October 31, 2019

Ra Medical Systems Announces Substantial Completion of Audit Committee Investigation

CARLSBAD, Calif.--(BUSINESS WIRE)-- Ra Medical Systems, Inc. (NYSE: RMED), a medical device company focusing on commercializing excimer laser systems to treat vascular and dermatological diseases, today announced that the Audit Committee of the Board of Directors (the “Audit Committee”) has substantially completed its internal investigation, which was originally announced in August. The Audit Committee, assisted by independent legal counsel, Morrison & Foerster LLP, conducted a thorough investigation of allegations raised by an employee, as well as additional matters discovered during the course of the investigation.

The Audit Committee’s primary investigative findings are: (i) the DABRA catheter frequently failed to calibrate and occasionally overheated, posing a risk of injury to physicians and patients; (ii) the Company’s explanations regarding the Company’s fourth quarter 2018 and first quarter 2019 sales created a risk of confusion because they did not explicitly reference inconsistent DABRA catheter performance and catheter failures; (iii) the Company failed to timely make at least two Medical Device Reports, or MDRs, to the FDA; (iv) the Company, out of a concern for the DABRA catheters’ performance, engaged in systematic efforts to replace product held by customers, which constituted product recalls, but were not documented as such, (v) the Company lacks documentation of sufficient detail and specificity to support certain payments to physicians, ostensibly for training and consulting services, and as to three physicians did not accurately reflect the purpose and nature of approximately $300,000 of payments, which could be perceived as an improper attempt to obtain business or to gain special advantage, (vi) while the indication for use in the 510(k) clearance the Company obtained for the DABRA system is not for atherectomy, the Company’s salespeople were instructed to characterize DABRA as performing atherectomy and to encourage doctors to seek reimbursement using atherectomy codes, (vii) Company determinations to direct potentially valuable benefits and opportunities to doctors were informed in part by sales prospects, and (viii) the Company received complaints regarding regulatory or compliance concerns that, because they implicated executive officers, should have been brought to the attention of the Board or the Audit Committee, but were not.

The Audit Committee, in reviewing the allegations, identified certain behavior inconsistent with the Company’s Code of Ethics and Conduct and related policies involving certain current and former executive officers and employees of the Company. With respect to current Company executives and employees, the Audit Committee referred these matters to the Board or the Company for appropriate action and discipline.

The Audit Committee made a number of recommendations which the Board of Directors has

adopted, including: separation of certain employees, implementing additional and enhanced policies and training, strengthening the Company's quality regulatory systems, and adopting certain enhanced controls related to the matters investigated.

In addition, the Company has continued to take steps in an effort to improve the performance and reliability of the Company's DABRA laser system, including hiring a VP, Quality, Regulatory and Clinical, conducting extensive internal and external audits of its quality systems, clinical trial data and manufacturing process, as well as initiating the previously announced voluntary recall of DABRA catheters.

Based on the results of the investigation, the Company is in the process of evaluating the impact of the results of the investigation on its previously issued or announced financial statements, and its internal controls over financial reporting and compliance procedures.

As previously disclosed, due to the Audit Committee investigation the Company has not filed its Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 (the "Form 10- Q") with the SEC. The Company is working diligently to evaluate the Audit Committee investigation findings, including the assessment of the impact on the Company's financial statements, if any, and its internal controls over financial reporting. After the conclusion of the Audit Committee investigation and the Company's evaluation, the Company will file its Form 10-Q as soon as practicable thereafter.

The Company notes that its physician customers continue to use the DABRA laser system with success, and the Company believes that the previously announced change in shelf life will significantly reduce the number of catheters that fail to calibrate and thereby improve customer satisfaction with the product. The Company is focusing its efforts on improving the manufacturing process, with the goals of improving product consistency and extending the shelf life.

In addition, in order to more effectively market DABRA, the Company currently is pursuing expanded indications for use of DABRA to include an atherectomy indication for use, which the FDA currently defines to include a prespecified improvement in luminal patency, or a prespecified increase in the openness of the artery at a pre-defined time point. To satisfy the FDA's data requirements to support an atherectomy indication, the Company submitted an investigational device exemption, or IDE, designed to gather the clinical data necessary to determine substantial equivalence in support of the atherectomy indication. This IDE was approved in July 2019. However, as a result of the DABRA catheter recall to change the shelf life, the Company plans to submit updates to the IDE and enroll the first patient in the first quarter of 2020.

As also previously announced, the Company voluntarily contacted the SEC regarding the Audit Committee's investigation. In October 2019, the Department of Justice provided the Company with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning whether the Company fraudulently obtained 510(k) marketing clearance for its ablation devices marketed under the trade name DABRA (which is not an item that has been investigated by the Audit Committee), whether the Company marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether the Company paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. The Company intends to cooperate with the SEC and the Department of

Justice's inquiries or investigations.

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 communication contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"). 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, statements regarding Ra Medical's implementation of remedial measures recommended by the Audit Committee, expectations with respect to future actions regarding the Company's employees, the results of management's review of its previously issued or announced financial statements and internal control over financial reporting and disclosure controls, the Company's expectations with respect to the impact of its recently announced change in shelf life, the timing of the Company's atherectomy trial, and expectations regarding the timing of Ra Medical's periodic reports. These forward-looking statements involve risks and uncertainties, and actual results could vary materially from these forward-looking statements. Factors that may cause future results to differ materially from management's current expectations include, among other things: how promptly and thoroughly the recommendations of the Audit Committee can be implemented, potential legal or regulatory action related to the matters under investigation, the results of further review by the Company or others of certain matters that came to the Audit Committee's attention during the course of its investigation, any matters arising out of the review and audit of Ra Medical's financial statements by the Company's independent registered public accounting firm, and other factors detailed from time to time in Ra Medical's SEC reports, including its most recent annual report on Form 10-K, subsequent quarterly reports on Form 10-Q, 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. Ra Medical disclaims any obligation to update information contained in these forward-looking statements whether as a result of new information, future events, or otherwise.

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.

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