# **RADICALLY CHANGING THE WAY** VASCULAR DISEASE IS TREATED





C) AVRIAGES

March 2022

14,23.07



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## **DISRUPTIVE IMAGE-GUIDED THERAPY** FOR VASCULAR DISEASE

**Commercial-Stage Medical Device Company** 

### Large Market Opportunity

In the U.S. over 20 million people projected to suffer from PAD<sup>1</sup>; U.S. atherectomy market estimated to be >\$500 million<sup>2</sup> with over 200,000 procedures performed each year

#### **Scalable Financial Model**

Ramping procedures expected to drive increased revenue and contribution margin, creating operating profit leverage

### **Robust Product Pipeline**

Multiple new product launches anticipated in 2022 – 2025 to expand the addressable market and drive new revenue opportunities

## **Extensive IP Portfolio**

**187 total patents granted and** pending covering key aspects of design, manufacturing and therapeutic use of OCT imaging platform and devices

### FIRST AND ONLY THERAPEUTIC CATHETERS WITH REAL-TIME IMAGE GUIDANCE





#### **PERIPHERAL ARTERY DISEASE (PAD)**

(1) The Sage Group 2010 (2) Millennium Research Group, December 2014. Image: Armstrong. Endovascular Today 2018



## LUMIVASCULAR PLATFORM REAL-TIME IMAGE-GUIDED THERAPY





- 100+ active installed units
- FDA 510(k) cleared; CE Marking
- High-definition OCT imaging for diagnostic and therapeutic applications

## **OCT-GUIDED CATHETERS**

#### ATHERECTOMY





#### **CTO CROSSING**













## **OCT-GUIDED THERAPY** UNSURPASSED VISUALIZATION

FLUOROSCOPY (X-RAY)







#### **OPTICAL COHERENCE TOMOGRAPHY (OCT)**



#### High Definition, Laser Light-Based, No X-ray Radiation





## **ARTERIAL DAMAGE LEADS TO** RESTENOSIS

## **Healthy Artery**

The external elastic lamina (EEL) is the border between the media and the adventitia.



### Restenosis

Disruption to EEL and adventitia leads to an aggressive healing response, commonly referred to as restenosis





1. Tarricone, et al. J Endovasc Ther. 2015

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## **AVINGER'S PERSPECTIVE**

# The best long term outcomes result from avoiding injury during treatment and maximizing luminal gain



## PANTHERIS NEXT GENERATION ATHERECTOMY

### VISUALIZATION AT THE POINT OF THERAPY + DIRECTIONAL ATHERECTOMY



Targeted Therapy

Precise Control

Increased Efficiency

**Optimal Safety** 

## **UNSURPASSED CLINICAL OUTCOMES**





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## PANTHERIS **VISUALIZATION. PRECISION. SAFETY**

#### SEE















## PANTHERIS VISUALIZATION. PRECISION. SAFETY









## **IMAGING IMPROVES OUTCOMES VISION IDE CLINICAL STUDY<sup>1</sup>**

#### **130 PATIENTS | 20 SITES | 164 LESIONS**



1. VISION Data on File at Avinger, Inc.



## % **DISSECTIONS OR** PERFORATIONS % **ADVENTITIA**

### **TLR (Restenosis)**

100%		
80%		
60%		
40%		
20%		
0%	8%	

6 mo Target Lesion Revascularization (TLR) by Patient





## **PANTHERIS IN-STENT RESTENOSIS (ISR) INDICATION** FDA 510(K) CLEARANCE NOVEMBER 2021

#### Pantheris presents a highly differentiated solution for the treatment of in-stent-restenosis, a large and underserved market in the U.S. and globally



Each year, patients in U.S. treated with stents in femoral and popliteal arteries

Within 3 years, 30-40% of these stents develop in-stent restenosis or occlusions



**NON-LAYERED STRUCTURES** 

STENT STRUTS

MIDDLE MARKER

Each year, **ISR** patients are treated globally

Source: Lichtenberg, et al. J Cardiovasc Surg. 2017





## INSIGHT CLINICAL STUDY UNSURPASSED SAFETY AND EFFICACY FOR THE TREATMENT OF ISR

- Multi-center prospective, single-arm trial conducted at 17 institutions with 97 subjects enrolled
- Safety endpoint: 97% of subjects free of device-related MAE at 30 days post-procedure
- Efficacy endpoints:
  - 93% freedom from TLR at 6-months post procedure and 89% at 1-year post
  - 39% improvement in ABI to 0.96 at 6-months post procedure
  - 71% Rutherford Class improvement at 6-months post procedure, with 77% of subjects Rutherford Class 0 or 1





Source: INSIGHT Data on File at Avinger, Inc.





