UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended March 31, 2024
or
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number: 001-36817

AVINGER, INC.
(Exact name of registrant as specified in its charter)

Delaware	**20-8873453**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

400 Chesapeake Drive
Redwood City, California 94063
(Address of principal executive offices and zip code)

(650) 241-7900
(Telephone number, including area code)

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of May 3, 2024, the number of outstanding shares of the registrant’s common stock, par value $0.001 per share, was 1,702,226.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our ability to continue as a going concern;
- our ability to regain and remain in compliance with the listing requirements of the Nasdaq Capital Market;
- the outcome of and expectations regarding our current clinical studies, and any additional clinical studies we initiate;
- our plans to modify our current products, or develop new products, to address additional indications;
- our ability to obtain additional financing through future equity or debt financings;
- the expected timing of 510(k) clearances by the U.S. Food and Drug Administration (“FDA”) which may include but are not limited to additional versions of Pantheris, Ocelot, Tigereye and Lightbox;
- the expected timing of 510(k) submission to the FDA, and associated marketing clearances by the FDA, which may include but are not limited to additional versions of Pantheris, Ocelot, Tigereye and Lightbox;
- our ability to realize benefits from our license and collaboration agreements with Zylox-Tonbridge;
- the expected growth in our business and our organization;
- our expectations regarding government and third-party payor coverage and reimbursement, including the ability of Pantheris to qualify for reimbursement codes used by other atherectomy products;
- our ability to retain and recruit key personnel, including the continued development of our sales and marketing infrastructure;
- our ability to obtain and maintain intellectual property protection for our products;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for, or ability to obtain, additional financing;
- our expectations regarding revenue, cost of revenue, gross margins, and expenses, including research and development and selling, general and administrative expenses;
- our ability to identify and develop new and planned products and acquire new products, including those for the coronary market;
- our financial performance;
- our ability to remain in compliance with laws and regulations that currently apply or become applicable to our business, both in the United States and internationally; and
- developments and projections relating to our competitors or our industry.

We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Quarterly Report on Form 10-Q may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 20, 2024. We urge you to consider these factors carefully in evaluating the forward-looking statements. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. We assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Quarterly Report on Form 10-Q to conform these statements to actual results or to changes in our expectations.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed with the United States Securities and Exchange Commission ("SEC") as exhibits to the Quarterly Report on Form 10-Q with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

AVINGER, INC.
AS OF AND FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2024

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PART I. FINANCIAL INFORMATION

ITEM 1. UNAUDITED FINANCIAL STATEMENTS

AVINGER, INC.
CONDENSED BALANCE SHEETS
(unaudited)
(In thousands, except share and per share data)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 7,174	$ 5,275
Accounts receivable, net of allowance for doubtful accounts of $ 56 and $41 at March 31, 2024 and December 31, 2023, respectively	1,377	1,014
Inventories, net	4,562	5,298
Prepaid expenses and other current assets	1,008	575
Total current assets	14,121	12,162
Right of use asset	1,991	1,102
Property and equipment, net	523	487
Other assets	225	19
Total assets	$ 16,860	$ 13,770
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 747	$ 777
Accrued compensation	2,523	2,311
Preferred stock dividends payable	65	—
Accrued expenses and other current liabilities	822	817
Leasehold liability, current portion	1,156	1,102
Borrowings	14,751	14,293
Total current liabilities	20,064	19,300
Leasehold liability, long-term portion	835	—
Other long-term liabilities	15	672
Total liabilities	20,914	19,972
Commitments and contingencies (Note 6)		
Stockholders' deficit:		
Convertible preferred stock issuable in series, par value of $ 0.001		
Shares authorized: 5,000,000 at March 31, 2024 and December 31, 2023		
Shares issued and outstanding: 19,229 and 62,881 at March 31, 2024 and December 31, 2023, respectively; aggregate liquidation preference related to Series E and Series F convertible preferred stock of $7,338 at March 31, 2024 and $ 62,796 at December 31, 2023 related to Series A and Series E convertible preferred stock	—	—
Common stock, par value of $ 0.001;		
Shares authorized: 100,000,000 at March 31, 2024 and December 31, 2023		
Shares issued and outstanding: 1,586,434 and 1,279,928 at March 31, 2024 and December 31, 2023, respectively	2	1
Additional paid-in capital	422,157	414,493
Accumulated deficit	(426,213)	(420,696)
Total stockholders' deficit	(4,054)	(6,202)
Total liabilities and stockholders' deficit	$ 16,860	$ 13,770

All share, per share data, par values, and additional paid-in-capital amounts reflect the impact of the reverse stock split effective September 12, 2023. See accompanying notes.

AVINGER, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(In thousands, except per share data)

	Three Months Ended March 31,	
	2024	**2023**
Revenues	$ 1,859	$ 1,888
Cost of revenues	1,516	1,252
Gross profit	343	636
Operating expenses:		
Research and development	1,062	1,356
Selling, general and administrative	4,370	3,538
Total operating expenses	5,432	4,894
Loss from operations	(5,089)	(4,258)
Interest expense, net	(416)	(392)
Other (expense) income, net	(12)	6
Net loss and comprehensive loss	(5,517)	(4,644)
Accretion of preferred stock dividends	(65)	(1,218)
Gain on exchange of Series A for Series A-1 convertible preferred stock	1,908	—
Net loss applicable to common stockholders	$ (3,674)	$ (5,862)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.49)	$ (10.70)
Weighted average common shares used to compute net loss per share, basic and diluted	1,477	548

All share and per share data reflect the impact of the reverse stock split effective September 12, 2023. See accompanying notes.

AVINGER, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' DEFICIT
(unaudited)
(In thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balance at December 31, 2022	60,961	$ —	522,177	$ 8	$ 406,514	$ (402,376)	$ 4,146
Issuance of common stock in public offerings, net of commissions and issuance costs	—	—	794	—	(21)	—	(21)
Exercise of pre-funded warrants for common stock	—	—	49,858	1	(1)	—	—
Issuance of common stock upon vesting of restricted stock units	—	—	2,294	—	—	—	—
Employee stock-based compensation	—	—	—	—	245	—	245
Accretion of Series A preferred stock dividends	—	—	—	—	(1,218)	—	(1,218)
Net and comprehensive loss	—	—	—	—	—	(4,644)	(4,644)
Balance at March 31, 2023	60,961	$ —	575,123	$ 9	$ 405,519	$ (407,020)	$ (1,492)

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance at December 31, 2023	62,881	$ —	1,279,928	$ 1	$ 414,493	$ (420,696)	$ (6,202)
Issuance of common stock and Series F preferred stock in a Private Placement, net of commissions and issuance costs	7,224	—	75,327	—	6,880	—	6,880
Issuance of common stock warrants in connection with the Private Placement	—	—	—	—	127	—	127
Cancellation of Series A preferred stock	(60,876)	—	—	—	—	—	—
Issuance of Series A-1 preferred stock, net of commissions and issuance costs	10,000	—	—	—	—	—	—
Issuance of common stock upon vesting of restricted stock awards	—	—	368,503	1	—	—	1
Net share settlement of restricted stock awards in satisfaction of tax obligations	—	—	(137,324)	—	(374)	—	(374)
Employee stock-based compensation	—	—	—	—	1,096	—	1,096
Accretion of preferred stock dividends	—	—	—	—	(65)	—	(65)
Net and comprehensive loss	—	—	—	—	—	(5,517)	(5,517)
Balance at March 31, 2024	19,229	$ —	1,586,434	$ 2	$ 422,157	$ (426,213)	$ (4,054)

All share and per share data reflect the impact of the reverse stock split effective September 12, 2023. See accompanying notes.

AVINGER, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(unaudited)
(In thousands)

	Three Months Ended March 31,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (5,517)	$ (4,644)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	83	72
Amortization of debt issuance costs and debt discount	16	21
Stock-based compensation	1,096	245
Noncash interest expense and other charges	442	486
Change in right of use asset	4	14
Provision for excess and obsolete inventories	34	179
Other	15	(50)
Changes in operating assets and liabilities:		
Accounts receivable	(378)	94
Inventories	584	(469)
Prepaid expenses and other current assets	(433)	(616)
Other assets	(210)	2
Accounts payable	(30)	(114)
Accrued compensation	212	367
Accrued expenses and other current liabilities	5	68
Other long-term liabilities	(657)	133
Net cash used in operating activities	(4,734)	(4,212)
Cash flows from investing activities		
Investing activities	—	—
Net cash used in investing activities	—	—
Cash flows from financing activities		
Proceeds from the issuance of common stock and convertible preferred stock, net of commissions and issuance costs	7,007	—
Net share settlement on restricted stock awards in satisfaction of tax obligations	(374)	—
Proceeds from the issuance of common stock in public offerings, net of commissions and issuance costs	—	(21)
Net cash (used in) provided by financing activities	6,633	(21)
Net change in cash and cash equivalents	1,899	(4,233)
Cash and cash equivalents, beginning of period	5,275	14,603
Cash and cash equivalents, end of period	$ 7,174	$ 10,370
Supplemental disclosure of cash flow information		
Noncash investing and financing activities:		
Increase to right of use asset and leasehold liability arising from lease amendment	$ 1,177	$ —
Accretion of preferred stock dividends	$ 65	$ 1,218
Reclassification of other long-term liabilities to accrued compensation	$ —	$ 638
Transfers between inventory and property and equipment	$ 118	$ (62)

See accompanying notes.

AVINGER, INC.

Notes to Condensed Financial Statements

1. Organization

Organization, Nature of Business

Avinger, Inc. (the "Company"), a Delaware corporation, was incorporated in March 2007. The Company designs, manufactures and sells image-guided, catheter-based systems that are used by physicians to treat patients with peripheral artery disease ("PAD"). Patients with PAD have a build-up of plaque in the arteries that supply blood to areas away from the heart, particularly the pelvis and legs. The Company manufactures and sells a suite of products in the United States ("U.S.") and in select international markets. The Company has developed its Lumivascular platform, which integrates optical coherence tomography ("OCT") visualization with interventional catheters and is the industry's only system that provides real-time intravascular imaging during the treatment portion of PAD procedures. The Company's Lumivascular platform consists of a capital component, Lightbox consoles, as well as a variety of disposable catheter products. The Company's current catheter products include Ocelot, Tigereye and Tigereye ST, which are designed to allow physicians to penetrate a total blockage in an artery, known as a chronic total occlusion ("CTO"). The Company also has image-guided atherectomy products, Pantheris, Pantheris SV and Pantheris LV, which are designed to allow physicians to precisely remove arterial plaque in PAD patients. The Company is in the process of developing next-generation CTO crossing devices to target coronary CTO markets. The Company is located in Redwood City, California.

Liquidity Matters

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") No. 2014-15, *Presentation of Financial Statements - Going Concern (Subtopic 205-40)* requires the Company to make certain disclosures if it concludes that there is substantial doubt about the entity's ability to continue as a going concern within one year from the date of the issuance of these financial statements.

In the course of its activities, the Company has incurred losses and negative cash flows from operations since its inception. On March 5, 2024, the Company entered into a financing as part of a broader strategic collaboration with Zylox-Tonbridge Medical Technology Co., Ltd. ("Zylox-Tonbridge") in which the Company received an aggregate of $7.5 million before any commissions, legal and accounting fees, and other ancillary expenses as described more fully below. As of March 31, 2024, the Company had an accumulated deficit of $426.2 million. The Company expects to incur losses for the foreseeable future. The Company believes that its cash and cash equivalents of $7.2 million at March 31, 2024, together with debt and other financing activities and expected revenues from operations will be sufficient to allow the Company to fund its current operations through the second quarter of 2024. The Company received net proceeds of approximately $6.5 million from the sale of its common stock under an At The Market Offering Agreement from the time of activation through March 31, 2024. The Company may seek to raise additional funds in future equity offerings to meet its operational needs and capital requirements for product development, clinical trials and commercialization or other strategic objectives.

The Company can provide no assurance that it will be successful in raising funds pursuant to additional equity or debt financings or that such funds will be raised at prices that do not create substantial dilution for its existing stockholders. Given the volatility in the Company's stock price, any financing that the Company may undertake in the next twelve months could cause substantial dilution to its existing stockholders, and there can be no assurance that the Company will be successful in acquiring additional funding at levels sufficient to fund its various endeavors. These conditions raise substantial doubt about the Company's ability to continue as a going concern. In addition, the macroeconomic environment has in the past resulted in and could continue to result in reduced consumer and investor confidence, instability in the credit and financial markets, volatile corporate profits and reduced business and consumer spending, which could increase the cost of capital and/or limit the availability of capital to the Company.

If the Company is unable to raise additional capital in sufficient amounts or on terms acceptable to it, the Company may have to significantly reduce its operations or delay, scale back or discontinue the development and sale of one or more of its products. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. The Company's ultimate success will largely depend on its continued development of innovative medical technologies, its ability to successfully commercialize its products and its ability to raise significant additional funding.

Additionally, due to the substantial doubt about the Company's ability to continue operating as a going concern and the "Material Adverse Change" clause in the Loan Agreement with CRG Partners III L.P. and certain of its affiliated funds (collectively "CRG"), the entire amount of outstanding borrowings at March 31, 2024 and December 31, 2023 has been classified as current in these financial statements. CRG has not purported that an Event of Default (as defined in the Loan Agreement) has occurred due to a Material Adverse Change.

Currently substantially all of our cash and cash equivalents are held at a single financial institution, First Citizens Bank, which acquired our prior banking partner, Silicon Valley Bank, in March 2023. On March 10, 2023, the Federal Deposit Insurance Corporation announced that Silicon Valley Bank had been closed by the California Department of Financial Protection and Innovation. While we have regained access to our accounts at Silicon Valley Bank, now a division of First Citizens Bank, and are evaluating our banking relationships, future disruptions of financial institutions where we bank or have credit arrangements, or disruptions of the financial services industry in general, could adversely affect our ability to access our cash and cash equivalents. If we are unable to access our cash and cash equivalents as needed, our financial position and ability to operate our business will be adversely affected.

Public Offerings

At The Market Offering Agreement

On May 20, 2022, the Company entered into an At The Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC (the "Agent"), as sales agent, pursuant to which the Company may offer and sell shares of common stock, par value $0.001 per share (the "Shares") up to an aggregate offering price of $7,000,000 from time to time, in an at the market public offering. Sales of the Shares are to be made at prevailing market prices at the time of sale, or as otherwise agreed with the Agent. The Agent will receive a commission from the Company of 3.0% of the gross proceeds of any Shares sold under the ATM Agreement. The Shares sold under the ATM Agreement are offered and sold pursuant to the Company's shelf registration statement on Form S-3, which was initially filed with the Securities and Exchange Commission (the "SEC") on March 29, 2022 and declared effective on April 7, 2022, and a prospectus supplement and the accompanying prospectus relating to the At The Market Offering filed with the SEC on May 20, 2022. On August 3, 2022, the Company suspended sales under the ATM Agreement. On March 17, 2023, the Company reactivated the ATM Agreement. During the year ended December 31, 2023, the Company sold 607,241 shares of common stock at an average price of $ 9.01 per share for aggregate proceeds of approximately $5.5 million, of which approximately $164,000 was paid in the form of commissions to the Agent. There were no sales under the ATM Agreement during the three months ended March 31, 2024. While the Company may attempt additional sales in the future, there can be no assurance that the Company will be successful in acquiring additional funding through these means.

Other than the ATM Agreement, the Company currently does not have any commitments to obtain additional funds.

Strategic Partnership and Private Placement

On March 4, 2024, the Company entered into a License and Distribution Agreement (the "License Agreement") with Zylox-Tonbridge effective as of the Initial Closing (defined below), pursuant to which the Company will license and distribute certain of the Company's products (including consumables) in the Greater China region, including mainland China, Hong Kong, Macao, and Taiwan (the "Territory"). Zylox-Tonbridge will lead all regulatory activities for the registration of the Avinger products in the Territory. Avinger will also license its intellectual property and know-how related to Avinger products to Zylox-Tonbridge so that Zylox-Tonbridge can manufacture the localized products in the Territory. Avinger will supply Avinger products to Zylox-Tonbridge until Zylox-Tonbridge's manufacturing capability has been established and Zylox-Tonbridge has obtained the regulatory approval of the localized products manufactured by Zylox-Tonbridge. All sales of Avinger products locally manufactured by Zylox-Tonbridge with regulatory approval by the regulatory authorities in the Territory and commercialized in the Territory will be royalty bearing to Avinger at a rate from a mid-single to high-single digit percentage depending on the amount of gross revenue as defined in the License Agreement, with certain increases depending on the amount of product gross margin. The License Agreement has an initial term of 20 years, which shall be further automatically extended for additional 20-year terms, subject to certain conditions. The License Agreement may not be terminated by either party, other than for certain uncured material breaches or the other party's insolvency. In March 2024, the Company received approximately $0.2 million from Zylox-Tonbridge related to inventory consumed for regulatory approval which is recorded as a reduction to research and development expenses in the Condensed Statement of Operations and Comprehensive Loss for the three months ended March 31, 2024 which substantially offset the related expenditures associated with the inventory consumption.

In connection with the License Agreement, on March 4, 2024, the Company and Zylox-Tonbridge also entered into a Strategic Cooperation and Framework Agreement in conjunction with the Initial Closing (the "Collaboration Agreement" and, together with the License Agreement, the "Strategic Collaboration"), which provides the opportunity for the Company to access certain Zylox-Tonbridge peripheral vascular products for distribution in the U.S. and Germany. The agreement also provides the option for Avinger to source finished goods inventory from Zylox-Tonbridge following registration of Zylox-Tonbridge's manufacturing facility with the FDA.

Private Placement

On March 4, 2024, in connection with the Strategic Collaboration, the Company and Zylox-Tonbridge Medical Limited, a wholly-owned subsidiary of Zylox-Tonbridge (the "Purchaser"), entered into a Securities Purchase Agreement (the "Purchase Agreement"), pursuant to which the Purchaser agreed to purchase, in two tranches, up to an aggregate of $15 million in shares of the Company's common stock, par value $ 0.001 per share (the "Common Stock"), and shares of two new series of the Company's preferred stock (the "Private Placement"). On March 5, 2024, (the "Initial Closing"), the Company issued to the Purchaser 75,327 shares of the Common Stock at a purchase price per share of $ 3.664 (the "Purchase Price"), and 7,224 shares of a newly authorized Series F convertible preferred stock, par value $0.001 per share (the "Series F Preferred Stock"), at a purchase price per share of $1,000, for an aggregate purchase price of $7.5 million.

Each share of Series F Preferred Stock has a stated value of $ 1,000 and is initially convertible into approximately 273 shares of Common Stock at a conversion price equal to the Purchase Price, subject to the terms of the Certificate of Designation of Preferences, Rights, and Limitations of the Series F Preferred Stock (the "Series F Certificate of Designation").

Upon completion of the following as mutually agreed upon by the Company and the Purchaser: (i) the successful registration and listing under 21 CFR part 807 with the FDA of the Purchaser and one of its designated affiliates to manufacture Avinger's products, and (ii) the Company achieving an aggregate of $10 million in gross revenue within any four consecutive fiscal quarters after the Initial Closing, excluding any gross revenue achieved by Avinger under the License Agreement discussed above (together, the "Milestones"), the Purchaser will invest an additional $7.5 million (the "Milestone Closing") to purchase shares of the Company new Series G convertible preferred stock, par value $0.001 per share (the "Series G Preferred Stock"). Each share of Series G Preferred Stock will have a stated value of $1,000 and will be convertible into shares of Common Stock at a conversion price of equal to the lowest of (x) the Purchase Price, (y) the closing price of the Common Stock on the date immediately preceding the Milestone Closing, and (z) the average closing price for the last five trading days preceding the Milestone Closing, provided that the conversion price will be no less than $0.20. The Milestone Closing was determined to be a separate freestanding equity-classified instrument issued together with the common stock and Series F preferred stock, all of which are classified within equity.

The Company's obligations to (i) accept conversion of the shares of Series F Preferred Stock in excess of 19.9% of the Company's outstanding common stock as of the date of the Purchase Agreement and (ii) issue and sell shares of Series G Preferred Stock upon completion of the Milestones are each subject to receipt of the approval of the Company's stockholders as is necessary under the rules and regulations of Nasdaq (including, without limitation, Nasdaq Rule 5635(d)).

The Company engaged two financial advisors in connection with the Private Placement and agreed to pay them an aggregate cash fee equal to 7% of the gross proceeds to the Company. Additionally, the Company agreed to issue to one financial advisor warrants to purchase an aggregate number of shares of common Stock equal to 2% of the gross proceeds. In connection with the Private Placement, the Company issued the financial advisor warrants (the "Advisor Warrants") to purchase 40,938 shares of common stock. The cash fee of approximately $ 0.5 million and warrants with a fair value of approximately $0.1 million are considered financing costs and are recognized as a reduction of the proceeds from the Private Placement.

Series A Preferred Stock Exchange

On March 5, 2024, the Company entered into a Securities Purchase Agreement (the "A-1 Securities Purchase Agreement") with CRG to exchange all outstanding shares of Series A preferred stock for 10,000 shares of Series A-1 preferred stock (the "Exchange"). Among other things, the shares of Series A-1 preferred stock: (i) are convertible into an aggregate of approximately 2,729,257 shares of common stock at a conversion price equal to the Purchase Price, (ii) do not accrue or pay dividends payable solely on the Series A-1 preferred stock, (iii) will have no liquidation preference and (iv) will be junior in rank to shares of the Company's Series E preferred stock, Series F preferred stock and Series G preferred stock. The Exchange resulted in approximately $1.9 million gain included in the net loss applicable to common holders for the three months ended March 31, 2024.

CRG Loan Amendment

Also on March 5, 2024, the Company entered into Amendment No. 9 to Loan Agreement effective as of the Initial Closing (the "Amendment") with CRG, which amends the Loan Agreement to, among other things:

- extend the interest-only period through December 31, 2026;
- provide that interest payable through December 31, 2026 may be payable in kind rather than in cash; and
- permit the payment of dividends on the preferred stock issued or issuable to the Purchaser.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") and pursuant to the rules and regulations of the SEC. The accompanying unaudited condensed interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the Company's financial information. The results for the three months ended March 31, 2024 are not necessarily indicative of results to be expected for the year ending December 31, 2024, or for any other interim period or for any future year. The December 31, 2023 condensed balance sheet data has been derived from audited financial statements. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to SEC rules and regulations relating to interim financial statements. These unaudited condensed financial statements and notes should be read in conjunction with the financial statements included in the Company's Form 10-K for the fiscal year ended December 31, 2023, which was filed with the SEC on March 20, 2024. The Company's significant accounting policies are more fully described in Note 2 of the Notes to Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

On September 8, 2023, the Company's Board of Directors approved an amendment to the Company's amended and restated certificate of incorporation to effect a 1-for-15 reverse stock split of the Company's issued and outstanding common stock. The reverse stock split became effective on September 12, 2023.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements. Management uses significant judgment when making estimates related to its stock-based compensation, accruals related to compensation, the valuation of the common stock warrants, provisions for doubtful accounts receivable and excess and obsolete inventories, clinical trial accruals, and its reserves for sales returns and warranty costs. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Concentration of Credit Risk, and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to credit risk consist of cash and cash equivalents and accounts receivable to the extent of the amounts recorded on the balance sheets.

The Company's policy is to invest in cash and cash equivalents, consisting of money market funds. These financial instruments are held in Company accounts at one financial institution, First Citizens Bank, which acquired our prior banking partner, Silicon Valley Bank, in March 2023. The counterparties to the agreements relating to the Company's investments consist of financial institutions of high credit standing. The Company provides for uncollectible amounts when specific credit problems arise. Management's estimates for uncollectible amounts have been adequate, and management believes that all significant credit risks have been identified at March 31, 2024 and December 31, 2023. On March 10, 2023, the Federal Deposit Insurance Corporation announced that Silicon Valley Bank had been closed by the California Department of Financial Protection and Innovation. While we have regained access to our accounts at Silicon Valley Bank, now a division of First Citizens Bank, and are evaluating our banking relationships, future disruptions of financial institutions where we bank or have credit arrangements, or disruptions of the financial services industry in general, could adversely affect our ability to access our cash and cash equivalents. If we are unable to access our cash and cash equivalents as needed, our financial position and ability to operate our business will be adversely affected.

The Company's accounts receivable are due from a variety of healthcare organizations in the United States and select international markets. The Company provides for uncollectible amounts when specific credit problems arise. Management's estimates for uncollectible amounts have been adequate, and management believes that all significant credit risks have been identified at March 31, 2024 and December 31, 2023. At March 31, 2024, there was one customer that represented 32% of the Company's accounts receivable. At December 31, 2023, there was one customer that represented 24% of the Company's accounts receivable. For the three months ended March 31, 2024, there was one customer that represented 17% of revenues and another that represented 10% of revenues. For the three months ended March 31, 2023, there was one customer that represented 13% of revenues. Disruption of sales orders or a deterioration of financial condition of its customers would have a negative impact on the Company's financial position and results of operations.

Product Warranty Costs

The Company typically offers a one-year warranty on its products commencing upon the transfer of title and risk of loss to the customer. The Company accrues for the estimated cost of product warranties upon invoicing its customers, based on historical results. Warranty costs are reflected in the statement of operations and comprehensive loss as a cost of revenues. The warranty obligation is affected by product failure rates, material usage and service delivery costs incurred in correcting a product failure. Should actual product failure rates, material usage or service delivery costs differ from these estimates, revisions to the estimated warranty liability would be required. Periodically the Company assesses the adequacy of its recorded warranty liabilities and adjusts the amounts as necessary. Warranty provisions and claims are summarized as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
Beginning balance	$ 193	$ 109
Warranty provision	15	19
Usage/Release	(26)	(14)
Ending balance	$ 182	$ 114

Net Loss per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is computed by dividing the net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration for potential dilutive common shares. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss applicable to common stockholders by the weighted average number of shares of common stock and dilutive potential shares of common stock outstanding during the period. Any common stock shares subject to repurchase are excluded from the calculations as the continued vesting of such shares is contingent upon the holders' continued service to the Company. As of March 31, 2024 and 2023, there were no shares subject to repurchase. Since the Company was in a loss position for both periods presented, basic net loss per share attributable to common stockholders is the same as diluted net loss per share attributable to common stockholders as the inclusion of all potentially dilutive common shares would have been anti-dilutive.

