
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 8-K

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

Date of report (Date of earliest event reported): **October 29, 2021**

IRADIMED CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-36534

(Commission File Number)

73-1408526

(IRS Employer Identification No.)

1025 Willa Springs Dr., Winter Springs, FL

(Address of principal executive offices)

32708

(Zip Code)

(407) 677-8022

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

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	IRMD	NASDAQ Capital Market

Item 2.02 Results of Operations and Financial Condition.

On October 29, 2021, iRADIMED CORPORATION issued a press release (the “Press Release”) announcing its financial results for the third quarter ended September 30, 2021. A copy of the Press Release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that Section. Furthermore, such information, including Exhibit 99.1, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Press release dated October 29, 2021.</u>
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

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 hereunto duly authorized.

IRADIMED CORPORATION

Date: October 29, 2021

By: /s/Chris Scott

Name: Chris Scott

Title: Chief Financial and Operating Officer



IRADIMED CORPORATION Announces Third Quarter 2021 Financial Results

- Reports third quarter 2021 revenue of \$10.9 million, GAAP diluted EPS of \$0.20 and non-GAAP diluted EPS of \$0.23
- Increases full-year 2021 financial guidance

Winter Springs, Florida, October 29, 2021 – iRADIMED CORPORATION (the “Company”) (NASDAQ: IRMD), a leader in the development of innovative magnetic resonance imaging (“MRI”) medical devices and the only known provider of a non-magnetic intravenous (“IV”) infusion pump system, and non-magnetic patient vital signs monitoring systems that are designed for use during MRI procedures, today announced financial results for the three and nine months ended September 30, 2021.

“I am pleased with these financial results and continue to be proud of our performance and resiliency in an everchanging environment marked by the continued uncertainties of COVID. With these financial results, we are on pace to post approximately 8 percent revenue growth over the pre-COVID 2019 year as well as achieve the highest full-year revenue in Iradimed’s history,” said Roger Susi, President and Chief Executive Officer of the Company.

Three Months Ended September 30, 2021

For the third quarter ended September 30, 2021, the Company reported revenue of \$10.9 million compared to \$7.7 million for the third quarter 2020. Net income was \$2.6 million, or \$0.20 per diluted share, compared to \$1.1 million, or \$0.09 per diluted share for the third quarter 2020. The increase in net income and diluted earnings per share is primarily the result of a \$3.2 million increase in revenue for the third quarter 2021.

Non-GAAP net income was \$2.8 million, or \$0.23 per diluted share, for the quarter ended September 30, 2021, and excludes \$0.3 million of stock compensation expense, net of tax expense. Non-GAAP net income for the quarter ended September 30, 2020 was \$1.4 million, or \$0.11 per diluted share, and excludes \$0.3 million of stock compensation expense, net of tax.

Nine Months Ended September 30, 2021

For the nine months ended September 30, 2021, the Company reported revenue of \$29.9 million compared to \$23.2 million for the same period in 2020. Net income was \$5.4 million, or \$0.43 per diluted share, compared to \$0.7 million, or \$0.06 per diluted share for the same period in 2020. The increase in net income and diluted earnings per share is primarily the result of a \$6.8 million increase in revenue and a \$2.8 million decrease in general and administrative expenses, partially offset by a \$3.3 million increase in income tax expense for the nine months ended September 30, 2021. During the nine months ended September 30, 2020, the Company recognized total general and administrative expense of \$3.2 million related to our former CEO.

Non-GAAP net income was \$6.2 million, or \$0.50 per diluted share, for the nine months ended September 30, 2021, and excludes \$0.8 million of stock compensation expense, net of tax expense. Non-GAAP net income for the nine months ended September 30, 2020 was \$4.2 million, or \$0.33 per diluted share, which excludes \$1.1 million of on-going stock compensation expense, net of tax, and \$2.4 million of expenses, net of tax, related to the separation of our former CEO.

