
**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 30, 2020**

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 30, 2020, iRADIMED CORPORATION issued a press release (the “Press Release”) announcing its financial results for the third quarter ended September 30, 2020. 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

Exhibit No.	Description
<u>99.1</u>	<u>Press release dated October 30, 2020.</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.

Date: October 30, 2020

IRADIMED CORPORATION

By: /s/Chris Scott

Name: Chris Scott

Title: Chief Financial Officer



IRADIMED CORPORATION Announces Third Quarter 2020 Financial Results

- Reports third quarter 2020 revenue of \$7.7 million, GAAP diluted EPS of \$0.09 and non-GAAP diluted EPS of \$0.11
- Reports combined cash and investments of \$49.9 million as of September 30, 2020

Winter Springs, Florida, October 30, 2020 – 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 system that are designed for use during MRI procedures, today announced financial results for the three and nine months ended September 30, 2020.

“I am very happy with these results, especially considering the continued challenging environment resulting from the pandemic. Our teams continue finding ways to engage our customers and present the benefits our products offer. Recent customer order trends are positive, and while the pandemic continues to set the pace of business, we believe these positive trends will continue,” said Roger Susi, President and Chief Executive Officer of the Company.

Three Months Ended September 30, 2020

For the third quarter ended September 30, 2020, the Company reported revenue of \$7.7 million compared to \$10.0 million for the third quarter 2019. Net income was \$1.1 million, or \$0.09 per diluted share, compared to \$2.5 million, or \$0.20 per diluted share for the third quarter 2019.

Non-GAAP net income was \$1.4 million for the quarter ended September 30, 2020, which excludes \$0.3 million of stock compensation expense, net of tax expense. Non-GAAP net income for the quarter ended September 30, 2019 was \$2.8 million, which excludes \$0.3 million of stock compensation expense, net of tax expense. Non-GAAP earnings per diluted share was \$0.11 for the third quarter 2020, compared to \$0.23 for the third quarter 2019.

Nine Months Ended September 30, 2020

For the nine months ended September 30, 2020, the Company reported revenue of \$23.2 million compared to \$27.6 million for the same period in 2019. Net income was \$0.7 million, or \$0.06 per diluted share, compared to net income of \$6.4 million, or \$0.52 per diluted share for the same period in 2019.

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, of which \$2.7 million relates to the separation.

Non-GAAP net income was \$4.2 million for the nine months ended September 30, 2020, which excludes \$1.1 million of on-going stock compensation expense, net of tax expense, and \$2.4 million of expenses, net of tax, related to the separation of our former CEO. Non-GAAP net income for the nine months ended September 30, 2019 was \$6.8 million, which excludes \$1.0 million of stock compensation expense, net of tax expense and a \$0.6 million reduction to non-GAAP net income resulting from an infrequent tax item related to excess tax benefits recognized in the provision for income taxes for the exercise and sale of certain incentive stock options. Non-GAAP earnings per diluted share was \$0.33 for the nine months ended September 30, 2020, compared to \$0.56 for the same period in 2019.

Revenue Information:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2020	2019	2020	2019
	(unaudited)		(unaudited)	
Devices:				
MRI Compatible IV Infusion Pump Systems	\$ 2,153,699	\$ 4,769,252	\$ 6,693,692	\$ 13,512,548
MRI Compatible Patient Vital Signs Monitoring Systems	2,282,943	2,557,889	6,829,932	6,215,528
Total Devices revenue	4,436,642	7,327,141	13,523,624	19,728,076
Disposables, service and other	2,802,039	2,162,602	8,269,487	6,513,030
Amortization of extended warranty agreements	460,415	473,556	1,378,218	1,385,382
Total revenue	\$ 7,699,096	\$ 9,963,299	\$ 23,171,329	\$ 27,626,488

For the third quarter 2020, domestic sales were 84.0 percent of total revenue, compared to 83.1 percent for the third quarter 2019. Gross profit margin was 74.6 percent for the third quarter 2020, compared to 78.2 percent for the third quarter 2019.

For the nine months ended September 30, 2020, domestic sales were 75.2 percent of total revenue, compared to 83.0 percent for the same period in 2019. Gross profit margin was 73.9 percent for the nine months ended September 30, 2020, compared to 78.0 percent for the same period in 2019.

Cash Flow and Balance Sheet:

For the nine months ended September 30, 2020, cash from operations was \$3.3 million, compared to \$6.3 million for the same period in 2019.

For the third quarter ended September 30, 2020, free cash flow was \$1.3 million, compared to \$3.1 million for the third quarter 2019. For the nine months ended September 30, 2020, free cash flow was \$3.0 million, compared to \$6.1 million for the same period in 2019.

As of September 30, 2020, the Company had combined cash and investments of \$49.9 million.

Financial Guidance

The Company announced its full-year 2020 financial guidance on February 6, 2020. Due to the high degree of uncertainty created by the global impact of COVID-19, the Company withdrew its previous guidance on April 7, 2020 and is not providing any additional financial guidance at this time.

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 via share repurchases.

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 30, 2020. 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 7073833.