Net loss per share applicable to common stockholders was determined as follows (in thousands, except per share data):

	Three Months Ended March 31,	
	2024	2023
Net loss applicable to common stockholders	$ (3,674)	$ (5,862)
Weighted average common stock outstanding, basic and diluted	1,477	548
Net loss per share attributable to common stockholders, basic and diluted	$ (2.49)	$ (10.70)

The following potentially dilutive securities outstanding have been excluded from the computations of diluted weighted average shares outstanding because such securities have an anti-dilutive impact due to losses reported:

	Three Months Ended March 31,	
	2024	2023
Common stock warrants equivalents	467,343	525,415
Common stock options	15	15
Convertible preferred stock	50,409	60,961
Unvested restricted stock awards	116,916	79,408
	634,683	665,799

Segment and Geographical Information

The Company operates and manages its business as one reportable and operating segment. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. Primarily all of the Company's long-lived assets, which are comprised of property and equipment, are based in the United States. For the three months ended March 31, 2024 and 2023, 94% and 92% of the Company's revenues were in the United States, based on the shipping location of the external customer. The remaining revenues for the three months ended March 31, 2024 and 2023, were primarily derived in Germany.

Fair Value Measurements

As of March 31, 2024 and December 31, 2023, cash equivalents were all categorized as Level 1 and consisted of money market funds. As of March 31, 2024 and December 31, 2023, there were no financial assets and liabilities categorized as Level 2 or 3. There were no transfers between fair value hierarchy levels during the three months ended March 31, 2024.

Recent Accounting Pronouncements

Recent accounting standards adopted

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity 's Own Equity*, which among other things, simplifies the accounting models for the allocation of proceeds attributable to the issuance of a convertible debt instrument. As a result, after adopting the ASU's guidance, entities will not separately present in equity an embedded conversion feature in such debt. Instead, they will account for a convertible debt instrument wholly as debt, and for convertible preferred stock wholly as preferred stock (i.e., as a single unit of account), unless (i) a convertible instrument contains features that require bifurcation as a derivative under ASC 815 or (ii) a convertible debt instrument was issued at a substantial premium. The standard becomes effective for the Company, as a smaller reporting company as defined by the SEC, in the first quarter of 2024 and early adoption is permitted. This new standard did not have a material impact on the Company's financial statements.

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures*. This ASU requires that a public entity provide additional segment disclosures on an interim and annual basis. The amendments in this ASU should be applied retrospectively to all prior periods presented in the financial statements unless impracticable. Upon transition, the segment expense categories and amounts disclosed in the prior periods should be based on the significant segment expense categories identified and disclosed in the period of adoption. The ASU is effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. This new standard did not have a material impact on the Company's financial statements.

Recent accounting standards not yet adopted

In December 2023, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"), which will require the Company to disclose specified additional information in its income tax rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold. ASU 2023-09 will also require the Company to disaggregate its income taxes paid disclosure by federal, state and foreign taxes, if any, with further disaggregation required for significant individual jurisdictions. The Company will adopt ASU 2023-09 in its first quarter of 2025. ASU 2023-09 allows for adoption using either a prospective or retrospective transition method.

3. Inventories

Inventories consisted of the following (in thousands):

	March 31, 2024	December 31, 2023
Raw materials	$ 2,741	$ 3,203
Work-in-process	130	25
Finished products	1,691	2,070
Total inventories	$ 4,562	$ 5,298

4. Borrowings

CRG

On September 22, 2015, the Company entered into a Term Loan Agreement, as amended (the "Loan Agreement") with CRG under which, subject to certain conditions, the Company had the right to borrow up to $50 million in principal amount from CRG on or before the end of the twenty-fourth (24th) month period commencing on the first Borrowing Date (as defined in the Loan Agreement). The Company borrowed $ 30 million on September 22, 2015. The Company borrowed an additional $10 million on June 15, 2016 under the Loan Agreement.

On February 14, 2018, the Company and CRG further amended the Loan Agreement concurrent with the conversion of $ 38 million of the principal amount of the senior secured term loan (plus $3.8 million in back-end fees and prepayment premium applicable thereto) into a newly authorized Series A convertible preferred stock.

On August 2, 2023, the Company and CRG entered into a Securities Purchase Agreement (“SPA”) pursuant to which the Company issued 1,920 shares of a newly authorized Series E convertible preferred stock (“Series E Preferred Stock”) in exchange for CRG surrendering for cancellation $1.92 million of outstanding principal and accrued interest of the senior secured term loan under the Loan Agreement. Each share of Series E preferred stock has a stated value of $1,000 per share and is convertible into 93 shares of the Company’s common stock at a conversion price of $ 10.725 per share, provided that the shares of Series E preferred stock cannot be converted into common stock to the extent the applicable holder would beneficially own in excess of 19.99% of the Company’s outstanding voting power, unless approved by the Company's stockholders in accordance with Nasdaq Listing Rule 5635(b).

The Company has entered into several amendments to the Loan Agreement (the “Amendments”) with CRG since September 2015. The Amendments, among other things: (1) extended the interest-only period through December 31, 2026; (2) extended the period during which the Company may elect to pay a portion of interest in payment-in-kind (“PIK”), interest payments through December 31, 2026 so long as no Default (as defined in the Loan Agreement) has occurred and is continuing; (3) permitted the Company to make the entire interest payments in PIK interest payments through December 31, 2026 so long as no Default has occurred and is continuing; (4) extended the Stated Maturity Date (as defined in the Loan Agreement) to December 31, 2025; (5) reduced the minimum liquidity covenant to $3.5 million at all times; (6) eliminated the minimum revenue covenants for all years (7) changed the date under the on-going stand-alone representation regarding no “Material Adverse Change” to December 31, 2020; (8) amended the on-going stand-alone representation and stand-alone Event of Default (as defined in the Loan Agreement) regarding Material Adverse Change such that any adverse change in or effect upon the revenue of the Company and its subsidiaries due to the outbreak of COVID-19 will not constitute a Material Adverse Change; (9) provided CRG with board observer rights and (10) provide that the board observer may be appointed or removed by written notice from the Majority Lenders (as defined in the Loan Agreement).

On January 26, 2024, the Company entered into Amendment No. 8 to the Loan Agreement with CRG, which reduces the minimum liquidity requirement of the Loan Agreement from $3.5 million to $1.0 million until April 1, 2024. Thereafter, the Company will be subject to the minimum liquidity requirement of $3.5 million.

On March 5, 2024, the Company entered into Amendment No. 9 to the Loan Agreement with CRG, which (1) extended the interest-only period through December 31, 2026; (2) extended the period during which the Company may elect to pay a portion of interest in PIK interest payments through December 31, 2026 so long as no Default (as defined in the Loan Agreement) has occurred and is continuing; (3) permitted the Company to make the entire interest payments in PIK interest payments through December 31, 2026 so long as no Default has occurred and is continuing; and (4) permit the payment of dividends on the preferred stock issued or issuable to the Purchaser.

The Company assessed Amendments Nos. 8 and 9 to the Loan Agreement entered into during the quarter ended March 31, 2024 and determined that these represented loan modifications. As such, the unamortized portion of previous issuance costs incurred will be amortized over the modified term, and costs incurred with third parties was expensed as incurred.

Under the amended Loan Agreement, no cash payments for either principal or interest are required until the first quarter of 2027. The interest will be accrued and included in the debt balance based (to the extent not paid) on principal amounts outstanding at the beginning of the quarter at an interest rate of 12.5%. Beginning in the first quarter of 2027, the Company will be required to make quarterly principal payments (in addition to the interest) of $2.4 million with total principal payments of $ 9.4 million in 2027 and $ 9.4 million in 2028. The maturity date of the Loan (as defined in the Loan Agreement) is December 31, 2028.

The Company may voluntarily prepay the borrowings in full, with a prepayment premium beginning at 5.0% and declining by 1.0% annually thereafter, with no premium being payable if prepayment occurs after seven and half years of the loan. There is currently no prepayment premium payable. Each tranche of borrowing required the payment, on the borrowing date, of a financing fee equal to 1.5% of the borrowed loan principal, which is recorded as a discount to the debt. In addition, a facility fee equal to 15.0% of the amounts borrowed plus any PIK is to be payable at the end of the term or when the borrowings are repaid in full. A long-term liability is being accreted using the effective interest method for the facility fee over the term of the Loan Agreement with a corresponding discount to the debt. The borrowings are collateralized by a security interest in substantially all of the Company’s assets.

The Loan Agreement requires that the Company adheres to certain affirmative and negative covenants, including financial reporting requirements, certain minimum financial covenants for pre-specified liquidity and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the Loan Agreement. In particular, the covenants of the amended Loan Agreement included a covenant that the Company maintain a minimum of $3.5 million of cash and certain cash equivalents. The minimum liquidity requirement was temporarily reduced to $1.0 million until April 1, 2024. In addition, the Loan Agreement prohibits the payment of cash dividends on the Company’s capital stock and also places restrictions on mergers, sales of assets, investments, incurrence of liens, incurrence of indebtedness and transactions with affiliates. CRG may accelerate the payment terms of the Loan Agreement upon the occurrence of certain “Events of Default” set forth therein, which include the failure of the Company to make timely payments of amounts due under the Loan Agreement, the failure of the Company to adhere to the covenants set forth in the Loan Agreement, the insolvency of the Company or upon the occurrence of a “Material Adverse Change” thereunder.

As of March 31, 2024, the Company was in compliance with all applicable covenants under the Loan Agreement.

As of March 31, 2024, principal, final facility fee and PIK payments under the Loan Agreement, as amended, were as follows (in thousands):

Year Ending December 31,	
2024 (remaining nine months of the year)	$ —
2025	—
2026	—
2027	11,378
2028	13,017
Total	24,395
Less: Amount of PIK additions and final facility fee to be incurred subsequent to March 31, 2024	(9,494)
Less: Amount representing debt issuance costs	(150)
Borrowings, current portion, as of March 31, 2024	$ 14,751

In connection with drawdowns under the Loan Agreement, the Company recorded aggregate debt discounts of $ 1.3 million as contra-debt. The debt discounts are being amortized as non-cash interest expense using the effective interest method over the term of the Loan Agreement. As of March 31, 2024 and December 31, 2023, the balance of the aggregate debt discount was approximately $150,000 and $166,000, respectively. The Company's interest expense associated with the amortization of debt discount was approximately $16,000 and $21,000 during the three months ended March 31, 2024 and 2023, respectively. For the three months ended March 31, 2024 and 2023, the Company incurred total interest expense of approximately $458,000 and $507,000, respectively.

While, as of the date hereof, CRG has not purported that an Event of Default has resulted due to a Material Adverse Change (as those terms defined in the Loan Agreement), due to the substantial doubt about the Company's ability to continue operating as a going concern, the entire outstanding amount of borrowings under the Loan Agreement and associated aggregate debt discount at March 31, 2024 and December 31, 2023 were classified as current in these financial statements.

5. Leases

The Company's operating lease obligations primarily consist of leased office, laboratory, and manufacturing space under a non-cancelable operating lease. In addition to the minimum future lease commitments presented below, the lease requires the Company to pay property taxes, insurance, maintenance, and repair costs. The most recent amendment also provides an optional one-year extension of the lease following the end of the current term on November 30, 2025, which was not included in the assessment of the lease term as it is not reasonably certain the Company will elect to exercise this option. Rent expense is recognized using the straight-line method over the term of the lease.

The current lease was to expire on November 30, 2024. On March 6, 2024, the Company entered into an amendment to the lease which extended the lease term for a period of one year, subsequent to the original expiration. As amended, the lease will expire on November 30, 2025. Under the terms of the amendment, the Company will be obligated to pay an additional $1.3 million in base rent payments through November 2025, beginning on December 1, 2024. In total, the Company is obligated to pay approximately $7.1 million in base rent payments through November 2025, which began on December 1, 2019. The weighted average remaining lease term as of March 31, 2024 is 1.7 years.

In connection with the amendment the Company adjusted its right-of-use asset and lease liability to $ 2.2 million. As of the date of the amendment, the operating lease was included on the balance sheet at the present value of the future base payments discounted at a 6.5% discount rate using the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and amount equal to the lease payments in a similar economic environment as the lease do provide an implicit rate.

The Company's operating lease expense, excluding variable maintenance fees and other expenses on a monthly basis, was approximately $105,000. Rent expense for the three months ended March 31, 2024 and 2023 was approximately$ 315,000 and $314,000, respectively. The Company's variable expenses for the three months ended March 31, 2024 and 2023 were approximately $90,000 and $65,000, respectively. Operating right-of-use asset amortization for the three months ended March 31, 2024 and 2023 was approximately $292,000 and $280,000, respectively. Due to payments being made in excess of operating lease expense recognized, the Company recorded approximately $9,000 and $13,000 as prepaid rent included in other assets on the condensed balance sheet as of March 31, 2024 and December 31, 2023, respectively.

The following table presents the future operating lease payments and leasehold liability included on the balance sheet related to the Company's operating lease as of March 31, 2023 (in thousands):

Year Ending December 31,	
2024 (remaining nine months of the year)	$ 934
2025	1,166
Total	2,100
Less: Imputed interest	(109)
Leasehold liability as of March 31, 2024	$ 1,991

The following table shows ROU assets and lease liabilities, and the associated financial statement line items, as of March 31, 2024 and December 31, 2023 (in thousands):

Lease-Related Assets and Liabilities	Financial Statement Line Items	March 31, 2024	December 31, 2023
Right of use assets:			
Operating lease	Right of use asset	$ 1,991	$ 1,102
Total right of use assets		$ 1,991	$ 1,102
Lease liabilities:			
Operating lease	Leasehold liability, current portion	$ 1,156	$ 1,102
	Leasehold liability, long-term portion	835	—
Total lease liabilities		$ 1,991	$ 1,102

6. Commitments and Contingencies

Purchase Obligations

Purchase obligations consist of agreements to purchase goods and services entered into in the ordinary course of business. The Company had non-cancelable commitments to suppliers for purchases totaling approximately $0.4 million as of March 31, 2024. The majority of this amount is related to commitments to purchase inventory components and services related to the manufacturing of inventory.

Legal Proceedings

The Company is not currently involved in any pending legal proceedings that it believes could have a material adverse effect on our financial condition, results of operations or cash flows. From time to time, the Company may be involved in legal proceedings or investigations, which could harm our reputation, business and financial condition and divert the attention of our management from the operation of our business.

7. Stockholders' Equity

Convertible Preferred Stock

As of March 31, 2024 and December 31, 2023, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 5,000,000 shares of convertible preferred stock with $ 0.001 par value per share. As of March 31, 2024 and December 31, 2023, 19,229 and 62,881 shares, respectively, were issued and outstanding.

Series A Preferred Stock Exchange

On March 5, 2024, the Company entered into the A-1 Securities Purchase Agreement with CRG to exchange all 60,876 outstanding shares of Series A preferred stock for 10,000 shares of Series A-1 preferred stock. Consequently, there are no shares of Series A preferred stock outstanding as of March 31, 2024.

The exchange was accounted for as a capital transaction constituting an extinguishment of the Series A preferred stock through the issuance of Series A-1 preferred stock with no net impact to stockholders' deficit. At the time of the exchange, the Series A preferred stock had approximately $ 1.9 million excess fair value in comparison to the Series A-1. The difference in fair value is treated as an adjustment to net loss applicable to common stockholders for the purpose of calculating earnings per share, see *Note 2* for details.

Series A-1 Convertible Preferred Stock

Each share of Series A-1 preferred stock has a stated value of $ 1,000 per share and is convertible into 273 shares of the Company's common stock at $3.664 per share. The Series A-1 preferred stock is convertible into a total of 2,729,257 shares of common stock subject to certain limitations contained in the A-1 Securities Purchase Agreement. Shares of Series A-1 preferred stock cannot be converted into common stock to the extent the applicable holder would beneficially own in excess of 19.99% of the Company's outstanding voting power, unless approved by the Company's stockholders in accordance with Nasdaq Listing Rule 5635(b).The Series A-1 preferred stock has no liquidation preference, no voting rights and ranks junior to shares of the Company's Series E Preferred Stock, Series F Preferred Stock and Series G Preferred Stock in terms of repayment and certain other rights. The Series A-1 preferred stock is immediately convertible at the option of the holder, has no stated maturity, and does not pay regularly stated dividends or interest. As of March 31, 2024, 10,000 shares of Series A-1 preferred stock were outstanding.

Series B Convertible Preferred Stock

The Series B preferred stock has a liquidation preference of $ 0.001 per share, full ratchet price based anti-dilution protection, has no voting rights and is subject to certain ownership limitations. The Series B preferred stock is immediately convertible at the option of the holder, has no stated maturity, and does not pay regularly stated dividends or interest. As of March 31, 2024 and December 31, 2023, 85 shares of Series B preferred stock remained outstanding, which are currently convertible into shares of the Company's common stock at $3.664 per share.

Series E Convertible Preferred Stock

Each share of Series E preferred stock has a stated value of $ 1,000 per share and is convertible into 93 shares of the Company's common stock at a conversion price of $10.725 per share. The Series E preferred stock is convertible into a total of 178,560 shares of common stock subject to certain limitations contained in the Series E Purchase Agreement. Shares of Series E preferred stock cannot be converted into common stock to the extent the applicable holder would beneficially own in excess of 19.99% of the Company's outstanding voting power, unless approved by the Company's stockholders in accordance with Nasdaq Listing Rule 5635(b). The holders of Series E preferred stock are entitled to receive annual accruing dividends at a rate of 8%, payable in additional shares of Series E preferred stock or cash, at the Company's option. The shares of Series E preferred stock have full voting rights, on an as-converted basis, subject to certain limitations. The Series E preferred stock rank senior to all other classes and series of the Company's equity in terms of repayment and certain other rights. The Series E preferred stock accrued additional dividends of less than $0.1 million during the three months ended March 31, 2024, which were recognized as a reduction to additional paid-in capital in the statement of stockholders' deficit. As of March 31, 2024 and December 31, 2023, 1,920 shares of Series E preferred stock were outstanding.

Series F Convertible Preferred Stock

On March 4, 2024, in connection with the Purchase Agreement (see *Note 1*), the Company issued 7,224 shares of Series F Preferred Stock, at a purchase price per share of $1,000. Each share of Series F preferred stock is convertible into 273 shares of the Company's common stock at a conversion price of $3.664 per share. The Series F preferred stock is convertible into a total of 1,971,616 shares of common stock subject to certain limitations contained in the Purchase Agreement. Shares of Series F preferred stock cannot be converted into common stock to the extent the applicable holder would beneficially own in excess of 19.9% of the Company's outstanding voting power, unless approved by the Company's stockholders in accordance with Nasdaq Listing Rule 5635(b). The holders of Series F preferred stock are entitled to receive annual accruing dividends at a rate of 5% until the third anniversary of their issuance and 8% thereafter. The dividends are payable in additional shares of Series F preferred stock or cash, at the Company's option through the third anniversary of their issuance, and at the holder's option thereafter. The shares of Series F preferred stock have full voting rights, on an as-converted basis, subject to certain limitations. The Series F preferred stock rank pari passu with Series E preferred stock and senior to all other classes and series of the Company's equity in terms of repayment and certain other rights. The Series F preferred stock accrued additional dividends of less than $0.1 million during the three months ended March 31, 2024, which were recognized as a reduction to additional paid-in capital in the statement of stockholders' deficit. As of March 31, 2024, 7,224 shares of Series F preferred stock were outstanding.

Common Stock

As of March 31, 2024, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 100,000,000 shares of common stock with $0.001 par value per share, of which 1,586,434 shares were issued and outstanding.

March 2024 Offering

On March 5, 2024, in connection with the Purchase Agreement (see *Note 1*), the Company issued 75,327 shares of common stock at a purchase price per share of $3.664.

Common Stock Warrants

As of March 31, 2024 and December 31, 2023, warrants and preferred investment options to purchase an aggregate of 497,034 and 456,096 shares of common stock were outstanding, respectively, all of which were classified within the equity section of the respective balance sheets.

As of March 31, 2024, the Company had outstanding warrants to purchase common stock as follows:

	Total Outstanding and Exercisable	Underlying Shares of Common Stock	Exercise Price per Share	Expiration Date
Series 1 Warrants issued in the February 2018 Series B financing	8,979,000	2,993	$ 6,000.00	February 2025
Series 2 Warrants issued in the February 2018 Series B financing	8,709,500	2,903	$ 6,000.00	February 2025
Placement agent warrants issued in the January 2022 financing	1,330,000	4,433	$ 150.00	January 2027
Warrants issued in the January 2022 financing	16,150,000	53,833	$ 144.00	July 2027
Series A Preferred Investment Options issued in August 2022 financing	2,853,883	190,259	$ 22.53	February 2028
Series B Preferred Investment Options issued in August 2022 financing	2,853,883	190,259	$ 22.53	August 2024
Placement agent Preferred Investment Options issued in the August 2022 financing	171,233	11,416	$ 32.85	August 2027
Advisor Warrants issued in the March 2024 financing	40,938	40,938	$ 3.664	March 2029
Total as of March 31, 2024	41,088,437	497,034		

As of December 31, 2023, the Company had outstanding warrants to purchase common stock as follows:

	Total Outstanding and Exercisable	Underlying Shares of Common Stock	Exercise Price per Share	Expiration Date
Series 1 Warrants issued in the February 2018 Series B financing	8,979,000	2,993	$ 6,000.00	February 2025
Series 2 Warrants issued in the February 2018 Series B financing	8,709,500	2,903	$ 6,000.00	February 2025
Placement agent warrants issued in the January 2022 financing	1,330,000	4,433	$ 150.00	January 2027
Warrants issued in the January 2022 financing	16,150,000	53,833	$ 144.00	July 2027
Series A Preferred Investment Options issued in August 2022 financing	2,853,883	190,259	$ 22.53	February 2028
Series B Preferred Investment Options issued in August 2022 financing	2,853,883	190,259	$ 22.53	August 2024
Placement agent Preferred Investment Options issued in the August 2022 financing	171,233	11,416	$ 32.85	August 2027
Total as of December 31, 2023	41,047,499	456,096		

March 2024 Private Placement

On March 7, 2024, in connection with the closing of the Strategic Partnership and Private Placement, the Company issued warrants to financial advisors to purchase up to an aggregate of 40,938 shares of the Company's common stock (the "Advisor Warrants") at an exercise price of $ 3.664 per share which were immediately exercisable. The Advisor Warrants will expire five years following the time they become exercisable, or March 5, 2029.

The exercise price and the number of shares of common stock issuable upon exercise of each Advisor Warrants are subject to appropriate adjustments in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the common stock. In addition, in certain circumstances, upon a fundamental transaction, a holder of Advisor Warrants will be entitled to receive, upon exercise, the kind and amount of securities, cash or other property that such holder would have received had they exercised the Advisor Warrants prior to the fundamental transaction.

The Advisor Warrants can be exercised at the option of the holders at any time after they become exercisable provided that shares cannot be exercised into common stock if the applicable holder would beneficially own in excess of 4.99% of the Company's outstanding common stock immediately after giving effect to the exercise. A holder of the Advisor Warrants may, upon notice to the Company, increase or decrease such beneficial ownership limitation, but not in excess of 9.99%.

8. Stock-Based Compensation

Stock Plans

In January 2015, the Board of Directors adopted and the Company's stockholders approved the 2015 Equity Incentive Plan ("2015 Plan"). On December 22, 2023, the Company's stockholders approved an additional 300,000 shares of common stock for issuance under the 2015 Plan, which was later registered in an S-8 registration statement filed on January 10, 2024. The 2015 Plan provides for the grant of incentive stock options ("ISOs") to employees and for the grant of non-statutory stock options ("NSOs"), restricted stock, restricted stock awards ("RSAs"), restricted stock units ("RSUs"), stock appreciation rights, performance units and performance shares to employees, directors and consultants. As of March 31, 2024, 68,109 shares were available for grant under the 2015 Plan.

The Company's RSUs and RSAs generally vest annually over two years in equal increments. RSAs and RSUs largely contain the same contractual terms except RSAs have the ability to vote along with common holders as an RSA is considered an outstanding security at the time of grant, subject to certain vesting and other restrictions. The Company measures the fair value of RSAs using the closing stock price of a share of the Company's common stock on the grant date and is recognized as expense on a straight-line basis over the vesting period of the award. A summary of all RSA activity is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term
Awards outstanding at December 31, 2023	90,190	$ 18.45	1.04
Awarded	394,105	$ 2.75	—
Released	(368,503)	$ 4.89	—
Forfeited	—	$ —	—
Awards outstanding at March 31, 2024	115,792	$ 8.16	0.8

As of March 31, 2024, there was approximately $ 0.8 million of remaining unamortized stock-based compensation expense associated with RSAs, which will be expensed over a weighted average remaining service period of approximately 0.8 years. The outstanding non-vested and expected to vest RSAs at March 31, 2024 have an aggregate fair value of approximately $0.4 million. The Company used the closing market price of $ 3.10 per share at March 28, 2024, to determine the aggregate fair value for the RSAs outstanding at that date. For the three months ended March 31, 2024 and 2023, the fair value of RSAs vested was approximately $1.0 million and less than $ 0.1 million, respectively. For the three months ended March 31, 2024 and 2023, stock-based compensation expense recognized associated with the vesting of RSAs was $1.1 million and $ 0.2 million, respectively. All awards outstanding as of March 31, 2024 are RSAs.

Total noncash stock-based compensation expense relating to the Company's RSAs recognized, before taxes, during the three months ended March 31, 2024 and 2023, is as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
Cost of revenues	$ 158	$ 28
Research and development expenses	314	83
Selling, general and administrative expenses	624	134
	$ 1,096	$ 245

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the unaudited financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q. This discussion and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions, that are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the sections of this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K filed with the SEC on March 20, 2024 titled "Risk Factors."

Overview

We are a commercial-stage medical device company that designs, manufactures, and sells real-time high-definition image-guided, minimally invasive catheter-based systems that are used by physicians to treat patients with peripheral artery disease ("PAD"). Patients with PAD have a build-up of plaque in the arteries that supply blood to areas away from the heart, particularly the pelvis and legs. Our mission is to significantly improve the treatment of vascular disease through the introduction of products based on our Lumivascular platform, the only intravascular real-time high-definition image-guided system available in this market.

