

**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):

August 11, 2019

Ra Medical Systems, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38677
(Commission
File Number)

38-3661826
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.0001 per share	RMED	New York Stock Exchange

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 2.02. Results of Operations and Financial Condition.

On August 12, 2019 Ra Medical Systems, Inc. (“Ra Medical” or the “Company”) issued a press release announcing certain preliminary financial results for the three months ended June 30, 2019. A copy of the press release is attached as Exhibit 99.1 to this current report on Form 8-K and is incorporated by reference herein.

All financial results in the press release were prepared by management and are preliminary.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Separation of Principal Executive Officer

On August 11, 2019, the Company terminated Dean Irwin as its Chief Executive Officer, Co-President, Chief Technology Officer and as an employee of the Company, effective August 12, 2019. Mr. Irwin’s termination by the Company was without “Cause,” as defined in his Change in Control and Severance Agreement (the “Severance Agreement”) which has been filed as Exhibit 10.8 to the Company’s Registration Statement on Form S-1 (File No. 333-226191) with the Securities and Exchange Commission on July 16, 2018. Mr. Irwin remains on the Company’s Board of Directors (“Board”), and the Board appointed Martin Colombatto as Chairman to replace Mr. Irwin. Mr. Irwin is also eligible to receive the severance compensation benefits set forth and in accordance with the terms of the Severance Agreement. Additionally, Mr. Irwin’s equity incentive awards will remain subject to the terms of his existing equity award agreements with the Company.

Appointment of Interim Chief Executive Officer

On August 11, 2019 the Board appointed Andrew Jackson, Ra Medical’s Chief Financial Officer, to serve as Ra Medical’s Interim Chief Executive Officer and Principal Executive Officer, in addition to continuing as Chief Financial Officer and Principal Financial Officer. Mr. Jackson’s appointment as Interim Chief Executive Officer and Principal Executive Officer was effective on August 12, 2019.

Mr. Jackson, age 50, has served as Ra Medical’s Chief Financial Officer since April 2018. From October 2016 to April 2018 he was Chief Financial Officer for AltheaDx, Inc., a molecular diagnostics company specializing in precision medicine. From March 2014 to March 2016, Mr. Jackson held senior financial positions, including Chief Financial Officer, at Celladon Corporation, a publicly-traded, clinical stage biotechnology company. From April 2013 to March 2014 he held senior financial positions at Sapphire Energy, an industrial biotechnology company. Mr. Jackson received a MSBA in Finance in December 2006 from San Diego State University and a BSB in Accounting in June 1992 from the University of Minnesota. Mr. Jackson is also a certified public accountant (inactive).

In connection with his appointment as Interim Chief Executive Officer, on August 11, 2019, the compensation committee also approved an Interim Chief Executive Officer offer letter that includes an additional \$6,000 per month stipend amount, less applicable tax withholdings, to Mr. Jackson during the period in which Mr. Jackson serves as Ra Medical’s Interim Chief Executive Officer. This stipend will be discontinued once Mr. Jackson no longer serves as Interim Chief Executive Officer. The foregoing description of the terms of Mr. Jackson’s Interim Chief Executive Officer offer letter does not purport to be complete and is qualified in its entirety by reference to the complete text of such agreement, which will be filed as an exhibit in a subsequent filing.

There are no transactions between Mr. Jackson and the Company which are reportable under Item 404(a) of Regulation S-K.

The Board of Directors is also undertaking a search for Ra Medical’s next Chief Executive Officer.

Item 7.01 Regulation FD Disclosure.

Independent Investigation

The Audit Committee of Ra Medical's Board of Directors has commenced an independent investigation in connection with an anonymous complaint. The Audit Committee has retained independent counsel to assist it in its investigation. Ra Medical has contacted the Securities and Exchange Commission ("SEC") to advise it that an independent investigation is underway, and the Audit Committee intends to provide additional information to the SEC as appropriate as the investigation proceeds. Ra Medical cannot predict the duration or outcome of the investigation, and will not be in a position to file its Form 10-Q until the Audit Committee completes its investigation.