## **PANTHERIS SV (SMALL VESSEL)** FDA 510(K) CLEARANCE APRIL 2019



#### **COMMERCIAL LAUNCH SEPTEMBER 2019** Product shipped to >100 accounts

- Differentiated solution for complex disease in high need population; addressable market of ~\$180M<sup>1</sup>
- Longer length and lower profile to enable treatment of smaller vessels, including those below-the-knee (BTK), estimated to account for 1/3 of atherectomy procedures
- IMAGE-BTK post-market clinical study currently enrolling; anticipated completion 2H 2022

**Pre-treatment** 



**Post-treatment** 



**Pantheris SV Case Study** 

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## OCELOT CTO-CROSSING FIRST OCT-GUIDED THERAPEUTIC SYSTEM



CTO = chronic total occlusion



# PLAQUE THE IS IN MIDDLE MARKER LAYERED-STRUCTURES







## **TIGEREYE NEXT GENERATION CTO CROSSING**

FDA 510(K) CLEARANCE AUGUST 2020

- Full commercial launch January 2021
- Successful limited launch Fourth Quarter 2020
- Enhanced imaging and CTO crossing capability
  - Up to 1000 rpm rotation speed generates Pantheris-like imaging
  - Proprietary tip design and faster rotation improves crossing capability
- Variable angle tip deflection delivers precise maneuverability
- Low profile design allows for 5F sheath compatibility









## STRATEGIC GROWTH DRIVERS

# 1

## **Drive Utilization**

Drive utilization at current sites and open new sites in current markets

## **3** Expand Markets

Expand sales team, launch new sites in underserved areas





# 2

## **Launch New Devices**

Devices in development to expand available market and revenue per site

# 4

## **Advance Clinical Data**

Produce compelling clinical outcomes data to support utilization and value





## **NEW AND IMPROVED PRODUCTS DRIVE REVENUE GROWTH**

**Total Pantheris, Pantheris SV, Tigereye Revenue (\$000)** 



## **3 NEW PRODUCTS IN PAST 3 YEARS**

## **PANTHERIS** NEXT GEN

## **PANTHERIS** SV

## TIGEREYE



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## LIGHTBOX 3 IMAGING CONSOLE FDA 510(K) CLEARANCE JANUARY 2022

#### Radically reduced footprint and lower cost

- Weighs <20 pounds and fits in carry-on suitcase
- Cost reduction of up to 50%
- Next generation solid state laser for enhanced OCT imaging and variable high-speed catheter rotation capability
- Portable with multiple lab installation options
- Reimagined software system and user interface emphasis on speed and simplicity
- Full commercial launch expected Q2 2022









## PERIPHERAL LINE EXTENSIONS EXPAND PORTFOLIO AND STREAMLINE PROCEDURE

### **CTO-Crossing:** Tigereye ST

- Spinning outer tip for tough caps and calcium
- Advanced shaft design for pushability and torque response
- New design, lower profile tip for trackability
- Three-marker system for consistent imageinterpretation across platform

## Anticipated 510(k) filing First Half 2022



Currently in development at Avinger. Not available for sale.

#### **Atherectomy:** Pantheris LV

- Proprietary design for optimal plaque apposition without balloon
- Ability to operate at higher rotational speeds in challenging plaque
- Rotational control for efficient guidewire management
- Modified plaque management system for tissue packing and removal

## Anticipated 510(k) filing Second Half 2022





## **CORONARY CTO-CROSSING OPPORTUNITY TO REDEFINE A MARKET**

- Treatment of CTOs in the coronary arteries represents a clinically challenging and largely underserved market
- Percutaneous coronary intervention to treat CTOs (CTO-PCI) is a highly complex procedure, requiring specialized and demanding technique, the use of multiple devices, and significant time under fluoroscopy (high radiation and contrast burden)
- Estimated approximately 50,000 CTO-PCI procedures performed in the U.S. each year, with sub-optimal success and complication rates
- Estimated >200,000 highly invasive CABG surgeries performed in U.S. annually, with up to 30% related to treatment of coronary CTOs
- **On-board intravascular imaging and precise control of Avinger** platform provides opportunity to expand the number of CTO-PCI procedures and potentially reduce the number of CABG surgeries



Currently in development at Avinger. Not available for sale.