We design, manufacture, and sell a suite of products in the United States and select international markets. We are located in Redwood City, California. Our current Lumivascular platform consists of products including our Lightbox imaging console, the Ocelot and Tigereye family of devices, which are image-guided devices designed to allow physicians to penetrate a total blockage in an artery, known as a chronic total occlusion ("CTO"), and the Pantheris family of catheters, our image-guided atherectomy catheters which are designed to allow physicians to precisely remove arterial plaque in PAD patients.

We are in the process of developing CTO crossing devices to target the coronary CTO market. However, the market for medical devices in the coronary artery disease ("CAD") space is highly competitive, dynamic, and marked by rapid and substantial technological development and product innovation and there is no guarantee that we will be successful in developing and commercializing any new CAD product. At this stage, we are working on understanding market requirements, and initiated the development process for the new CAD product, which we anticipate will require additional expenses.

We obtained CE Marking for our original Ocelot product in September 2011 and received from the U.S. Food and Drug Administration ("FDA"), 510(k) clearance in November 2012. We also received 510(k) clearance from the FDA for commercialization of Pantheris in October 2015. We received an additional 510(k) clearance for an enhanced version of Pantheris in March 2016 and commenced sales of Pantheris in the United States and select European countries promptly thereafter. In May 2018, we received 510(k) clearance from the FDA for our current next-generation version of Pantheris. In April 2019, we received 510(k) clearance from the FDA for our Pantheris Small Vessel ("SV"), a version of Pantheris targeting smaller vessels, and commenced sales in July 2019. In September 2020, we received 510(k) clearance for Tigereye, a next-generation CTO crossing system utilizing Avinger's proprietary image-guided technology platform. Tigereye is a product line extension of Avinger's Ocelot family of image-guided CTO crossing catheters. In January 2022, we received 510(k) clearance from the FDA for our Lightbox 3 imaging console, an advanced version of our Lightbox that allows for easy portability and offers significant reductions in size, weight, and production cost in comparison to the incumbent version.

In April 2023, we received 510(k) clearance from the FDA for Tigereye Spinning Tip ("ST"), a next-generation image-guided CTO crossing system. Tigereye ST is a line extension of our Ocelot and Tigereye family of CTO crossing catheters. This new image-guided catheter incorporates design upgrades to the tip configuration and catheter shaft to increase crossing power and procedural success in challenging lesions, as well as design enhancements for ease of image interpretation during the procedure. The low-profile Tigereye ST has a working length of 140 cm and 5 French sheath. We initiated a limited launch of Tigereye ST in the second quarter of 2023 and subsequently expanded to full commercial availability within the United States during the third quarter of 2023.

In June 2023, we received 510(k) clearance from the FDA for Pantheris Large Vessel ("LV"), a next generation image guided atherectomy system for the treatment of larger vessels, such as the superficial femoral artery ("SFA") and popliteal arteries. Pantheris LV is a line extension of our Pantheris and Pantheris SV family of atherectomy products. This catheter offers higher speed plaque excision for efficient removal of challenging occlusive tissue and multiple features to streamline and simplify user-operation, including enhanced tissue packing and removal, a radiopaque gauge to measure volume of plaque excised during the procedure, and enhanced guidewire management. We initiated a limited launch of the Pantheris LV during the third quarter of 2023 and expect to expand to full commercial availability within the United States around mid-year 2024.

Current treatments for PAD, including bypass surgery, can be costly and may result in complications, high levels of post-surgery pain, and lengthy hospital stays and recovery times. Minimally invasive, or endovascular, treatments for PAD include stenting, angioplasty, and atherectomy, which is the use of a catheter-based device for the removal of plaque. These treatments all have limitations in their safety or efficacy profiles and frequently result in recurrence of the disease, also known as restenosis. We believe one of the main contributing factors to high restenosis rates for PAD patients treated with endovascular technologies is the amount of vascular injury that occurs during an intervention. Specifically, these treatments often disrupt the membrane between the outermost layers of the artery, which is referred to as the external elastic lamina ("EEL").

We believe our Lumivascular platform is the only technology that offers radiation-free, high-definition real-time visualization of the inside of the artery during PAD treatment through the use of optical coherence tomography ("OCT"), a high resolution, light-based, radiation-free imaging technology. Our Lumivascular platform provides physicians with high-definition real-time OCT images from the inside of an artery, and we believe Ocelot and Pantheris are the first products to offer intravascular visualization during CTO crossing and atherectomy, respectively. We believe this approach will significantly improve patient outcomes by providing physicians with a clearer picture of the artery using radiation-free image guidance during treatment, enabling them to better differentiate between plaque and healthy arterial structures. Our Lumivascular platform is designed to improve patient safety by enabling physicians to direct treatment towards the plaque, while avoiding damage to healthy portions of the artery.

During the first quarter of 2015, we completed enrollment of patients in VISION, a clinical trial designed to support our August 2015 510(k) submission to the FDA for our Pantheris atherectomy device. VISION was designed to evaluate the safety and efficacy of Pantheris to perform atherectomy using intravascular imaging and successfully achieved all primary and secondary safety and efficacy endpoints. We believe the data from VISION allows us to demonstrate that avoiding damage to healthy arterial structures, and in particular disruption of the external elastic lamina, which is the membrane between the outermost layers of the artery, reduces the likelihood of restenosis, or re-narrowing, of the diseased artery. Although the original VISION study protocol was not designed to follow patients beyond six months, we worked with 18 of the VISION sites to re-solicit consent from previous clinical trial patients in order for them to evaluate patient outcomes through 12 and 24 months following initial treatment. Data collection for the remaining patients from participating sites was completed in May 2017, and we released the final 12- and 24-month results for a total of 89 patients in July 2017.

During the fourth quarter of 2017, we began enrolling patients in INSIGHT, a clinical trial designed to support a submission to the FDA to expand the indication for our Pantheris atherectomy device to include the treatment of in-stent restenosis. Patient enrollment began in October 2017 and was completed in July 2021. Patient outcomes were evaluated at thirty days, six months and one year following treatment. In November 2021, we received 510(k) clearance from the FDA for this new clinical indication for treating in-stent restenosis with Pantheris using the data collected and analyzed from INSIGHT. We expect this will expand our addressable market for Pantheris to include a high-incidence disease state for which there are few available indicated or effective treatment options.

We are pursuing additional clinical data programs including a post-market study, IMAGE-BTK, that is designed to evaluate the safety and efficacy of Pantheris SV in the treatment of PAD lesions below-the-knee. We completed enrollment in 2023. Patient outcomes are being evaluated at thirty days, six months and one year following treatment. We expect this will bolster the application of Pantheris SV as a primary interventional tool to address below-the-knee lesions for which there are few available effective treatment options.

We focus our direct sales force, marketing efforts and promotional activities on interventional cardiologists, vascular surgeons and interventional radiologists. We also work on developing strong relationships with physicians and hospitals that we have identified as key opinion leaders. Although our sales and marketing efforts are directed at these physicians because they are the primary users of our technology, we consider the hospitals and medical centers where the procedure is performed to be our customers, as they typically are responsible for purchasing our products. We are designing additional future products to be compatible with our Lumivascular platform, which we expect to enhance the value proposition for hospitals to invest in our technology. Pantheris qualifies for existing reimbursement codes currently utilized by other atherectomy products, further facilitating adoption of our products.

We have assembled a team with extensive medical device development and commercialization experience in both start-up and large, multi-national medical device companies. We assemble all of our catheter products at our manufacturing facility but certain critical processes, such as coating and sterilization, are performed by outside vendors. Our Lightbox 3 imaging console is assembled through a qualified contract manufacturer. We expect our current manufacturing facility in California, will be sufficient through at least 2024.

We generated revenues of $10.1 million in 2021, $8.3 million in 2022 and $7.7 million in 2023. Revenues during these years were tangentially affected by COVID-19 as hospitals continued to defer elective procedures in certain jurisdictions while increasing volume to accommodate previously deferred procedures in others, which among other things, created unpredictability in case volume. This unpredictability created more volatility in our revenues which continued to affect our business in the aforementioned years. The decline in revenue in 2022 and 2023 was primarily attributable to the adverse effects of staffing shortages, resource constraints on our customers as hospitals deferred elective procedures, and the impact of a very competitive market for talent on the retention of our commercial team.

Recent Developments

Hospital Capacity and Resource Constraints Update

As a result of the effects of hospital staffing shortages, we have continued to experience significant volatility in sales, particularly as individuals, as well as hospitals and other medical providers, deferred elective procedures in response to resource constraints and capacity issues. We have continued to experience fluctuating sales as practitioners in certain jurisdictions were able to perform elective procedures while other jurisdictions were continuing to experience capacity issues. Hospital staffing shortages have had and are likely to continue to have adverse impacts on our business and results of operations. This situation has created a significant amount of volatility in the medical industry which makes future developments and results difficult to predict.

We believe capacity issues and resource constraints and the related increased cost pressures and burdens on the hospital systems have had and may continue to have an adverse effect on our ability to generate sales due to the fluctuating and unpredictable levels of capacity medical providers have to perform procedures that require the use of our products. In addition, we have experienced disruptions in our manufacturing and supply chain, as well as delays in site initiation and patient enrollment for our clinical studies. If we are unable to successfully complete these or other clinical studies, our business and results of operations could be harmed.

Nasdaq Delisting Notice

On April 25, 2023, we received notice (the “Bid Price Deficiency Letter”) from the Listing Qualifications Department (the “Staff”) of The Nasdaq Stock Market, LLC (“Nasdaq”) notifying us that we were not in compliance with Nasdaq Listing Rule 5550(a)(2) (the “Bid Price Requirement”), as the minimum bid price for our listed securities was less than $1.00 for the previous 30 consecutive business days. We had a period of 180 calendar days, or until October 23, 2023, to regain compliance with the rule referred to in this paragraph. As part of our efforts to regain compliance with the aforementioned rule, we effected a 1-for-15 reverse stock split on September 12, 2023.

On September 27, 2023, we received a letter from Nasdaq notifying us that the Staff had determined that the closing bid price of our common stock had been at $1.00 per share or greater for at least 10 consecutive business days and, accordingly, that we had regained compliance with the Bid Price Requirement. While we have regained compliance with the Bid Price Requirement, there can be no assurance that we will be able to maintain compliance with the Bid Price Requirement, or other continued listing requirements of Nasdaq, in the future.

On May 18, 2023, we received notice (the “Stockholders’ Equity Deficiency Letter”) from the Staff that we no longer satisfy the $2.5 million stockholders’ equity requirement for continued listing on The Nasdaq Capital Market, or the alternatives to that requirements – a $35 million market value of listed securities or $500,000 in net income in the most recent fiscal year or two of the last three fiscal years – as required by Nasdaq Listing Rule 5550(b) (the “Equity Requirement”).

As with the Bid Price Deficiency Letter, the Stockholders’ Equity Deficiency Letter had no immediate effect on our continued listing on The Nasdaq Capital Market. In accordance with the Nasdaq Listing Rules, we were provided 45 calendar days, or until July 3, 2023, to submit a plan to regain compliance with the Equity Requirement (the “Compliance Plan”). We submitted the Compliance Plan to Nasdaq on July 3, 2023. On July 31, 2023, we received a letter from Nasdaq notifying us that the Staff had determined to grant us an extension of 180 calendar days from the date of the Staff’s notice, or November 14, 2023, to regain compliance with the Equity Requirement.

On November 21, 2023, the Staff formally notified us that the Staff had determined that we were unable to demonstrate compliance with the Equity Requirement and that our securities would be delisted at the open of business on November 30, 2023, unless we timely requested a hearing before the Nasdaq Hearings Panel (the “Panel”). On November 28, 2023, we requested and were granted a hearing before the Panel which took place on February 20, 2024. At the hearing, we presented a plan to regain and sustain compliance with the Equity Requirement and requested an extension to do so. On March 14, 2024, the results from the hearing were rendered in which we were granted an extension by the Panel. This extension stayed any further action by Nasdaq with respect to our continued listing until May 20, 2024.

We are taking definitive steps pursuant to our plan as presented to the Panel to ensure our compliance with the Equity Requirement and all other applicable criteria for continued listing on Nasdaq. We have already undertaken certain actions such as converting outstanding indebtedness into equity, issuing additional shares of capital stock and obtaining waivers of dividends to holders of certain classes of our preferred stock for the year ended December 31, 2023. In March 2024, we also entered into a securities purchase agreement as part of a larger strategic partnership and collaboration transaction representing entry into a number of financing, licensing and other agreements ("Strategic Collaboration") in which we received gross proceeds of $7.5 million and expect to receive another $7.5 million upon the successful completion of certain milestones, discussed in more detail below. This financing transaction was an integral part of the plan presented to the Panel.

We anticipate we will need to issue additional shares of capital stock through various other financing transactions in order to regain compliance with the Equity Requirement. However, we may not be successful in executing such transactions on terms favorable to us, or at all. In addition, there can be no guarantee that such efforts will succeed in helping us regain compliance with the Nasdaq Listing Rules. There can be no assurance that we will evidence compliance within the extension period that was granted by the Panel.

Global Supply Chain

We are closely monitoring the general economic conditions on global supply chain, manufacturing, and logistics operations. As inflationary pressures increase, we anticipate that our production and operating costs may similarly increase, including costs and availability of materials and labor. In addition, port closures and labor shortages have resulted in manufacturing and shipping constraints. While we have had sufficient inventory on-hand to meet our current production requirements and customer demand, we have experienced some constraints with respect to the availability of certain materials and extended lead times from certain key suppliers. We have also experienced some delays in shipping products to our customers. Any significant delay or interruption in our supply chain could impair our ability to meet the demands of our customers in the future and could harm our business.

We may need to identify and qualify new suppliers in response to disruptions and difficulties experienced by some of our current suppliers. The process of identifying and qualifying suppliers is lengthy with no guarantee of mitigating the current issues we are experiencing. This process can include but is not limited to delays in qualification, quality issues on components, and higher costs to source these components. All of these issues may impair our ability to meet the demands of our customers in the future.

Reverse Stock Split

On September 11, 2023, our board of directors approved an amendment to our amended and restated certificate of incorporation to effect a 1-for-15 reverse stock split of our issued and outstanding common stock. The reverse stock split became effective on September 12, 2023. The par value of the common stock was not adjusted as a result of the reverse stock splits. All common stock, stock options, restricted stock units, and per share amounts in the financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock splits.

Strategic Collaboration

On March 4, 2024, we entered into a License and Distribution Agreement (the "License Agreement") with Zylox-Tonbridge, pursuant to which we will license and distribute certain of our products (including consumables) in the Greater China region, including mainland China, Hong Kong, Macao, and Taiwan (the "Territory"). Zylox-Tonbridge will lead all regulatory activities for the registration of our products in the Territory. We will also license our intellectual property and know-how related to our products to Zylox-Tonbridge so that Zylox-Tonbridge can manufacture the localized products in the Territory. All sales of our products locally manufactured by Zylox-Tonbridge with regulatory approval by the regulatory authorities in the Territory and commercialized in the Territory will be royalty bearing to us at varying percentages depending on the amount of gross revenue and product gross margin.

In connection with the License Agreement, we also entered into a Strategic Cooperation and Framework Agreement with Zylox-Tonbridge (the "Collaboration Agreement" and, together with the License Agreement, the "Strategic Collaboration"), which provides the opportunity for us to access certain Zylox-Tonbridge peripheral vascular products for distribution in the U.S. and Germany. The agreement also provides the option for us to source finished goods inventory from Zylox-Tonbridge following registration of Zylox-Tonbridge's manufacturing facility with the FDA.

Financing Agreements

On March 4, 2024, in connection with the Strategic Collaboration, we and Zylox-Tonbridge Medical Limited, a wholly-owned subsidiary of Zylox-Tonbridge (the "Purchaser"), entered into a Securities Purchase Agreement (the "Purchase Agreement"), pursuant to which the Purchaser agreed to purchase, in two tranches, up to an aggregate of $15 million in shares of our common stock, par value $0.001 per share (the "Common Stock"), and shares of two new series of our preferred stock (the "Private Placement"). On March 5, 2024, (the "Initial Closing"), we issued to the Purchaser 75,327 shares of the Common Stock at a purchase price per share of $3.664 (the "Purchase Price"), and 7,224 shares of a newly authorized Series F convertible preferred stock, par value $0.001 per share (the "Series F Preferred Stock"), at a purchase price per share of $1,000, for an aggregate purchase price of $7.5 million.

Each share of Series F Preferred Stock has a stated value of $1,000 and is initially convertible into approximately 273 shares of Common Stock at a conversion price equal to the Purchase Price, subject to the terms of the Certificate of Designation of Preferences, Rights, and Limitations of the Series F Preferred Stock (the "Series F Certificate of Designation").

Upon completion of the following as mutually agreed upon by us and the Purchaser: (i) the successful registration and listing under 21 CFR part 807 with the FDA of the Purchaser and one of its designated affiliates to manufacture our products, and (ii) us achieving an aggregate of $10 million in gross revenue within any four consecutive fiscal quarters after the Initial Closing, excluding any gross revenue achieved by us under the License Agreement discussed above (together, the "Milestones"), the Purchaser will invest an additional $7.5 million (the "Milestone Closing") to purchase shares of our new Series G convertible preferred stock, par value $0.001 per share (the "Series G Preferred Stock"). Each share of Series G Preferred Stock will have a stated value of $1,000 and will be convertible into shares of Common Stock at a conversion price of equal to the lowest of (x) the Purchase Price, (y) the closing price of the Common Stock on the date immediately preceding the Milestone Closing, and (z) the average closing price for the last five trading days preceding the Milestone Closing, provided that the conversion price will be no less than $0.20.

Our obligations to (i) accept conversion of the shares of Series F Preferred Stock in excess of 19.9% of our outstanding common stock as of the date of the Purchase Agreement and (ii) issue and sell shares of Series G Preferred Stock upon completion of the Milestones are each subject to receipt of the approval of our stockholders as is necessary under the rules and regulations of Nasdaq (including, without limitation, Nasdaq Rule 5635(d)).

Series A Preferred Stock Exchange

On March 5, 2024, we entered into a Securities Purchase Agreement (the "A-1 Securities Purchase Agreement") to exchange all outstanding shares of Series A Preferred Stock for 10,000 shares of Series A-1 Preferred Stock (the "Exchange"). Among other things, the shares of Series A-1 Preferred Stock: (i) are convertible into an aggregate of approximately 2,729,257 shares of Common Stock at a conversion price equal to the Purchase Price, (ii) do not accrue or pay dividends payable solely on the Series A-1 Preferred Stock, (iii) will have no liquidation preference and (iv) will be junior in rank to shares of our Series E Preferred Stock, Series F Preferred Stock and Series G Preferred Stock.

CRG Loan Amendment

On March 5, 2024, we also entered into Amendment No. 9 to the Loan Agreement effective as of the Initial Closing with CRG, which amends the Loan Agreement to, among other things: (i) extend the interest-only period through December 31, 2026; (ii) provide that interest payable through December 31, 2026 may be payable in kind rather than in cash; and (iii) permit the payment of dividends on the preferred stock issued or issuable to the Purchaser.

Lease Extension

On March 6, 2024, we entered into an amendment to the lease which extended the lease term for a period of one year, subsequent to the original expiration of November 30, 2024. As amended, the lease will expire on November 30, 2025. Under the terms of the amendment, we will be obligated to pay approximately $1.3 million in base rent payments through November 2025, beginning on December 1, 2024. This amendment also provides an optional one year extension of the lease following the end of the current term, as amended.

Financing

During the three months ended March 31, 2024, our net loss and comprehensive net loss was $5.5 million; during the years ended December 31, 2023 and 2022, our net loss and comprehensive loss was $18.3 million and $17.6 million, respectively. We have not been profitable since inception, and as of March 31, 2024, our accumulated deficit was $426.2 million. Since inception, we have financed our operations primarily through private and public placements of our preferred and common securities and, to a lesser extent, debt financing arrangements.

In September 2015, we entered into a Term Loan Agreement (the "Loan Agreement") with CRG Partners III L.P. and certain of its affiliated funds (collectively, "CRG"), under which we were able to borrow up to $50.0 million on or before the end of the twenty-four (24) month period commencing on the first Borrowing Date (as defined in the Loan Agreement), subject to certain terms and conditions. Under the Loan Agreement we borrowed $30.0 million on September 22, 2015 and an additional $10.0 million on June 15, 2016. Contemporaneously with the execution of the Loan Agreement, we entered into a Securities Purchase Agreement with CRG (the "Securities Purchase Agreement"), pursuant to which CRG purchased 3 shares of our common stock on September 22, 2015 at a price of $1,678,920 per share, which represents the 10-day average of closing prices of our common stock ending on September 21, 2015. Pursuant to the Securities Purchase Agreement, we filed a registration statement covering the resale of the shares sold to CRG and must comply with certain affirmative covenants during the time that such registration statement remains in effect.

On February 14, 2018, we entered into a Series A preferred stock Purchase Agreement (the "Series A Purchase Agreement") with CRG, pursuant to which it agreed to convert $38.0 million of the outstanding principal amount of its senior secured term loan (plus the back-end fee and prepayment premium applicable thereto) under the Loan Agreement into newly authorized Series A-1 preferred stock. In March 2024, all outstanding shares of Series A preferred stock were cancelled in exchange for the issuance of Series A-1 preferred stock. The Series A-1 preferred stock, which is immediately convertible, carries no liquidation preference or dividend rights.

We have entered into several amendments (collectively, the "Amendments") to the Loan Agreement with CRG since September 2015. The Amendments, among other things: (1) extended the interest-only period through December 31, 2026; (2) extended the period during which we may elect to pay a portion of interest in payment-in-kind ("PIK"), interest payments through December 31, 2026 so long as no Default (as defined in the Loan Agreement) has occurred and is continuing; (3) permitted us to make our entire interest payments in PIK interest payments through December 31, 2026 so long as no Default has occurred and is continuing; (4) extended the Stated Maturity Date (as defined in the Loan Agreement) to December 31, 2028; (5) reduced the minimum liquidity covenant to $3.5 million at all times; (6) eliminated the minimum revenue covenant for all years; (7) changed the date under the on-going stand-alone representation regarding no "Material Adverse Change" to December 31, 2020; (8) amended the on-going stand-alone representation and stand-alone Event of Default (as defined in the Loan Agreement) regarding Material Adverse Change such that any adverse change in or effect upon the revenue of us and our subsidiaries due to the outbreak of COVID-19 will not constitute a Material Adverse Change; (9) provided CRG with board observer rights; and (10) provide that the board observer may be appointed or removed by written notice from the Majority Lenders (as defined in the Loan Agreement).

On August 2, 2023, we entered into a Series E preferred stock Purchase Agreement (the "Series E Purchase Agreement") with CRG, pursuant to which we issued 1,920 shares of newly authorized Series E convertible preferred stock in exchange for CRG surrendering for cancellation $1.92 million of outstanding principal and accrued interest of the senior secured term loan. Each share of Series E preferred stock has a stated value of $1,000 per share and is convertible into 93 shares of our common stock at a conversion price of $10.725 per share. The Series E preferred stock is initially convertible into 178,560 shares of common stock subject to certain limitations contained in the Series E Purchase Agreement. Under the terms of the Series E Purchase Agreement, the holders of Series E preferred stock are entitled to receive annual accruing dividends at a rate of 8%, payable in additional shares of Series E preferred stock or cash, at our option. The shares of Series E preferred stock have full voting rights, on an as-converted basis, subject to certain limitations. The Series E preferred stock rank senior to all other classes and series of the Company's equity in terms of repayment and certain other rights.

On September 29, 2023, the Company entered into the Waiver Agreement with CRG, who held all of the outstanding shares of the Company's Series A and Series E preferred stock. Pursuant to the Waiver Agreement, CRG waived their rights to receive the Series A and Series E preferred dividends for the year ending December 31, 2023. Such waived preferred dividends were not cumulative or accrued.

On January 26, 2024, we entered into Amendment No. 8 to the Loan Agreement with CRG, which reduced the minimum liquidity requirement of the Loan Agreement from $3.5 million to $1.0 million until April 1, 2024. Thereafter, we would be subject to the minimum liquidity requirement of $3.5 million.

As part of our Strategic Collaboration, we entered into Amendment No. 9 to the Loan Agreement with CRG, which amends the Loan Agreement to, among other things: (i) extend the interest-only period through December 31, 2026; (ii) provide that interest payable through December 31, 2026 may be payable in kind rather than in cash; and (iii) permit the payment of dividends on the preferred stock issued or issuable to the Purchaser. In addition, we completed the Private Placement for gross proceeds, before expenses, of $7.5 million.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenues, expenses and related disclosures of contingent assets and liabilities. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. There have been no significant and material changes in our critical accounting policies during the three months ended March 31, 2024, as compared to those disclosed in "Management's Discussion and Analysis of Financial Conditions and Results of Operations - Critical Accounting Policies and Significant Judgments and Estimates" in our most recent Annual Report on Form 10-K, as filed with the SEC on March 20, 2024.

Components of Our Results of Operations

Revenues

All of our revenues are currently derived from sales of our various PAD catheters in the United States and select international markets, Lightbox consoles, and related services. We expect our revenues to increase in 2024 due to the introduction of our Tigereye ST and Pantheris LV products, investments in sales personnel and easing conditions involving hospital staffing and capacity issues. For the three months ended March 31, 2024, there was one customer that represented 17% of revenues and another that represented 10% of revenues. For the three months ended March 31, 2023, there was one customer that represented 13% of revenues.

Revenues may fluctuate from quarter to quarter due to a variety of factors including capital equipment purchasing patterns that are typically increased towards the end of the calendar year and decreased in the first quarter and our ability to have product available in light of supply chain challenges. In addition, during the first quarter, our results can be harmed by adverse weather and by resetting of annual patient healthcare insurance plan deductibles, both of which may cause patients to delay elective procedures. In the third quarter, the number of elective procedures nationwide is historically lower than other quarters throughout the year, which we believe is primarily attributable to the summer vacations of physicians and their patients. Additionally, we believe hospital capacity and staffing issues have had and will continue to have an adverse effect on our ability to generate sales due to the fluctuating and unpredictable levels of capacity medical providers have to perform procedures that require the use of our products.

Cost of Revenues and Gross Margin

Cost of revenues consists primarily of costs related to manufacturing overhead, materials and direct labor. We expense all warranty costs and inventory provisions as cost of revenues. We periodically write-down inventory for estimated excess, obsolete and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions. A significant portion of our cost of revenues currently consists of manufacturing overhead costs. These overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. We expect overhead costs as a percentage of revenues to become less significant as our production volume increases. Cost of revenues also includes depreciation expense for production equipment, depreciation and related maintenance expense for placed Lightboxes held by customers and certain direct costs such as those incurred for shipping our products.