Press Release

On August 12, 2019, Ra Medical issued a press release announcing the foregoing management changes, the independent investigation, and the delayed filing of Ra Medical's Form 10-Q. A copy of the press release is attached as Exhibit 99.1 to this current report on Form 8-K and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated August 12, 2019.

Disclaimer of Filing

The information in Items 2.02 and 7.01 of this current report on Form 8-K and Exhibit 99.1 attached hereto 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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

Forward Looking Statements

This communication 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 communication include, but are not limited to, Ra Medical's expectations as to the timing and outcome of its Audit Committee investigation, the filing of its periodic reports, and its expected financial and operational results; Ra Medical's expectations with respect to its search for a permanent CEO; Ra Medical's intentions to analyze and correct issues with its DABRA catheter manufacturing and performance; and the potential impact of its cost savings initiatives. These statements are based on management's current expectations, estimates and projections, are not guarantees of future outcomes or performance, and are subject to certain risks, uncertainties and other factors, some of which are beyond Ra Medical's control and are difficult to predict, including, but not limited to, discovering additional information relevant to the Audit Committee investigation; the findings, conclusions and recommendations of the Audit Committee (and their timing); the Board and Ra Medical's response to the Audit Committee's findings, conclusions and recommendations; the review by Ra Medical's independent registered public accounting firm of the Audit Committee's findings, conclusions and recommendations

and Ra Medical's financial statements; the risk that completing and filing reports with the SEC will take longer than expected; the risk that Ra Medical will not be able to timely characterize and correct its issues with its DABRA catheter manufacturing and performance; and the risk that cost savings will not materialize from Ra Medical's cost savings initiatives. In addition, Ra Medical's business is subject to numerous additional risks and uncertainties, including, among others, challenges inherent in developing, manufacturing, launching, marketing, and selling 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 Ra Medical's 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, and 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 (including with respect to ongoing securities litigation); adverse outcomes of regulatory inspections, reviews, or audits; 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 and in its other filings with the Securities and Exchange Commission. The forward-looking statements in this communication 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.

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: August 12, 2019

By: /s/ Daniel Horwood

Daniel Horwood

General Counsel and Secretary



Ra Medical Systems Reports Preliminary Second Quarter 2019 Financial Results

Announces leadership transition

Announces delayed second-quarter 2019 earnings release and Form 10-Q filing

Provides manufacturing update and reports cost savings initiatives

Announces Audit Committee investigation

CARLSBAD, Calif. (August 12, 2019) – Ra Medical Systems, Inc. (NYSE: RMED), a medical device company focusing on commercializing excimer laser systems to treat vascular and dermatological diseases today reported certain preliminary results for the quarter ended June 30, 2019, as well as a leadership transition. Ra Medical also announced that it will delay its earnings release and investor conference call for the second quarter of 2019 and the filing of its Quarterly Report on Form 10-Q for the quarter ended June 30, 2019.

Leadership Transition

Ra Medical today announced that Dean Irwin was terminated without cause from his position as Ra Medical's Chief Executive Officer, Co-President, and Chief Technology Officer, and as Chairman of Ra Medical's Board of Directors. Andrew Jackson, currently serving as Chief Financial Officer, has been appointed to serve as Interim Chief Executive Officer while the Company continues its search for a permanent Chief Executive Officer.

"On behalf of the entire Ra Medical Board, I want to thank Dean for his contributions and for his years of service to Ra Medical. The Board is focused on finding a CEO who can guide us through the next phase of commercialization and growth," said newly-appointed Chairman Martin Colombatto.

Recent Operational Highlights

- Received approval for an Investigational Device Exemption (IDE) by the U.S. Food and Drug Administration (FDA) to initiate a clinical trial to evaluate the safety and efficacy of the DABRA excimer laser system in atherectomy procedures.
- Commenced strategic shift to service existing accounts and target key new accounts with a smaller sales and marketing team, with expected cost savings of \$1 million per quarter once these changes are complete.
- Continued efforts to upgrade manufacturing process to improve product consistency.

