
**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): **July 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 July 30, 2020, IRADIMED CORPORATION issued a press release (the “Press Release”) announcing its financial results for the second quarter ended June 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

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

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: July 30, 2020

By: /s/Chris Scott

Name: Chris Scott

Title: Chief Financial Officer



IRADIMED CORPORATION Announces Second Quarter 2020 Financial Results

- Reports second quarter 2020 revenue of \$6.8 million, GAAP diluted EPS of \$(0.17) and non-GAAP diluted EPS of \$0.05
- Reports combined cash and investments of \$47.8 million as of June 30, 2020

Winter Springs, Florida, July 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 six months ended June 30, 2020.

“As our customers continue being pressured in their efforts to respond to the current pandemic’s impacts, second quarter revenue was, as expected, depressed. Additionally, earnings were impacted by a significant one-time charge resulting from costs incurred from the separation of our former CEO,” said Roger Susi, President and Chief Executive Officer of the Company.

“However, we are seeing encouraging signs from healthy international demand and an increased ability to engage U.S. customers via video conferencing and in some cases, face-to-face interactions, specifically with existing customers. Sales of our services and disposables have been picking up, pointing towards a trend that MR imaging of patients needing IV therapy is strengthening. Still, with the constantly changing waves and locations of COVID-19 outbreaks, continued unpredictability must be expected, but to be clear, we are enthusiastic about the progress we are making with our sales tactics and confident that as the pandemic and the uncertainties it brings subside, strong demand for our products will result,” said Susi.

Three Months Ended June 30, 2020

For the second quarter ended June 30, 2020, the Company reported revenue of \$6.8 million compared to \$9.2 million for the second quarter 2019. Net loss was \$(2.1) million, or \$(0.17) per diluted share, compared to net income of \$2.1 million, or \$0.17 per diluted share for the second quarter 2019.

During the three months ended June 30, 2020, the Company recognized total general and administrative expense of \$2.8 million related to our former CEO, of which \$2.7 million relates to the separation.

Non-GAAP net income was \$0.6 million for the quarter ended June 30, 2020, which excludes \$0.3 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. Non-GAAP net income for the quarter ended June 30, 2019 was \$2.4 million, which excludes \$0.4 million of stock compensation expense, net of tax expense. Non-GAAP earnings per diluted share was \$0.05 for the second quarter 2020, compared to \$0.20 for the second quarter 2019.

Six Months Ended June 30, 2020

For the six months ended June 30, 2020, the Company reported revenue of \$15.5 million compared to \$17.7 million for the same period in 2019. Net loss was \$(0.3) million, or \$(0.03) per diluted share, compared to net income of \$3.9 million, or \$0.32 per diluted share for the same period in 2019.

During the six months ended June 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 \$2.8 million for the six months ended June 30, 2020, which excludes \$0.7 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. Non-GAAP net income for the six months ended June 30, 2019 was \$4.0 million, which excludes \$0.6 million of stock compensation expense, net of tax 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 \$0.22 for the six months ended June 30, 2020, compared to \$0.33 for the same period in 2019.

Revenue Information:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(unaudited)		(unaudited)	
Devices:				
MRI Compatible IV Infusion Pump Systems	\$ 1,875,159	\$ 4,550,542	\$ 4,539,993	\$ 8,743,296
MRI Compatible Patient Vital Signs Monitoring Systems	1,927,473	1,891,031	4,546,988	3,657,639
Total Devices Revenue	3,802,632	6,441,573	9,086,981	12,400,935
Disposables and Services	2,535,548	2,313,755	5,467,449	4,350,428
Amortization of extended warranty agreements	456,512	470,268	917,803	911,826
Total revenue	\$ 6,794,692	\$ 9,225,596	\$ 15,472,233	\$ 17,663,189

For the second quarter 2020, domestic sales were 68.3 percent of total revenue, compared to 82.0 percent for the second quarter 2019. Gross profit margin was 72.6 percent for the second quarter 2020, compared to 79.9 percent for the second quarter 2019.

For the six months ended June 30, 2020, domestic sales were 70.9 percent of total revenue, compared to 82.9 percent for the same period in 2019. Gross profit margin was 73.6 percent for the six months ended June 30, 2020, compared to 77.9 percent for the same period in 2019.

Cash Flow and Balance Sheet:

For the six months ended June 30, 2020, the Company generated \$2.0 million of cash from operations, compared to \$3.1 million for the same period in 2019.

For the second quarter ended June 30, 2020, free cash flow was \$0.7 million, compared to \$2.4 million for the second quarter 2019. For the six months ended June 30, 2020, free cash flow was \$1.7 million, compared to \$3.0 million for the same period in 2019.

As of June 30, 2020, the Company had combined cash and investments of \$47.8 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, July 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 8281889.