We calculate gross margin as gross profit divided by revenues. Our gross margin has been and will continue to be affected by a variety of factors, primarily production volumes, manufacturing costs, product yields, headcount, charges for excess and obsolete inventories and cost-reduction strategies. We intend to use our design, engineering and manufacturing capabilities to further advance and improve the efficiency of our manufacturing processes, which we believe will reduce costs and increase our gross margin. In the future, we may seek to manufacture certain of our products outside the United States to further reduce costs. Our gross margin will likely fluctuate from quarter to quarter as we continue to introduce new products and sales channels, and as we adopt new manufacturing processes and technologies.

Research and Development Expenses

Research and development ("R&D"), expenses consist primarily of engineering, product development, clinical and regulatory affairs, consulting services, materials, depreciation and other costs associated with products and technologies in development. These expenses include employee compensation, including stock-based compensation, supplies, materials, quality assurance expenses allocated to R&D programs, consulting, related travel expenses and facilities expenses. Clinical expenses include clinical trial design, clinical site reimbursement, data management, travel expenses and the cost of manufacturing products for clinical trials. We expect R&D expenses to vary over time depending on the level and timing of our new product development efforts, as well as our clinical development, clinical trial and other related activities.

Selling, General and Administrative Expenses

Selling, general and administrative ("SG&A"), expenses consist primarily of compensation for personnel, including stock-based compensation, selling and marketing functions, physician education programs, business development, finance, information technology and human resource functions. Other SG&A expenses include commissions, training, travel expenses, educational and promotional activities, marketing initiatives, market research and analysis, conferences and trade shows, professional services fees, including legal, audit and tax fees, insurance costs and general corporate expenses. We expect SG&A expenses to increase as we expand our commercial efforts and additional costs related to corporate matters.

Interest Expense, Net

Interest expense, net consists primarily of interest incurred on our outstanding indebtedness and non-cash interest related to the amortization of debt discount and issuance costs associated with our debt agreement.

Other (Expense) Income, Net

Other (expense) income, net primarily consists of gains and losses resulting from the remeasurement of foreign exchange transactions and other miscellaneous income and expenses.

Results of Operations:

	Three Months Ended March 31,	
	2024	**2023**
Revenues	$ 1,859	$ 1,888
Cost of revenues	1,516	1,252
Gross profit	343	636
Gross margin	18%	34%
Operating expenses:		
Research and development	1,062	1,356
Selling, general and administrative	4,370	3,538
Total operating expenses	5,432	4,894
Loss from operations	(5,089)	(4,258)
Interest expense, net	(416)	(392)
Other (expense) income, net	(12)	6
Net loss and comprehensive loss	$ (5,517)	$ (4,644)

Comparison of Three Months Ended March 31, 2024 and 2023

Revenues.

Revenues during the three months ended March 31, 2024 remained flat compared to the three months ended March 31, 2023. Our revenues reflect the fluctuating demand partially due to the adverse impacts of hospital staffing shortages as capacity limitations in hospitals have limited the ability of practitioners to perform elective surgical procedures using our products in certain jurisdictions. In addition, we have experienced and expect that we will continue to experience attrition and turnover of our sales professionals which has resulted in a less experienced sales team and limited our ability to maintain an adequate presence in some markets. The attrition and turnover are largely attributable to the increasingly competitive labor market landscape, which has had an adverse effect on our ability to generate revenues for the three months ended March 31, 2024.

Cost of Revenues and Gross Margin.

Cost of revenues increased $0.3 million, or 21%, to $1.5 million during the three months ended March 31, 2024 in comparison to the three months ended March 31, 2023. This increase was primarily attributable fluctuations in labor costs and inventory production, increased material costs and other ancillary expenditures. Stock-based compensation expense within cost of revenues totaled $158,000 and $28,000 for the three months ended March 31, 2024 and 2023, respectively.

Gross margin for the three months ended March 31, 2024 decreased to 18%, compared to 34% in the three months ended March 31, 2023. There are significant amounts of overhead costs, specifically in the form of labor, associated with manufacturing and production of inventory embedded in cost of revenues that will typically fluctuate due to the levels of inventory being produced, production schedule changes, lead times and other factors. The decrease in gross margin was primarily due to the decrease in the production levels of inventory and rising costs of materials.

Research and Development Expenses.

R&D expense for the three months ended March 31, 2024 decreased $0.3 million or 22% compared to the three months ended March 31, 2023. The decrease is primarily due to the completion of our development efforts of Tigereye ST and Pantheris LV occurring during 2023, partially offset by ongoing product development of our coronary device program. Stock-based compensation expense within R&D totaled $314,000 and $83,000 for the three months ended March 31, 2024 and 2023, respectively. We expect R&D expense to fluctuate based on the ongoing product development of our coronary device.

Selling, General and Administrative Expenses .

SG&A expense for the three months ended March 31, 2024 increased by $0.8 million or 24%, compared to the three months ended March 31, 2023. This increase was primarily attributable to increases in sales personnel costs resulting from the investments made to increase the number of sales personnel deployed in the United States, and increases in third-party professional services and other ancillary expenses related to the consummation of the Zylox-Tonbridge transaction and other corporate activities. Stock-based compensation expense within SG&A totaled $624,000 and $134,000 for the three months ended March 31, 2024 and 2023, respectively. We expect SG&A expense to fluctuate based on the number of sales personnel deployed within the United States, variable compensation related to fluctuations in revenues and other corporate activities that we undertake.

Interest Expense, Net.

Interest expense, net is comprised of interest expense net of interest income. Interest expense, net for the three months ended March 31, 2024 increased by 6% or $24,000, compared to the three months ended March 31, 2023, primarily due to decreases in interest income due a lower average cash balance, partially offset by lower interest expense resulting from a lower CRG loan balance from PIK interest being compounded.

Other (Expense) Income, Net.

Other (expense) income, net primarily consists of gains and losses resulting from the remeasurement of foreign exchange transactions, which are typically a small percentage of transaction volume, and other miscellaneous income and expenses. Other (expense) income, net for the three months ended March 31, 2024 remained relatively flat in comparison to the three months ended March 31, 2023 as both periods consisted primarily of remeasurement gains and losses from foreign exchange transactions, resulting in nominal changes between periods.

Liquidity and Capital Resources

As of March 31, 2024, we had cash and cash equivalents of $7.2 million and an accumulated deficit of $426.2 million, compared to cash and cash equivalents of $5.3 million and an accumulated deficit of $420.7 million as of December 31, 2023. We expect to incur losses for the foreseeable future. We believe that our cash and cash equivalents of $7.2 million at March 31, 2024 and expected revenues, debt and financing activities and funds from operations will be sufficient to allow us to fund our current operations through the end of the second quarter of 2024.

To date, we have financed our operations primarily through net proceeds from the issuance of our preferred stock, common stock and debt financings, our “at-the-market” program, our initial public offering (“IPO”), our follow-on public offerings and warrant issuances. We do not know when or if our operations will generate sufficient cash to fund our ongoing operations. We will need to raise additional capital through future equity or debt financings in the near future to meet our operational needs and capital requirements for product development, clinical trials and commercialization, and to regain compliance with the Equity Requirement of the Nasdaq Listing Rules. Additional debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any additional debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders and require significant debt service payments, which divert resources from other activities. Additional financing may not be available at all, or if available, may not be in amounts or on terms acceptable to us. If we are unable to obtain additional financing, we may be required to delay the development, commercialization and marketing of our products and we may be required to significantly scale back our business and operations. In the event we determine that additional sources of liquidity will not be available to us or will not allow us to meet our obligations as they become due, we may need to file a voluntary petition for relief under the United States Bankruptcy Code in order to implement a restructuring plan or liquidation. Our financial statements for the three months ended March 31, 2024 do not include any adjustments that might result from the outcome of this uncertainty.

Currently, substantially all of our cash and cash equivalents are held at a single financial institution, First Citizens Bank, which acquired our prior banking partner, Silicon Valley Bank, in March 2023. On March 10, 2023, the Federal Deposit Insurance Corporation announced that Silicon Valley Bank had been closed by the California Department of Financial Protection and Innovation. While we have regained access to our accounts at Silicon Valley Bank, now a division of First Citizens Bank, we are evaluating our banking relationships, future disruptions of financial institutions where we bank or have credit arrangements, or disruptions of the financial services industry in general, that could adversely affect our ability to access our cash and cash equivalents. If we are unable to access our cash and cash equivalents as needed, our financial position and ability to operate our business will be adversely affected.

Equity Financings

At The Market Offering Agreement

On May 20, 2022, we entered into an At The Market Offering Agreement (the “ATM Agreement”) with H.C. Wainwright & Co., LLC (the “Agent”), as sales agent, pursuant to which we may offer and sell shares of common stock, par value $0.001 per share (the “Shares”) up to an aggregate offering price of $7,000,000 from time to time, in an at the market public offering. Sales of the Shares are to be made at prevailing market prices at the time of sale, or as otherwise agreed with the Agent. The Agent will receive a commission from us of 3.0% of the gross proceeds of any Shares sold under the ATM Agreement. The Shares sold under the ATM Agreement are offered and sold pursuant to our shelf registration statement on Form S-3, which was initially filed with the SEC on March 29, 2022 and declared effective on April 7, 2022, and a prospectus supplement and the accompanying prospectus relating to the At The Market Offering filed with the SEC on May 20, 2022. On August 3, 2022, we suspended sales under the ATM Agreement. On March 17, 2023, we reactivated the ATM Agreement. During the year ended December 31, 2023, we sold 607,241 shares of common stock at an average price of $9.01 per share for aggregate proceeds of approximately $5.5 million, of which approximately $164,000 was paid in the form of commissions to the Agent. There were no sales under the ATM Agreement during the three months ended March 31, 2024. While the Company may attempt additional sales in the future, there can be no assurance that the Company will be successful in acquiring additional funding through these means.

Other than the ATM Agreement, we currently do not have any commitment to obtain additional funds.

March 2024 Financing

In connection with our the Strategic Collaboration, we entered into a Securities Purchase Agreement (the “Purchase Agreement”) with Zylox-Tonbridge Medical Limited, a wholly-owned subsidiary of Zylox-Tonbridge (the “Purchaser”), pursuant to which the Purchaser agreed to purchase, in two tranches, up to an aggregate of $15 million in shares of our common stock, par value $0.001 per share (the “Common Stock”), and shares of two new series of our preferred stock (the “Private Placement”). On March 5, 2024, (the “Initial Closing”), we issued to the Purchaser 75,327 shares of the Common Stock at a purchase price per share of $3.664 (the “Purchase Price”), and 7,224 shares of a newly authorized Series F convertible preferred stock, par value $0.001 per share (the “Series F Preferred Stock”), for an aggregate purchase price of $7.5 million. Each share of Series F Preferred Stock has a stated value of $1,000 and is initially convertible into approximately 273 shares of Common Stock at a conversion price equal to the Purchase Price, subject to the terms of the Certificate of Designation of Preferences, Rights, and Limitations of the Series F Preferred Stock (the “Series F Certificate of Designation”).

Upon completion of the following as mutually agreed upon by us and the Purchaser: (i) the successful registration and listing under 21 CFR part 807 with the FDA of the Purchaser and one of its designated affiliates to manufacture our products, and (ii) our achieving an aggregate of $10 million in gross revenue within any four consecutive fiscal quarters after the Initial Closing, excluding any gross revenue related to sales of our products to Zylox-Tonbridge (together, the "Milestones"), the Purchaser will invest an additional $7.5 million (the "Milestone Closing") to purchase shares of our new Series G convertible preferred stock, par value $0.001 per share (the "Series G Preferred Stock"). Each share of Series G Preferred Stock will have a stated value of $1,000 and will be convertible into shares of Common Stock at a conversion price of equal to the lowest of (x) the Purchase Price, (y) the closing price of the Common Stock on the date immediately preceding the Milestone Closing, and (z) the average closing price for the last five trading days preceding the Milestone Closing, provided that the conversion price will be no less than $0.20. There can be no guarantee that such Milestone Closing will occur.

Contractual Obligations

Our principal obligations consist of the operating lease for our facility, our Loan Agreement with CRG and non-cancelable purchase commitments. The following table sets out, as of March 31, 2024, our contractual obligations due by period (in thousands):

	Payments Due by Period				
	Less Than 1 Year	2 - 3 Years	4-5 Years	More Than 5 Years	Total
Operating lease obligations (1)	$ 1,252	$ 848	$ —	$ —	$ 2,100
CRG Loan (2)	—	2,949	21,446	—	24,395
Non-cancelable purchase commitments (3)	390	21	—	—	411
	$ 1,642	$ 3,818	$ 21,446	$ —	$ 26,906

(1) Operating lease obligations primarily consist of leased office, laboratory, and manufacturing space under a non-cancelable operating lease. In addition to the minimum future lease commitments presented above, the lease requires the Company to pay property taxes, insurance, maintenance, and repair costs. The lease will expire on November 30, 2025.

(2) The total CRG Loan amount, shown as borrowings on the balance sheet as of March 31, 2024, is $14.8 million. The contractual obligation in the table above of $24.4 million under the CRG Loan includes future interest to be accrued but not paid in cash as well as a $2.8 million back-end fee to be paid in December 2028 upon maturity of the CRG Loan which is being accreted. For more information, see Part I, Item 1 "Unaudited Financial Statements, Note 4. Borrowings."

(3) Non-cancelable purchase commitments consist of agreements to purchase goods and services entered into in the ordinary course of business.

CRG Loan

We have entered into several amendments to the Loan Agreement (the "Amendments") with CRG since September 2015. The Amendments, among other things: (1) extended the interest-only period through December 31, 2026; (2) extended the period during which we may elect to pay a portion of interest in payment-in-kind, or PIK, interest payments through December 31, 2026 so long as no Default (as defined in the Loan Agreement) has occurred and is continuing; (3) permitted us to make the entire interest payments in PIK interest payments through December 31, 2026 so long as no Default has occurred and is continuing; (4) extended the Stated Maturity Date (as defined in the Loan Agreement) to December 31, 2028; (5) reduced the minimum liquidity covenant to $3.5 million at all times; (6) eliminated the minimum revenue covenant for all years; (7) changed the date under the on-going stand-alone representation regarding no "Material Adverse Change" to December 31, 2020; (8) amended the on-going stand-alone representation and stand-alone Event of Default (as defined in the Loan Agreement) regarding Material Adverse Change such that any adverse change in or effect upon the revenue of us and our subsidiaries due to the outbreak of COVID-19 will not constitute a Material Adverse Change; (9) provided CRG with board observer rights, and (10) provide that the board observer may be appointed or removed by written notice from the Majority Lenders (as defined in the Loan Agreement). The total Loan amount under the Loan Agreement (the "CRG Loan"), shown as short-term borrowings on the balance sheet as of March 31, 2024, is $14.8 million. However, upon maturity of the obligations under the Loan Agreement in December 2028, we will be obligated to pay $24.4 million under the Loan Agreement, which includes future interest to be accrued but not paid in cash as well as a $2.8 million back-end fee to be paid in December 2028 upon maturity of the CRG Loan which is being accreted to the maturity date. Due to the substantial doubt about our ability to continue operating as a going concern and the "Material Adverse Change" clause under the Loan Agreement, the entire amount of outstanding borrowings at March 31, 2024 and December 31, 2023 is classified as current. CRG has not purported that any Event of Default (as defined in the Loan Agreement) has occurred as a result a "Material Adverse Change" under the Loan Agreement. Refer to Part 1, Item 1, "Unaudited Financial Statements," Note 4 for additional details.

On January 26, 2024, we entered into Amendment No. 8 to the Loan Agreement with CRG, which reduces the minimum liquidity requirement of the Loan Agreement from $3.5 million to $1.0 million until April 1, 2024. Thereafter, we will be subject to the minimum liquidity requirement of $3.5 million.

As part of our Strategic Collaboration, we entered into Amendment No. 9 to the Loan Agreement with CRG, which amends the Loan Agreement to, among other things: (i) extend the interest-only period through December 31, 2026; (ii) provide that interest payable through December 31, 2026 may be payable in kind rather than in cash; and (iii) permit the payment of dividends on the preferred stock issued or issuable to the Purchaser.

Lease Agreements

Our operating lease obligations primarily consist of leased office, laboratory, and manufacturing space under a non-cancelable operating lease. In addition to the minimum future lease commitments presented above, the lease requires us to pay property taxes, insurance, maintenance, and repair costs. Rent expense is recognized using the straight-line method over the term of the lease.

The lease will expire on November 30, 2025. We are obligated to pay a total of approximately $7.1 million in base rent payments through November 2024, which began on December 1, 2019. The weighted average remaining lease term as of March 31, 2024 is 1.7 years.

On March 6, 2024, we entered into an amendment to the lease which extended the lease term for a period of one year, subsequent to the original expiration of November 30, 2024. As amended, the lease will expire on November 30, 2025. Under the terms of the amendment, we will be obligated to pay approximately $1.3 million in base rent payments through November 2025, beginning on December 1, 2024. This amendment also provides an optional one year extension of the lease following the end of the current term, as amended.

Cash Flows

	Three Months Ended March 31,	
	2024	2023
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (4,734)	$ (4,212)
Investing activities	—	—
Financing activities	6,633	(21)
Net change in cash and cash equivalents	$ 1,899	$ (4,233)

Net Cash Used in Operating Activities

Net cash used in operating activities for the three months ended March 31, 2024 was $4.7 million, consisting primarily of a net loss of $5.5 million and an increase in net operating assets of $0.9 million, partially offset by non-cash charges of $1.7 million. Non-cash charges primarily related to non-cash interest expense of $0.5 million and stock-based compensation of $1.1 million. The increase in net operating assets was primarily due to the increase in prepaid expenses and other current assets due to annual renewals of certain expenses, including insurance coming due; an increase in accounts receivable due to timing of sales occurring during the quarter and timing of payments; and a decrease in long-term liabilities relating to certain variable compensation being reclassified to accrued compensation as it became due within less than one year. These increases were partially offset by a decline in inventory which include components and labor, in an effort to optimize inventory levels in anticipation of forecasted demand in light of extended lead times and shifting product mix primarily related to new product introductions of Tigereye ST and Pantheris LV.

Net cash used in operating activities for the three months ended March 31, 2023 was $4.2 million, consisting primarily of a net loss of $4.6 million and an increase in net operating assets of $0.5 million, partially offset by non-cash charges of $1.0 million. Non-cash charges largely related to non-cash interest expense of $0.5 million and stock-based compensation of $0.2 million. The increase in net operating assets was primarily due to the increase in prepaid expenses and other current assets due to annual renewals of certain expenses, including insurance coming due; and purchases of inventory components in anticipation of forecasted demand in light of extended lead times. These increases were partially offset by the increase in other long-term liabilities as certain variable compensation continues to accrue and accrued compensation due to timing of payments.

Net Cash Used in Investing Activities

There was no cash used in investing activities during either of the three months ended March 31, 2024 or 2023.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2024 of $6.6 million primarily relates to proceeds, net of commissions and various issuance costs, from the issuance of preferred stock and common stock in the Private Placement in March 2024. This was partially offset by the payment of approximately $0.4 million in satisfaction of certain tax obligations related to net share settlement on restricted stock awards vesting during the quarter.

Net cash used in financing activities for the three months ended March 31, 2023 of less than $0.1 million primarily related to the costs of reactivating the ATM, partially offset by proceeds of less than $0.1 million, net of commissions and various issuance costs, from the sale of common stock pursuant to the ATM Agreement.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

The risk associated with fluctuating interest rates is primarily limited to our cash equivalents, which are carried at quoted market prices. Due to the short-term maturities and low risk profile of our cash equivalents, an immediate 100 basis point change in interest rates would not have a material effect on the fair value of our cash equivalents. We do not currently use or plan to use financial derivatives in our investment portfolio.

Credit Risk

As of March 31, 2024, our cash and cash equivalents were maintained largely with one financial institution in the United States, and our current deposits are in excess of insured limits. We have reviewed the financial statements of this institution and believe it has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us.

Our accounts receivable primarily relate to revenues from the sale of our Lumivascular platform products to hospitals and medical centers in the United States. At March 31, 2024, there was one customer that represented 32% of the Company's accounts receivable. At December 31, 2023, there was one customer that represented 24% of the Company's accounts receivable. For the three months ended March 31, 2024, there was one customer that represented 17% of revenues and another that represented 10% of revenues. For the three months ended March 31, 2023, there was one customer that represented 13% of revenues.

Foreign Currency Risk

Our business is primarily conducted in U.S. dollars. Any transactions that may be conducted in foreign currencies are not expected to have a material effect on our results of operations, financial position or cash flows.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) under the Exchange Act, our management, under the supervision and with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of March 31, 2024. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of March 31, 2024, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal controls over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended March 31, 2024 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

Except as described below, there have been no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K filed with the SEC on March 20, 2024.The disclosure of risks identified below does not imply that the risk has not already materialized.

Nasdaq may delist our securities from its exchange, which could harm our business and limit our stockholders ' liquidity.

Our common stock is currently listed on the Nasdaq Capital Market, which has qualitative and quantitative listing criteria. However, we cannot assure you that our common stock will continue to be listed on Nasdaq in the future. In order to continue listing our common stock on Nasdaq, we must maintain certain financial, distribution and stock price levels. Generally, we must maintain a minimum amount in stockholders' equity, a minimum number of holders of our common stock and a minimum bid price.

On April 25, 2023, we received notice (the "Bid Price Deficiency Letter") from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market, LLC ("Nasdaq") notifying us that we were not in compliance with Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Requirement"), as the minimum bid price for our listed securities was less than $1.00 for the previous 30 consecutive business days. We had a period of 180 calendar days, or until October 23, 2023, to regain compliance with the rule referred to in this paragraph. As part of our efforts to regain compliance with the aforementioned rule, we effected a 1-for-15 reverse stock split on September 12, 2023.

On September 27, 2023, we received a letter from Nasdaq notifying us that the Staff had determined that the closing bid price of our common stock had been at $1.00 per share or greater for at least 10 consecutive business days and, accordingly, that we had regained compliance with the Bid Price Requirement. While we have regained compliance with the Bid Price Requirement, there can be no assurance that we will be able to maintain compliance with the Bid Price Requirement, or other continued listing requirements of Nasdaq, in the future.

On May 18, 2023, we received notice (the "Stockholders' Equity Deficiency Letter") from the Staff that we no longer satisfy the $2.5 million stockholders' equity requirement for continued listing on The Nasdaq Capital Market, or the alternatives to that requirements - a $35 million market value of listed securities or $500,000 in net income in the most recent fiscal year or two of the last three fiscal years - as required by Nasdaq Listing Rule 5550(b) (the "Equity Requirement").

As with the Bid Price Deficiency Letter, the Stockholders' Equity Deficiency Letter had no immediate effect on our continued listing on The Nasdaq Capital Market. In accordance with the Nasdaq Listing Rules, we were provided 45 calendar days, or until July 3, 2023, to submit a plan to regain compliance with the Equity Requirement (the "Compliance Plan"). We submitted the Compliance Plan to Nasdaq on July 3, 2023. On July 31, 2023, we received a letter from Nasdaq notifying us that the Staff had determined to grant us an extension of 180 calendar days from the date of the Staff's notice, or November 14, 2023, to regain compliance with the Equity Requirement.

On November 21, 2023, the Staff formally notified us that the Staff had determined that we were unable to demonstrate compliance with the Equity Requirement and that our securities would be delisted at the open of business on November 30, 2023, unless we timely requested a hearing before the Nasdaq Hearings Panel (the "Panel"). On November 28, 2023, we requested and were granted a hearing before the Panel which took place on February 20, 2024. At the hearing, we presented a plan to regain and sustain compliance with the Equity Requirement and requested an extension to do so. On March 14, 2024, the results from the hearing were rendered in which we were granted an extension by the Panel. This extension stayed any further action by Nasdaq with respect to our continued listing until May 20, 2024.

We anticipate we will need to issue additional shares of capital stock through various other financing transactions in order to regain compliance with the Equity Requirement. However, we may not be successful in executing such transactions on terms favorable to us, or at all. In addition, there can be no guarantee that such efforts will succeed in helping us regain compliance with the Nasdaq Listing Rules. There can be no assurance that we will evidence compliance within the extension period that was granted by the Panel.

If Nasdaq delists our common stock from trading on its exchange and we are not able to list our securities on another national securities exchange, we expect our securities could be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as "covered securities." If our common stock continues to be listed on NASDAQ, our common stock will be a covered security. Although the states are preempted from regulating the sale of our securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case.

There is substantial doubt about our ability to continue as a going concern, and we will need additional financing to execute our business plan, to fund our operations and to continue as a going concern, and, if we are unable to obtain additional financing, may be required to pursue a reorganization proceeding under applicable bankruptcy or insolvency laws, including under Chapter 11 of the U.S. Bankruptcy Code.

Since inception, we have experienced recurring operating losses and negative cash flows and we expect to continue to generate operating losses and consume significant cash resources for the foreseeable future. There is substantial doubt regarding our ability to continue as a going concern. Our independent registered public accounting firm has expressed in its auditors' report on our 2023 financial statements, included our Annual Report on Form 10-K filed on March 20, 2024, an emphasis of matter paragraph relating to our ability to continue as a "going concern," meaning that our recurring losses from operations and negative cash flows from operations raise substantial doubt regarding our ability to continue as a going concern. We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our financial statements do not include any adjustment to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty, with the exception that all borrowings are classified as current on the balance sheets.

Under our Term Loan Agreement (the "Loan Agreement") with CRG Partners III L.P. and certain of its affiliated funds (collectively "CRG"), a "Material Adverse Change" or "Material Adverse Effect" (each as defined in the Loan Agreement) is an "Event of Default" thereunder, which gives Majority Lenders (as defined in the Loan Agreement) the right to declare amounts outstanding under the Loan Agreement immediately due and payable. Due to the substantial doubt about our ability to continue operating as a going concern and the Event of Default that could result due to a Material Adverse Change under the Loan Agreement, the entire amount of borrowings at March 31, 2024 and December 31, 2023 are classified as current. In addition, we may not be able to generate sufficient liquidity or revenue to satisfy minimum liquidity and minimum revenue covenants under the Loan Agreement. If we fail to satisfy such requirements, we will be in default under the Loan Agreement and all outstanding amounts under the Loan Agreement will become immediately due.

