of unrecognized compensation cost related to unvested restricted stock units, which is expected to be recognized over a weighted-average period of 2.5 years. As of September 30, 2021, we had \$200,926 of unrecognized compensation cost related to unvested performance-based restricted stock units, which is expected to be recognized over a weighted-average period of 2.2 years.

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The following table presents a summary of our stock-based compensation activity for the nine months ended September 30, 2021 (shares):

	Stock Options	Restricted Stock Units	Performance Based Restricted Stock Units
Outstanding beginning of period	230,510	151,139	11,891
Awards granted	—	17,989	—
Awards exercised/vested	(25,375)	(9,347)	—
Awards canceled	—	(10,635)	(2,546)
Outstanding end of period	205,135	149,146	9,345

11 — Income Taxes

For the three and nine months ended September 30, 2021, we recorded a provision for income tax expense of \$517,767 and \$1,289,988, respectively. Our effective tax rate was 16.7 percent and 19.2 percent, respectively, and differed from the U.S. Federal statutory rate primarily due to benefits from foreign derived intangible income, stock compensation and research and development tax credits, partially offset by U.S. state income tax expense.

For the three and nine months ended September 30, 2020, we recorded a provision for income tax benefit of \$(280,536) and \$(2,012,998), respectively. Our effective tax rate was (35.3) percent and 157.1 percent, respectively, and differed from the U.S. Federal statutory rate primarily due to discrete items related to tax benefits associated with stock-based compensation and a U.S. state tax benefit, partially offset by a limitation on the deductibility of certain executive compensation associated with the separation of our former Chief Executive Officer. Additionally, we recognized a benefit in our effective tax rate resulting from the Coronavirus Aid, Relief, and Economic Security Act, which allowed us to carryback net operating losses to years prior to the enactment of the Tax Cuts and Jobs Act.

As of September 30, 2021, and December 31, 2020, we had not identified or accrued for any uncertain tax positions. We are currently unaware of any uncertain tax positions that could result in significant payments, accruals or other material deviations in this estimate over the next 12 months. We believe that our tax positions comply in all material respects with applicable tax law. However, tax law is subject to interpretation, and interpretations by taxing authorities could be different from ours, which could result in the imposition of additional taxes and penalties.

We file tax returns in the United States Federal jurisdiction and many U.S. state jurisdictions. Our returns are not currently under examination by the Internal Revenue Service. The Company remains subject to income tax examinations for our United States Federal and certain U.S. state income taxes for 2017 and subsequent years and various other U.S. state income taxes for 2016 and subsequent years.

12 — Leases

We have entered into operating lease contracts for our office and various office equipment.

We have one material lease contract outstanding. In January 2014, we entered into a non-cancelable operating lease, commencing July 1, 2014, for our manufacturing and headquarters facility in Winter Springs, Florida owned by Susi, LLC, an entity controlled by our President, Chief Executive Officer, and Chairman of the Board, Roger Susi. Pursuant to the terms of our lease for this property, the monthly base rent is \$34,133, adjusted annually for changes in the consumer price index. Under the terms of the lease, we are responsible for property taxes, insurance and maintenance expenses. Prior to May 31, 2019, the expiration date of the initial lease term, and pursuant to the terms of the lease contract, we renewed the lease for an additional five years, resulting in a new lease expiration date of May 31, 2024. Unless advance written notice of termination is timely provided, the lease will automatically renew for one additional successive term of five years beginning in 2024, and thereafter, will be renewed for successive terms of one year each. We concluded that we would exercise the remaining five-year option, resulting in a remaining lease term of 7.7 years as of September 30, 2021. This lease agreement does not contain any residual value guarantee or material restrictive covenants.

