# 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 28, 2020**

# Ra Medical Systems, Inc.
(Exact name of registrant as specified in its charter)

| **Delaware** | **001-38677** | **38-3661826** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

**2070 Las Palmas Drive**
**Carlsbad, California 92011**
(Address of principal executive offices, including zip code)

**(760) 804-1648**
(Registrant's telephone number, including area code)

**Not Applicable**
(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(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, par value $0.0001 per share | RMED | NYSE American |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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.**

On December 28, 2020, Ra Medical Systems, Inc. (the "Company") entered into a Settlement Agreement with the United States of America, acting through the United States Department of Justice (the "DOJ") and on behalf of the Inspector General of the United States Department of Health and Human Services ("OIG"), to resolve the pending DOJ investigation and a related civil action concerning the Company's marketing of the DABRA laser system and DABRA-related remuneration to certain physicians, as disclosed in the Company press release attached as Exhibit 99.1 hereto. In connection with the Settlement Agreement, the Company also has reached tentative agreements that, if executed by participating states, resolve previously disclosed related investigations conducted by certain state attorneys general.

The Settlement Agreement recites that a complaint filed by a former employee of the Company on behalf of the federal government in the United States District Court for the Eastern District of Michigan, and subsequently amended to assert claims on behalf of certain states, alleged, among other things, that the Company violated the False Claims Act, 31 U.S.C. § 3729, and certain state false claims acts by paying kickbacks to certain physicians in order to induce them to use the DABRA laser system, promoting off-label use of the DABRA laser system, failing to report adverse events to the United States Food and Drug Administration, marketing a device that does not work as advertised, and failing to adhere to Current Good Manufacturing Practices. The complaint also alleges that the Company unlawfully retaliated against the former employee. Separate from the former employee's allegations in the civil action, the United States and the participating states contend that from May 1, 2017 through October 31, 2019, the Company (a) paid illegal remuneration to certain physicians to induce them to use the DABRA laser system in violation of the federal anti-kickback statute and (b) marketed the DABRA laser system for off-label use in atherectomy procedures despite product performance issues causing calibration and overheating problems, which posed a risk to physicians and patients (the "Covered Conduct"). The Company denies the allegations in the civil action and those asserted by the United States and the participating states, and the settlement does not constitute an admission of liability or wrongdoing by the Company.

Under the Settlement Agreement, and the tentative agreements with the participating states, the Company will make an initial payment of $2.5 million no later than five (5) business days after the Settlement Agreement is fully executed. Pursuant to the terms of the Settlement Agreement, (a) if the Company's revenue exceeds $10 million in any of the next four fiscal years (2021-2024), it also is required to pay an additional amount in settlement for the corresponding year: $500,000 for 2021, $750,000 for 2022, $1 million for 2023, and $1.25 million for 2024; (b) if the Company is acquired or is otherwise involved in a change in control transaction in the years 2020 through 2024, the Company is required to pay an additional settlement amount of $5 million, plus 4% of the value attributed to the Company in the transaction, so long as the attributed value is in excess of $100 million, with the total change in control payment never to exceed $28 million; and (c) if the Company's obligations under the Settlement Agreement are avoided by bankruptcy, the United States may rescind the releases and bring an action against the Company in which the Company agrees is not subject to an automatic stay, is not subject to any statute of limitations, estoppel or laches defense, and is a valid claim in the amount of $56 million, minus any prior change in control payments. Under the Settlement Agreement, the Company will also pay the former employee's reasonable expenses, costs and attorneys' fees, which amount to $200,000.

Under the terms of the Settlement Agreement and related tentative agreements with the participating states, upon receipt of the initial payment of $2.5 million, (a) the United States and the former employee will promptly sign and file in the civil action a joint stipulation of dismissal of the complaint against Ra Medical Systems with prejudice, and (b) assuming the tentative agreements are signed, the participating states will dismiss their claims in the civil action within ninety-one (91) days of receipt of this initial payment. The United States, the former employee and the participating states have agreed to release the Company from any civil or administrative monetary liability arising from the Covered Conduct under

the False Claims Act, 31 U.S.C. §§ 3729-3733, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812, or the common law theories of payment by mistake, unjust enrichment, and fraud.

The OIG has agreed, conditioned upon the Company's full payment of amounts owed in the Settlement Agreement, and in consideration of the Company's obligations under a Corporate Integrity Agreement, to release its permissive exclusion rights and refrain from instituting any administrative action seeking to exclude the Company from participating in Medicare, Medicaid, or other federal health care programs as a result of the Covered Conduct. The Corporate Integrity Agreement has a five-year term and imposes monitoring, reporting, certification, documentation, oversight, screening, and training obligations on the Company, including the hiring of a compliance officer and independent review organization.

The Settlement Agreement does not include a release for any conduct other than the Covered Conduct or any criminal liability related to the Covered Conduct. The Settlement Agreement does not release any claims under investigation by the United States Securities and Exchange Commission.