Majority Lenders have not purported that an Event of Default has occurred as a result of a Material Adverse Change or breach of other financial covenants. However, there can be no guarantee that Majority Lenders will not invoke such Event of Default in the future, or that we will not experience other Material Adverse Changes or other Material Adverse Effects, or otherwise breach our financial or other covenants under the Loan Agreement, that could give rise to an Event of Default under the Loan Agreement.

If we are unable to generate sufficient revenue and liquidity to service our debt, we may be required to pursue a reorganization proceeding under applicable bankruptcy or insolvency laws, including protection ("Bankruptcy Protection") under Chapters 7 or 11 of the U.S. Bankruptcy Code. Holders of our common stock will likely not receive any value or payments in a restructuring or similar scenario.

In the event we pursue Bankruptcy Protection, we will be subject to the risks and uncertainties associated with such proceedings

In the event we file for relief under the United States Bankruptcy Code, our operations, our ability to develop and execute our business plan and our continuation as a going concern will be subject to the risks and uncertainties associated with bankruptcy proceedings, including, among others: our ability to execute, confirm and consummate a plan of reorganization; the high costs of bankruptcy proceedings and related fees; our ability to obtain sufficient financing to allow us to emerge from bankruptcy and execute our business plan post-emergence, and our ability to comply with terms and conditions of that financing; our ability to continue our operations in the ordinary course; our ability to maintain our relationships with our customers, business partners, counterparties, employees and other third parties; our ability to obtain, maintain or renew contracts that are critical to our operations on reasonably acceptable terms and conditions; our ability to attract, motivate and retain key employees; the ability of third parties to use certain limited safe harbor provisions of the United States Bankruptcy Code to terminate contracts without first seeking Bankruptcy Court approval; and the actions and decisions of our stakeholders and other third parties who have interests in our bankruptcy proceedings that may be inconsistent with our operational and strategic plans. Any delays in our bankruptcy proceedings would increase the risks of our being unable to reorganize our business and emerge from bankruptcy proceedings and may increase our costs associated with the bankruptcy process or result in prolonged operational disruption for us. Also, we would need the prior approval of the bankruptcy court for transactions outside the ordinary course of business during the course of any bankruptcy proceedings, which may limit our ability to respond timely to certain events or take advantage of certain opportunities. Because of the risks and uncertainties associated with any bankruptcy proceedings, we cannot accurately predict or quantify the ultimate impact of events that could occur during any such proceedings. There can be no guarantees that if we seek Bankruptcy Protection, we will emerge from Bankruptcy Protection as a going concern or that holders of our common stock will receive any recovery from any bankruptcy proceedings.

In the event we are unable to pursue Bankruptcy Protection under Chapter 11 of the United States Bankruptcy Code, or, if pursued, successfully emerge from such proceedings, it may be necessary to pursue Bankruptcy Protection under Chapter 7 of the United States Bankruptcy Code for all or a part of our businesses.

In the event we are unable to pursue Bankruptcy Protection under Chapter 11 of the United States Bankruptcy Code, or, if pursued, successfully emerge from such proceedings, it may be necessary for us to pursue Bankruptcy Protection under Chapter 7 of the United States Bankruptcy Code for all or a part of our businesses. In such event, a Chapter 7 trustee would be appointed or elected to liquidate our assets for distribution in accordance with the priorities established by the United States Bankruptcy Code. We believe that liquidation under Chapter 7 would result in significantly smaller distributions being made to our stakeholders than those we might obtain under Chapter 11 primarily because of the likelihood that the assets would have to be sold or otherwise disposed of in a distressed fashion over a short period of time rather than in a controlled manner and as a going concern.

We may not be able to secure additional financing on favorable terms, or at all, to meet our future capital needs and our failure to obtain additional financing when needed could force us to delay, reduce or eliminate our product development programs and commercialization efforts or cause us to become insolvent.

On March 5, 2024, we entered into a financing as part of a broader strategic collaboration with Zylox-Tonbridge Medical Technology Co., Ltd. (“Zylox-Tonbridge”) in which we received an aggregate of $7.5 million before any commissions, legal and accounting fees, and other ancillary expenses. We believe that our cash and cash equivalents at March 31, 2024, together with the aforementioned financing, debt and other financing activities and expected revenues from operations, will be sufficient to satisfy our capital requirements and fund our operations through the second quarter of 2024. Even though we received net proceeds of approximately $7.0 million from the sale of our Common Stock and Series F Convertible Preferred Stock in the Private Placement in March 2024, and $6.5 million from the sale of our common stock under our at-the-market program that we entered into on May 20, 2022, we will need to raise additional funds through future equity or debt financings in the near future to meet our operational needs and capital requirements for product development, clinical trials and commercialization, and to regain compliance with the Equity Requirement under the Nasdaq Listing Rules. We can provide no assurance that we will be successful in raising funds pursuant to additional equity or debt financings or that such funds will be raised at prices that do not create substantial dilution for our existing stockholders. Given the volatility of our stock price, any financing that we undertake could cause substantial dilution to our existing stockholders. Macroeconomic challenges and volatility in capital markets could further limit our ability to raise capital when needed on terms favorable to us, or at all. In addition, while we have been able to raise capital from the sale of shares under our at-the-market program, the limitations under instruction I.B.6 of Form S-3, as well as possible low volume of trading in our securities, will limit our ability to continue raising funds through such program.

To date, we have financed our operations primarily through sales of our products and net proceeds from the issuance of our preferred stock and debt financings, our initial public offering ("IPO"), private offerings, strategic investment, and our follow-on public offerings of our securities. We do not know when or if our operations will generate sufficient cash to fund our ongoing operations. We cannot be certain that additional capital will be available as needed on acceptable terms, or at all. In the future, we may require additional capital in order to (i) continue to conduct research and development activities, (ii) conduct post-market clinical studies, as well as clinical trials to obtain regulatory clearances and approvals necessary to commercialize our Lumivascular platform products, (iii) expand our sales and marketing infrastructure, (iv) acquire complementary businesses technologies or products; or (v) respond to business opportunities, challenges, a decline in sales, increased regulatory obligations or unforeseen circumstances. Our future capital requirements will depend on many factors, including:

- the degree of success we experience in commercializing our Lumivascular platform products, particularly Pantheris, Ocelot, Tigereye and any future versions of such products;
- the costs, timing and outcomes of clinical trials and regulatory reviews associated with our future products;
- the costs and expenses of maintaining or expanding our sales and marketing infrastructure and our manufacturing operations;
- the costs and timing of developing variations of our Lumivascular platform products and, if necessary, obtaining FDA clearance of such variations;
- the costs and timing of developing our Coronary products, timing and outcomes of clinical trials and regulatory reviews associated with this product and eventual timing and expenses related to obtaining FDA clearance;
- the extent to which our Lumivascular platform is adopted by hospitals for use by interventional cardiologists, vascular surgeons and interventional radiologists in the treatment of PAD;
- the number and types of future products we develop and commercialize;
- the costs of defending ourselves against future litigation;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the extent and scope of our general and administrative expenses.

We may attempt to raise additional funds in equity or debt financings or enter into credit facilities in order to access funds for our capital needs. Any debt financing obtained by us in the future would cause us to incur additional debt service expenses and could include restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and pursue business opportunities. In addition, due to our current level of debt, future equity investors may require that we convert all or a portion of our debt to equity, and our debtholders may not agree to such terms. If we raise additional funds through further issuances of equity or convertible debt securities, and/or if we convert all or a portion of our existing debt to equity, our existing stockholders could suffer significant dilution in their percentage ownership of our company, and any new equity securities we issue could have rights, preferences and privileges senior to those of holders of our common stock.

If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay clinical trials necessary to market our products, delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products, and significantly scale back our operations, or we may become insolvent. In addition, as described above under the risk factor "*Nasdaq may delist our securities from its exchange, which could harm our business and limit our stockholders' liquidity*," if we are unable to raise capital in a manner accretive to our stockholders' equity, our common stock could be delisted from Nasdaq. If this were to occur, our ability to continue to grow and support our business and to respond to business challenges could be significantly limited.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

10b5-1 Trading Plans

During the first quarter of 2024, none of our directors or executive officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement” (as each term is defined in Item 408(a) of Regulation S-K).

ITEM 6. EXHIBITS

The following exhibits are filed as part of, or incorporated by reference into, this Quarterly Report on Form 10-Q:

Exhibit Number	Exhibit Title
3.1	Certificate of Designation of Preferences, Rights, and Limitations of Series F Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed March 7, 2024).
3.2	Certificate of Designation of Preferences, Rights, and Limitations of Series A-1 Convertible Preferred Stock (incorporated by reference to Exhibit 3.2 to our Current Report on Form 8-K filed March 7, 2024).
3.3	Certificate of Amendment to the Certificate of Designation of Preferences, Rights, and Limitations of Series E Convertible Preferred Stock (incorporated by reference to Exhibit 3.3 to our Current Report on Form 8-K filed March 7, 2024).
10.1	Amendment No. 8 to Term Loan Agreement, dated January 26, 2024, by and among Avinger Inc. and the lenders party thereto (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed January 26, 2024).
10.2	Strategic Cooperation and Framework Agreement, dated March 4, 2024, made by and between Avinger, Inc. and Zylox-Tonbridge Medical Technology Co., Ltd (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed March 7, 2024).
10.3	Securities Purchase Agreement, dated March 4, 2024, made by and between Avinger, Inc. and Zylox-Tonbridge Medical Limited (incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed March 7, 2024).
10.4	Registration Rights Agreement, dated March 5, 2024, made by and between Avinger, Inc. and Zylox-Tonbridge Medical Limited (incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K filed March 7, 2024).
10.5	Amendment No. 9 to Term Loan Agreement, dated March 5, 2024, made by and among Avinger, Inc. and GRG Partners III L.P. and certain of its affiliated funds, as lenders (incorporated by reference to Exhibit 10.4 to our Current Report on Form 8-K filed March 7, 2024).
10.6	Form of Common Stock Purchase Warrant of Avinger, Inc (incorporated by reference to Exhibit 10.5 to our Current Report on Form 8-K filed March 7, 2024).
10.7	Securities Purchase Agreement, dated March 5, 2024, by and between Avinger, Inc. and the purchasers party thereto (incorporated by reference to Exhibit 10.6 to our Current Report on Form 8-K filed March 7, 2024).
10.8	Registration Rights Agreement, dated March 5, 2024, by and between Avinger, Inc. and the holders party thereto (incorporated by reference to Exhibit 10.7 to our Current Report on Form 8-K filed March 7, 2024).
10.9	Fourth Amendment to Lease Agreement dated March 6, 2024 by and between Avinger, Inc. and HCP LS Redwood City, LLC (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed March 12, 2024).
10.10*†	License and Distribution Agreement, dated March 4, 2024, made by and between Avinger, Inc. and Zylox-Tonbridge Medical Technology Co., Ltd
31.1	Certification of the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File - the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

* Filed herewith.

† Certain information, schedules and exhibits to this agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

The certifications filed as Exhibits 32.1 are not deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the Company under the Securities Exchange Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof irrespective of any general incorporation by reference language contained in any such filing, except to the extent that the registrant specifically incorporates it by reference.

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 thereunto duly authorized.

Avinger, Inc.
(Registrant)

Date: May 15, 2024

/s/ Jeffrey M. Soinski
Jeffrey M. Soinski
Chief Executive Officer
(Principal Executive Officer)

Date: May 15, 2024

/s/ Nabeel Subainati
Nabeel Subainati
Vice President, Finance
(Principal Financial and Accounting Officer)

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH NOT MATERIAL AND THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

LICENSE AND DISTRIBUTION AGREEMENT

By and Between

AVINGER, INC.

And

ZYLOX-TONBRIDGE MEDICAL TECHNOLOGY CO., LTD.

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LICENSE AND DISTRIBUTION AGREEMENT

This **License and Distribution Agreement** (the "**Agreement**") is entered into as of March 4, 2024 by and between **Avinger, Inc.**, a company organized and existing under the laws of State of Delaware in the United States of America ("**USA**" or "**US**"), legally represented by Jeffrey M. SOINSKI, having its address at 400 Chesapeake Drive, Redwood City, CA 94063, USA (the "**Licensor**") and **Zylox-Tonbridge Medical Technology Co., Ltd.** , a company established in the People's Republic of China ("**PRC**"), legally represented by Dr. Jonathon Zhong ZHAO, with its registered office at 270 Shuyun Road, Yuhang District, Hangzhou, Zhejiang Province, China (the "**Licensee**"). Licensor and Licensee are referred to herein individually as a "**Party**" and collectively as the "**Parties**". Notwithstanding anything in this Agreement to the contrary, this Agreement will not be effective until the Initial Closing Date (the "**Effective Date**"), as defined in the Securities Purchase Agreement (as such term is defined below).

RECITALS

Whereas, Licensor owns or controls certain proprietary titles, patents, know-how and other intellectual property rights relating to the Avinger Products, including products for the treatment of peripheral and coronary artery disease (the "**Products**", as further defined below);

Whereas, the Parties entered into a "Project Artery Term Sheet" dated October 31, 2023 ("**Term Sheet**") regarding investment and strategic partnership undertaking related to the Products, which sets forth certain key principles of a business collaboration between the Parties and provides certain terms for the negotiation of a set of legal documents to be executed to definitively govern that collaboration, including this Agreement, upon execution of which the Term Sheet will be superseded;

Whereas, the Licensee is a company having legally required permits, approvals and qualifications, expertise, experience, skills, infrastructure and personnel to Commercialize, Localize and Manufacture the Products in the Territory (as further defined below);

Whereas, the Parties have agreed in the Term Sheet that the Licensee will make two tranches of investment into the Licensor ("**Tranche 1 Investment**" and "**Tranche 2 Investment**") to fund the Licensor's core business, subject to the terms and conditions agreed in the securities purchase agreement to be entered into on or about the date of this Agreement by the Parties (the "Securities Purchase Agreement"), on the condition that Licensee is to be granted an exclusive license related to imported Products and localized Products as mentioned below under this Agreement;

Whereas, the Parties have agreed in the Term Sheet that the Licensee is to be granted an exclusive license to import, Localize, and Commercialize the imported Products in the Territory, which license shall be governed according to the terms and conditions set forth in this Agreement;

Whereas, in accordance with the Parties' agreement in the Term Sheet, Licensee will be granted an exclusive license to Localize, Manufacture and Commercialize the localized Products, in the Territory, pursuant to the terms and conditions set forth in this Agreement; and

Whereas, in accordance with the Parties' agreement in the Term Sheet, Licensee will be an authorized OEM manufacturer for Licensor for certain Products to be sold by Licensor or its agents outside the Territory, upon regulatory approval and/or complete filing, which rights and authorization will be subject to an additional separate agreement to be negotiated and executed by the Parties;

Now, Therefore, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

ARTICLE 1
Definitions

1.1 **"Affiliate**" means, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such entity, whether by the ownership of fifty percent (50%) or more of the voting stock or equity of such entity, or by contract.

1.2 **"Applicable Law**" means the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, or permits of or from any court, arbitrator or governmental agency or authority (including Regulatory Authorities) having jurisdiction over or related to the subject matter in question.

1.3 **"Business**" has the meaning ascribed to it in the Article 2.1.

1.4 **"Business Day**" means any day that is not a Saturday, a Sunday or other day on which commercial banks in the USA and the Territory are not operative.

1.5 **"Change of Control**" with respect to a Party means (i) the acquisition (directly or indirectly, whether by merger, consolidation, purchase and sale, share exchange or otherwise) by any party other than an Affiliate of a beneficial interest in the securities of the Party representing more than 50% of the combined voting power of the then outstanding securities of the surviving entity immediately after acquisition (other than a capital raising transaction); or (ii) the transfer, sale or assignment of more than 50% of the assets of the Party to a party other than an Affiliate; or (iii) any other transfer to a party other than an Affiliate of the power and ability to control or direct the management and policies of that Party (including a change of the Executive Officer of Licensor, Mr. Jeffrey M. Soinski). For the avoidance of doubt, the following scenarios are explicitly excluded from the Change of Control of Licensee: any capital operations or equity restructure resulting in direct or indirect change of shareholding structure of Licensee.

1.6 **"Commercialization**," with a correlative meaning for "**Commercialize**" and "**Commercializing**," means all activities directed to marketing, promoting, selling, offering for sale, importing for sale, distributing, leasing and repairing the Products and providing after-sales services for the Products in the Territory, including activities relating to the importation, pre-launch, launch, detailing, advertising, pricing and reimbursement (including the obtaining of the required regulatory approvals for reimbursement), promotion, distribution, invoicing and sales of Products in the Territory. In addition to the foregoing, "Commercialization" in connection with the Product shall also include Post-Marketing Studies in the Territory and all types of cross-border direct sale or e-commerce in the Territory.

1.7 **"Commercially Reasonable Efforts**" means, with respect to a Party's obligations under this Agreement, the carrying out of such obligations with a level of efforts and resources consistent with the commercially reasonable practices of similarly situated companies in the medical device industry for the development and commercialization of similarly situated branded medical products as the applicable Products at a similar stage of development and commercialization, taking into account efficacy, safety, patent and regulatory exclusivity, anticipated or approved labeling, present and future market potential, competitive market conditions, the profitability of the product in light of pricing and reimbursement issues (but not taking into account any payment owed to the other Party under this Agreement), and all other relevant factors (such as financial).

1.8 **"Confidential Information**" of a Party means any and all Information of such Party that is disclosed to the other Party pursuant to this Agreement or during any transaction contemplated hereby (including information disclosed prior to the Effective Date pursuant to the Confidentiality Agreement) and that is not covered by clauses (a)-(e) of Article 12.1, regardless of whether such Information is specifically designated as confidential and regardless of whether such Information is in written, oral, electronic, or other form.

1.9 **"Confidentiality Agreement**" means that certain confidentiality agreement entered into by the Parties in anticipation of the negotiation of this Agreement, if any.

1.10 **"Control**" means, with respect to any material, Information, or Intellectual Property Right, the possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise (other than by operation of the license grants under this Agreement), to grant a license, sublicense or other right to or under such material, Information, or Intellectual Property Right on the terms and conditions set forth in this Agreement without violating the terms of any then-existing agreement or other arrangement with any Third Party.

1.11 **"Data**" means all material data related to Products, including manufacture data, production process data, non-clinical data, clinical data and clinical study reports, patient databases, and the like generated during the process of the development, Localization, Manufacturing and Commercialization of Products.

1.12 **"Designated Party**" means an Affiliate of Licensee or a Third Party (subject to the conditions in this Agreement), which has been designated by Licensee to exercise certain rights and/or perform certain of the Licensee's obligations under this Agreement.

1.13 **"Localization**" with a correlative meaning for "**Localize**" and "**Localizing**," refers to the undertakings and activities which the Licensee or its Designated Party is authorized to carry out under the terms of this Agreement which are strictly limited to:

(a) with respect to Imported Products research, testing, Product localization, and regulatory development activities which are (i) necessary for Commercialization of the Imported Products in the Territory, including but not limited to the adaptation of the software interface of the Imported Products, their artificial intelligence functions, and all other functions of the software application of the Imported Products, translation of the software interface, etc. (into simplified Chinese, traditional Chinese, or other languages in the Territory) for the purpose of Commercialization, or (ii) requested or required by Regulatory Authority only for the purpose of obtaining and maintaining Regulatory Approval for the Imported Products in the Territory for the purpose of Commercialization, including Mandatory Post-Approval Studies and Post-Marketing Studies;

(b) with respect to Domestic Products, all manufacture, research and development activities as reasonably necessary, or requested or required by Regulatory Authorities, for the purpose of obtaining and maintaining applicable Regulatory Approval of the Domestic Products (including the same types as the Imported Products, or as may be later agreed by the Parties, new types or new Indications) in the Territory for the purpose of Manufacturing and Commercialization of the Domestic Products, including activities related to preclinical and other non-clinical testing, quality assurance/quality control, clinical trials, toxicology studies, statistical analysis and report writing, preparation, submission and prosecution of clinical trial approvals/filings and all regulatory affairs relating to the foregoing for the purpose of obtaining and maintaining Regulatory Approval, and shall also include the research and development activities of a technical nature involving manufacturing, development, improvement, innovation or adaptation-related development regarding the Domestic Products or other technical research which are related to specifications of the Domestic Products for the market in the Territory only; and shall also include activities with respect to market development as reasonably necessary for Commercialization of the Domestic Products in the Territory, including but not limited to development/localization of the interface, artificial intelligence and all other functions of the software application of the Domestic Products or its translation (into simplified Chinese, traditional Chinese or other languages in the Territory) for the purpose of Commercialization.

For the avoidance of doubt, the term “Localization” includes clinical trials or studies initiated after receipt of Regulatory Approval in the country or region for which such trials or studies are mandatorily or necessarily required by a Regulatory Authority to be conducted after Regulatory Approval as a condition of or in connection with obtaining and maintaining such Regulatory Approval (“**Mandatory Post-Approval Studies**”).

1.14 **“Executive Officer**” means, (a) with respect to Licensor, its CEO or another senior officer of Licensor designated by its CEO and (b) with respect to Licensee, its Chairman of the Board of Directors, or another senior officer of Licensee designated by its Chairman of the Board of Directors.

1.15 "**FDA**" means the United States Food and Drug Administration.

1.16 **“Field**” means, treatment of any diseases or conditions in humans in the indications including but not limited to the following: for clinical use in vascular atherectomy and CTO crossing, and to use in medical institutions for vascular atherectomy and CTO crossing and for scientific research use in research related to vascular atherectomy and CTO crossing, and to use in medical institutions or non-medical institutions or companies for research and development related to vascular atherectomy and CTO crossing, as approved and updated by the Regulatory Authority from time to time of the respective country/region. To the avoidance of doubt, clinical use in Hainan is also included in the scope of the Field as approved, filed or updated by the Regulatory Authority from time to time.

1.17 **“First Commercial Sale**” means, as the case may be, the first sale of the Imported Products or Domestic Products in the Territory by Licensee or its Affiliates or permitted Sublicensees for value in an arm’s-length transaction to an independent Third-Party distributor, agent or end user in the Territory for end use or consumption for the general public of the Imported Product or Domestic Product.

1.18 **“GAAP**” means generally accepted accounting principles, as published by the Financial Accounting Standards Board.

1.19 **“Good Clinical Practices**” or “**GCP**” means the then-current good clinical practice standards, practices and procedures for designing, conducting, recording, and reporting clinical trials that involve the participation of human subjects promulgated or endorsed by the relevant Regulatory Authority and applicable to the Territory or any other jurisdiction where clinical trials involving human subjects related to any Product are or were performed, as they may be updated from time to time.

1.20 **"Good Manufacturing Practices**" or "**GMP**" means the then-current Good Manufacturing Practices promulgated or endorsed by the relevant Regulatory Authority and applicable to the manufacture and testing of medical devices in the Territory or any other jurisdiction where any Product is or was manufactured or tested, as may be updated from time to time.

1.21 **"Good Supply Practices**" or "**GSP**" means the then-current Good Supply Practices promulgated or endorsed by the relevant Regulatory Authority and applicable to the distribution (including traceability and the process of procurement, warehousing, sale and transportation) of medical devices in the Territory, as may be updated from time to time, including applicable rules promulgated by NMPA or its equivalent in Taiwan.

1.22 **"Government Centralized Procurement**", means centralized procurement and/or volume-based purchase organized by applicable Government Authorities in the Territory by means of open bidding and other means applicable to government procurement (including but not limited to provincial and national government, etc.).

1.23 **"Governmental Authority**" means any multi-national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.24 **"Indication**" means an illness or condition which is accepted by the applicable Regulatory Authorities as an approved indication for a specific treatment or for particular scientific research in the Field.

1.25 **"Information**" means any data (including Data), results, technology, business, financial, technical, scientific, trade, research, manufacturing, marketing, product, supplier, Intellectual Property Rights or other information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulae, software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, clinical test data and data resulting from non-clinical studies), stability data and other study data and procedures.

1.26 **"Insolvency Event**" shall mean "**Insolvency Event**" in relation to either Party, which means any one of the following:

(a) the Party commences a bankruptcy proceeding or similar proceeding (except in relation to a solvent reorganization), an assignment for the benefit of creditors, or otherwise seeks dissolution, that is not dismissed, rescinded, or stayed within ninety (90) days of commencement thereof;

(b) an involuntary petition in an insolvency proceeding is filed against a Party and is not dismissed or stayed within ninety (90) days of the filing thereof;

(c) a trustee in bankruptcy, receiver, administrative receiver, receiver and manager, court appointed receiver, interim receiver, custodian, sequestrator or similar officer is appointed in respect of that Party or over any material part of that Party's assets, other than to the extent that such officer is appointed at the request of the other Party to this Agreement;

1.27 **"Intellectual Property Rights**" means all rights (including the rights to prosecute) in, to and under Patents, Invention registrations, trademarks, copyrights, domain names, databases, data, know-how, trade secrets and confidential information, and all other intellectual or industrial property and other proprietary rights throughout the world.

1.28 **"Inventions**" means any inventions and discoveries, including processes, methods, assays, designs, protocols, and formulas, and improvements or modifications thereof, patentable or otherwise, that are generated, developed, conceived or reduced to practice by or on behalf of a Party or its Affiliate or permitted sublicensee pursuant to activities conducted under this Agreement, in each case including all rights, title and interest in and to the Intellectual Property Rights therein and thereto.

1.29 **"License Fees**" mean the license fees to be paid by Licensee to Licensor for the use of Licensor IP (Product Marks being granted with a royalty-free license) for the purpose of Localization, Manufacturing and Commercialization of the Domestic Products in the Territory as set forth in Exhibit E.

1.30 **"Licensee Information**" and "**Licensor Information**" (as the case may be) means any data (including Data), results, technology, business, financial, technical, scientific, trade, research, manufacturing, marketing, product, supplier, Intellectual Property Rights or other information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulae, software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, clinical test data and data resulting from non-clinical studies), stability data and other study data and procedures that are developed, conceived or reduced to practice by or on behalf of the Licensee, its Affiliate or Designated Party, or by or on behalf of Licensor or its Affiliates, as the case may be, during the Term of this Agreement and in connection to the same.