Antegrade wire escalation as primary approach **Retrograde dissection / re-entry as back-up** 





## **IMAGE-GUIDED CORONARY CTO-PCI INNOVATION FOR CLINICAL SUCCESS AND MARKET EXPANSION**

- Image-guidance + precise control / steerability provides opportunity for improved safety and • efficacy in an expanded patient population
- coronary usage
- diagnostic imaging already in place
- balloons and re-entry devices
- Small number of non-imaging competitive devices with high cost and clinical limitations
- with 50+ CTO-PCI cases in 2009, up to 124 centers in 2013
- **Development efforts underway with goal of initiating clinical study in 2023**



Currently in development at Avinger. Not available for sale.

Leverages Tigereye platform in a lower profile (4F) and more flexible device, designed specifically for

High U.S. reimbursement for coronary CTO-crossing *plus* incremental reimbursement for coronary OCT

Cost-efficient: reduces the need for multiple specialty wires, support catheters, recanalization devices,

Targets emerging hospital market with high growth potential – only 8 U.S. high volume centers in U.S.



## NEW PRODUCT PIPELINE AVINGER

PRODUCT	ESTIMATED MARKET OPPORTUNITY <sup>1</sup>	ANTICIPATED U.S. 510(k) FILING	
Lightbox 3 Imaging Console	\$100M	August 2021	
Tigereye ST Peripheral CTO	\$90M	1H 2022	
Pantheris LV Peripheral Atherectomy	\$250M	2H 2022	
Coronary CTO	\$350M	<b>2024</b>	

(1) Company estimate

ANTICIPATED U.S. PRODUCT AVAILABILITY	COMMENTARY
Q1 2022	Miniaturized solid-state console with full integration
2H 2022	Advanced image-guided device for crossing challenging CTOs
1H 2023	Advanced image-guided atherectomy device with streamlined workflow
TBD	First and only image-guided device for crossing CTOs in the coronary arteries (IDE clinical study required)

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## **U.S. AND INTERNATIONAL SALES REGIONS**

#### U.S.

EUROPE MIDDLE EAST

#### **25 Sales Professionals**

- VP/Regional Directors: 3
- Territory Sales Managers: 9
- Clinical Specialists: 13

#### **1 International VP**

Direct Sales in Germany Distributors in UAE, Israel and Turkey

Regulatory Status Approved

Approved





Approved (Australia & Hong Kong) Regulatory approval required (China & Japan)

#### **U.S. National Agreements**







As of December 31, 2021



## KEY UPCOMING MILESTONES COMMERCIAL EXPANSION AND ROBUST PIPELINE

#### 1H 2022

## 510(k) clearance for Lightbox 3 imaging console and U.S. commercial launch

510(k) filing for Tigereye ST peripheral CTO line extension

Finalize Pantheris LV design and advance to verification & validation testing

Advance coronary image-guided CTO crossingCoronary CTO design selection for verificationdesign and development& validation testing



### 2H 2022

Completion of enrollment and interim data release for Pantheris SV IMAGE-BTK study

510(k) clearance for Tigereye ST and U.S. commercial launch

510(k) filing for Pantheris LV peripheral atherectomy line extension





## **CAPITALIZATION TABLE AND SELECTED FINANCIALS AVINGER**

#### **SECURITIES**<sup>(1)</sup> **AT MARCH 22, 2022**

Common Stock

Series A Preferred (56,366 outstanding / \$400 conversion)

Series B Preferred (85 outstanding / \$5 conversion)

Series D Preferred (2,400 outstanding / \$8 conversion)

Warrants (~\$47 avg. exercise price)