The foregoing descriptions of the Settlement Agreement and the Corporate Integrity Agreement are qualified in their entirety by the full terms of the Settlement Agreement and Corporate Integrity Agreement, which will be filed as exhibits to the Company's Annual Report on Form 10-K for the year ended December 31, 2020. A copy of the Company's press release is filed as Exhibit 99.1 to this report and is incorporated by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release dated January 4, 2021. |

**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.

**RA MEDICAL SYSTEMS, INC.**

Date: January 4, 2021

By: /s/ Daniel Horwood
Daniel Horwood
General Counsel and Secretary

Exhibit 99.1

# Ra Medical Systems Announces Settlement Resolving Previously Announced United States Department of Justice and State Investigations

**CARLSBAD, Calif. (January 4, 2021)** – Ra Medical Systems, Inc. (NYSE American: RMED) today announced it has entered into a settlement agreement that resolves civil False Claims Act claims asserted by the United States Department of Justice in an investigation previously disclosed by the Company. Ra Medical Systems has settled these matters without admitting liability or wrongdoing. The allegations resolved as part of the settlement agreement reached with the U.S. Attorney's Office for the Eastern District of Michigan pertain to the Company's marketing of the DABRA laser system and DABRA-related remuneration paid to certain physicians. In connection with this settlement, the Company also has reached tentative agreements with the participating states that, if executed, resolve previously disclosed related investigations conducted by certain state attorneys general.

Pursuant to the terms of the settlement agreement and tentative agreements, Ra Medical Systems will pay in the near term a total of $2.5 million, an amount the Company has accrued in full since its fiscal second quarter. If the Company's revenue exceeds $10 million in any of the next four fiscal years, it also is required to pay an additional amount in settlement for the corresponding year: $500,000 for 2021, $750,000 for 2022, $1 million for 2023, and $1.25 million for 2024. If the Company is acquired or is otherwise involved in a change-in-control transaction prior to December 31, 2024, the Company also is required to pay an additional settlement amount of $5 million, plus 4% of the value of the transaction if the value of the transaction is in excess of $100 million, with the total change-in-control payment not to exceed $28 million.

As is common in settlements of this nature, the Company also entered into a five-year Corporate Integrity Agreement with the Office of the Inspector General of the U.S. Department of Health and Human Services (HHS-OIG), and HHS-OIG agreed to waive its permissive exclusion authority for the conduct covered by the settlement agreement.

"The Company has fully cooperated with these government investigations, and I am pleased settlements have been reached to resolve these matters," said Ra Medical Systems Chief Executive Officer Will McGuire. "Ra Medical Systems, under its new leadership, remains dedicated to the use of our advanced excimer laser-based platform for the treatment of vascular and dermatological immune-mediated inflammatory diseases. We remain committed to meeting the expectations of the federal and various state governments as we fulfill our mission of serving the needs of patients."

**About Ra Medical Systems**

Ra Medical Systems commercializes excimer lasers and catheters for the treatment of vascular and dermatological diseases. In May 2017 the DABRA excimer laser system received FDA 510(k) clearance in the U.S. for crossing chronic total occlusions, or CTOs, in patients with symptomatic infrainguinal lower extremity vascular disease with an intended use for ablating a channel in occlusive peripheral vascular disease. The Pharos excimer laser system is FDA-cleared and is used as a tool in the treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma. DABRA and Pharos are both based on Ra Medical's core excimer laser technology platform and deploy similar mechanisms of action. Ra Medical manufactures DABRA and Pharos excimer lasers and catheters in a 32,000-square-foot facility located in Carlsbad, Calif. The vertically integrated facility is ISO 13485 certified and is licensed by the State of California to manufacture sterile, single-use catheters in controlled environments.

**Cautionary Note Regarding Forward Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements generally relate to future events or Ra Medical's future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these words or other similar terms or expressions that concern Ra Medical's future expectations, strategy, plans or intentions. Forward-looking statements in this press release include, but are not limited to, statements regarding the timing and potential outcome of the DABRA atherectomy clinical study. Ra Medical's expectations and beliefs regarding these matters may not materialize, and actual results in future periods are subject to risks and uncertainties that could cause actual results to differ materially from those projected or implied by such forward-looking statements. The potential risks and uncertainties which contribute to the uncertain nature of these statements include, among others, challenges inherent in developing, manufacturing, launching, marketing, and selling new products; risks associated with acceptance of DABRA and Pharos and procedures performed using such devices by physicians, payors, and other third parties; development and acceptance of new products or product enhancements; clinical and statistical verification of the benefits achieved via the use of Ra Medical's products; the results from our clinical trials, which may not support intended indications or may require Ra Medical to conduct additional clinical trials or modify ongoing clinical trials; challenges related to commencement, patient enrollment, completion, an analysis of clinical trials; Ra Medical's ability to manage operating expenses; Ra Medical's ability to effectively manage inventory; Ra Medical's ability to recruit and retain management and key personnel; Ra Medical's need to comply with complex and evolving laws and regulations; intense and increasing competition and consolidation in Ra Medical's industry; the impact of rapid technological change; costs and adverse results in any ongoing or future legal proceedings; adverse outcome of regulatory inspections; and the other risks and uncertainties described in Ra Medical's news releases and filings with the Securities and Exchange Commission. Information on these and additional risks, uncertainties, and other information affecting Ra Medical's business and operating results is contained in Ra Medical's Annual Report on Form 10-K for the year

ended December 31, 2019 and in its other filings with the Securities and Exchange Commission. The forward-looking statements in this press release are based on information available to Ra Medical as of the date hereof, and Ra Medical disclaims any obligation to update any forward-looking statements, except as required by law.

Ra Medical Systems investors and others should note that we announce material information to the public about the company through a variety of means, including our website (www.ramed.com), our investor relations website (https://ir.ramed.com/), press releases, SEC filings, and public conference calls in order to achieve broad, non-exclusionary distribution of information to the public and to comply with our disclosure obligations under Regulation FD. We encourage our investors and others to monitor and review the information we make public in these locations as such information could be deemed to be material information. Please note that this list may be updated from time to time.

**Contacts**

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