1.31 **"Licensee Inventions**" means Inventions (whether patentable or not), that are generated, developed, conceived or reduced to practice by or on behalf of Licensee, its Affiliate or Designated Party pursuant to activities conducted under this Agreement, together with all Intellectual Property Rights therein and thereto, provided that such Inventions made by Licensee's or its Affiliate's employee(s) or Designated Party or on behalf of Licensee or its Affiliate or Designated Party during the performance of and in compliance with this Agreement, in each case not based on Licensor Information.

1.32 "Licensee Invention Patents" means:

(a) In relation to Imported Products, Patents in relation to Imported Products that become Controlled by Licensee or its Affiliate during the Term and that claim or cover Licensee Inventions;

(b) In relation to Domestic Products, Patents in relation to Domestic Products that become Controlled by Licensee or its Affiliate during the Term and that claim or cover Licensee Inventions.

1.33 "Licensor Inventions" means all Inventions that (a) (i) are Controlled by Licensor or its Affiliates as of the Effective Date or (ii) become Controlled by Licensor or its Affiliates during the Term, and (b) are reasonably necessary for the Localization, use, import, Manufacture, Commercialization or other exploitation of the Products in the Field in the Territory.

1.34 "Licensor IP" means, collectively, Licensor Know-How, Licensor Inventions, Licensor Patents, Product Marks, and all other applicable Intellectual Property Rights of Licensor and its Affiliates in and to the Products, as may be required to Localize, use, import, Manufacture, Commercialize, or otherwise exploit the same in the Field in the Territory, as provided for in this Agreement.

1.35 "Licensor Know-How" means all Information that (a) (i) is Controlled by Licensor or its Affiliates as of the Effective Date or (ii) becomes Controlled by Licensor or its Affiliates during the Term, and (b) is reasonably necessary for the Localization, use, import, registration, Manufacture, or Commercialization of the Products in the Field in or for the Territory.

1.36 "Licensor Patents" means all Patents in the Territory that (a) (i) are Controlled by Licensor or its Affiliates as of the Effective Date, or (ii) become Controlled by Licensor or its Affiliates during the Term, and (b) claim the composition or formulation of, or the method of making, using or delivering, the Products or are otherwise reasonably necessary for the Localization, use, import, Manufacture, or Commercialization of the Products in the Field in the Territory. Licensor Patents existing as of the Effective Date ("**Existing Licensor Patents**") are set forth in Exhibit F.

1.37 "Line Extension" means a new improvement and/or new technologies relating to the Products for vascular atherectomy and CTO crossing or any new indication, in terms of device, components, forms, presentations, or software with respect to a Product, and developed by either Party or its Affiliates or sub-licensees. For avoidance of doubt, Line Extension shall include upgrade generations of Products with improvements and/or new technologies as defined above.

1.38 "Manufacture" means to make a Product in compliance with the applicable GMP and the Marketing Authorization in the Territory, including to process, prepare, make and Test the raw materials used in the production of the Product and to Test the Product prior to release packaging, and "**Manufacturing**" has the corresponding meaning.

1.39 **"Manufacturing Information**" shall mean all ideas, inventions, information, data, writings, protocols, discoveries, improvements, trade secrets, know-how, materials or other proprietary information not generally known to the public that are required to manufacture the Product.

1.40 **"Market**" means for the purpose of this Agreement, each of, or, certain particular regions of the Territory.

1.41 **"Marketing Authorization**" or "**Market Authorization**" means that specific Regulatory Approval issued by a Regulatory Authority in a jurisdiction to register the Product and required for Commercialization in such jurisdiction, but excluding any pricing or reimbursement approval.

1.42 **"Marketing Authorization Application**" or "**MAA**" means an application for the Marketing Authorization or other applicable Regulatory Approval or any other application to the appropriate Regulatory Authority in a given country or regulatory jurisdiction for approval to market and Commercialize a Product.

1.43 **"Material Adverse Events**" means any objective event (excluding the activities of the Parties) that has or may have a material adverse effect on or frustrate the Manufacturing, Localization or Commercialization of the Products, including without limitation, any substantial change of Applicable Law or policies, change of market conditions or hindrance in Localization or Manufacturing, significant events/changes in respect to safety, technology, efficacy, or quality of Products, which will or may significantly reduce the prospect of Localization, Manufacturing or profit margin of the Commercialization of the Products.

1.44 **"NMPA**" means the National Medical Products Administration of the People's Republic of China, including its local counterparts and any successor agency thereto having substantially the same function and authority (as, for example, the TFDA or DOH in Taiwan).

1.45 **"Patents**" means (a) pending patent applications, issued patents, utility models and designs; (b) reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any of the foregoing; and (c) extension, renewals or restorations of any of the foregoing by existing or future extension, renewal or restoration mechanisms, including supplementary protection certificates or the equivalent thereof, whether or not the above are derived or arise from the domestic patent system under the Applicable Laws or international conventions under the international patent system (including the Paris Convention for the Protection of Industrial Property, Patent Cooperation Treaty and other treaty under which Licensor or Licensee would have an optional channel to obtain a patent for the Product in or for the Territory).

1.46 **"Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.47 **"Personnel**" means, with respect to a Party or its Affiliate that is involved in performance of this Agreement, such Party's and such Affiliate's directors, officers, employees, agents, and consultants who, in each case, may reasonably be expected to perform under this Agreement.

1.48 **"Post-Marketing Studies**" means clinical trials or other studies initiated after receipt of Regulatory Approval in the country for which such trials or studies are being conducted, including modeling, investigator-initiated clinical trials, and observational studies, but excluding any Mandatory Post-Approval Studies.

1.49 **"PRC**" or "**China**" means the People's Republic of China, excluding Hong Kong, Macao and Taiwan for the purpose of this Agreement;

1.50 **"Product(s)**" means, the Licensor medical device product portfolio for vascular atherectomy and CTO crossing, and consists of Peripheral Products (LightBox, Pantheris A400 series, Pantheris SV and LV, and Tigereye ST) and Coronary Products (Coronary CTO products). The Products include without limitation the medical device products applicable to all related Indications and inclusive of all components, consumables, forms and Line Extension thereof, which shall include the Imported Products, the Imported Products Consumables, the Domestic Products and the Domestic Products Consumables.

"Imported Product(s)" means those medical device products set forth in Exhibit A hereof.

"Imported Products Consumable(s)" means those consumables set forth in Exhibit A hereof. Imported Products Consumables are required for use of Imported Products.

"Domestic Product(s)" means those medical device products set forth in Exhibit B hereof.

"Domestic Products Consumable(s)" means those consumables set forth in Exhibit B hereof. Domestic Products Consumables are required for use of Domestic Products.

For the purpose of clarity, any software which is related to the Products shall also form part of the Products, regardless of whether such software shall form a software component of the Product or an independent software medical device for the purpose of obtaining Market Authorization and Regulatory Approvals.

1.51 **"Product Liability**" means, with regard to the safety or effectiveness of a Product and/or the research, Localization and Manufacture of the Product, any liability arising out of an alleged defect in a Product regardless of whether a Third Party claim is for breach of warranty, breach of contract, tort, negligence, strict liability or pursuant to any other legal theory at common law or under statute, including claims for personal injury (including death).

1.52 **"Product Marks**" means the trademarks set out in Exhibit G and/or logos and/or trade dress of the Products owned or controlled by Licensor, which are used or to be used by Licensee or its Affiliates or Designated Parties for the Commercialization of Product in the Territory and any registrations thereof or any pending applications relating thereto or any application related thereto to be made in the Territory (excluding, in any event, any corporate names and any trademarks that consist of or include any corporate name or corporate logo of the Licensor), along with all domain names associated therewith, and all goodwill associated therewith.

"Licensee's Product Marks" means the trademarks and/or logos and/or trade dress of the Products owned or controlled by Licensee, which are used or to be used by Licensee or its Affiliates or Designated Parties for the Commercialization of Products solely in the Territory and any registrations thereof or any pending applications relating thereto in the Territory (excluding, in any event, any corporate names and any trademarks that consist of or include any corporate name or corporate logo of the Licensor or Licensee), along with all domain names associated therewith, and all goodwill associated therewith.

1.53 **"Regulatory Approval**" means all approvals necessary for the Localization, Manufacture, marketing, importation and Commercialization of any Product in the Field in a given country or regulatory jurisdiction within the Territory, including Marketing Authorizations.

1.54 **"Regulatory Authority**" means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction.

1.55 **"Regulatory Materials**" means regulatory applications (including MAAs), submissions, notifications, communications, correspondence, registrations, Regulatory Approvals and/or other filings made to or received from a Regulatory Authority in order to Localize, Manufacture, import, market, sell or otherwise Commercialize a Product in a particular country or jurisdiction.

1.56 **"Required Information**" means, with respect to a particular Product, Information generated or obtained at any time from Localization activities conducted inside or outside the Territory by or on behalf of Licensor, its Affiliates or licensees that is required by Applicable Laws to be maintained or submitted to Regulatory Authorities in the Territory in order to obtain or maintain Regulatory Approval of such Imported Product and/or Domestic Product in the Territory, including such Information that is required by Applicable Laws for reexamination or re-registration of such Imported Product and/or Domestic Product in the Territory.

1.57 **"Rolling Forecast**" means, with respect to a particular Imported Product or Imported Product Consumable, the amount of such Products that Licensee expects to order each month for the next twelve months. Licensee will update Rolling Forecasts on a calendar quarter basis.

1.58 **"SC**" means the steering committee made up of one representative respectively from each Party, to discuss day to day issues and questions, and also to communicate on significant issues, changes, or dispute resolutions.

1.59 **"Territory**" means PRC, including Mainland China, Hong Kong, Macao and Taiwan.

1.60 **"Test**" means to test a product or its components prior to release for further processing or for shipping and Marketing in compliance with Applicable Law and "**Testing**" has the corresponding meaning.

1.61 "**Third Party**" means any entity other than Licensor or Licensee or an Affiliate of either of them.

1.62 Additional Definitions

The following table identifies the location of definitions set forth in various Articles of the Agreement, and the definitions include without limitation the following:

Defined Terms	**Article**
Breaching Party	13.2
Dispute	14.1
Localization Paradigm	7.1
Importation Paradigm	7.1
Indemnified Party	11.3
Indemnifying Party	11.3
Infringement	9.4
Licensee Indemnitees	11.1
Mandatory Post-Approval Studies	1
Non-Breaching Party	13.2
Permitted Purposes	5.3

Defined Terms	Article
Term	13.1
Licensor Indemnitees	11.2
Third Party Claims	11.3
Third Party IP Action	9.6
Lead Time	7.2(a)(1)
Securities Purchase Agreement	4th Whereas clause

1.63 Interpretation

Whenever used in this Agreement: (i) the words " **include**," "**includes**" or "**including**" shall be construed as incorporating also the phrase " **but not limited to**" or "**without limitation**" and shall mean including without limiting the generality of any description preceding or following such words; (ii) the word "**day**" or "**year**" or "**quarter**" shall mean a calendar day or calendar year or calendar quarter, respectively, unless otherwise specified; (iii) the words "**hereof**," "**herein**," "**hereby,**" "**hereunder**," and derivative or similar words refer to this Agreement as a whole and not merely to the particular provision in which such words appear; (iv) words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders; (v) the word "**or**" has the inclusive meaning represented by the phrase " **and/or**;" and (vi) the Exhibits to this Agreement form part of the operative provisions of this Agreement and references to this Agreement shall include references to the Exhibits. The headings of Articles contained in this Agreement preceding the text of the Articles, sub-Articles and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist.

ARTICLE 2
LICENSE

2.1 Rights and Licenses granted by Licensor

Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee an exclusive (subject to Article 2.2), transferrable (at the discretion of the Licensee, subject to prior written consent from the Licensor, which shall not be unreasonably withheld, except that 1) no prior written consent of Licensor will be required where the transfer is between Licensee and its Affiliate(s), provided that such Affiliate(s) shall fully comply with the obligations of the Licensee under this Agreement and be jointly and severally liable with the Licensee hereunder for all Licensee's obligations under this Agreement, and 2) no prior written consent of Licensor will be required in terms of transfer or sublicense of the right of Commercialization and distribution under this Agreement), sub-licensable (subject to Article 2.3), sub-contractable license under the Licensor IP and subject to the applicable Regulatory Approvals to use, import, ship and distribute within the Territory, Localize, register, Manufacture (subject to terms and conditions set forth in Article 7), supply and Commercialize the Products in Licensee's own name in the Field with the Trademark of Licensor and/or Licensee in and for the Territory ("**Business**"), commencing as of the Effective Date of this Agreement. Notwithstanding the foregoing, Licensor shall be obligated to manage and maintain the validity of the Licensor IP as required for Licensee to perform its obligations hereunder and operate the Business as licensed hereunder.

2.2 Maintenance of Exclusivity

(a) For Peripheral Products, the exclusivity granted hereunder shall subsist for as long as the Licensee has made Commercially Reasonable Efforts to gain Market Authorization and to commercially launch the Peripheral Products, and thereafter continues to make Commercially Reasonable Efforts to Commercialize the Peripheral Products in the Territory. If Licensee fails to gain Market Authorization within [***] of closing the Tranche 1 Investment or after Market Authorization, fails to make Commercially Reasonable efforts to Commercialize the Peripheral Products in the Territory, except for the circumstance when clinical trials are required for the Peripheral Products by Regulatory Authority (in which case the [***] will be extended through twenty-four months following the end of such clinical trials), or if Licensee fails to make Commercially Reasonable Efforts to Commercialize the Peripheral Products after obtaining Market Authorization from the Regulatory Authority, the license granted herein will become a non-exclusive license, unless an extension of exclusivity is mutually agreed to by the Parties.

For avoidance of doubt, if the Licensee can demonstrate both of the following, it shall be deemed to be fulfilling its obligation of "making Commercially Reasonable Efforts to Commercialize the Products": (1) The Licensee promotes the Peripheral Products at significant exhibitions in the Territory that promote similar products at least [***] on a yearly basis after obtaining the Market Authorization; and (2) the Licensee contacts a reasonable (given the nature of the Peripheral Products) selection of physicians and hospitals on a monthly basis for Peripheral Products after Market Authorization is obtained.

(b) For Coronary Products, the exclusivity granted hereunder shall subsist for as long as the Licensee has made Commercially Reasonable Efforts to gain Market Authorization and commercially launch the Coronary Products, and thereafter continues to make Commercially Reasonable Efforts to Commercialize the Coronary Products in the Territory following Regulatory Approval of such Coronary Products issued by the FDA, or the Licensee executes a sublicense to a Third Party which is not a subsidiary of the Licensee within 12 months after the Licensor obtains the Regulatory Approval of such Coronary Products issued by the FDA, which Third Party shall be a well-established and reputable firm in the Field in the Territory, with experience Commercializing products similar to the Products.

(c) Failure in registration of the Product Mark by the Licensor in the Territory which refrains or prevents the Licensee from Commercializing the Products bearing the said Product Marks shall not be deemed as a failure to make Commercially Reasonable Efforts.

2.3 Sublicense Rights.

Licensee shall have the right to grant sublicenses through multiple tiers of sub-licensees for the Territory under any or all of the rights granted in Article 2.1 to any subsidiary or other Affiliate, or to grant sublicenses through multiple tiers of sub-licensees for the Territory under the rights of use, import, distribute within Territory, supply and Commercializing rights and obligations to any Third Party, without having to obtain any approval from Licensor, provided that (i) Licensee shall cause each such sub-licensee to be in compliance with the applicable terms and conditions of this Agreement, (ii) Licensee shall serve as a surety to guarantee for the liabilities arising out of all acts or omissions of its sub-licensees.. For the avoidance of doubt, in addition to the rights and obligations of Licensee to itself exercise any of its rights or perform its obligations hereunder to use, import, distribute within Territory, Localization, register, Manufacture (subject to terms and conditions set forth in Article 7), supply and Commercialize Products hereunder, Licensee shall have the right to sublicense to any of its Affiliates any of such rights and obligations as provided in this Agreement.

However, for sublicensing of Localization, registration and Manufacturing rights and obligations of the Products by Licensee to any Third Party, prior written consent of the Licensor shall be required, which shall not be unreasonably withheld.

2.4 No Implied Licenses

Except as explicitly set forth in this Agreement, neither Party shall be deemed by estoppel or implication to have granted the other Party any license or other right to any Confidential Information or other Intellectual Property Rights of such Party.

2.5 Performance of Business in the Territory in Licensee ’s Name

Both Parties agree and acknowledge that the Business as licensed in Article 2.1 and Article 2.2 shall be conducted and performed in the name of Licensee or its Designated Parties for the purpose of Commercialization.

(a) Under Importation Paradigm as defined below in Article 7.1(a), the Licensor shall hold the Market Authorization of the Products in the Territory, and the Licensee shall act as the registration agent of Licensor to handle the registration of the Imported Products on behalf of the Licensor in the Territory, including but not limited to implementing necessary clinical trials, submitting Regulatory Materials and interfacing with Regulatory Authority, and shall to the extent permitted by Applicable Law, apply for and/or maintain the applicable Marketing Authorization in the name of the Licensor or Licensor’s designated Affiliate, for the purpose of Commercialization of the Imported Products in the Territory. As may be required by the Applicable Law, Licensor shall cooperate with Licensee in any commercially reasonable and lawful arrangements, including by executing a written binding document in an appropriate form as agreed by the Parties, to provide the Licensee with the benefit of such authorizations or rights as may be necessary for the purpose of Commercialization of the applicable Imported Product in the Territory, in which case Licensor shall be obligated to maintain in force such authorizations and rights throughout the Term of this Agreement.

(b) Under Localization Paradigm as defined below in Article 7.1(b), the Licensee shall be entitled to obtain and maintain the Marketing Authorization and other applicable Regulatory Approvals in its own name or its Designated Party’s name for the purpose of Manufacturing and Commercialization of Domestic Products in the Territory. The Parties agree that the Licensee at its discretion may designate its subsidiaries for obtaining and maintaining the Marketing Authorization and other applicable Regulatory Approvals without any consent from the Licensor; but if the Licensee intends to designate any Third Party for obtaining and maintaining the Marketing Authorization and other applicable Regulatory Approvals it shall be subject to the prior written consent of the Licensor and such consent shall be given unless the designation has, or is reasonably likely to have a detrimental impact on Licensor’s rights and benefits as owner and Licensor of the Products. The Licensee or its Designated Parties shall handle the registration work for the Domestic Products and the Licensor shall assist the Licensee by providing all Required Information.

ARTICLE 3
REPRESENTATIVES

3.1 Representatives

Each Party shall designate a representative to coordinate the performance of this Agreement. This representative from each Party respectively shall constitute the SC and shall be the designated contact for day to day issues and for communication on significant issues, changes, or dispute resolutions. The Parties’ representatives will communicate as frequently as necessary to ensure proper and effective performance of both Parties' obligations under this Agreement.

ARTICLE 4
LOCALIZATION

4.1 Rights of Localization; Costs

(a) **Rights of Localization**.

(1) Under Importation Paradigm, Licensee shall have the rights to conduct, by itself, or its Designated Party, the Localization as defined under Article 1.14(a) and/or to obtain or maintain Regulatory Approval in the Territory for the Imported Products (including Imported Products Consumables), without prejudice to the rights of Licensor under this Agreement for holding the Market Authorization of its Imported Products in the Territory, with the assistance and cooperation of Licensor or its Affiliates as provided in this Article 4.

(2) Under Localization Paradigm, Licensee shall have the right to conduct, by itself, or its Designated Party, the Localization related to registration, Manufacture and Commercialization of the Domestic Products and to obtain or maintain Regulatory Approval in the Territory for the Domestic Products (including Domestic Products Consumables) and for market development activities, with the assistance and cooperation of Licensor or its Affiliates as provided in this Article 4.

(b) **Costs**. Unless otherwise stipulated in this Agreement, Licensee shall be responsible for all the costs and expenses in connection with the Localization of the Imported Products (including Imported Products Consumables) and Domestic Products (including Domestic Products Consumables) conducted by Licensee or its Designated Parties in the Field in the Territory.

4.2 Localization Activities

Licensee shall have the rights to Localize, by itself, or its Designated Party, the Products and to apply for, obtain and maintain Regulatory Approvals of the Products in or for the Territory, to the extent permitted by Applicable Law and subject to Article 4.1 and other applicable provisions hereof. Licensee shall submit the details of Localization progress in the Territory to the Licensor for discussions and Licensor shall provide reasonable advice on the Localization activities to Licensee.

4.3 Performance

Licensee shall conduct Localization activities in and for the Territory in good scientific manner, and in compliance with all Applicable Laws, GCP and GMP (and GSP, if applicable), and always in such way that does not negatively affect the reputation and image of Licensor. Licensee shall be held accountable for any material negative impact on Licensor's reputation resulting from any decision or activity of Licensee provided that it has been proved that such material negative impact is caused by the acts or omissions of Licensee (or its Affiliates or subcontractors or Third Parties controlled by it) and the Licensor has provided for a reasonable and well-supported calculation of any losses incurred and supportive evidence of such material negative impact.

4.4 Localization Records.

Provided that the Localization activities are not protected by confidentiality and/or exclusivity agreements with Third Parties outside the Territory (and in such cases, subject to the applicable agreements), each Party shall maintain, including for the other Party's benefit, complete, current and accurate records of all Localization activities with regard to the Products by such Party, its Affiliates and subcontractors, and all Information resulting from such activities. Such records shall fully and properly reflect all work done and results achieved in the performance of the Localization activities in good scientific manner appropriate for regulatory and patent prosecution purposes. Without limiting the foregoing, promptly upon Licensee's request, Licensor shall provide Licensee with the Required Information requested by Licensee in order to obtain or maintain Regulatory Approvals in the Territory.

4.5 Localization Updates and Reports

Each Party shall regularly and at least on monthly basis provide the other Party with a summary of (i) the Localization activities performed in or for the Territory by or on behalf of the Licensee and (ii) the Localization activities performed by Licensor outside the Territory which may have a significant effect on the development and Localization and regulatory activities relating to the Products in the Territory, provided that such development or Localization activities are not protected by confidentiality and/or exclusivity agreements that prohibit their disclosure, including the progress and results of its and its Affiliate's and subcontractor's work. Such summary shall be at a level of detail reasonably requested by the SC. In addition, each Party shall promptly provide written notice to the other Party, through the SC, of any significant Localization matters for which such Party is responsible of which such Party becomes aware (*e.g.*, clinical trial initiation or completion, clinical holds, and receipt of clinical study reports). In addition and without limiting the foregoing, Licensor shall provide updates to Licensee, on at least a biweekly basis through the SC or upon the reasonable request of Licensee, regarding significant developments and advancements relating to the Product outside the Territory, provided *however*, that such updates shall be provided only if such events potentially impact the Licensee's ability to Localize the Product or Commercialize the Products in the Field in the Territory in accordance with the terms of this Agreement, especially events that will or potentially will lead to change of activities in the Regulatory Approval process for the Products. Licensee shall provide updates to Licensor regarding Licensee Inventions, if any, on at least a monthly basis through the SC or upon the reasonable request of Licensor.

4.6 Licensor Assistance

Upon the closing of Tranche 1 Investment pursuant to the Securities Purchase Agreement and upon Licensee's reasonable request, Licensor agrees to assist to identify Information that is reasonably necessary for Licensee to Localize the Product or Commercialize the Products in the Field in the Territory in accordance with this Agreement and which is not protected by confidentiality and/or exclusivity agreements applicable outside of the Territory. Throughout the Term, subject to Article 4.2, at any time that Licensor or Licensee identifies Licensor Know-How which is reasonably necessary for the purpose of the Localization and Commercialization of the Product in the Field in the Territory, Licensor shall promptly provide Licensee with copies of such Licensor Know-How free of charge.

In order to assist Licensee in the conduct of clinical studies of the Products, and obtain or maintain Regulatory Approvals in or for the Territory during the Term, Licensor shall at its own cost, (i) promptly upon Licensee's request, supply Licensee with Licensor Know-How and Information that is mandatory and/or reasonably necessary for Licensee to conduct clinical studies of the Product (if any) or obtain or maintain Regulatory Approvals in the Territory, and (ii) promptly after the Effective Date, provide Licensee, for use in clinical studies of the Products (if any) or to obtain or maintain Regulatory Approvals in the Territory, with relevant documents and information developed and validated by Licensor in the English language (e.g., patient diaries); and (iii) provide sample and reference Products for clinical development (if any) at the expense of the Licensee, provided that Licensor shall inform Licensee in writing and in advance of the related costs and obtain the prior written consent of the Licensee; and (iv) if requested by Licensee, implement necessary pre-clinical trials and clinical trials outside the Territory, provided that (x) such trials are required by the Regulatory Authority in the Territory for the application for or maintenance of the Regulatory Approvals in the Territory; and (y) such trials are permitted by the Applicable Law and acceptable for the Regulatory Authority in the Territory; and (z) Licensor shall be responsible for collaborating with Licensee to carry out such pre-clinical trials and clinical trials at the expense of Licensee, provided further that Licensor shall inform Licensee in writing and in advance of the related parties in charge of such trials and obtain the prior written consent of Licensee and secure for Licensee the right to directly communicate with that party to negotiate the relevant costs.

Without limiting the foregoing, in order to assist Licensee in the Commercialization of the Product, and obtain or maintain Regulatory Approvals in or for the Territory during the Term, Licensor shall upon Licensee's reasonable request, supply Licensee with the Licensor Know-How, training and Information related to the Product (including updates) that is necessary for Licensee to carry out the Commercialization of the Products.

Licensor agrees to provide source code applicable to use of the Product as may be necessary for the Licensee to Localize, register, or update the Products for the purpose of Commercialization of the Products in the Territory.

To avoid doubt, the salaries, labor costs, and managerial costs and other costs related to the employment of engineers or other Personnel of or designated by the Licensor in order to fulfill its obligation under this article shall be borne by the Licensor, while Licensee will pay reasonable travel and related costs that are incurred within the Territory and pay for pre-approved international travel costs.

ARTICLE 5
REGULATORY

5.1 Regulatory

(a) Subject to the terms and conditions of this Agreement and Applicable Law, especially Articles 4.1 and 4.2, Licensee shall have the rights to conduct, by itself, or its Designated Party, all regulatory activities related to Localization activities or regulatory activities to apply for, obtain and maintain Regulatory Approvals for the Products, as necessary and subject to Applicable Laws, including the preparation of Regulatory Materials and communications and interactions with Regulatory Authorities in the Territory with respect to the same, with the assistance and cooperation of Licensor or its Affiliates as provided in this Article 5. Licensee shall be responsible for all of its costs and expenses in connection with obtaining and maintaining Regulatory Approvals for Products in the Territory.