Operating lease cost recognized in the Condensed Statements of Operations is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(unaudited)		(unaudited)	
Cost of revenue	\$ 53,854	\$ 46,533	\$ 156,043	\$ 139,603
General and administrative	54,710	46,045	158,672	138,133
Sales and marketing	3,014	2,605	8,733	7,813
Research and development	8,350	7,216	24,195	21,646
Total	<u>\$ 119,928</u>	<u>\$ 102,399</u>	<u>\$ 347,643</u>	<u>\$ 307,195</u>

Lease costs for short-term leases were immaterial for the three and nine months ended September 30, 2021 and 2020.

Maturity of our operating lease liability as of September 30, 2021 is as follows:

Three months ending December 31, 2021	\$ 103,823
2022	415,294
2023	415,294
2024	415,294
2025	415,294
Thereafter	1,400,865
Total lease payments	3,165,864
Imputed interest	(617,162)
Present value of lease liability	<u>\$ 2,548,702</u>

13 — Commitments and Contingencies

Purchase commitments. We had various purchase orders for goods or services totaling \$5,612,633 and \$3,089,103 as of September 30, 2021 and December 31, 2020, respectively. No amounts related to these purchase orders have been recognized in our balance sheet.

Legal matters. We may from time to time become party to various legal proceedings or claims that arise in the ordinary course of business.

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 financial statements and the related notes to those statements included in this Quarterly Report, the discussion of certain risks and uncertainties contained in Part II, Item 1A of this Quarterly Report, the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business" included in our Annual Report filed on Form 10-K for the fiscal year ended December 31, 2020 and the cautionary information regarding forward-looking statements at the beginning of this Quarterly Report.

Our Business

We develop, manufacture, market and distribute Magnetic Resonance Imaging ("MRI") compatible medical devices and accessories and services relating to them.

We are a leader in the development of innovative MRI compatible medical devices. We are the only known provider of a non-magnetic intravenous ("IV") infusion pump system that is specifically designed to be safe for use during MRI procedures. We were the first to develop an infusion delivery system that largely eliminates many of the dangers and problems present during MRI procedures. Standard infusion pumps contain magnetic and electronic components which can create radio frequency interference and are dangerous to operate in the presence of the powerful magnet that drives an MRI system. Our patented MRidium® MRI compatible IV infusion pump system has been designed with a non-magnetic ultrasonic motor, uniquely designed non-ferrous parts and other special features to safely and predictably deliver anesthesia and other IV fluids during various MRI procedures. Our pump solution provides a seamless approach that enables accurate, safe and dependable fluid delivery before, during and after an MRI scan, which is important to critically ill patients who cannot be removed from their vital medications, and children and infants who must generally be sedated to remain immobile during an MRI scan.

Each IV infusion pump system consists of an MRidium® MRI compatible IV infusion pump, non-magnetic mobile stand, proprietary disposable IV tubing sets and many of these systems contain additional optional upgrade accessories.

Our 3880 MRI compatible patient vital signs monitoring system has been designed with non-magnetic components and other special features to safely and accurately monitor a patient's vital signs during various MRI procedures. The IRADIMED 3880 system operates dependably in magnetic fields up to 30,000 gauss, which means it can operate virtually anywhere in the MRI scanner room. The IRADIMED 3880 has a compact, lightweight design allowing it to travel with the patient from their critical care unit, to the MRI and back, resulting in increased patient safety through uninterrupted vital signs monitoring and decreasing the amount of time critically ill patients are away from critical care units. The features of the IRADIMED 3880 include: wireless ECG with dynamic gradient filtering; wireless SpO2 using Masimo® algorithms; non-magnetic respiratory CO2; invasive and non-invasive blood pressure; patient temperature, and optional advanced multi-gas anesthetic agent unit featuring continuous Minimum Alveolar Concentration measurements. The IRADIMED 3880 MRI compatible patient vital signs monitoring system has an easy-to-use design and allows for the effective communication of patient vital signs information to clinicians.

We generate revenue from the sale of MRI compatible medical devices and accessories, extended warranty agreements, services related to maintaining our products and the sale of disposable products used with our devices. The principal customers for our MRI compatible products include hospitals and acute care facilities, both in the U.S. and internationally.