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, 2020 (unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 47,549,619	\$ 43,481,781
Accounts receivable, net	4,252,329	7,293,303
Investments	2,320,407	2,768,287
Inventory, net	4,589,741	3,641,561
Prepaid expenses and other current assets	475,039	407,802
Prepaid income taxes	3,716,442	1,370,947
Total current assets	62,903,577	58,963,681
Property and equipment, net	2,164,391	2,053,806
Intangible assets, net	975,879	860,087
Operating lease right-of-use asset	2,776,599	2,955,873
Deferred income taxes, net	1,346,214	1,663,415
Other assets	258,457	232,002
Total assets	<u>\$ 70,425,117</u>	<u>\$ 66,728,864</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 580,309	\$ 993,742
Accrued payroll and benefits	1,642,772	2,166,209
Other accrued taxes	123,196	596,576
Warranty reserve	87,059	81,761
Deferred revenue	1,956,180	1,671,420
Current portion of operating lease liability	251,901	240,843
Other current liability	108,421	108,421
Accrued income taxes	10,390	—
Total current liabilities	4,760,228	5,858,972
Deferred revenue	2,423,733	2,630,467
Operating lease liability	2,524,698	2,715,030
Total liabilities	<u>9,708,659</u>	<u>11,204,469</u>
Stockholders' equity:		
Common stock	1,227	1,177
Additional paid-in capital	23,636,433	19,192,394
Retained earnings	37,032,037	36,300,450
Accumulated other comprehensive income	46,761	30,374
Total stockholders' equity	<u>60,716,458</u>	<u>55,524,395</u>
Total liabilities and stockholders' equity	<u>\$ 70,425,117</u>	<u>\$ 66,728,864</u>

IRADIMED CORPORATION
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue	\$ 7,699,096	\$ 9,963,299	\$ 23,171,329	\$ 27,626,488
Cost of revenue	1,958,036	2,168,208	6,036,353	6,074,323
Gross profit	5,741,060	7,795,091	17,134,976	21,552,165
Operating expenses:				
General and administrative	2,196,935	2,609,722	10,062,089	7,482,790
Sales and marketing	2,282,491	2,297,002	7,090,192	6,607,477
Research and development	476,876	369,526	1,389,812	1,053,409
Total operating expenses	4,956,302	5,276,250	18,542,093	15,143,676
Income (loss) from operations	784,758	2,518,841	(1,407,117)	6,408,489
Other income, net	9,352	110,064	125,706	280,663
Income (loss) before provision for income taxes	794,110	2,628,905	(1,281,411)	6,689,152
Provision for income tax (benefit) expense	(280,536)	174,035	(2,012,998)	299,876
Net income	\$ 1,074,646	\$ 2,454,870	\$ 731,587	\$ 6,389,276
Net income per share:				
Basic	\$ 0.09	\$ 0.22	\$ 0.06	\$ 0.57
Diluted	\$ 0.09	\$ 0.20	\$ 0.06	\$ 0.52
Weighted average shares outstanding:				
Basic	12,243,362	11,369,404	12,071,027	11,188,761
Diluted	12,493,309	12,309,948	12,414,932	12,248,102

IRADIMED CORPORATION
CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2020	2019
Operating activities:		
Net income	\$ 731,587	\$ 6,389,276
Adjustments to reconcile net income to net cash provided by operating activities:		
Change in allowance for doubtful accounts	41,786	27,532
Change in provision for excess and obsolete inventory	29,209	104,407
Depreciation and amortization	999,812	961,597
Stock-based compensation	3,644,115	1,306,430
Deferred income taxes, net	310,329	26,071
Gain on maturities of investments	(8,861)	(3,859)
Changes in operating assets and liabilities:		
Accounts receivable	2,999,188	(2,742,517)
Inventory	(1,062,455)	(570,242)
Prepaid expenses and other current assets	(642,982)	(547,694)
Other assets	(40,899)	(150,386)
Accounts payable	(468,615)	293,810
Accrued payroll and benefits	(523,437)	434,328
Other accrued taxes	(473,380)	(48,216)
Warranty reserve	5,298	2,973
Deferred revenue	119,658	537,700
(Prepaid) accrued income taxes	(2,335,105)	261,805
Other	(3,820)	859
Net cash provided by operating activities	<u>3,321,428</u>	<u>6,283,874</u>
Investing activities:		
Proceeds from maturities of investments	480,000	2,522,000
Purchases of property and equipment	(349,283)	(196,369)
Capitalized intangible assets	(184,281)	(59,912)
Net cash (used in) provided by investing activities	<u>(53,564)</u>	<u>2,265,719</u>
Financing activities:		
Proceeds from exercises of stock options	1,722,721	2,209,525
Taxes paid related to net share settlement of equity awards	(922,747)	(149,398)
Net cash provided by financing activities	<u>799,974</u>	<u>2,060,127</u>
Net increase in cash and cash equivalents	4,067,838	10,609,720
Cash and cash equivalents, beginning of period	43,481,781	28,027,688
Cash and cash equivalents, end of period	<u>\$ 47,549,619</u>	<u>\$ 38,637,408</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,	
	2020	2019	2020	2019
Net income	\$ 1,074,646	\$ 2,454,870	\$ 731,587	\$ 6,389,276
Excluding:				
Stock-based compensation expense, net of tax expense	315,507	342,596	1,070,897	982,305
Separation expenses, net of tax ¹	—	—	2,353,964	—
Infrequent tax item ²	—	—	—	(564,810)
Non-GAAP net income	\$ 1,390,153	\$ 2,797,466	\$ 4,156,448	\$ 6,806,771
Weighted-average shares outstanding – diluted	12,493,309	12,309,948	12,414,932	12,248,102
Non-GAAP net income per share – diluted	\$ 0.11	\$ 0.23	\$ 0.33	\$ 0.56

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.

² The infrequent tax item is related to the excess tax benefits recognized in the provision for income taxes associated with the exercise and sale of certain incentive stock options.

Free Cash Flow

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net cash provided by operating activities	\$ 1,334,197	\$ 3,138,242	\$ 3,321,428	\$ 6,283,874
Less:				
Purchases of property and equipment	48,725	77,407	349,283	196,369
Free cash flow	\$ 1,285,472	\$ 3,060,835	\$ 2,972,145	\$ 6,087,505

Media Contact:
Chris Scott
Chief Financial Officer
IRADIMED CORPORATION
(407) 677-8022
InvestorRelations@iradimed.com