(1) Under the Importation Paradigm, the Market Authorization of Imported Products (including Imported Products Consumables) shall be made in the name of the Licensor (without prejudice to Licensee's rights to Localize and Commercialize the Imported Products (including Imported Products Consumables) under this Agreement), to the extent permitted by the Applicable Law. The Licensee or its Designated Party (subject to Article 2.3) shall act as the entrusted domestic agent of the Licensor in the Territory and fulfill its statutory obligations as the entrusted domestic agent of the Licensor, and shall seek Licensor's input with respect to its obligations under this Article 5 to ensure any Licensor concerns regarding the Regulatory Approval process are resolved;

(2) Under the Localization Paradigm according to Article 7.1 (b), the Regulatory Approval for the Domestic Products (including Domestic Products Consumables) shall be in the name of the Licensee or its Designated Party, and Licensee shall similarly collaborate with Licensor to ensure a successful outcome.

(b) **Agency Service under the Importation Paradigm**. The Licensee has agreed to provide the following agency service for the Licensor by itself or its Designated Party under the Importation Paradigm:

(1) act as the domestic registrant agent of Licensor to handle the registration or re-registration work for the Imported Products on behalf of the Licensor in the Territory, including but not limited to implementing necessary clinical trials, submitting regulatory documentation and interfacing with the Regulatory Authority;

(2) guide the Licensor to provide all the information required for registration, provide English to Chinese translation of registration documents, assist in testing and approval process of the corresponding Localization changes, etc., until the Market Authorization of the Imported Products is issued by the Regulatory Authority;

(3) act as the domestic registrant agent of the Licensor to handle all relevant change registration or change filing formalities with the Regulatory Authority on behalf of the Licensor in the Territory;

(4) handle all relevant assistance which is legally required to be handled by the domestic registrant agent of the Licensor in the Territory, including but not limited to assistance in recalls, etc.

Notwithstanding the above, the Licensor shall provide to the Licensee the prototype of Imported Product and sample required for Imported Product registration, all at the costs of Licensee.

The Licensor shall also provide to the Licensee the prototype or sample of the components to be registered on the registration license of the Imported Products, separately from the complete Imported Products. All costs in relation to the same shall be borne by Licensee. The prototype and sample of the components to be registered on the registration license of the Imported Products will be provided by Licensor to Licensee at cost with no margin.

All costs in relation to the delivery of prototypes or samples required under the terms of this Agreement and their shipment shall be borne by Licensee and Licensee shall undertake all formalities and costs in regard to the import of the same into the Territory, including but not limited to the determination and contracting of the logistics service provider.

5.2 Licensor's assistance.

As reasonably required by the Licensee, Licensor shall:

(a) provide reference and retention samples as required by Licensee under the conditions set out in Article 5.1 above;

(b) provide all Licensor Know-how, technical requirement and Data (including but not limited to technical data related to development, manufacture, testing and packaging, and relevant quality management system documents, records, documentation and information), certifications (including but not limited to CE certification and ISO certifications), information regarding the manufacturing processes and procedures for the Imported Products, to the Licensee, only insofar they are necessary for the purpose of obtaining Regulatory Approvals of the Imported Products. Licensor shall provide the Information and documents related to the above Licensor Know-how according to the time schedule set forth in Exhibit D;

(c) transfer to Licensee any relevant pending applications related to the Imported Products in the Territory (i.e., to Licensee or its Designated Party) and terminate any agreements with Third Parties regarding the registration of the Imported Products in the Territory; a list of name and contact details of the above mentioned Third Parties regarding the registration of the Imported Products in the Territory shall be attached in Exhibit D. Licensor shall provide these documents according to the time schedule set forth in Exhibit D;

(d) provide reasonable assistance and support, in a timely manner, to prepare for any meeting or teleconference with Regulatory Authorities (or related advisory committees) in the Territory and, at Licensee's reasonable request and upon reasonably adequate prior written notice, representatives from Licensor or its Affiliates shall attend and participate in meetings and teleconferences scheduled by Licensee with Regulatory Authorities in the Territory relating to the Products. Notwithstanding the provisions of Article 4.6, all such costs and expenses incurred in the Territory related to the Regulatory Approval shall be borne by the Licensee. All the costs and expenses incurred outside of the Territory shall be borne the Licensor;

(e) cooperate with the Regulatory Authority in its on-site inspection and bear the fees incurred out of the Territory during any such on-site inspection;

(f) provide any useful materials available (or if none are available, make Commercially Reasonable Efforts to develop such materials) with respect to modifications of specifications, manufacturing quality systems or other aspects of the Products or their Manufacture reasonably necessary in order to obtain and maintain Market Authorization and Regulatory Approval of the Product or to reach the safety standards (referring to both the medical device compliance safety standards and the medical electrical safety standards, including but not limited to Medical electrical equipment—Part 1: General requirements for basic safety and essential performance) or other applicable standards in the Territory, and conduct such modification of specifications, manufacturing quality systems or other aspects of the Products outside of the Territory, provided that all the costs incurred therefrom shall be borne by the Licensee;

(g) conduct additional tests such as animal tests to be carried out outside of the Territory required by the Regulatory Authority in order to obtain and maintain Market Authorization and Regulatory Approval it being understood that all costs for such test shall be undertaken by Licensee, provided that Licensor shall inform Licensee in writing and in advance of the related Third Parties in charge of such activities and obtain the prior written consent of Licensee and authorize Licensee to directly communicate with such Third Party to negotiate the relevant costs;

(h) organize engineers to participate in on-site review of the Products during the clinical trial and registration process and provide guidance to Licensee, it being understood that all costs in relation to the same (not including salaries or managerial costs for Licensor Personnel) shall be undertaken by Licensee, provided that Licensor shall inform Licensee in writing and in advance of the related costs and obtain the prior written consent of the Licensee and authorize Licensee to directly communicate with any Third Party involved to negotiate the relevant costs;

(i) promptly upon Licensee's request, provide Licensee with all other necessary assistance reasonably required for the purpose of regulatory activities with respect to the Products for and in the Territory, including designating specially-assigned person to discuss and make recommendations with respect to the regulatory strategies and plans regarding the Products, and to prepare and execute applicable letters of certification or authorizations that will facilitate or enable Licensee or its Designated Party to fulfill its regulatory obligations in the Territory; and

(j) upon Licensee's request, and subject to and as required by Applicable Laws, accord to Licensee authorization as its representative or agent in the Territory for purposes of Regulatory Approval activities.

To avoid any doubt, the salaries, labor costs, managerial costs and other costs related to the employment of engineers or other personnel designated by the Licensor in order to fulfill its obligation under this article shall be borne by the Licensor. For the avoidance of doubt, the costs to be incurred inside or outside of the Territory for the purpose of Regulatory Approval by the FDA or by other Regulatory Authorities outside of the Territory for sale outside the Territory under the OEM Manufacturing undertaken by Licensee for Licensor, or for other markets outside the Territory, shall be borne by the Licensor to the extent they exceed the costs required to meet manufacturing requirement for NMPA Approval, CE mark and compliance with GMP which are regarded as ordinary costs applicable to other products of the Licensee in these markets, and shall be subject to a separate written agreement between the Parties.

5.3 Rights of Reference

Licensor hereby grants, at no cost, to the Licensee and sub-licensees (subject to Article 2.3) the right to use, cross-reference, file or incorporate by reference all Regulatory Materials and Required Information pertaining to the Product submitted by or on behalf of the Licensor and all Data Controlled by Licensor relevant or useful for Regulatory Approval in the Territory. Licensee and sub-licensees (subject to Article 2.3) may use such rights of reference solely for the purpose of seeking, obtaining and maintaining Regulatory Approval and Commercializing the Product in the Territory and otherwise performing under this Agreement, including to support any regulatory filings relating to the Product in the Territory and in interactions with any Regulatory Authority in connection with Localization or Commercialization of the Product in the Territory (collectively, the "**Permitted Purposes**"). In addition, Licensor hereby grants to Licensee and its Affiliates and sub-licensees (subject to Article 2.3) the right, solely for the Permitted Purposes, to use, cross-reference, file or incorporate by reference all Required Information related to the Products to the extent such Required Information is Controlled by Licensor and its Affiliates.

5.4 Adverse Event Reporting and Safety Data Exchange

(a) Under the Importation Paradigm, the Licensor shall be the responsible party for the applicable post marketing surveillance and vigilance obligation of the Imported Products in the Territory, in all cases with assistance from Licensee, and to the extent permitted by and subject to the Applicable Law, Licensee shall act as Licensor's authorized Person (i.e. the domestic agent of Licensor) to implement specific vigilance obligations with respect to the Imported Products in the Territory in accordance with the Applicable Law and this Agreement. For the avoidance of doubt, Licensor shall be responsible for Products' post marketing surveillance and vigilance activities, including maintaining the global and local safety database for the Products, at Licensor's expense, and Licensee shall be responsible for Imported Products vigilance activities as reasonably requested by Licensor, subject to Applicable Law and this Agreement, in the Territory at Licensor's expense. Each Party shall bear its own Personnel expenses in the manner provided for in the last paragraph of Article 4.6. Licensor shall be responsible to, upon Licensee's request, for the purpose of compliance with Applicable Law, promptly provide relevant information on Imported Product vigilance, vigilance training and risk analysis reporting, and relevant post approval development or regulatory data with respect to the Imported Product, in each case in a timely manner in accordance with the Applicable Law and requirements of Regulatory Authorities. Furthermore, Licensor will bear all costs of post-marketing surveillance for the Imported Products required by Applicable Laws in the Territory. To the extent required under and in accordance with this Agreement and Applicable Law, Licensee shall also be responsible for reporting adverse events and safety data related to the Imported Products to Licensor for inclusion in the global safety database and Licensor shall be responsible for reporting adverse events and safety data related to the Imported Products out of the Territory to Licensee for Licensee's information upon the occurrence of such adverse events. Licensor shall be responsible for global vigilance risk management with respect to the Imported Product, and shall promptly notify Licensee in writing of any change in Imported Product safety risk characteristics, or Imported Product recall due to safety reasons, etc., and perform its due diligence as the holder of Regulatory Approval of the Imported Products. Each Party hereby agrees to comply with its respective obligations under this Agreement and to cause its Affiliates to comply with such obligations.

For those costs arising out of adverse events and recall which are caused by or arise out of the quality of the Imported Products as supplied by Licensor, Licensor shall bear such costs incurred. For those costs arising out of adverse events and recall which are caused by the acts or omissions of Licensee, Licensee shall bear such costs incurred.

(b) Under the Localization Paradigm, the Licensee shall be the responsible party for the applicable post marketing surveillance and vigilance obligation of the Domestic Products in the Territory. For the avoidance of doubt, Licensee shall be responsible for Products' post marketing surveillance and vigilance activities, including maintaining local safety database for the Products, at Licensee's expense. Licensee will bear all costs of post-marketing surveillance for the Domestic Products required by Applicable Laws in the Territory. As the holder of Regulatory Approval of the Domestic Products, Licensee shall also be responsible for reporting adverse events to Regulatory Authority and implement product recall of the Domestic Products as required by the Applicable Law. Licensee will provide data on adverse events, and safety data related information, for the Domestic Products to Licensor for inclusion in the global safety database if Licensee deems it necessary. Licensor shall be responsible for global vigilance risk management with respect to the Product and shall promptly notify Licensee in writing of any change in Product safety risk characteristics, or any Product recall due to safety reasons, etc. in and out of the Territory. Each Party hereby agrees to comply with its respective obligations under this Agreement, to cause its Affiliates and subcontractors to comply with such obligations, and to collaborate to ensure Product safety and regulatory compliance.

For those costs arising out of adverse events and recall which arise out of or relate to the Manufacturing of the Domestic Products as supplied by Licensee, Licensee shall bear such costs incurred.

5.5 Availability for On-site Inspection

If the Regulatory Authority in the Territory (such as NMPA) requests an on-site inspection on the Regulatory Materials and Required Information Controlled by the Licensor or with respect to the manufacturing of the Imported Products, the Licensee will notify (except such requests are given to the Licensor or its designated party) Licensor in advance together with the relevant official notice from competent Regulatory Authority and Licensor shall use Commercially Reasonable Efforts to coordinate with Licensee in preparing for such official on-site inspection at Licensor's cost and expense, including allowing Licensee to carry out a preparatory inspection, and ensuring the Regulatory Materials and Required Information be kept properly and made available to such official on-site inspection, and providing access to such officials for on-site inspection of the manufacturing of the Imported Products.

5.6 Changes to Imported Products

Licensor shall promptly inform Licensee of any plan regarding changes to Imported Products, including but not limited to place of Manufacture, suppliers, software updates, manufacturing quality system, materials, structures, specifications, technical requirements and standards, and/or any other potential changes which may have an impact on the Regulatory Approval of the Products.

For those changes that will lead to changes of items registered as part of the Regulatory Approval (attached as Exhibit I), Licensor shall not make such changes unless it has informed Licensor in writing, as soon as practicable so that Licensee can proceed with the change of registered items subject to Regulatory Approval for the Products. If any such changes are proposed by Licensor as a result of factors outside Licensor's control (e.g., change in components due to a supplier no longer providing a component), or if improvements to a Product are proposed by Licensor, then the Parties will confer to determine the most appropriate solution to the issue. If such changes are to take place before the obtaining of Regulatory Approval of Imported Products, Licensee shall be notified no less than 18 months prior to such change (or Licensor, if feasible, may continue to provide an unchanged version of the Imported Product), and if such changes are to take place after the obtaining of Regulatory Approval of Imported Products Licensee shall be notified no less than 12 months prior to such change, subject to the same efforts by the Parties to find the best solution. The Parties will meet and confer with respect to any such changes for which it was not possible to give the afore-mentioned term of prior notice. For those changes that will not lead to changes of registered items subject to Regulatory Approval, Licensor shall inform Licensee as soon as practicable.

ARTICLE 6
COMMERCIALIZATION

6.1 Overview

Subject to the terms and conditions of this Agreement, Licensee will have the right to exclusively Commercialize the Products (including Imported Products and Domestic Products and their components) in the Field in the Territory in its own or Designated Parties' name with full control and discretion over all aspects of the Commercialization of Products in the Field in the Territory through either online or offline sales channels in compliance with the Applicable Laws, including without limitation with respect to each Product:

(a) developing and executing a commercial launch,

(b) negotiating with applicable Governmental Authorities regarding product pricing and reimbursement status in connection with the use of the Products;

(c) marketing, advertising, promotion, tendering, bidding and hospital listing;

(d) participating in Government Centralized Procurement activities;

(e) booking sales, distribution and performance of related services (logistics, storage, training, etc.);

(f) handling all aspects of order processing, invoicing and collection, inventory and receivables;

(g) determining pricing and terms of sale of Products;

(h) providing customer support, including handling medical queries, and performing other related functions; and

(i) conforming its practices and procedures to Applicable Laws relating to the marketing, distribution and promotion of the Products in the Field in the Territory.

Licensee shall bear all of the costs and expenses incurred in connection with such Commercialization activities. Licensee shall develop all the promotional materials to be used in conjunction with the Commercialization of Products in the Field in the Territory in compliance with Applicable Laws, consistent with the safety and efficacy data supplied by Licensor, and Licensee shall reasonably consider Licensor's suggestion and comments with respect to the promotional materials and shall comply with the provisions of Article 9.7 with respect to Product Marks. For avoidance of doubt, but subject to Article 9.7, Licensee has the full and sole discretion in determining the promotional materials and shall therefor bear sole liability for the content of the same.

6.2 Bidding

Licensee shall be responsible and have full decision-making power for conducting bidding activities for all Products in the Field in the Territory in its own or the Designated Parties' name. Licensee shall reasonably consider Licensor's comments with respect to Licensee's or its Designated Parties' bidding activities for all Products in the Territory. To facilitate the performance of bidding activities by Licensee in the Territory, Licensor shall provide reasonable assistance, including executing applicable letters of certification, authorization or other binding legal documents in an appropriate form as requested by Licensee.

6.3 Licensor's assistance

(a) Upon reasonable request of the Licensee, Licensor shall provide, provide access to, and grant rights to use and/or reference, at no cost to the Licensee, all data, books, records, dossiers, commercial and medical information, and other necessary information specifically required for the Commercialization of the Products in the Territory and provided the same is available to or under the Control of the Licensor and within the limits of any Applicable Law. Upon Licensee's request and subject to Article 4.2, Licensor shall prepare and execute applicable letters of certification or authorization or other applicable legal documents that will facilitate or enable Licensee or its Designated Party to Localize and Commercialize the Products in the Field in the Territory**.**

(b) Upon Licensee's reasonable request, Licensor shall fully cooperate with Licensee for marketing activities in the Territory. Licensor shall share with Licensee, at no cost, the experts' data regarding the Products and other documents as listed in Exhibit N hereof. Under the management of Licensee, Licensor shall assist Licensee to conduct certain marketing activities in the Territory, including without limitation, to participate in marketing events, to carry out conference promotions, doctor training, etc., however always subject to mutual agreement between the Parties with regard to all related practical matters and it being understood that all costs to be undertaken in relation to such cooperation and activities shall be borne by Licensee.

(c) The Licensee shall maintain such sales and distribution Personnel and facilities as are appropriate to and sufficient for the Commercialization of the Products. The Licensee will independently hire sales teams.

(d) To avoid any doubt, the salaries, labor costs, managerial costs and other costs of employment of engineers or other Personnel of or designated by the Licensor to fulfill its obligation under this article shall be borne by the Licensor, while Licensee will pay reasonable travel and related costs that are incurred within the Territory, and pay for pre-approved international travel costs.

6.4 Market Development and Promotion in the Territory

The Parties shall make their Commercially Reasonable Efforts to work together to maximize the benefits of Localization, registration and Commercialization activities with respect to the Product in the Territory, with the supply price stipulated in EXHIBIT C. Licensor shall provide the details of such prices as well as the supporting documentation (as requested) related to such costs to Licensee for Licensee's review. With respect to any supply price specified herein as "at cost" or "cost plus" a margin, Licensee shall have the right, no more frequently than once each year, and subject confidentiality undertakings, to commission a mutually acceptable, reputable, third-party auditor to audit such costs and calculations in accordance with GAAP.

Promotional sales shall be held during periods set by Applicable Laws (if any) and/or usual business practices in the PRC. The Licensee shall have the sole discretion in carrying out any promotional sales plans.

The Licensee shall, at all times during the term of this Agreement, identify itself, in all commercial documents relating to the Products, as the authorized and independent distributor, acting in its own name and for its own account for the distribution of the Products.

The Licensee shall not, in any manner (i) pledge the credit of Licensor; (ii) represent itself as an agent of Licensor for any purpose other than identifying itself as the distributor under this Agreement, except that the Licensee or its Designated Party will act as entrusted domestic agent under the Importation Paradigm as specified in Article 5.1(b); (iii) receive any money on behalf of Licensor; (iv) make any contract or commitment on behalf of Licensor; or (v) make any warranty or representation regarding the Imported Products other than such warranties or representations as are authorized by Licensor in writing or are required by any applicable law in the PRC. Licensee shall provide written copies of any representation or warranty required by Applicable Law to Licensor promptly upon such representation or warranty becoming a requirement.

In addition to medical treatment purpose, and only as a means to promote the Commercialization of the Products, the Licensee is entitled to Commercialize the Products for scientific research and development purposes in the Territory or for other special purpose otherwise permissible under PRC law and communicated to Licensor, including but not limited to the Commercialization in Hainan. Licensor shall provide all necessary assistance at the cost of Licensee for such Imported Products and make relevant mentions in the labelling to identify such Imported Products as medical devices to be used for scientific research or development purposes only.

6.5 No existing business in the Territory

The Licensor confirms that neither itself nor any of its Affiliates has any existing business regarding the Products in the Territory at time of execution of this Agreement.

6.6 Promotion of the Imported Products

Given that the form and manner of the Commercialization of the Imported Products is left entirely to the discretion of Licensee, Licensee agrees to make Commercially Reasonable Efforts to launch and maintain commercial sales of Peripheral Products in the Territory before the Domestic Products have obtained Regulatory Approval in the corresponding Territory.

ARTICLE 7
MANUFACTURE AND SUPPLY

7.1 Supply Terms Importation Paradigm

(a) **Supply Terms Importation Paradigm.**

Subject to the terms and conditions set forth in this Agreement, Licensor shall have the sole right and obligation to Manufacture and supply the Imported Products for the Territory, and shall act as the Market Authorization holder for the Imported Products and, with assistance from Licensee, comply with Applicable Laws including without limitation the *Regulations on Supervision and Administration of Medical Devices* ("**Importation Paradigm**"). Under the Importation Paradigm, Licensor shall bear liabilities under the Applicable Law in relation to the quality of the Imported Products supplied by Licensor. Licensee shall, or shall cause the Designated Party to, purchase the finished Imported Products including its Imported Products Consumables exclusively from the Licensor and the Licensor shall supply the finished Imported Products, including the Imported Products Consumables, exclusively to Licensee against fixed prices (as defined in accordance with Exhibit C, the applicable price shall be referred to as "**Supply Price**"). The Parties agree on a [***] lead time for any order of Imported Products within 10% of the Rolling Forecast provided by Licensee. Licensor commits to ensure a sufficient manufacturing capacity to satisfy the expected demand of the Territory (as provided by Licensee in the Rolling Forecast) with [***] lead time, and in case of any situation that might affect the supply of Imported Products, Licensor shall communicate with Licensee without delay. Licensee shall pay for each order of Imported Products as per the payment schedule of the corresponding Purchase Order, in USD by bank wire transfer to such bank account opened in Licensor's name at a bank located in the USA as is designated in writing by Licensor (from time to time upon at least thirty (30) days' prior written notice). Upon receiving and acceptance of Licensee's order for Imported Products, the Licensor shall invoice 25% of the total price of the order to the Licensee. The payment term shall be thirty (30) calendar days as from the invoice issuance date, it being understood that the order will only be confirmed and the [***] lead time will only start when the payment of the invoice for 25% of the total price of the order has been received. The Licensor shall make sure that the Supply Price complies with the price requirements stipulated in this Agreement. Under Importation Paradigm and before the obtaining of Market Authorization in the Territory, Licensor shall make sure that the Supply Price (including the Imported Product, prototypes, and components, in each case limited to that which is required to be used for Regulatory Approval and Market Authorization purposes) shall be based on the actual production cost prices, with no commercial mark-up. After obtaining Market Authorization in the Territory, the Supply Price shall be based on the actual production cost prices with a fixed markup of [***]% (see Exhibit C). However, such fixed markup of [***]% will not apply to the Supply Price of those Products supplied to Licensee which are actually manufactured and supplied to Licensor by Licensee under the OEM mode. Under the business mode afore-mentioned, Licensor shall make sure that the Supply Price shall be based on the actual production cost prices, with no commercial mark-up, provided that any additional Licensor production costs with respect to such Products supplied by Licensee shall be subject to the [***]% fixed markup, and further provided that the Parties shall agree on the transfer pricing and other financial components of such import/export transactions to provide the best outcome for both Parties.

Licensor shall compensate Licensee for all direct losses that Licensee may suffer if:

- Licensor unilaterally increases the Supply Price other than for an increase in costs;

- Licensor fails to supply the Imported Products at the Supply Price and in the agreed quantity (i.e., within 10% of the amounts provided by Licensee in the Rolling Forecast) of the Imported Products within [***] lead time after Licensee won a bid for Government Centralized Procurement or other public procurements.

If Licensor unilaterally increases the Supply Price for an increase in costs, it shall be subject to the following conditions:

- Licensor shall inform Licensee at least four (4) months in advance of such increase of Supply Price;

- Licensor shall provide supporting documents justifying such price increase to the reasonable satisfaction of Licensee; and

- Such increase of Supply Price shall be proposed by Licensor no more than once in a calendar year.

If due to the Government Centralized Procurement, the price to be offered is significantly lowered, Licensee has the right to renegotiate the Supply Price with the Licensor, but Licensor shall not be obligated to accept a different Supply Price than that provided for in this Agreement.

(b) **Localization Paradigm.**

The Parties confirm that Importation Paradigm is the transitional arrangement between the Parties and the Parties shall exercise Commercially Reasonable Efforts to achieve the Localization Paradigm according to the time schedule of Localization Paradigm set forth in Exhibit K. Under the Localization Paradigm, the Licensee or the Designated Parties (subject to Article 2.3) shall be the manufacturer of the Domestic Products. The Parties shall enter into a separate agreement governing the specific terms of such OEM Manufacture and supply arrangement.

The Licensor shall provide Licensor Know-how, and the technical data (including but not limited to technical data of product Development, Manufacture, testing and packaging, and relevant quality management system documents, records, documentations and information) to Licensee for the purpose of Manufacturing of the Domestic Products within 2 months of execution of this Agreement. The hand-over list of Licensor Know-how and technical data is listed in Exhibit D and the listed items shall all be provided within the afore-mentioned term of two (2) months. Among such documents, Licensor shall provide Licensee with Information regarding maintenance of the Products, including without limitation the following:

- list of spare parts used for maintenance with clarification of whether such spare parts are procured by Licensor or through third party suppliers and relevant information of such third-party suppliers. Licensor shall make sure that there are sufficient stocks of such spare parts, and share its own stock of such spare parts with Licensee.

Under the Localization Paradigm, the Licensor shall use Commercially Reasonable Efforts to perform all the necessary activities and provide all necessary assistance and resources as required by the Applicable Law and applicable Regulatory Authority to assist Licensee in procuring the Manufacturing of Domestic Products in the Territory lawfully and smoothly conducted and processed by Licensee as legally qualified for such Manufacturing in the Territory, including the technical assistance and on-site personal support for building up the production line and Manufacturing of the Domestic Products in accordance with the Licensor Know-how and applicable GMP until Licensee has obtained the Regulatory Approvals of the Domestic Products in the Territory and the First Commercial Sale of Domestic Products by Licensee in the Territory. Licensor is entitled to rely on Licensee's good faith continuation of Commercially Reasonable Efforts to Commercialize the Imported Products during the course of the Parties' efforts to achieve Localization.