Selling cycles for our devices have varied widely and have historically ranged between three and six months in duration with more recent trends lengthening beyond this historical range due to the COVID-19 pandemic. We also enter into agreements with healthcare supply contracting companies, commonly referred to as Group Purchasing Organizations ("GPOs"), in the U.S., which facilitates our ability to sell and distribute our products to their member hospitals. Under these agreements, we are required to pay these GPOs a fee of three percent of the sales of our products to their member hospitals.

Financial Highlights

Beginning in the second quarter 2020, our business was significantly impacted by the COVID-19 pandemic, which negatively impacted our operations and financial results. Additionally, during the nine months ended September 30, 2020, we recognized \$2.8 million of general and administrative expense related to the separation of our former CEO.

For the third quarter ended September 30, 2021, our revenue increased \$3.2 million, or 41.7 percent, to \$10.9 million, compared to \$7.7 million for the third quarter last year. Income before the provision for income taxes was \$3.1 million for the third quarter 2021, compared to \$0.8 million for the third quarter last year. Net income was \$2.6 million, or \$0.20 per diluted share in the third quarter ended September 30, 2021, compared to \$1.1 million, or \$0.09 per share in the third quarter last year.

For the remainder of 2021, we expect higher revenue when compared to the same period in 2020 due to higher sales of our medical devices, related accessories, disposables, and services. We also expect higher operating expenses compared to the same period in 2020 primarily due to higher sales and marketing, and general and administrative expenses.

Effects of the COVID-19 Pandemic

The COVID-19 pandemic, and related governmental and societal responses thereto, continue to cause disruption in global supply and distribution channels and significantly change the way companies manage their business. From the beginning of this global health crisis, our priority has been the safety and well-being of our employees and continuing to supply our customers with access to our therapeutic and diagnostic device solutions.

We continue to monitor the developments associated with the COVID-19 pandemic and its effects on our employees, customers, supply chain and distribution channels. The ongoing impact of the pandemic depends on several factors including the severity and duration of the pandemic and the extent and severity of the impact on our customers, which is uncertain and unpredictable. Our future results of operations and cash flows may suffer adverse effects from disruptions in our supply chain and manufacturing operations, delays in payments on outstanding accounts receivable, uncertain demand for our products, and effects of any actions we may take to address financial and operational challenges our customers may face. Our future results may potentially be heavily determined by global vaccination rates, duration of the pandemic, its geographic spread, further business disruptions and the overall impact on the global economy. Other risks and uncertainties that we face include, but are not limited to:

- disruptions in our supply chain that may limit our ability to procure materials necessary to manufacture our products or procuring materials at elevated costs resulting in diminished financial results;
- postponement or cancellation of MRI medical procedures and their uncertain return which adversely impacts our business;
- potential temporary or prolonged closure of our office and production facility;
- the health of our employees and ability to meet staffing needs;
- potential new or continued governmental actions that may limit employees' ability to work;
- civil unrest relating to government, corporate and societal responses to the pandemic;
- volatility in economic conditions and the financial markets, and
- other unanticipated effects that remain unknown.

We are actively managing our response to the COVID-19 pandemic and working with our customers, distributors, vendors, and suppliers and assessing the potential effects to our financial position, results of operations and cash flows. As of the date of the issuance of these financial statements, the extent to which COVID-19, or its variants, may materially impact our financial condition, liquidity, or results of operations in future periods remains uncertain.

Application of Critical Accounting Policies

We prepare our financial statements in conformity with GAAP. The preparation of these financial statements requires us to make estimates and use assumptions that affect the reported amounts of assets, liabilities and related disclosures at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

We believe that the following critical accounting policies require the use of significant estimates, assumptions, and judgments:

- Revenue recognition;
- Accounts receivable and allowance for doubtful accounts;
- Inventory carried at the lower of cost or net realizable value;
- Stock-based compensation; and
- Income taxes.

