

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A
(Amendment No. 1)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended December 31, 2018
OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Transition Period From _____ to _____

Commission file number: 001-38677

Ra Medical Systems, Inc.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

2070 Las Palmas Drive
Carlsbad, California

(Address of principal executive offices)

38-3661826

(I.R.S. Employer
Identification No.)

92011

(Zip Code)

(760) 804-1648

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class

Common Stock, \$0.0001 par value

Name of the exchange on which registered

New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Non-accelerated filer

Accelerated filer

Smaller reporting company

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing price of a share of common stock on September 27, 2018 as reported by the New York Stock Exchange on such date was approximately \$157.8 million. The registrant has elected to use September 27, 2018, which was the initial trading date on the New York Stock Exchange, as the calculation date because on June 30, 2018 (the last business day of the registrant's most recently completed second fiscal quarter), the registrant was a privately held company. Shares of the registrant's common stock held by each executive officer, director and other persons who may be deemed an affiliate of the registrant have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of March 13, 2019, the registrant has 12,689,251 shares of common stock, par value \$0.0001, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Information required by Part III of this Form 10-K is incorporated by reference to the registrant's proxy statement (the "Proxy Statement") for the 2019 annual meeting of stockholders, which proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Form 10-K.

EXPLANATORY NOTE

Ra Medical Systems, Inc. (the “Company”) is filing this Amendment No. 1 to its Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (the “Amended Form 10-K”), which was originally filed with the SEC on March 15, 2019, (the “Original Filing”) to amend Part II, Item 9-A- Controls and Procedures to address management's re-evaluation of disclosure controls and procedures and reflect the identification of material weaknesses in internal control over financial reporting.

Part IV, Item 15-Exhibits and Financial Statement Schedules also has been amended to include currently dated certifications from the Company's Principal Executive and Principal Financial Officer as required by sections 302 and 906 of the Sarbanes Oxley Act of 2002. The certifications are attached to this Amended Form 10-K as Exhibits 31 and 32.

This Amended Form 10-K does not modify, amend, or update in any way the financial statements set forth in the Original Filing and there have been no changes to the XBRL data filed in Exhibit 101 of the Original Filing.

This Amended Form 10-K has not been updated for other events or information subsequent to the date of the filing of the Original Filing, except as noted above, and should be read in conjunction with the Original Filing and our other filings with the SEC.

ITEM 9A. CONTROLS AND PROCEDURES

In connection with filing the Original Filing, management, under the supervision of and with the participation of our Chief Executive Officer and our Chief Financial Officer, had previously evaluated the effectiveness of our disclosure controls and procedures, as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of the end of the period covered by our Annual Report on Form 10-K for the fiscal year ended December 31, 2018. Based on such evaluation as of March 15, 2019, our Chief Executive Officer and our Chief Financial Officer had previously concluded that, as of the end of such period, our disclosure controls and procedures were effective. Subsequent to that evaluation, our Chief Financial Officer who is also serving as our Interim Chief Executive Officer, concluded that, as of December 31, 2018, our disclosure controls and procedures were not effective at the reasonable assurance level due to the material weaknesses in internal control over financial reporting that are described below.

In reviewing the allegations and findings from an Audit Committee investigation related to an initially anonymous complaint, as well as additional matters discovered during the course of the investigation, we have identified certain deficiencies in our internal controls which have been considered material weaknesses. Although no material misstatements or omissions in our financial statements or disclosures were identified, the material weaknesses in internal controls could have resulted in material misstatements or omissions to our financial statements or disclosures.

Control environment

We identified certain deficiencies in our internal controls, which aggregated to a material weakness in the control environment component of the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control - Integrated Framework (the "COSO Framework")*. The material weakness results from the aggregation of control deficiencies in the Company's control environment, in particular an inappropriate "tone at the top" set by certain members of senior management, including a failure to promote adherence to our Code of Ethics and Conduct, and the lack of sufficient competent resources in key roles at the organization. The ineffective control environment resulted in the following:

- behavior that was inconsistent with our Code of Ethics and Conduct and related policies involving certain former executive officers and employees of the Company;
- explanations regarding the issues that had an impact on our fourth quarter 2018 and first quarter 2019 sales created a risk of confusion because the explanations did not explicitly reference the effect of inconsistent catheter performance and catheter failures;
- failure to timely make at least two Medical Device Reports, or MDRs, to the FDA;
- engagement in systematic efforts to replace product held by customers, which constituted product recalls, were not documented as such;
- lack of documentation of sufficient detail and specificity to support certain payments to physicians, ostensibly for training and consulting services, 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;
- while the indication for use in the 510(k) clearance we obtained for the DABRA system is not for atherectomy, our salespeople were instructed to characterize DABRA as performing atherectomy and to encourage doctors to seek reimbursement using atherectomy codes;
- determinations to direct potentially valuable benefits and opportunities to doctors were informed in part by sales prospects.