Employee Options and Restricted Stock Units

Outstanding Shares Assuming Full Conversion incl. Series A

#### **SELECTED FINANCIALS AT DECEMBER 31, 2021**

Cash Balance<sup>(2)</sup>

**Debt Balance** 



(1) All share and related amounts reflect the 1:20 reverse stock split implemented in March 2022

Cash balance does not include capital raise of \$7.6 million in gross proceeds in January 2022 (2)

#### **COMMON EQUIVALENTS**

5,428,770 140,915 17,000 300,000 1,006,285
140,915 17,000
140,915
5,428,770

#### \$19.5 million

#### \$11.9 million

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## **OPPORTUNITY SUMMARY** AVINGER



Proprietary solutions for large and growing PAD market, with planned expansion to Coronary Artery Disease (CAD) market



Lumivascular platform is the only technology that combines real-time intravascular imaging with highly effective therapy for the treatment of vascular disease



#### **Recent new product launches**

driving positive sales results and growing recurring revenue base



#### **Robust product pipeline for**

peripheral and coronary applications to position the company for future growth







#### **Clinical study programs**

generating compelling clinical data to support expanded labeling and incremental reimbursement initiatives



Efficient, lean operating structure focused on driving recurring revenue and scale





# Appendix



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## MANAGEMENT TEAM AVINGER

#### Jeff Soinski – Chief Executive Officer

Jeff Soinski has served as our President, Chief Executive Officer and a member of our Board of Directors since December 2014. From its formation in September 2009 until the acquisition of its Unisyn business by GE Healthcare in May 2013, Mr. Soinski served as Chief Executive Officer of Medical Imaging Holdings and its primary operating company Unisyn Medical Technologies, a national provider of technology-enabled products and services to the medical imaging industry. Mr. Soinski served periodically as a Special Venture Partner from July 2008 to June 2013 and as a Special Investment Partner since October 2016 for Galen Partners, a leading healthcare-focused private equity firm. From 2001 until its acquisition by C.R. Bard in 2008, Mr. Soinski was President and CEO of Specialized Health Products International, a publicly-traded manufacturer and marketer of proprietary safety medical products. Earlier in his career, Mr. Soinski was President and CEO of ViroTex Corporation, a venture-backed pharmaceutical drug delivery company he sold to Atrix Laboratories in 1998.

Mr. Soinski served on the board of directors of Merriman Holdings, parent of Merriman Capital, a San Francisco-based investment banking and brokerage firm, from 2008 until March 2016. He holds a B.A. degree from Dartmouth College.

#### Mark Weinswig – Chief Financial Officer

Mr. Weinswig joined Avinger in June 2018 and brings extensive strategic and operational financial experience, including almost 20 years in financial leadership positions in private and publicly-traded technology companies. Mr. Weinswig previously served as the CFO of Emcore, One Workplace, and Aqua Metals. Earlier in his career, he held senior financial positions at Coherent and Oclaro. Mr. Weinswig began his career in public accounting at PricewaterhouseCoopers and worked at Morgan Stanley as an Equity Research Analyst.

Mr. Weinswig has held both Certified Public Accountant (CPA) and Chartered Financial Analyst (CFA) designations. He received an MBA from Santa Clara University and a BS in Accounting from Indiana University.







## MANAGEMENT TEAM **AVINGER**

#### Himanshu Patel – Chief Technology Officer

Himanshu Patel has served as Chief Technology Officer of Avinger since cofounding the Company in 2007. Mr. Patel brings over 25 years of design experience developing medical devices, primarily for cardiovascular and peripheral artery disease treatment. He has extensive experience leading R&D and manufacturing operations across several companies and has served as a named inventor in more than 25 medical device patents. Mr. Patel spearheaded engineering efforts of the current platform of image-guided ("Lumivascular") interventional devices at Avinger and has played a central role in the development of products that have generated over \$1 billion in shareholder value over the course of his career. Prior to Avinger, Mr. Patel led R&D activities as the Director of Advanced Technologies at FoxHollow, where he led the engineering efforts of a \$180 million revenue product. His other experience includes medical device design and development at EndoTex Interventional Systems and improving the manufacturing processes of medical devices at General Surgical Innovations, amongst others. Mr. Patel has a proven track record of developing products that exceed customer expectations, with a focus on cost containment, speed to market, and manufacturability.