These critical accounting policies are described in more detail in our Annual Report filed on Form 10-K, under *Management's Discussion and Analysis and Results of Operations*. Except as disclosed in Note 1 to the unaudited condensed financial statements contained herein related to the adoption of recent accounting pronouncements, there have been no changes to these policies during the three and nine months ended September 30, 2021.

The use of different estimates, assumptions, and judgments could have a material effect on the reported amounts of assets, liabilities and related disclosures as of the date of the financial statements and revenue and expenses during the reporting period.

Results of Operations

The following table sets forth selected statements of operations data as a percentage of total revenue for the periods indicated. Our historical operating results are not necessarily indicative of the results for any future period.

	Percent of Revenue Three Months Ended September 30,		Percent of Revenue Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue	100.0 %	100.0 %	100.0 %	100.0 %
Cost of revenue	22.9	25.4	23.9	26.1
Gross profit	77.1	74.6	76.1	73.9
Operating expenses:				
General and administrative	20.6	28.5	24.2	43.4
Sales and marketing	23.7	29.6	24.8	30.6
Research and development	4.4	6.2	4.7	6.0
Total operating expenses	48.8	64.4	53.7	80.0
Income (loss) from operations	28.3	10.2	22.4	(6.1)
Other income, net	0.1	0.1	0.0	0.5
Income (loss) before provision for income taxes	28.4	10.3	22.5	(5.5)
Provision for income tax expense (benefit)	4.7	(3.6)	4.3	(8.7)
Net income	23.6 %	14.0 %	18.1 %	3.2 %

Three and Nine Months Ended September 30, 2021 and 2020

Revenue by Geographic Region

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
United States	\$ 8,676,488	\$ 6,465,184	\$ 23,992,474	\$ 17,430,206
International	2,230,814	1,233,912	5,949,247	5,741,123
Total revenue	<u>\$ 10,907,302</u>	<u>\$ 7,699,096</u>	<u>\$ 29,941,721</u>	<u>\$ 23,171,329</u>

Revenue by Type

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Devices:				
MRI Compatible IV Infusion Pump Systems	\$ 3,369,068	\$ 2,153,699	\$ 9,329,182	\$ 6,693,692
MRI Compatible Patient Vital Signs Monitoring Systems	3,779,442	2,282,943	9,760,991	6,829,932
Total Devices revenue	7,148,510	4,436,642	19,090,173	13,523,624
Disposables, services and other	3,285,656	2,802,039	9,412,091	8,269,487
Amortization of extended warranty agreements	473,136	460,415	1,439,457	1,378,218
Total revenue	<u>\$ 10,907,302</u>	<u>\$ 7,699,096</u>	<u>\$ 29,941,721</u>	<u>\$ 23,171,329</u>

For the three months ended September 30, 2021, revenue increased \$3.2 million, or 41.7 percent, to \$10.9 million from \$7.7 million for the same period in 2020.

Revenue from sales in the U.S. increased \$2.2 million, or 34.2 percent, to \$8.7 million for the third quarter 2021, from \$6.5 million for the third quarter 2020. Revenue from sales internationally increased \$1.0 million, or 80.8 percent, to \$2.2 million for the third quarter 2021, from \$1.2 million for the third quarter 2020. Domestic sales accounted for 79.5 percent of revenue for the third quarter 2021, compared to 84.0 percent for the third quarter 2020.

Revenue from sales of devices increased \$2.7 million, or 61.1 percent, to \$7.1 million for the three months ended September 30, 2021, from \$4.4 million for the same period in 2020.

The average selling price of our MRI compatible IV infusion pump system during the three months ended September 30, 2021 was approximately \$33,000, compared to approximately \$37,800 for the same period in 2020. The decrease in ASP is the result of higher international unit sales when compared to the same period in 2020.

