**Product Name:** Pantheris Atherectomy System  
*(Lower Limb Advanced Arterial Therapeutics, Pathway Clinical Trial MarketTracks, Medtronic PV Lower Limb Advanced Arterial Therapeutics)*

**Description:**
Pantheris is the first-ever lumectomy catheter for image-guided atherectomy to treat patients with Peripheral Artery Disease (PAD), a system that combines directional atherectomy capabilities with real-time intravascular visualization to remove plaque from blocked arteries.

**Company/Sponsor:**
- Avinger, Inc.

**Vessels:**
- Tibial Arteries
- Femoral Arteries (SFA/Superficial)
- Popliteal Arteries
- Lower Limb Arteries
- Femoral-Popliteal Arteries (FemPop)
- Deep Femoral Arteries

**General Modality:**
- Medical Devices

**Specific Modality:**
- Other Medical Devices / Systems

**General Product Type:**
- Image-Guided Atherectomy

**Clinical Trials:**
- COMBINE II - A Non-randomized, Multi-center Feasibility Trial of the Avinger Pantheris System  
- INSIGHT Study - Pantheris Atherectomy  
- Treatment of In-Stent Restenosis In Lower Extremity Arteries  
- VISION Trial - Evaluating Safety and Efficacy of Pantheris Image-Guided Atherectomy

**Please Note:** All links will open in the current window - to open a link in a new window please right click the link and select "Open in New Window" or "Open in New Tab"

**Product Image:**

**Commercial Approval:**
- On October 18 2018 Avinger, Inc. a leading developer of innovative treatments for peripheral artery disease (PAD), today announced Conformité Européenne (CE) Marking approval of Pantheris SV (Small Vessel), a product line extension of the Lumivascular atherectomy system.
- On October 31, 2017 Avinger Inc received 510(K) clearance from the US FDA for modifications to the company’s Pantheris Lumivascular atherectomy system. The modifications were designed to enhance cutting efficiency, increase product reliability, and improve overall ease of use of the Pantheris system.
- On December 20, 2017 Avinger received CE Marking approval for its next generation Pantheris Lumivascular atherectomy system, this next generation device incorporates the feedback we have received from our physician partners over nearly two years and should deliver the next level of quality, efficiency, and ease of use to the Pantheris atherectomy system.
- On May 23, 2018 Avinger Inc(NASDAQ:AVGR), a leading developer of innovative treatments for peripheral artery disease (PAD), announced today that the Company received 510(k) clearance from the U.S. Food & Drug Administration (FDA) for its next generation Pantheris Lumivascular atherectomy system.
- On August 30, 2018 Avinger Inc announced the Company submitted a new 510(k) application to the U.S Food & Drug Administration (FDA) for the Pantheris SV (Small Vessel) Lumivascular atherectomy system.

Pantheris SV is a line extension of the Pantheris family of catheters, the first and only image-guided atherectomy devices for the treatment of PAD. Designed with a lower profile and longer length, Pantheris SV is intended to expand the number of addressable procedures for Pantheris by allowing physicians to target lesions in smaller diameter vessels and more distal regions of the vasculature.

- On October 12, 2017 Avinger receives CE Mark for In stent Restenosis indication with Pantheris Image Guided Atherectomy
- On September 26, 2017 Avinger receives CE Marking Approval for In-Stent Restenosis Treatment Indication With Pantheris Image-Guided Atherectomy
- On April 10, 2019 Avinger, Inc, a leading developer of image-guided, catheter-based systems for the 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 Pantheris SV (Small Vessel) image-guided atherectomy system.
- March 2, 2016 - Avinger received 510(k) clearance from the United States Food and Drug Administration (FDA) for an enhanced version of its Pantheris™ lumivascular atherectomy system, the first-ever image-guided atherectomy device for the treatment of PAD. Avinger will commence U.S. commercialization of this enhanced version of Pantheris immediately, which features improved ergonomics, physician controls and manufacturability.
- Awarded a CE Mark on August 28, 2013
Received FDA Approval on October 14, 2015.

Development Status - Commercial Events:

On July 29, 2019 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 Peripheral Artery Disease (PAD), today announced that physicians in four U.S. sites have successfully treated several patients with the Pantheris SV (Small Vessel) image-guided atherectomy system. These initial cases are part of a limited launch at up to 13 leading clinical centers prior to expanding commercial distribution to additional treatment facilities in the U.S.