Mr. Patel holds a B.S. in Mechanical Engineering from M.S. University of Baroda, India, and an M.S. in Mechanical Engineering from the University of Florida.

#### Jaafer Golzar, MD, FACC, FSCAI – Chief Medical Officer

Jaafer Golzar, MD, joined Avinger in July 2018 and serves as our Chief Medical Officer. Dr. Golzar is a practicing interventional cardiologist with Advocate Medical Group and a key opinion leader in the treatment of peripheral artery disease. He is the Director of Limb Salvage and Endovascular Intervention at Advocate Trinity Hospital in Chicago. Dr. Golzar is also a leading educator on interventional techniques and technologies and is the founder of the Chicago Endovascular Conference (CVC), an international-scale annual conference designed to address the educational needs of physicians treating patients with peripheral arterial and venous diseases. Prior to joining Avinger, Dr. Golzar was also Medical Director – Interventional Vascular for BTG International. He has participated in multiple clinical research trials, including studies of PAD treatment with atherectomy, drug-eluting balloons and stents and has authored numerous publications in peer-reviewed journals. As a recognized leader in the endovascular community, Dr. Golzar has received multiple accolades including the prestigious Pioneers in Performance - North America Award in 2014. He is a Fellow of the American College of Cardiology and of the Society for Cardiovascular Angiography and Interventions.

Dr. Golzar has a B.S. from the University of Arkansas at Little Rock and an M.D. degree from the University of Arkansas College of Medicine.

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## **ATTRACTIVE AND GROWING MARKET AVINGER**

**U.S. PV Device Market** (\$ IN BILLIONS)

(\$ IN MILLIONS)



#### U.S. PV Device Market is expected to be \$3.6 billion in 2018 and expected to grow at a rate of 2.3% until 2023

Source: Unless otherwise noted, data is from Millennium Research Group, December 2014

- 1) The Sage Group, 2014
- 2) Journal of Vascular Surgery, 2009
- 3) For PAD, includes only Iliac, Femoropopliteal and Infrapopliteal indications
- 4) Total endovascular procedures are less than sum of the individual categories due to use of same technologies in same procedure



#### 2016 U.S. Market by Device Type



Atherectomy procedures and CTO procedures are expected to grow at 11.4% and 7.7% through 2023

TREATMENT	PROCEDURES	MARKET SIZE	
Amputations <sup>(1)</sup>	200,000	-	
Bypass <sup>(2)</sup>	160,000	-	
Surgical	260.000		
Procedures	360,000	-	
Stents <sup>(3)</sup>	314,000	\$523M	
Angioplasty <sup>(3)</sup>	560,000	\$240M	
Atherectomy	149,000	\$464M	
CTOs	155,000	\$82M	
Endovascular Procedures <sup>(4)</sup>	620,000	\$1,309M	

**Total atherectomy and CTO market size in 2016** was \$546 million





## **PHYSICIAN RADIATION** EFFECTS

**INTERVENTIONAL PHYSICIANS** HAVE THE HIGHEST RADIATION EXPOSURE <sup>6,7</sup>

#### **BRAIN**<sup>1</sup>

Increasing prevalence of left sided brain tumors (85%) in interventional physicians (n=31)

#### EYES<sup>2</sup>

> 3.2X risk of accelerated lens opacification (cataracts) among interventional practitioners

#### SKIN<sup>3</sup>

Soft tissue cancers, hair loss, and skin mottling noticeable in non-dominant hand of MDs

#### **BLOOD**<sup>4</sup>

Exacerbation of reactive oxygen species and bloodborne cancers

#### LOWER EXTREMITY<sup>5</sup>

Revascularization procedures pose the greatest radiation risk in the hospital

1. Roguin et al. AJC. 2013 | 2. Vano et al. Radiation Research. 2010 | 3. Shope TB. Radiographics. 1996 | 4. Ruso G. et al. European Heart Journal. 2001 | 5. Segal E. et al. JVS. 2013 | 6. International Atomic Energy Agency (IAEA) | 7. Zakeri, et al. in interventional cardiologist. 2010