The average selling price of our MRI compatible patient vital signs monitoring system during the three months ended September 30, 2021 was approximately \$40,600, compared to approximately \$43,000 for the same period in 2020. The decrease in ASP relates to higher international unit sales and when compared to the same period in 2020.

Revenue from sales of our disposables, service and other increased \$0.5 million, or 17.3 percent, to \$3.3 million for the three months ended September 30, 2021, from \$2.8 million for the same period in 2020. Revenue from the amortization of extended warranty agreements was consistent at \$0.5 million for the three months ended September 30, 2021 and 2020.

For the nine months ended September 30, 2021, revenue increased \$6.7 million, or 29.2 percent, to \$29.9 million from \$23.2 million for the same period in 2020.

Revenue from sales in the U.S. increased \$6.6 million, or 37.6 percent, to \$24.0 million for the nine months ended September 30, 2021, from \$17.4 million for the same period in 2020. Revenue from sales internationally increased \$0.2 million, or 3.6 percent, to \$5.9 million for the nine months ended September 30, 2021, from \$5.7 million for the same period in 2020. Domestic sales accounted for 80.1 percent of revenue for the nine months ended September 30, 2021, compared to 75.2 percent for the same period in 2020.

Revenue from sales of devices increased \$5.6 million, or 41.2 percent, to \$19.1 million for the nine months ended September 30, 2021, from \$13.5 million for the same period in 2020.

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The average selling price of our MRI compatible IV infusion pump system during the nine months ended September 30, 2021 was approximately \$34,800, compared to approximately \$32,200 for the same period in 2020. The increase in ASP relates to higher domestic sales unit when compared to the same period in 2020.

The average selling price of our MRI compatible patient vital signs monitoring system during the nine months ended September 30, 2021 was approximately \$39,700, compared to approximately \$35,800 for the same period in 2020. The increase in ASP relates to higher domestic unit sales when compared to the same period in 2020.

Revenue from sales of our disposables, service and other increased \$1.1 million, or 13.8 percent, to \$9.4 million for the nine months ended September 30, 2021, from \$8.3 million for the same period in 2020. Revenue from the amortization of extended warranty agreements was consistent at \$1.4 million for the nine months ended September 30, 2021 and 2020.

Cost of Revenue and Gross Profit

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue	\$ 10,907,302	\$ 7,699,096	\$ 29,941,721	\$ 23,171,329
Cost of revenue	2,501,745	1,958,036	7,141,547	6,036,353
Gross profit	\$ 8,405,557	\$ 5,741,060	\$ 22,800,174	\$ 17,134,976
Gross profit percentage	77.1 %	74.6 %	76.1 %	73.9 %

For the three months ended September 30, 2021, cost of revenue increased \$0.5 million, or 27.8 percent, to \$2.5 million from \$2.0 million for the same period last year. Gross profit increased \$2.7 million, or 46.4 percent, to \$8.4 million for the third quarter 2021 from \$5.7 million for the same period in 2020. Gross profit margin was 77.1 percent for third quarter 2021, compared to 74.6 percent for the third quarter 2020. The increase in gross profit margin is primarily due to favorable overhead absorption from higher unit production, partially offset by an unfavorable geographic sales mix.

For the nine months ended September 30, 2021, cost of revenue increased \$1.1 million, or 18.3 percent, to \$7.1 million from \$6.0 million for the same period last year. Gross profit increased \$5.7 million, or 33.1 percent, to \$22.8 million for the nine months ended September 30, 2021 from \$17.1 million for the same period in 2020. Gross profit margin was 76.1 percent for nine months ended September 30, 2021, compared to 73.9 percent for the same period in 2020. The increase in gross profit margin is primarily due to favorable overhead absorption from higher unit production and a favorable geographic sales mix, partially offset by unfavorable inventory reserve adjustments.

