

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Avinger Inc

Form: 8-K

Date Filed: 2020-09-11

Corporate Issuer CIK: 1506928

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):

September 9, 2020

Avinger, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-36817

(Commission File Number)

20-8873453

(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))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	AVGR	The NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR § 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR § 240.12b-2).

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

On September 9, 2020, the compensation committee of the board of directors of Avinger, Inc. (the "Company") approved the following annual target bonus percentages, subject to achievement of mutually agreed performance goals and payable semi-annually, effective July 1, 2020: Jeffrey Soinski, President and Chief Executive Officer, 75%; Mark Weinswig, Chief Financial Officer; 60%, and Himanshu Patel, Chief Technology Officer, 60%.

Item 7.01 Regulation FD Disclosure.

On September 10, 2020, the Company received 510(k) clearance from the U.S. Food & Drug Administration for its Ocelaris next generation image-guided chronic total occlusion (CTO) crossing system. The new device will be marketed under the brand name TIGEREYE™ to reinforce its highly differentiated benefit of providing real-time imaging from inside the vessel during a CTO-crossing procedure.

In addition, on September 11, 2020, Avinger issued a press release announcing that it had received 510(k) clearance from the U.S. Food & Drug Administration for its Ocelaris next generation image-guided CTO crossing system, which press release is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 8.01 Other Items.

The information contained in Item 7.01 other than Exhibit 99.1 is incorporated by reference into this item.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release dated September 11, 2020.

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: September 11, 2020

By: /s/ Mark Weinswig
Mark Weinswig
Chief Financial Officer



FOR IMMEDIATE RELEASE

Avinger Receives FDA Clearance of Ocelaris Next Generation Image-guided CTO Crossing System

Innovative New Product to be Marketed under TIGEREYE™ Brand Name

Redwood City, Calif., September 11, 2020 - Avinger, Inc. (NASDAQ: AVGR), a commercial-stage medical device company marketing the first and only intravascular image-guided, catheter-based system for diagnosis and treatment of patients with Peripheral Artery Disease (PAD), today announced that the Company received 510(k) clearance from the U.S. Food & Drug Administration (FDA) for its Ocelaris next generation image-guided chronic total occlusion (CTO) crossing system. The new device will be marketed under the brand name TIGEREYE™ to reinforce its highly differentiated benefit of providing real-time imaging from inside the vessel during a CTO-crossing procedure.

TIGEREYE is a product line extension of Avinger's Ocelot family of image-guided CTO crossing catheters. Its design elements include an upgrade of the image capture rate to provide high definition, real-time intravascular imaging similar to the Company's Pantheris image-guided atherectomy system and a user-controlled deflectable tip designed to assist in steerability within the lumen. TIGEREYE also features a new distal tip configuration with faster rotational speeds up to 1000 RPM designed to penetrate challenging lesions. The TIGEREYE catheter has a working length of 140 cm and 5 French sheath compatibility for treatment of lesions in the peripheral vessels both above and below the knee.

"We are excited to receive U.S. pre-marketing clearance for TIGEREYE, which we believe will be a significant growth driver for our CTO-crossing business," said Jeff Soinski, Avinger's President and CEO. "Our Ocelot catheters have helped physicians cross thousands of CTOs since introduction of the product line in 2013. TIGEREYE brings compelling new features and benefits to expand upon this platform to help physicians safely cross challenging CTOs. We anticipate initiating a limited launch of TIGEREYE in the U.S. in the fourth quarter of this year, then leveraging our growing commercial infrastructure and installed base of Lumivascular accounts for national launch in early 2021."

Dr. Jaafer Golzar, Avinger's Chief Medical Officer, commented, "I believe that TIGEREYE represents a major advancement for patients with chronic total occlusions, which presents one of the most significant technical challenges to physicians treating peripheral artery disease. By combining real-time intravascular imaging and the ability to precisely control the device within the vessel, TIGEREYE provides an important new tool to help interventionalists stay within the true lumen while successfully crossing these challenging lesions. Intraluminal crossing provides for a wider variety of treatment options following crossing of the CTO and results in less potential for vascular injury, which has been shown to improve long-term clinical outcomes for patients."

Soinski continued, "The FDA clearance of TIGEREYE provides another market growth opportunity for Avinger, further building on the market gains we have made with our Pantheris Next Generation and Pantheris SV catheters. TIGEREYE will be the third new product released by Avinger in less than 3 years, putting us on the leading edge of innovation for PAD therapy. We have grown our commercial sales team and advanced our clinical studies to drive case activity and build data in support of our image-guided approach. The Company has a robust pipeline of new products and a strong balance sheet with more than \$25 million in cash to fuel our product launch and growth plans."

Avinger's proprietary Lumivascular technology allows physicians, for the first time ever, to see from inside the artery during an atherectomy or CTO crossing procedure by using an imaging modality called optical coherence tomography, or OCT, that is displayed on Avinger's Lightbox console. Physicians performing atherectomy or crossing CTOs with other devices must rely solely on X-ray as well as tactile feedback to guide their interventions while treating complicated arterial disease. With the Lumivascular approach, physicians can more accurately navigate their devices and treat PAD lesions, thanks to the real-time OCT images generated from inside the artery, without exposing healthcare workers and patients to the negative effects of ionizing radiation.

About Avinger, Inc.

Avinger is a commercial-stage medical device company that designs and develops the first and only image-guided, catheter-based system for the diagnosis and treatment of patients with Peripheral Artery Disease (PAD). PAD is estimated to affect over 12 million people in the U.S. and over 200 million worldwide. Avinger is dedicated to radically changing the way vascular disease is treated through its Lumivascular platform, which currently consists of the Lightbox imaging console, the Ocelot family of chronic total occlusion (CTO) catheters, and the Pantheris® family of atherectomy devices. Avinger is based in Redwood City, California. For more information, please visit www.avinger.com.

Forward-Looking Statements

This news release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements include statements regarding our future performance, the potential benefits of TIGEREYE, the potential of TIGEREYE to be a significant growth driver for our CTO-crossing business, the benefits of TIGEREYE in the treatment of CTOs, and the anticipated launch timing of TIGEREYE into the U.S. market. Such statements are based on current assumptions that involve risks and uncertainties that could cause actual outcomes and results to differ materially. These risks and uncertainties, many of which are beyond our control, include the resource requirements related to Ocelaris; the outcome of clinical trial results; competition from other products, and requirements to obtain regulatory approval to commercialize Ocelaris; as well as the other risks described in the section entitled "Risk Factors" and elsewhere in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 6, 2020. These forward-looking statements speak only as of the date hereof and should not be unduly relied upon. Avinger disclaims any obligation to update these forward-looking statements, except as required by law .

Investor Contact:

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