Preliminary Results for Second Quarter 2019

Ra Medical anticipates revenue of between \$2.0 million and \$2.2 million for the second quarter of 2019, including vascular revenue of between \$0.4 million and \$0.5 million and an aggregate balance of approximately \$48.4 million in cash and cash equivalents and short-term investments.

All financial results in this press release were prepared by management and are preliminary.

Cost Savings Initiatives

In August 2019, Ra Medical commenced significant operational efficiency and cost-savings initiatives intended to align its resources with its product strategy, reduce its operating expenses, and manage its cash flows. These cost efficiency initiatives included significant workforce reductions of its sales and marketing teams. In the near term, with the reduced sales headcount, Ra Medical intends to focus on servicing priority existing accounts and targeting key new accounts in certain existing territories while it corrects the production limitations referenced below and re-evaluates its marketing strategy.

Manufacturing Update

In the fourth quarter of 2018 and first quarter of 2019, Ra Medical experienced inconsistencies in its DABRA catheter manufacturing process, due to issues controlling the temperature of the oven used in that process, which had an adverse impact on revenue during the fourth quarter of 2018 and the first half of 2019. In response, Ra Medical upgraded its temperature control regulator and made certain changes in its production flow and validated the changes that Ra Medical believed corrected the production limitations. After manufacturing several well-performing lots with this upgraded process, Ra Medical is again experiencing inconsistent performance. The percentage of catheters that fail to calibrate at customer sites prior to a procedure being performed began to increase after decreasing during April and May 2019. Ra Medical is fully committed to resolving the inconsistencies in performance, but until these are fully resolved, our DABRA sales may continue to be adversely impacted.

Audit Committee Investigation

The Audit Committee of Ra Medical's Board of Directors has commenced an independent investigation in connection with an anonymous complaint. The Audit Committee of the Board of Directors is responsible for investigating the allegations and has retained independent counsel to assist it in the process. The investigation is not yet completed and no conclusions with respect thereto have been reached. Ra Medical cannot predict the duration or outcome of the investigation, and the Company will not be in a position to file the Form 10-Q until the Audit Committee completes its work.

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 laser system and single-use DABRA catheter received FDA 510(k) clearance in the U.S. as a device 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. 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, California. 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, Ra Medical's expectations as to the timing and outcome of its Audit Committee investigation, the filing of its periodic reports, and its expected financial and operational results; Ra Medical's expectations with respect to its search for a permanent CEO; Ra Medical's intentions to analyze and correct issues with its DABRA catheter manufacturing and performance; and the potential impact of its cost savings initiatives. These statements are based on management's current expectations, estimates and projections, are not guarantees of future outcomes or performance, and are subject to certain risks, uncertainties and other factors, some of which are beyond Ra Medical's control and are difficult to predict, including, but not limited to, discovering additional information relevant to the Audit Committee investigation; the findings, conclusions and recommendations of the Audit Committee (and their timing); the Board and Ra Medical's response to the Audit Committee's findings, conclusions and recommendations; the review by the Ra Medical's independent registered public accounting firm of the Audit Committee's findings, conclusions and recommendations and Ra Medical's financial statements; the risk that completing and filing reports with the SEC will take longer than expected; the risk that Ra Medical will not be able to timely characterize and correct its issues with its DABRA catheter manufacturing and performance; and the risk that cost savings will not materialize from Ra Medical's cost savings initiatives. In addition, Ra Medical's business is subject to numerous additional risks and uncertainties, including, among others, challenges inherent in developing , manufacturing, launching, marketing, and selling 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 Ra Medical's 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 (including with respect to ongoing securities litigation); adverse outcome of regulatory inspections, reviews, or audits; 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 Quarterly Report on Form 10-Q for the quarter ended March 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 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

At the Company:

Jeffrey Kraws
President, Ra Medical Systems
760-707-7516
jkraws@ramed.com

Investors:

LHA Investor Relations
Jody Cain / Kevin McCabe
310-691-7100
jcain@lhai.com / kmccabe@lhai.com

Media:

KCSA Strategic Communications
Caitlin Kasunich / Lisa Lipson
212-896-1241 / 508-843-6428
ckasunich@kcsa.com / llipson@kcsa.com