Operating Expenses

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
General and administrative	\$ 2,252,274	\$ 2,196,935	\$ 7,247,262	\$ 10,062,089
Percentage of revenue	20.6 %	28.5 %	24.2 %	43.4 %
Sales and marketing	\$ 2,585,702	\$ 2,282,491	\$ 7,434,603	\$ 7,090,192
Percentage of revenue	23.7 %	29.6 %	24.8 %	30.6 %
Research and development	\$ 480,696	\$ 476,876	\$ 1,410,192	\$ 1,389,812
Percentage of revenue	4.4 %	6.2 %	4.7 %	6.0 %

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General and Administrative

For the three months ended September 30, 2021, general and administrative expense increased \$0.1 million, or 2.5 percent, to \$2.3 million from \$2.2 million for the same period last year. This increase is primarily due to higher payroll and benefits expenses, partially offset by lower stock compensation expense.

For the nine months ended September 30, 2021, general and administrative expense decreased \$(2.9) million, or (28.0) percent, to \$7.2 million from \$10.1 million for the same period last year. This decrease is primarily due to stock and cash compensation expenses incurred during the nine months ended September 30, 2020 related to the separation of our former Chief Executive Officer, partially offset by higher regulatory affairs expenses.

Sales and Marketing

For the three months ended September 30, 2021, sales and marketing expense increased \$0.3 million, 13.3 percent, to \$2.6 million from \$2.3 million for the same period last year. This increase is primarily due to higher sales commissions and sales activities expenses, partially offset by lower payroll and benefits expenses.

For the nine months ended September 30, 2021, sales and marketing expense increased \$0.3 million, 4.9 percent, to \$7.4 million from \$7.1 million for the same period last year. This increase is primarily due to higher sales commissions and sales activities expenses, partially offset by lower payroll and benefits expenses.

Research and Development

For the three months ended September 30, 2021, research and development expense was consistent at \$0.5 million. For the nine months ended September 30, 2021, research and development expense was consistent at \$1.4 million. There were no significant changes in these accounts during the three and nine months ended September 30, 2021, compared to the same periods last year.

Other Income, Net

Other income, net consists of interest income, foreign currency gains and losses, and other miscellaneous income. For the three months ended September 30, 2021, we reported other income of approximately \$7,000, compared to \$9,000 for the three months ended September 30, 2020. There were no significant changes in these accounts during the three months ended September 30, 2021, compared to the same quarter last year.

For the nine months ended September 30, 2021, we reported other income of approximately \$15,000, compared to \$126,000 for the nine months ended September 30, 2020. This decrease is primarily due to lower interest income during the nine months ended September 30, 2021.

Income Taxes

For the three and nine months ended September 30, 2021, we recorded a provision for income tax expense of \$517,767 and \$1,289,988, respectively. Our effective tax rate was 16.7 percent and 19.2 percent, respectively, and differed from the U.S. Federal statutory rate primarily due to benefits from foreign derived intangible income, stock compensation and research and development tax credits, partially offset by U.S. state income tax expense.

For the three and nine months ended September 30, 2020, we recorded a provision for income tax benefit of \$(280,536) and \$(2,012,998), respectively. Our effective tax rate was (35.3) percent and 157.1 percent, respectively, and differed from the U.S. Federal statutory rate primarily due to discrete items related to tax benefits associated with stock-based compensation and a U.S. state tax benefit, partially offset by a limitation on the deductibility of certain executive compensation associated with the separation of our former Chief Executive Officer. Additionally, we recognized a benefit in our effective tax rate resulting from the Coronavirus Aid, Relief, and Economic Security Act, which allowed us to carryback net operating losses to years prior to the enactment of the Tax Cuts and Jobs Act.

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As of September 30, 2021, and December 31, 2020, we had not identified or accrued for any uncertain tax positions. We are currently unaware of any uncertain tax positions that could result in significant payments, accruals or other material deviations in this estimate over the next 12 months. We believe that our tax positions comply in all material respects with applicable tax law. However, tax law is subject to interpretation, and interpretations by taxing authorities could be different from ours, which could result in the imposition of additional taxes and penalties.

