

Avinger Inc
Form 8-K
April 10, 2019

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):

April 9, 2019

Avinger, Inc.

(Exact name of registrant as specified in its charter)

Delaware

001-36817

20-8873453

(State or other jurisdiction of incorporation) (Commission File Number) (IRS Employer
Identification No.)

400 Chesapeake Drive

Redwood City, California 94063

(Address of principal executive offices, including zip code)

(650) 241-7900

(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))

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 7.01. Regulation FD Disclosure.

On April 10, 2019, Avinger, Inc. issued a press release announcing receipt of 510(k) clearance from the U.S. Food & Drug Administration on April 9, 2019 for its Pantheris SV (Small Vessel) image-guided atherectomy system. A copy of the press release is furnished as Exhibit 99.1 to this report. The information furnished pursuant to this Item 7.01 and the exhibit hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act except as shall be expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On April 9, 2019, Avinger, Inc. received 510(k) clearance from the U.S. Food & Drug Administration for its Pantheris SV (Small Vessel) image-guided atherectomy system.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 Press Release dated April 10, 2019.

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.

AVINGER, INC.

Date: April 10, 2019 By: /s/ Mark Weinswig
Mark Weinswig

Chief Financial
Officer