Revenue Information:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(unaudited)		(unaudited)	
Devices:				
MRI compatible IV infusion pump system	\$ 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	\$ 10,907,302	\$ 7,699,096	\$ 29,941,721	\$ 23,171,329

For the third quarter 2021, domestic sales were 79.5 percent of total revenue, compared to 84.0 percent for the third quarter 2020. Gross profit margin was 77.1 percent for the third quarter 2021, compared to 74.6 percent for the third quarter 2020.

For the nine months ended September 30, 2021, domestic sales were 80.1 percent of total revenue, compared to 75.2 percent for the same period in 2020. Gross profit margin was 76.1 percent for the nine months ended September 30, 2021, compared to 73.9 percent for the same period in 2020.

Cash Flow:

For the nine months ended September 30, 2021, cash from operations was \$7.9 million, compared to \$3.3 million for the same period in 2020.

For the third quarter ended September 30, 2021, free cash flow was \$3.2 million, compared to \$1.3 million for the third quarter 2020. For the nine months ended September 30, 2021, free cash flow was \$7.5 million, compared to \$3.0 million for the same period in 2020.

Financial Guidance

For the fourth quarter 2021, the Company expects to report revenue of \$11.5 million to \$11.7 million, GAAP diluted earnings per share of \$0.17 to \$0.18, and non-GAAP diluted earnings per share of \$0.20 to \$0.21.

The Company increased its full-year financial guidance, and now expects to report revenue of \$41.4 million to \$41.6 million, GAAP diluted earnings per share of \$0.60 to \$0.61, and non-GAAP diluted earnings per share of \$0.70 to \$0.71. The Company's previously expected full-year 2021 revenue was \$40.0 million to \$40.4 million, GAAP diluted earnings per share of \$0.53 to \$0.55, and non-GAAP diluted earnings per share of \$0.60 to \$0.62.

The Company's non-GAAP diluted earnings per share guidance excludes stock-based compensation expense, net of tax, which the Company expects to be approximately \$0.3 million and \$1.1 million for the fourth quarter and full year 2021, respectively.

Use of non-GAAP Financial Measures

The Company believes the use of non-GAAP net income, free cash flow and infrequent income tax items are helpful to our investors. These measures, which we refer to as our non-GAAP financial measures, are not prepared in accordance with U.S. GAAP.

We calculate non-GAAP net income as net income excluding (1) stock-based compensation expense, net of tax. Because of varying available valuation methodologies, subjective assumptions and the variety of equity instruments that can impact a company's non-cash expenses, we believe that providing non-GAAP financial measures that exclude stock-based compensation expense allows for meaningful comparisons between our operating results from period to period; (2) operating expenses, net of tax, that we believe are not indicative of the Company's on-going core operating performance, and; (3) infrequent tax items are considered based on their nature and are excluded from the provision for income taxes as these costs or benefits are not indicative of our normal or future provision for income taxes. We calculate free cash flow as net cash provided by operating activities, less net cash used in investing activities for purchases of property and equipment.

We consider free cash flow to be a liquidity measure that provides useful information to management and investors about the amount of cash generated by our business that can be used for strategic opportunities, including investing in our business, making strategic acquisitions, strengthening our balance sheet and returning cash to our shareholders through various means.

All of our non-GAAP financial measures are important tools for financial and operational decision making and for evaluating our on-going core operating results.

A reconciliation of the non-GAAP financial measures used in this release to the most comparable U.S. GAAP measures for the respective periods can be found in the table later in this release immediately following the condensed statements of cash flows. **These non-GAAP financial measures should not be considered in isolation or as a substitute for a measure of the Company's operating performance or liquidity prepared in accordance with U.S. GAAP and are not indicative of net income or cash provided by operating activities.**

Conference Call

iRADIMED has scheduled a conference call to discuss this announcement beginning at 11:00 a.m. Eastern Time today, October 29, 2021. Individuals interested in listening to the conference call may do so by dialing 1-844-413-1781 for domestic callers, or 1-716-247-5767 for international callers, and entering the reservation code 1675895.