We file tax returns in the United States Federal jurisdiction and many U.S. state jurisdictions. Our returns are not currently under examination by the Internal Revenue Service. The Company remains subject to income tax examinations for our United States Federal and certain U.S. state income taxes for 2017 and subsequent years and various other U.S. state income taxes for 2016 and subsequent years.

Liquidity and Capital Resources

Our principal sources of liquidity have historically been our cash and cash equivalents balances, our investments, cash flow from operations and access to the financial markets. Our principal uses of cash are operating expenses, working capital requirements and capital expenditures.

As of September 30, 2021, we had cash and investments of \$59.3 million, stockholders' equity of \$67.9 million, and working capital of \$65.3 million. As of December 31, 2020, we had cash and investments of \$52.0 million, stockholders' equity of \$61.4 million, and working capital of \$58.8 million.

We believe that our current cash, investments and any cash generated from operations will be sufficient to meet our ongoing operating requirements for at least the next 12 months. We do not anticipate requiring additional capital; however, if required or desirable, we may seek to obtain a credit facility, raise debt or issue additional equity in private or public markets.

	Nine Months Ended September 30,	
	2021	2020
Net cash provided by operating activities	\$ 7,892,113	\$ 3,321,428
Net cash provided by (used in) investing activities	388,463	(53,564)
Net cash provided by financing activities	22,268	799,974

Cash provided by operating activities increased \$4.6 million, to \$7.9 million for the nine months ended September 30, 2021, compared to \$3.3 million for the same period in 2020. During the nine months ended September 30, 2021, cash provided by operations was positively impacted by net income and cash inflows from accounts receivable and deferred revenue, and negatively impacted by cash outflows from prepaid expenses, income tax payments and inventory purchases.

Cash provided by (used in) investing activities increased \$0.5 million, to \$0.4 million for the nine months ended September 30, 2021, compared to \$(0.1) million for the same period in 2020. During the nine months ended September 30, 2021, cash provided by (used in) investing activities was positively impacted by cash inflows from maturities of securities, and negatively impacted by capital expenditures and capitalized intangible assets.

Cash provided by financing activities decreased \$(0.8) million, to approximately \$22,000 for the nine months ended September 30, 2021, compared to approximately \$0.8 million for the same period in 2020. This decrease is primarily due to lower proceeds from the exercise of stock options, partially offset by lower cash outflows for the net share settlement of restricted stock units.

We market our products to end users in the U.S. and to distributors internationally. Sales to end users in the U.S. are generally made on open credit terms. Management maintains an allowance for potential credit losses.

Our manufacturing and headquarters facility has been leased from Susi, LLC, an entity controlled by our Chairman of the Board and Chief Executive Officer, Roger Susi. Pursuant to the terms of our lease, the monthly base rent is \$34,133, adjusted annually for changes in the consumer price index.

Off-Balance Sheet Arrangements

As of September 30, 2021 and December 31, 2020, we did not have any off-balance sheet arrangements, as such term is defined under Item 303 of Regulation S-K, that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Contractual Obligations

There have been no material changes outside the ordinary course of business to our contractual obligations and commercial commitments since December 31, 2020.

Recent Accounting Pronouncements

See Note 1 to the unaudited condensed financial statements contained herein for a full description of recent accounting pronouncements including the respective expected dates of adoption and status of evaluation of expected effects on results of our operations and financial condition.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Foreign Currency Exchange Risk

We have foreign currency risks related to our revenue and operating expenses denominated in currencies other than the U.S. Dollar, principally the Japanese yen (“Yen”). The volatility of the Yen depends on many factors that we cannot forecast with reliable accuracy. We have experienced and will continue to experience fluctuations in our net income because of transaction gains (losses) related to revaluing Yen denominated accounts payable balances. In the event our Yen denominated accounts payable or expenses increase, our operating results may be affected by fluctuations in the Yen exchange rate. If the U.S. Dollar uniformly increased or decreased in strength by 10 percent relative to the Yen, our net income would have correspondingly increased or decreased by an immaterial amount for the three and nine months ended September 30, 2021 and 2020.