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

	June 30, 2020	December 31, 2019
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 45,457,652	\$ 43,481,781
Accounts receivable, net	4,505,599	7,293,303
Investments	2,326,186	2,768,287
Inventory, net	4,868,721	3,641,561
Prepaid expenses and other current assets	657,679	407,802
Prepaid income taxes	2,268,898	1,370,947
Total current assets	60,084,735	58,963,681
Property and equipment, net	2,227,020	2,053,806
Intangible assets, net	937,131	860,087
Operating lease right-of-use asset	2,837,253	2,955,873
Deferred income taxes, net	2,492,124	1,663,415
Other assets	246,474	232,002
Total assets	<u>\$ 68,824,737</u>	<u>\$ 66,728,864</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 703,530	\$ 993,742
Accrued payroll and benefits	1,693,504	2,166,209
Other accrued taxes	508,125	596,576
Warranty reserve	88,372	81,761
Deferred revenue	1,873,090	1,671,420
Current portion of operating lease liability	248,159	240,843
Other current liability	139,562	108,421
Total current liabilities	5,254,342	5,858,972
Deferred revenue	2,617,075	2,630,467
Operating lease liability	2,589,094	2,715,030
Total liabilities	10,460,511	11,204,469
Stockholders' equity:		
Common stock	1,220	1,177
Additional paid-in capital	22,351,673	19,192,394
Retained earnings	35,957,391	36,300,450
Accumulated other comprehensive income	53,942	30,374
Total stockholders' equity	58,364,226	55,524,395
Total liabilities and stockholders' equity	<u>\$ 68,824,737</u>	<u>\$ 66,728,864</u>

IRADIMED CORPORATION
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue	\$ 6,794,692	\$ 9,225,596	\$ 15,472,233	\$ 17,663,189
Cost of revenue	1,864,587	1,858,288	4,078,317	3,906,115
Gross profit	4,930,105	7,367,308	11,393,916	13,757,074
Operating expenses:				
General and administrative	5,002,427	2,460,372	7,865,154	4,873,068
Sales and marketing	2,374,134	2,199,823	4,807,701	4,310,475
Research and development	482,654	331,310	912,936	683,883
Total operating expenses	7,859,215	4,991,505	13,585,791	9,867,426
(Loss) income from operations	(2,929,110)	2,375,803	(2,191,875)	3,889,648
Other income, net	17,852	78,025	116,354	170,599
(Loss) income before provision for income taxes	(2,911,258)	2,453,828	(2,075,521)	4,060,247
Provision for income taxes	(798,988)	364,987	(1,732,462)	125,841
Net (loss) income	\$ (2,112,270)	\$ 2,088,841	\$ (343,059)	\$ 3,934,406
Net (loss) income per share:				
Basic	\$ (0.17)	\$ 0.19	\$ (0.03)	\$ 0.35
Diluted	\$ (0.17)	\$ 0.17	\$ (0.03)	\$ 0.32
Weighted average shares outstanding:				
Basic	12,076,399	11,163,506	11,983,913	11,096,942
Diluted	12,076,399	12,226,660	11,983,913	12,227,949

IRADIMED CORPORATION
CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

	Six Months Ended June 30,	
	2020	2019
Operating activities:		
Net (loss) income	\$ (343,059)	\$ 3,934,406
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Change in allowance for doubtful accounts	40,029	15,124
Change in provision for excess and obsolete inventory	35,376	115,600
Depreciation and amortization	668,823	672,676
Stock-based compensation	3,227,590	850,789
Deferred income taxes, net	(834,179)	35,574
(Gain) loss on maturities of investments	(8,861)	3,778
Changes in operating assets and liabilities:		
Accounts receivable	2,747,675	(1,682,525)
Inventory	(1,360,074)	(494,108)
Prepaid expenses and other current assets	(674,047)	(600,485)
Other assets	(26,402)	(10,830)
Accounts payable	(319,583)	178,912
Accrued payroll and benefits	(472,705)	(243,044)
Other accrued taxes	(88,451)	(80,451)
Warranty reserve	6,611	533
Deferred revenue	255,298	371,317
Other current liability	31,141	—
(Prepaid) accrued income taxes	(897,951)	78,366
Net cash provided by operating activities	<u>1,987,231</u>	<u>3,145,632</u>
Investing activities:		
Proceeds from maturities of investments	480,000	1,050,000
Purchases of property and equipment	(300,558)	(118,962)
Capitalized intangible assets	(122,534)	(34,399)
Net cash provided by investing activities	<u>56,908</u>	<u>896,639</u>
Financing activities:		
Proceeds from exercises of stock options	790,989	500,247
Taxes paid related to net share settlement of equity awards	(859,257)	(148,212)
Net cash (used in) provided by financing activities	<u>(68,268)</u>	<u>352,035</u>
Net increase in cash and cash equivalents	1,975,871	4,394,306
Cash and cash equivalents, beginning of period	43,481,781	28,027,688
Cash and cash equivalents, end of period	<u>\$ 45,457,652</u>	<u>\$ 32,421,994</u>

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

Non-GAAP Net Income and Diluted EPS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net (loss) income	\$ (2,112,270)	\$ 2,088,841	\$ (343,059)	\$ 3,934,406
Excluding:				
Stock-based compensation expense, net of tax expense	322,031	352,217	749,831	639,708
Separation expenses, net of tax ¹	2,353,964	—	2,353,964	—
Infrequent tax item ²	—	—	—	(564,810)
Non-GAAP net income	\$ 563,725	\$ 2,441,058	\$ 2,760,736	\$ 4,009,304
Weighted-average shares outstanding – diluted	12,388,190	12,226,660	12,375,844	12,227,949
Non-GAAP net income per share – diluted	\$ 0.05	\$ 0.20	\$ 0.22	\$ 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.

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net cash provided by operating activities	\$ 790,596	\$ 2,480,428	\$ 1,987,231	\$ 3,145,632
Less:				
Purchases of property and equipment	133,965	36,019	300,558	118,962
Free cash flow	\$ 656,631	\$ 2,444,409	\$ 1,686,673	\$ 3,026,670

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