## **OCT: AN ALTERNATIVE TO RADIATION REDUCING EXPOSURE DURING DIAGNOSTIC, CROSSING & THERAPY**



FLUOROSCOPY-GUIDED INTERVENTION



OCT-GUIDED INTERVENTION

1. Staniloae, et al. Journal of Invasive Cardiology. 2011 | 2. Davis T. Vascular Disease Management. 2015. | 3. Laird et al. Catheterization and Cardiovascular Interventions. 2014 | 5. Brodmann. Lumivascular Case Series. LINC 2016



## **IVUS & OCT** AN IMAGING COMPARISON



#### **PLAQUE & LAYERS**



## OCT



1. Pavillard E, L Sewell. (SCAN) Medical Imaging 2020





## **REAL-TIME IMAGE-GUIDED** CATHETERS

**ATHERECTOMY & CTO CROSSING** 

## PANTHERIS



The Pantheris System is intended to remove plaque (atherectomy) from partially occluded vessels in the peripheral vasculature with a reference diameter of 3.0 mm to 7.0 mm, using OCT-assisted orientation and imaging. The system is an adjunct to fluoroscopy by providing images of vessel lumen, wall structures and vessel morphologies. The Pantheris System is NOT intended for use in the iliac, coronary, cerebral, renal or carotid vasculature. The Ocelot System is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including sub and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention using OCT-assisted orientation and imaging. The system is an adjunct to fluoroscopy by providing images of vessel lumen and wall structures. The Ocelot System is contraindicated for use in the iliac, coronary, cerebral, renal or carotid vasculature. Lightbox is intended for use in peripheral vascular procedures in conjunction with a compatible Avinger product.







## COMPETITIVE POSITIONING ATHERECTOMY MARKET

	COMPANY	PRODUCT	MARKET SHARE	APPROACH
нининини	Avinger	Pantheris	<5%	Directional Atherecton
	Covidien / Medtronic	SilverHawk	29%	Directional Atherectom
	CSI	Diamondbac k 360	35%	Orbital Atherectom
	Philips (Spectranetics)	Turbo Elite	19%	Laser Ablat
	Boston Scientific	Jetstream / Rotablator	<b>11%</b> <sup>(1)</sup>	Rotational Atherectom
	Philips (Volcano)	Phoenix	<5%	Rotational Atherectom
		Source: Estimate	ed Market Share 12 n	nos, ended Sept 2



Source: Estimated Market Share 12 mos. ended Sept 2017 (based on DRG and other sources)(1) Boston Scientific market share not differentiated between Jetstream and Rotablator







#### Plaque removed from artery during Pantheris procedure





#### **Pre Pantheris**



#### **Post Pantheris**







## **CLINICAL DATA PROGRAMS**

## **SCAN Clinical Study – OCT vs. IVUS in Peripheral Arteries**

- Post-market study comparing Pantheris OCT imaging to IVUS as a diagnostic imaging tool – supports incremental reimbursement initiative
- Publication in February 2020

### **INSIGHT IDE Clinical Trial – In-Stent Restenosis (ISR)**

- IDE trial to support 510(k) submission for ISR label expansion; 16 US/OUS Sites.
- Data capture and analysis expected to be completed 1H 2021
- 510(k) clearance for Pantheris ISR indication in November 2021

### **IMAGE-BTK Clinical Study – Pantheris SV**

- Post-market study evaluating safety and efficacy in real-world clinical setting
- Multi-center study with evaluation at 30 days, 6 months and 1-year post-procedure
- 3 U.S. clinical sites open for enrollment; 2 German sites to be added in Q2 2022
- **Completion of enrollment and 30-day data anticipated 2H 2022**



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## **INSIGHT CLINCIAL STUDY IN COMPARISON: PANTHERIS VS. LASER**



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## ROBUST INTELLECTUAL PROPERTY PORTFOLIO PATENT OVERVIEW

Avinger has an extensive IP portfolio covering key aspects of the design, manufacturing and therapeutic use of OCT imaging catheters, atherectomy devices and imaging console

## 187 Total patents and pending applications

As of December 31, 2021

#### 73 U.S. patents and patent applications

- 49 issued & allowed U.S. patents
- 21 pending utility and 3 pending provisional applications

#### **114 Ex-U.S.** patents and patent applications

- 77 issued & allowed ex-U.S. patents
- 35 pending ex-U.S. applications
- **2** PCT application pending