Interest Rate Risk

When able, we invest excess cash in bank money-market funds, corporate debt securities or discrete short-term investments. The fair value of our cash equivalents and short-term investments is sensitive to changes in the general level of interest rates in the U.S., and the fair value of these investments will decline if market interest rates increase. As of September 30, 2021, we had \$0.9 million in corporate bonds, all of which are maturing in less than 1 year. These corporate bonds have fixed interest rates and semi-annual interest payment dates. If market interest rates were to change by 100 basis points from levels at September 30, 2021, we expect the corresponding change in fair value of our investments would be immaterial. This is based on sensitivity analyses performed on our financial position as of September 30, 2021. Actual results may differ as our analysis of the effects of changes in interest rates does not account for, among other things, sales of securities prior to maturity and repurchase of replacement securities, the change in mix or quality of the investments in the portfolio, and changes in the relationship between short-term and long-term interest rates.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), are designed to ensure that: (1) information required to be disclosed in reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms; and (2) such information is accumulated and communicated to management, including the principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

Our management, including our Chief Executive Officer and Chief Financial and Operating Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2021. Our Chief Executive

Officer and Chief Financial and Operating Officer have concluded that our disclosure controls and procedures as of September 30, 2021 were effective.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We may from time to time become party to various legal proceedings or claims that arise in the ordinary course of business. Our management reviews these matters if and when they arise and believes that the resolution of any such matters currently known will not have a material effect on our results of operations or financial position.

Item 1A. Risk Factors

We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. The occurrence of any of these risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. In evaluating the Company and its business, you should carefully consider the information included in this Quarterly Report on Form 10-Q and the factors discussed under Part I, Item 1A “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as well as in other documents we file with the SEC. There have been no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

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

None.

Item 3. Default Upon Senior Securities

Not Applicable.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Description of Document
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rule, 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rule, 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 I.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document
104**	Inline XBRL for the cover page of this Quarterly Report on Form 10-Q, included as part of this Exhibit 101 inline XBRL Document set

* This exhibit shall not be deemed “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any filings.

** In accordance with Rule 402 of Regulation S-T, this interactive data file is deemed not filed or part of this Quarterly Report on Form 10-Q for purposes of Sections 11 or 12 of the Securities Act or Section 18 of the Exchange Act and otherwise is not subject to liability under these sections.

IRADIMED CORPORATION

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.

IRADIMED CORPORATION

Dated: November 5, 2021

/s/ Roger Susi

By: Roger Susi

Its: Chief Executive Officer and President (Principal Executive Officer and Authorized Officer)

/s/ Chris Scott

By: Chris Scott

Its: Chief Financial and Operating Officer and Secretary (Principal Financial and Accounting Officer)

Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Roger Susi, certify that:

1. I have reviewed this quarterly report on Form 10-Q of IRADIMED CORPORATION;
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 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 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2021

/s/ Roger Susi

By: Roger Susi

Chief Executive Officer and President

(Principal Executive Officer)

Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Chris Scott, certify that:

1. I have reviewed this quarterly report on Form 10-Q of IRADIMED CORPORATION;
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 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 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2021

/s/ Chris Scott

By: Chris Scott

Chief Financial and Operating Officer and Secretary

(Principal Financial and Accounting Officer)

Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the quarterly report of IRADIMED CORPORATION (the “Company”) on Form 10-Q for the quarter ending September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), each of the undersigned, in the capacities and on the date indicated below, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

- (1) The 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 Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Roger Susi

By: Roger Susi
Chief Executive Officer and President
(Principal Executive Officer)
November 5, 2021

/s/ Chris Scott

By: Chris Scott
Chief Financial and Operating Officer and Secretary
(Principal Financial and Accounting Officer)
November 5, 2021
