
**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): **December 12, 2019**

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 (*see* General Instruction A.2. below):

- ☐ 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))

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

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. ☒

Item 8.01 Other Events.

Winter Springs, Florida, December 12, 2019 – iRADIMED CORPORATION (NASDAQ: IRMD), today announced that it resumed shipments of its MRI compatible patient vital signs monitoring systems into European Commission markets after completing the CE Mark renewal process.

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, receive FDA 510(k) clearance for new products; 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; our significant reliance on a single product; 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated December 12, 2019.

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: December 12, 2019

By: /s/Chris Scott
Name: Chris Scott
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Document
<u>99.1</u>	<u>Press release dated December 12, 2019.</u>



IRADIMED CORPORATION Completes CE Mark Renewal Process For Its MRI Compatible Patient Vital Signs Monitoring System

- Immediately resumes shipments of patient vital signs monitoring systems into all markets requiring CE Mark

Winter Springs, Florida, December 12, 2019 – IRADIMED CORPORATION (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 that it resumed shipments of its MRI compatible patient vital signs monitoring systems into European Commission markets after completing the CE Mark renewal process.

“We are very pleased with obtaining the CE Mark renewal certificate for our patient monitors. With the renewed certificate, we are immediately resuming shipments to the impacted customers and thank them for their patience,” said Leslie McDonnell, President and Chief Executive Officer of the Company.

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; non-invasive blood pressure; 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.

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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.

Media Contact:

Chris Scott

Chief Financial Officer

iRADIMED CORPORATION

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