On June 4, 2019 Avinger, Inc. a commercial-stage medical device company marketing the first-ever image-guided, catheter-based system for diagnosis and treatment of Peripheral Artery Disease (PAD), announced it has entered into an exclusive distribution agreement with Integmed Ltd. for the sales and marketing of Avinger’s Lumivascular products in Hong Kong.

On May 16, 2019 Avinger Inc 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 physicians in 78 clinical sites have successfully treated more than 1,000 patients with the next-generation Pantheris image-guided atherectomy system.

On April 17, 2019 Avinger, Inc.a leading developer of image-guided, catheter-based systems for the diagnosis and treatment of patients with Peripheral Artery Disease (PAD), today announced the issuance of a new U.S. patent related to the Company’s proprietary optical coherence tomography (OCT) intravascular imaging system. The Company also announced the allowance of five additional U.S. patent applications that are expected to issue over the next six months.

On February 2, 2018 Pantheris was featured in Live Case Transmission at Leipzig Interventional Course 2018. This device treated a 57 year-old male suffering from ischemic rest pain of the left foot due to extensive stenoses and occlusion of the superficial femoral artery and popliteal artery and the results were remarkable.

On June 26, 2018 Avinger, Inc. (Nasdaq:AVGR), a leading developer of innovative treatments for peripheral artery disease (PAD), today announced that several physicians have successfully treated over 40 patients in the US across 13 sites with the next-generation Pantheris image-guided atherectomy system for the treatment of peripheral artery disease (PAD).

On August 29, 2018 Avinger, Inc, a leading developer of innovative treatments for peripheral artery disease (PAD), today announced the issuance of an important new patent covering the Company’s Pantheris image-guided atherectomy system. The issuance of this patent by the USPTO is an important milestone in Avinger’s development of image-guided devices for the treatment of PAD.

On September 5 2018, Avinger Inc announced that physicians in 35 sites globally have successfully treated over 200 patients with the next-generation Pantheris image-guided atherectomy system for the treatment of peripheral artery disease (PAD).

On November 15, 2018 Avinger Inc a commercial-stage medical device company that designs and develops the first-ever image-guided, catheter-based system that diagnoses and treats patients with peripheral artery disease (PAD), announced the successful treatment of the first nine patients with Pantheris SV (Small Vessel) at two separate hospitals in Germany.

On December 13, 2018 Avinger, Inc announced that physicians in 59 sites globally have successfully treated more than 500 patients with the next-generation Pantheris image-guided atherectomy system for the treatment of peripheral artery disease (PAD).

On January 28, 2019 Avinger, Inca leading developer of innovative treatments for peripheral artery disease (PAD), today announced that its Pantheris® SV (Small Vessel) image-guided atherectomy system was featured in a live case transmission at Leipzig Interventional Course (LINC) 2019.

Development Status - Clinical Trials:

On April 12, 2018 - Successful treatment results of 3 patients with extended nosecone version of the next generation Pantheris Lumivascular atherectomy system. This product is a line extension of the existing next generation platform, with a longer nosecone that enhances the plaque removal capacity of the device in addition to the feature improvements of the next generation of devices. This new device qualifies for commercial sale in the European Union (EU) under the existing CE Marking for Pantheris.

On April 30, 2018 Avinger, Inc.announced that its next generation Pantheris® Lumivascular atherectomy system with extended nosecone was featured in a live case transmission at Charing Cross Symposium (CX) 2018 held in London, England. “The combination of Ocelot and the Pantheris with the extended nosecone in this case contributed towards a great outcome for this patient in what can typically be an extremely challenging procedure,” Dr. Schwindt stated.
Sources:


June 4, 2019 --- "Development Status - Commercial Events" - added exclusive distribution agreement to market products in Hong Kong --- "Source" <https://irdirect.net/prviewer/release_only/id/3848399>


April 17, 2019 --- "Development Status - Commercial Events" - added patent issuance & 5 more patent application over the next 6 months --- "Source" <https://irdirect.net/prviewer/release_only/id/3748159>


November 15, 2018 --- "Commercial Event" - 9 successful patients treated with Pantheris SV in Germany --- "Source" <https://irdirect.net/prviewer/release/id/3474093>


In January 2015, the preliminary patient demographics for the VISION trial (Multi-center, non-randomized safety and efficacy study to evaluate the Pantheris system Atherectomy while using directional visualization and imaging as an adjunct to fluoroscopy to aid the removal of plaque from diseased lower extremity arteries) were presented at LINC 2015.

Last Update: August 1, 2019