The conference call will also be available real-time via the internet at <http://www.iradimed.com/en-us/investors/events/>. A recording of the call will be available on the Company's website following the completion of the call.

About iRADIMED CORPORATION

iRADIMED CORPORATION is a leader in the development of innovative magnetic resonance imaging (“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.

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.

For more information please visit www.iradimed.com.

Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Act of 1995, particularly statements regarding our expectations, beliefs, plans, intentions, future operations, financial condition and prospects, and business strategies. These statements relate to future events or our future financial performance or condition and involve unknown risks, uncertainties and other factors that could cause our actual results, level of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. The risks and uncertainties referred to above include, but are not limited to, risks associated with the Company’s ability to receive an EC Certificate or CE Mark for our existing products and product candidates, receive FDA 510(k) clearance for new products and product candidates; unexpected costs, delays or diversion of management’s attention associated with the design, manufacture or sale of new products; the Company’s ability to implement successful sales techniques for existing and future products and evaluate the effectiveness of its sales techniques; additional actions, warnings or requests from the FDA or other regulatory bodies; our significant reliance on a limited number of products; potential disruptions in our limited supply chain for our products; a reduction in international distribution; actions of the FDA or other regulatory bodies that could delay, limit or suspend product development, manufacturing or sales; the effect of recalls, patient adverse events or deaths on our business; difficulties or delays in the development, production, manufacturing and marketing of new or existing products and services; changes in laws and regulations or in the interpretation or application of laws or regulations.

Further information on these and other factors that could affect the Company's financial results is included in filings we make with the Securities and Exchange Commission from time to time. 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.

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	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	2,548,702	2,715,030
Deferred income taxes, net	870,028	1,272,672
Other assets	225,749	261,993
Total assets	<u>\$ 78,398,559</u>	<u>\$ 71,066,620</u>
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	2,276,204	2,459,332
Total liabilities	<u>10,507,142</u>	<u>9,682,008</u>
Stockholders' equity:		
Common stock	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	<u>\$ 78,398,559</u>	<u>\$ 71,066,620</u>

IRADIMED CORPORATION
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	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
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

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
Prepaid income taxes	(422,728)	(2,335,105)
Other	—	(3,820)
Net cash provided by operating activities	<u>7,892,113</u>	<u>3,321,428</u>
Investing activities:		
Proceeds from maturities 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	<u>388,463</u>	<u>(53,564)</u>
Financing activities:		
Proceeds from exercises of stock options	85,615	1,722,721
Taxes paid related to net share settlement of equity awards	(63,347)	(922,747)
Net cash provided by financing activities	<u>22,268</u>	<u>799,974</u>
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	<u>\$ 58,371,572</u>	<u>\$ 47,549,619</u>

IRADIMED CORPORATION
RECONCILIATION OF NON-GAAP FINANCIAL MEASURES (UNAUDITED)

Non-GAAP Net Income and Diluted EPS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net income	\$ 2,576,261	\$ 1,074,646	\$ 5,432,804	\$ 731,587
Excluding:				
Stock-based compensation expense, net of tax expense	273,175	315,507	805,998	1,070,897
Separation expenses, net of tax ¹	—	—	—	2,353,964
Non-GAAP net income	\$ 2,849,436	\$ 1,390,153	\$ 6,238,802	\$ 4,156,448
Weighted-average shares outstanding – diluted	12,603,566	12,493,309	12,570,925	12,414,932
Non-GAAP net income per share – diluted	\$ 0.23	\$ 0.11	\$ 0.50	\$ 0.33

¹ Separation expenses recognized pursuant to a separation agreement as described in Exhibit 10.1 to Form 8-K filed with the Securities and Exchange Commission on June 16, 2020.

Free Cash Flow

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net cash provided by operating activities	\$ 3,378,341	\$ 1,334,197	\$ 7,892,113	\$ 3,321,428
Less:				
Purchases of property and equipment	150,760	48,725	391,303	349,283
Free cash flow	\$ 3,227,581	\$ 1,285,472	\$ 7,500,810	\$ 2,972,145

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