

Edgar Filing: Cardiovascular Systems Inc - Form 8-K

Cardiovascular Systems Inc  
Form 8-K  
June 28, 2016

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 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): June 28, 2016

Cardiovascular Systems, Inc.  
(Exact name of Registrant as Specified in its Charter)

Delaware                                      000-52082      41-1698056  
(State or Other Jurisdiction    (Commission    (IRS Employer  
of Incorporation)                      File Number)    Identification No.)  
1225 Old Highway 8 NW  
St. Paul, Minnesota 55112-6416  
(Address of Principal Executive Offices and Zip Code)  
(651) 259-1600  
(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:

- 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))

Item 1.01 Entry into a Material Definitive Agreement.

On June 28, 2016, Cardiovascular Systems (the “Company”) entered into a Settlement Agreement (the “Settlement Agreement”) with the United States of America, acting through the United States Attorney for the Western District of North Carolina (the “DOJ”) and on behalf of the Office of Inspector General of the Department of Health and Human Services (the “OIG”), and Travis Thams (the “Relator”), to resolve the previously disclosed investigation by the DOJ and the qui tam complaint filed by the Relator pursuant to the False Claims Act in the United States District Court for the Western District of North Carolina, Charlotte Division (the “Civil Action”). The Company had previously announced an agreement in principle to resolve these matters.

Under the Settlement Agreement, the Company will pay \$8,000,000 (the “Settlement Payment”), as follows: an initial payment of \$3,000,000 payable no later than 10 days after the effective date of the Settlement Agreement, with the remaining \$5,000,000, which bears interest at 1.8% per annum, payable in 11 equal quarterly installments, beginning January 1, 2017. The Company will also be required to pay Relator’s reasonable expenses, costs and attorney’s fees, which amount has not yet been determined. The Settlement Agreement contains no admissions of liability on the part of the Company. The United States and the Relator have agreed to release the Company from any civil or administrative monetary liability arising from allegations that the Company caused the submission of false claims to federal health care programs based on alleged violations of the Anti-Kickback Statute in connection with alleged marketing arrangements and practice development activities conducted on behalf of physicians. The OIG has agreed, conditioned upon the Company’s full payment of the Settlement Payment, to release its permissive exclusion rights and to refrain from instituting proceedings to exclude the Company or any Company affiliates from participating in Medicare, Medicaid or other Federal health care programs. The parties have agreed to file a stipulation of dismissal of the Civil Action, with the United States dismissing with prejudice the claims asserted in the Civil Action that are covered under the Settlement Agreement and any remaining claims without prejudice, the Relator dismissing the Civil Action in its entirety with prejudice, and the Plaintiff-States dismissing their claims without prejudice.

In connection with the resolution of this matter, the Company has entered into a five-year corporate integrity agreement (the “Corporate Integrity Agreement”) with the OIG. The Corporate Integrity Agreement requires that the Company maintain its existing compliance programs and imposes certain expanded compliance-related requirements during the term of the Corporate Integrity Agreement, including establishment of specific procedures and requirements regarding consulting activities, co-marketing activities and other interactions with healthcare professionals and healthcare institutions and the sale and marketing of the Company’s products; ongoing monitoring, reporting, certification and training obligations; and the engagement of an independent review organization to perform certain auditing and reviews and prepare certain reports regarding the Company’s compliance with federal health care programs. In the event of a breach of the Corporate Integrity Agreement, the Company could become liable for payment of certain stipulated penalties or could be excluded from participation in federal health care programs.

The foregoing descriptions of the Settlement Agreement and the Corporate Integrity Agreement are not complete and are qualified in their entirety by reference to such agreements, which are attached hereto as Exhibits 10.1 and 10.2.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

| Exhibit Number | Description                                                                                                                                                                                                |
|----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10.1           | Settlement Agreement, among Cardiovascular Systems, Inc., the United States of America acting through the United States Attorney for the Western District of North Carolina and on behalf of the Office of |

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Inspector General of the Department of Health and Human Services, and Travis Thams, dated June 28, 2016.

10.2 Corporate Integrity Agreement, between Cardiovascular Systems, Inc. and the Office of Inspector General of the Department of Health and Human Services, dated June 28, 2016.

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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.

Date: June 28, 2016

CARDIOVASCULAR  
SYSTEMS, INC.

By: /s/ Laurence L. Betterley  
Laurence L. Betterley  
Chief Financial Officer

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EXHIBIT INDEX

| Exhibit<br>Number | Description                                                                                                                                                                                                                                                                                                         |
|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
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| 10.2              | Corporate Integrity Agreement, between Cardiovascular Systems, Inc. and the Office of Inspector General of the Department of Health and Human Services, dated June 28, 2016.                                                                                                                                        |