The ineffective control environment contributed significantly to the material weakness described below.

Information and communication

We have identified a deficiency in the information and communication component of the COSO Framework that resulted in a material weakness. This deficiency related to the ineffective design of internal communication of information, including objectives and responsibilities for internal control, necessary to support the functioning of internal control. The deficiency resulted in the receipt of complaints regarding regulatory or compliance concerns that, because the complaints implicated executive officers, should have been brought to the attention of the board of directors or the Audit Committee, but were not.

Remediation Plan and Activities

We commenced measures to remediate the identified material weaknesses in the third quarter of 2019. Management, with the participation and input of the Audit Committee and the board of directors, is engaged in remedial activities to address the material weaknesses described above. The remedial activities we are taking include separation of certain employees, hiring qualified personnel including a VP Quality, Regulatory and Clinical, implementing additional and enhanced policies and training, including with respect to our Code of Business Ethics and Conduct, strengthening our quality and regulatory systems, bolstering documentation requirements for certain third-party consulting, advisory and training agreements, and adopting certain enhanced controls related to the matters investigated by the Audit Committee.

We are committed to maintaining a strong internal control environment, and we believe we are making progress toward achieving the effectiveness of our internal controls and disclosure controls. The actions that we are taking are subject to ongoing senior management review, as well as Audit Committee oversight. We will not be able to conclude whether the steps we are taking will fully remediate the material weaknesses in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness. We may also conclude that additional measures may be required to remediate the material weaknesses in our internal control over financial reporting, which may necessitate additional implementation and evaluation time. We will continue to assess the effectiveness of our internal control over financial reporting and take steps to remediate the known material weaknesses expeditiously.

Changes in Internal Control over Financial Reporting

In connection with our 2017 audit, as part of the restatement to the 2016 financial statements, we had previously disclosed a material weakness in our internal control over financial reporting related to the administration of capital stock transactions, including stock issuances and a reverse stock split which were not effected in accordance with the requirements of applicable law and the communication of stock option awards which were not validly authorized.

We took actions to remediate the material weakness relating to our internal controls over financial reporting, as described below. The controls and processes we implemented to remediate the identified material weakness included:

- hiring qualified personnel with expertise to perform specific functions, including our Chief Financial Officer, General Counsel and Corporate Controller;
- the engagement of third-party legal counsel to assist in the administration of capital stock transactions; and
- designing and implementing improved processes and internal controls, including ongoing senior management review and audit committee oversight.

As a result of the remediation activities and controls in place as of December 31, 2018 described above, we have remediated this previously disclosed material weakness. However, completion of remediation does not provide assurance that our remediated controls will continue to operate properly or that our financial statements will be free from error.

Other than the remediation steps taken above, there were no additional changes in our internal control over financial reporting that occurred during the period covered by this Annual Report on Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control Over Financial Reporting and Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies. Further, our independent public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting as long as we are an "emerging growth company" pursuant to the provisions of the JOBS Act.

Inherent Limitations on Effectiveness of Controls

Management recognizes that a control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or error, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART IV — FINANCIAL INFORMATION

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(b) EXHIBIT INDEX

Exhibit Number	Description
31	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32*	Certifications of Principal Executive and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished pursuant to this item will not be deemed "filed" for purposes of Section 18 of the Exchange Act (15 U.S.C. 78r), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements of Section 13 or 15 (d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

RA MEDICAL SYSTEMS, INC.

(Registrant)

Date: November 27, 2019

By: /s/ Andrew Jackson
Andrew Jackson
Chief Financial Officer and Interim Chief Executive Officer

**CERTIFICATION OF PRINCIPAL EXECUTIVE AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT
OF 2002**

I, Andrew Jackson, certify that:

1. I have reviewed this Amendment No. 1 to the Annual Report on Form 10-K of Ra Medical Systems, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 27, 2019

By: /s/ Andrew Jackson
Andrew Jackson
Interim Chief Executive Officer and Chief Financial Officer
(principal executive officer and principal financial officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Andrew Jackson, hereby certify that, to my knowledge:

- (i) the Company's Amendment No. 1 to the Annual Report on Form 10-K for the year ended December 31, 2018 to which this Certification is attached as Exhibit 32 (the "Report") fully complies with the requirements of section 13(a) or 15(d) of the Exchange Act, and
- (ii) that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Ra Medical Systems, Inc.

Date: November 27, 2019

By: /s/ Andrew Jackson
Andrew Jackson
Interim Chief Executive Officer and Chief Financial Officer
(principal executive officer and principal financial officer)

This certification accompanies the Amendment No. 1 to the Annual Report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Ra Medical Systems, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.