Licensee is entitled to purchase components by itself or through its Designated Party from other qualified suppliers. If the Licensee decides to purchase components from the suppliers of Licensor, the Licensor shall communicate the name and contact person of its suppliers. In case of change of suppliers, of potential software requirements, need to improve the production system of the Domestic Products, Licensee has the right to find alternative suppliers of the components as long as the technical requirements are consistent with the technical requirements of the Domestic Products. Licensor shall agree to provide necessary support regarding the update of its software and Licensee shall have the right to have access to the source code of the software of the Licensor in order to ensure compatibility with alternative components, always subject to the requirements of Applicable Law.

Under the Localization Paradigm, Licensee or its Designated Parties (subject to Article 2.3) shall be entitled and responsible for obtaining registration of the Domestic Product, Marketing Authorization and other Regulatory Approvals for the Manufacturing of Domestic Products in the Territory (as applicable), and its or their maintenance and re-registration, in Licensee's or its Designated Parties' name.

(c) **License Fee**

Licensee agrees to pay License Fee's to Licensor for Commercialization the Domestic Products. The License Fees, as well as applicable payment terms, are set out in Exhibit E.

7.2 Ordering of Imported Products

(a) Forecast and Lead Time

(1) Forecast and Lead Time of Imported Product

Licensee acknowledges that the average lead time for the manufacturing of the Imported Products (including Imported Products Consumables) is [***] ("**Lead Time**"). Licensee will provide its Rolling Forecast to Licensor no less frequently than at the end of each calendar quarter.

(2) Spare Parts Without Forecast

The Parties acknowledge that there will not be any Rolling Forecast for the spare parts. Licensor shall share with Licensee inventory information and recommended inventory levels for the spare parts and shall inform Licensee in advance each time it orders spare parts from its suppliers so that Licensee can determine its order for spare parts needed.

(3) Forecast and Lead Time for Prototype, Sample and Imported Products for Clinical/Non-clinical Trial and Similar Use

The Parties agree that for the supply of prototypes or samples of Imported Products, and Imported Products for clinical/non-clinical trial or study or research use during the registration process for the Imported Products, its lead time shall be 2 month. Binding forecast of samples of Imported Products, and Imported Products for clinical/non-clinical use shall be ordered by Licensee according to the bidding forecast agreed between the Parties as set forth in Exhibit M, rather than the Rolling Forecast, which shall apply to ordinary (i.e., not prototype or sample) Purchase Orders.

Notwithstanding the above, the Parties agree that in order to speed up the registration process for the Imported Products, the first batch of prototypes and samples of Imported Products shall be supplied in accordance with the schedule attached in Exhibit K.

(b) **Contents of Purchase Orders.** Licensee shall, by itself or through its Designated Parties, deliver to Licensor purchase orders (each, a "**Purchase Order**") for Licensee's demand for quantities of the Imported Products at least [***] in advance. Unless the Parties agree otherwise in writing, Purchase Orders shall not vary more than 10% from the applicable Rolling Forecast. Each Purchase Order shall be in the form mutually agreed between the Parties from time to time, and shall include (i) the specifications of type and quantities of the Imported Products, (ii) shipping instructions and destination(s), and (iii) the desired delivery date(s). In the event that any term or condition of a Purchase Order is different from, or contrary to, the terms and conditions of this Agreement, the terms and conditions of this Agreement shall prevail.

(c) **Confirmation of Purchase Orders.** The Lead Time for the Imported Products is understood to be [***] Licensor shall confirm to Licensee or its Designated Party acceptance of all Purchase Orders in writing within seven (7) Business days after receipt of such Purchase Orders, provided that the Purchase Order is in accordance with the Lead Time, Rolling Forecast and other provisions of this Agreement. Upon confirmation by Licensor and payment of 25% of the total value of the order by Licensee, the Purchase Order shall become binding on both Parties and the Lead Time shall begin to run.

7.3 Delivery of Imported Products

(a) **Delivery against Purchase Orders.** Licensor shall be obliged to supply the ordered Imported Products by the delivery date as per the confirmed and accepted Purchase Order (including the Rolling Forecast requirements). The Imported Products shall be delivered in Licensor's standard packing and as per labelling requirements reasonably instructed in advance by Licensee. All expenses related to any special labelling and packaging requirements under the Applicable Law of the Territory shall be borne by Licensee, provided that Licensor shall inform Licensee of the cost and other relevant information regarding the service party that shall handle the labelling and packaging and authorize Licensee to communicate and check with that Third Party directly regarding the costs. Prior written consent of the Licensee to such arrangements is required. Should Licensor for any reason be unable or expect that it will be unable to deliver the Imported Products as per the delivery schedule set forth in the confirmed and accepted Purchase Order, Licensor shall inform Licensee (or its Designated Party) of such delay in delivery at least fifteen (15) Business Days in advance of delivery date. In principle, Shortfall (which means the amount by which the quantity of Imported Products actually delivered to Licensee or its Designated Party pursuant to a confirmed and accepted Purchase Order agreed between the Parties is less than the quantity set out in that Purchase Order, the "**Shortfall**") is not acceptable. In case any Shortfall occurs or is expected to occur in Licensor's best judgment, for example, due to special circumstances, Licensor shall promptly notify Licensee of the details of such Shortfall, and the relevant Imported Products covered by such Purchase Order shall only be delivered upon Licensee's written consent. In case of late delivery of the Imported Products by the Licensor, unless otherwise agreed in advance by Licensee, this will lead to application of late delivery penalty at the rate of 0.05% of the value of the delayed products per day of delay.

(b) **Incoterms.** The delivery, title transfer and risk of loss with respect to the ordered Imported Products under this Agreement are agreed to be Ex Works pursuant to Incoterms 2020 (see Exhibit C), except as otherwise agreed by Parties in writing. Each shipment shall be accompanied by the following documentation: (i) a Certificate of Analysis with respect to each batch of Imported Products contained in such shipment; (ii) a relevant Purchase Order in the form mutually agreed between the Parties; (iii) a commercial invoice; (iv) a packing list detailing the contents of the delivery; (v) an air/sea waybill evidencing the agreement for the carriage of the Imported Products which shall be provided in pro forma fashion a minimum of 1 month in advance of dispatch; (vi) product inspection/testing certificates; and (v) any other documentation as informed in advance by Licensee and agreed to by Licensor to the extent reasonably necessary for import and acceptance of the Imported Products.

(c) **Formalities.** Licensee shall be responsible for and bear all related expenses for obtaining all applicable licenses, permits, and approvals necessary for transporting and importing the Imported Products ordered under this Agreement into the Territory, and Licensor shall, as reasonably required by Licensee in advance, also timely provide Licensee with the necessary documents and assistances for facilitating the process of transportation and importation of the Imported Products into the Territory.

7.4 Inspection, Acceptance and Return of Imported Products

(a) **Inspection and Acceptance.** Licensee shall, within fifteen (15) Business Days of the arrival of the Imported Products, by itself or cause its Designated Party to conduct incoming inspection and analysis of the ordered Imported Products to confirm if they conform to the specifications provided by Licensor or have any visible defects, and either accept the Imported Products or send a written notice ("**Defect Notice**") to Licensor should it determines that the ordered Imported Products do not conform to the specifications or have any visible defects, along with a copy of its analysis report. (For the avoidance of doubt, Licensee shall be solely responsible for resolving any issues related to damage to Imported Products during shipping or storage.) If after inspection and analysis of such non-conforming or defective Imported Products by or for Licensor, or waiver of its right to inspect, Licensor determines that the defects or non-conformance mentioned in the Defect Notice are present (if the defect is caused by Licensor's fault, Licensor shall accept such Defect Notice), then Licensor shall, at Licensor's option, i) replace the non-conforming Imported Products without any charges to Licensee or its Designated Party as applicable within one (1) month from the date of acceptance of Defect Notice by Licensor or ii) reduce the invoiced amount to Licensee or its Designated Party as applicable or return or credit the amount paid by Licensee or its Designated Party for the non-conforming or defective Imported Products, and Licensor shall be obliged to correct its manufacturing process in order to avoid further defects or non-conformance of Imported Products due to the same reason, if possible, before the next delivery, and if not possible, it may delay deliver to correct such shipment, however Licensee still is entitled to claim penalty for late delivery at the rate of 0.05% of the value of the delayed products per day of delay. At Licensor's option, it may in writing instruct Licensee or its Designated Party to destroy (at the cost of Licensor) or return (to the extent permitted by the Applicable Law) the non-conforming and/or defective Imported Products. In the event of returning non-conforming or defective Imported Products, Licensor shall reimburse relevant re-shipping charges to Licensee or its Designated Party.

The inspection and/or acceptance of the Imported Products by the Licensee does not exempt or diminish the regulatory obligations of the Licensor under this Agreement to provide the Imported Products in compliance with the terms and conditions between the Parties under this Agreement and the Quality Agreement attached as Exhibit J.

(b) **Disagreement with the Inspection Results.** In the event Licensor does not accept the Defect Notice, Licensee shall submit the sample retained by itself or its Designated Party to a competent inspection institution acknowledged by applicable Regulatory Authority and agreed to by Licensor (which agreement shall not be unreasonably withheld, conditioned, or delayed), whose adjudication as to whether the Imported Products conforms to the specifications or not shall be final and binding on the Parties provided that a reasoned written report citing test results or other competent evidence supports such adjudication. The report and findings shall address and quantify the quantity or pervasiveness of the defect rate within the shipment (or non-conformance rate) or provide reasoned analysis for why such issue is not specifically addressed (such as visual confirmation of pervasive non-conformance or defects). The expenses incurred for such independent competent institution determination shall be borne by the Party against whom the findings are made. If the said institution finds the Imported Products do not conform to the specifications and/or the defects are due to Licensor's fault, Licensor shall, at Licensee's option, i) replace the same without any charges to Licensee or its Designated Party within one (1) month from the date of report by the institution or ii) reduce the invoiced amount to Licensee or its Designated Party or return or credit the amount paid by Licensee or its Designated Party for the non-conforming or defective Imported Products. At Licensor's option, it may instruct Licensee or its Designated Party to destroy (at the cost of Licensor) or return (to the extent permitted by the Applicable Law) the non-conforming and/or defective Imported. In the event of returning non-conforming Imported Products, Licensor shall reimburse freight charges incurred by Licensee or its Designated Party in connection with such re-shipment.

7.5 Quality Control

(a) **Quality Agreement**

Licensor warrants to the Licensee that the Imported Products it supplies or will be supplied in compliance with Applicable Laws, Regulatory Approvals, applicable GMP, GSP, specifications, minimum remaining shelf-life requirements, quality certificate, instructions for use, labels and other documents required and agreed by Licensor and Licensee, other covenants and requirements under this Agreement and standards applicable to the Imported Products. The Manufacture of Imported Products shall comply with Applicable Law, Regulatory Approvals of the Imported Products and relevant requirements of competent Regulatory Authorities. Licensee or its Designated Affiliates and Licensor agree that they will prepare and sign a Quality Agreement to be attached as Exhibit J regarding the quality control of the Manufacture of Imported Products in order to comply with the PRC law, and such Quality Agreement will be signed after obtaining the Regulatory Approval regarding the Imported Products. However, depending on changes and updates to Applicable Laws of the Territory, the Parties may further discuss in good faith, and agree to modify the Quality Agreement so that the commercial supply and distribution of the Imported Products in the Territory is in accordance with then effective Applicable Law.

(b) **Maintenance and Retention of Records**

Both Parties shall maintain detailed records with respect to the Imported Products in accordance with the Quality Agreement and Applicable Laws.

7.6 Recall

(a) Under Importation Paradigm in case of any recalls as required under the Applicable Laws and Regulations, the Licensor shall at its own expense, and pursuant to the consultations with Licensee, recall the Imported Products within the Territory, while Licensee shall fulfill its obligations as the designated agent of Licensor of the Imported Products in the Territory in accordance with Applicable Laws and this Agreement to carry out such recall on behalf of Licensor. If the recall is due to improper storage or handling of the Imported Products by, or other acts or omissions of, Licensee or its distributors, the recall obligations shall be performed at Licensee's expense. In all other cases, the Licensor shall compensate the Licensee for all the costs and expenses incurred by the Licensee during the recall under Importation Paradigm, including but not limited to costs of return of the recalled Imported Product to the Licensor (if applicable), cost of refund of the supply price of the recalled Imported Product paid by Licensee, costs related to preparation and submission of recall analysis forms, implementation of the recall plan, any required recall investigation and assessment, recall completion report, etc., and compensate all damages and/or administrative penalties that Licensee may suffer due to the claim of a Third Party and/or Regulatory Authority regarding the recalled Imported Product. Licensor shall promptly provide Information to Licensee regarding the defect of the Imported Product that is the cause of such recall and assist Licensee to carry out the recall at the expense of the Licensor.

(b) Under Localization Paradigm and in case of any circumstances of recalls as required under the Applicable Laws and Regulations, the Licensee shall at its own expense recall the Domestic Products within the Territory.

(c) **Joint Statement with respect to Recall.** Following the decision to implement a Product recall, the Parties shall mutually agree on a prepared statement for use in response to any inquiries regarding such recall.

7.7 Technical Service and Maintenance

(a) **General**

(1) Under the Importation Paradigm, the Licensee is generally in charge of after sales service for the Imported Products in the Territory ("**Imported Products After-sale Services**"), parts incurred thereof are at its own cost, provided that (i) Licensor shall supply parts according to mutually agreed Spare Parts Price List and, (ii) the warranty period of the Imported Products shall be 12 months commencing from the earlier of when the Imported Products are first used in the field by Licensee on a portable basis or have been installed at or delivered to (in case installation is not required) the end-user after a successful installation or delivery report is issued, while the warranty period for the spare parts shall be 12 months commencing from when the spare parts have been accepted by Licensee, and (iii) for those Imported Products or spare parts which are defective upon receipt, such Imported Products or spare parts shall be returned to or replaced by the Licensor at the cost of Licensor; and (iv) upon Licensee's reasonable request, Licensor shall provide necessary and timely technical training and support to Licensee, free of charge (exclusive of reasonable travel and related costs that are incurred within the Territory, which shall be paid by Licensee, along with any pre-approved international travel costs), with respect to Imported Products After-sale Services. The terms and conditions that shall apply during the Warranty Period are defined in Article 7.9.

(2) Under the Localization Paradigm, the Licensee is fully responsible for the after sales service for the Domestic Products in the Territory ("**Domestic Products After-sale Services**"), including parts and labour costs incurred with respect thereto, all at its own cost. If the components are supplied from suppliers of the Licensor, the Licensor should provide the Licensee with the detailed information regarding the relevant suppliers of the components and the Licensee will contact and interface with that supplier by itself. Upon Licensee's reasonable request, Licensor shall provide necessary and timely technical training and support to Licensee, free of charge (exclusive of reasonable travel and related costs that are incurred within the Territory, which shall be paid by Licensee, along with any pre-approved international travel costs), with respect to Domestic Products After-sale Services. The terms and conditions that shall apply during the Warranty Period are defined in Article 7.9.

(b) **Licensor's Assistance**

(1) General Training Schedule

i. Training for Imported Products

Licensor shall train Licensee on the use (including using the software incorporated in the Imported Products), testing, acceptance and installation of the Imported Products.

Licensor shall also help Licensee to establish Imported Products After-sale Services (including maintenance, issuance of certifications for such Imported Products After-sale Services capacity, etc.) system as reasonably requested by the Licensee and help to train the Personnel of Licensee to the extent that they should be able work on their own in the provision of such Imported Products After-sales Services.

Licensor shall assist Licensee to build the capability described above for the Imported Products in the Territory, which shall include the following after-sale services:

- hotline service, including without limitation to response to customer complaints, to identify and preliminarily deal with any after-sale problems;

- repair service, which will be handled by replacements using spare parts or having door-to-door repair service by dispatching experts for repair while spare Imported Product is provided to the customer for use during the term of repair, and then swap back after the repair.

Licensor undertakes to assist Licensee to establish the Imported Products After-sale Services system for the Imported Products in the Territory. Licensor acknowledges that Licensee is the sole service provider of such Imported Products After-sales Services within the Territory, and that Licensee has the sole discretion regarding the service content, means and methods of providing service and charging amounts and methods based on its negotiation with end-users.

ii. Training for Domestic Products

Licensor shall train the personnel of the Licensee on the Manufacturing process for the Domestic Products on the basis of its process for Manufacturing Imported Products. In this process, Licensee shall be solely responsible for accounting for and training for any differences between its processes and Licensor's processes.

Licensor shall train the personnel of the Licensee on the use (including using the software incorporated in the Domestic Products as provided by Licensor before Localization), testing, acceptance and installation of the Domestic Products. Licensee shall be solely responsible for accounting for any differences between the software as provided by Licensor and the Localized software.

Licensor shall also train the Personnel of Licensee to the extent that they should be able to work on their own for all after-sales issues (including maintenance) with respect to the Domestic Products, provided that Licensor shall not be responsible for any differences between the Domestic Products and the Imported Products or the impact of such differences on the training of Licensee's Personnel.

Licensor shall assist Licensee to build the capability described above for the Domestic Products in the Territory, which shall include the following after-sale services:

- hotline service, including without limitation to response to customer complaints, to identify and preliminarily deal with any after-sale problems;

- repair service which will be handled by replacement using spare parts or having door-to-door repair service by dispatching experts for repair while spare Domestic Product is provided to the customer for use during the term of repair, and then swap back after the repair.

Licensor undertakes to assist Licensee to establish the Domestic Products After-sale Services system for the Domestic Products in the Territory. Licensor acknowledges that Licensee is the sole service provider of such Domestic Products After-sales Services within the Territory, and that Licensee has the sole discretion regarding the service content, means and methods of providing service and charging amounts and methods based on its negotiation with end-users.

For the purpose of training for Imported Products and training for Domestic Products as mentioned above, Licensor shall agree to provide training to the Licensee at the reasonable frequency and training course quarterly as requested by the Licensee.

Any travel or related costs associated with the training and assistance described above shall be paid by Licensee.

(2) Software Upgrade Training

In case of upgrading of the software contained in the Imported Products or Domestic Products, Licensor shall provide training to the Licensee at the expense of the Licensor so that the Licensee can independently operate such software, subject to the limitation that training for Localized software will be limited in scope to the same training provided for Imported Products software (i.e., before Localization), unless the Parties otherwise agree in writing.

To avoid any doubt, the salaries, labor costs, managerial costs and other costs of employment of engineers or other Personnel of or designated by the Licensor to fullfil its obligation under this article shall be borne by the Licensor.

7.8 **Training and Certification.** Subject to Article 7.7(b) Licensor shall provide periodic comprehensive training and certification courses upon reasonable request by Licensee.

7.9 **Warranty.** Licensor warrants to the Licensee that all Imported Products supplied hereunder shall comply with quality standard as defined in Article 7.5(a) of this Agreement. For Imported Products a 12 months' warranty from the earlier of the date when the Imported Product is first used in the field by Licensee on a portable basis or properly installed at the end user (or delivered if no installation is required) with successful installation or delivery report applies **("Warranty Period")**. The Warranty shall only apply provided the Imported Product was properly installed and was used by a duly trained medical professional under normal circumstances and in accordance with Licensor's instructions. If any of the Products sold to the Licensee do not comply with such warranty (whether by reason of defective materials, production faults or otherwise) Licensor shall, at its election, (i) replace the Imported Products in question without any charge to Licensee; or (ii) refund the prices of the Imported Products in question (if already paid). Further conditions for warranty are defined in Exhibit A.

ARTICLE 8
FINANCIAL TERMS

8.1 Invoices. Any payment to be made by Licensee in accordance with this Agreement, shall be after receipt from Licensor of an invoice, proforma or actual, and Licensee shall pay such invoiced amount of money within the applicable timeframe.

8.2 Payment Method; Foreign Exchange. Unless otherwise mutually agreed by the Parties, all payments of Supply Price of Imported Products or License Fees due to Licensor hereunder shall be made in USD by wire transfer of immediately available funds into an account designated by Licensor within 30 days of the receipt of the invoices from the Licensor. For purposes of making Imported Products purchase price payments, the applicable supply price shall be converted by applicable rate of exchange from Chinese Yuan (RMB) to USD using the middle exchange rate published by European Central Bank on its official website (or any replacement source agreed to by the Parties which displays that rate) on the date 10 Business Days prior to the date of invoice. The payment of the License Fees shall be further subject to the agreement in Exhibit E.

8.3 Taxes and Other Charges. Unless otherwise specified herein, each of the Parties hereto shall be responsible for its own costs and expenses occurred in connection with this Agreement and the transactions contemplated hereby. All amounts of payment will exclude any tax. No Party may charge the other Party for payment of any taxes related to its net income, gross revenue, or similar taxes. Each Party shall be responsible for payment of value-added or sales taxes or the like in accordance with Applicable Law. For the avoidance of doubt, this means that Licensee shall generally be responsible for the payment of such taxes. Licensee shall also be responsible for the payment of duties, tariffs, import fees, excise fees, or any similar fees in connection with its importation, receipt, distribution, or other activities with respect to Products (including Product Consumables) and spare parts. Each Party agrees to reasonably assist the other Party in lawfully claiming exemptions from or minimizing payment of taxes and any deductions or withholdings, whether pursuant to double taxation laws, tax treaties or similar regimes or circumstances. Both Parties further agree that the above provisions are agreed in accordance with the relevant Applicable Laws of the US and the PRC (Mainland China, Hong Kong, Macau and Taiwan) regarding taxes currently in force on the Effective Date. If the Applicable Laws of the US or the PRC (Mainland China, Hong Kong, Macau and Taiwan) regarding taxes change during the Term, so as to substantially affect the economic interests of either Party, both Parties will further negotiate in good faith on a fair resolution of such tax issues.

ARTICLE 9
INTELLECTUAL PROPERTY MATTERS

9.1 Ownership of Data and Inventions

(a) **Licensee Data; License Grants.** Licensee shall solely own the Data generated from the Commercialization, Manufacturing and the Localization of the Products conducted by Licensee or its Affiliates, sublicensees or subcontractors.

Licensee hereby grants to Licensor a perpetual, irrevocable, worldwide (exclusive of the Territory), nonexclusive, fully paid up, royalty-free license to use such Data generated from the registration and Localization of the Imported Products for any legally permissible purpose and in any legally permissible manner, in each case as related to the Imported Products or their successor products or derivatives (however excluding Domestic Products or its successor products or derivatives, which should be subject to the succeeding paragraph). The Data Controlled by Licensor related to the Imported Products from or for the purpose of clinical trials shall be included in the Licensor Know-How that is licensed to Licensee under Article 2.1 and Article 2.2, subject to the limitations of those sections.

Licensee hereby grants to Licensor a worldwide (exclusive of the Territory), nonexclusive, fully paid up, royalty-free license to use such Data generated from the registration, Localization and Manufacturing of the Domestic Products for any legally permissible purpose and in any legally permissible manner, in each case as related to the Domestic Products or their successor products or derivatives. However, such license of Data regarding Domestic Products shall cease to be effective upon the termination of this Agreement in accordance with Article 13 hereof, and Licensor shall stop using such Data regarding Domestic Products upon the termination of this Agreement.

For the purpose of clarity, commercial data for the purpose of Commercialization of Imported Products and Domestic Products, such as distributor networks, sales allocation, biddings etc. in different provinces are not included in the above Data granted to Licensor.

(b) **Licensor Inventions; Licensor License Grant.** As between the Parties, Licensor shall solely own all Inventions (including all related Intellectual Property Rights) generated, invented, discovered, developed, made or otherwise created by Licensor or its Affiliates, or subcontractors. For clarity, all Inventions Controlled by Licensor required for Licensee to exercise its rights with respect to the Products, together with any Licensor Patents covering such Inventions in relation to the Products and included in the Licensor IP, are licensed to Licensee under Article 2.1 and Article 2.2, subject to the limitations of those sections.

(c) **Licensee Inventions**. As between the Parties, Licensee shall solely own the Intellectual Property Rights for the Inventions generated by it or on its behalf in the course of Localization related to specifications of the Domestic Products and the Localization related to the adaptation of the Imported Products for the purpose of the Commercialization of the Products only and strictly for the market in the Territory.

(d) **License to Licensor.** The Licensee hereby grants a license to Licensor for use outside of the Territory, under all Licensee's Intellectual Property Rights related to Inventions, know-how or any new or modified source code generated by Licensee in the course of registration and Localization of the Imported Products (including as described above in subsection (c)). This license is an irrevocable, worldwide (exclusive of the Territory), exclusive, fully paid up, royalty-free license to make, have made, use, and commercialize (including rights to sublicense through multiple tiers) the Imported Products and other products, including those related to, derived from, or similar to the Imported Products (however excluding Domestic Products or its successor products or derivatives, which should be subject to the succeeding paragraph).

The Licensee hereby grants a license to Licensor for use outside of the Territory, under all Licensee's Intellectual Property Rights related to Inventions, know-how or any new or modified source code generated by Licensee in the course of registration, Localization and Manufacturing of the Domestic Products (including as described above in subsection (c)). This license is an irrevocable, worldwide (exclusive of the Territory), exclusive, fully paid up, royalty-free license to make, have made, use, and commercialize (including rights to sublicense through multiple tiers) the Domestic Products and other products, including those related to, derived from, or similar to the Domestic Products. However, such license of Intellectual Property Rights regarding Domestic Products shall cease to be effective upon the termination of this Agreement in accordance with Article 13 hereof, and Licensor shall stop using such Intellectual Property Rights regarding Domestic Products upon the termination of this Agreement.

(e) **New Licensor Patents**. In the event Licensor or any of its Affiliates, or subcontractors, including their employees, agents and independent contractors, makes an Invention relating to the Products and Licensor files any new Licensor Patents in the Territory covering such Inventions relating to the Products, Licensor shall promptly disclose free of charge such Invention and such filed Licensor Patents in writing to Licensee provided that Licensee shall keep confidential such disclosed Invention and Licensee shall be entitled to use such new Licensor Patents only in the Territory and only regarding the Products in the Field. Such disclosure shall include all invention disclosures and other similar documents submitted to Licensor or its Affiliates, or subcontractors, or by their employees, agents or independent contractors describing any such Invention.

9.2 Update of Inventions and Licensor Know-how

Licensor may update and improve its Inventions and Licensor Know-how related to the Products on a regular basis, and shall provide such updates of Inventions and Licensor Know-how to Licensee on a quarterly basis provided that such updates or improvements have been put into service on Products on the US market, and grant such updated Inventions and Licensor Know-how to Licensee so as to make sure that Licensee has access to the most updated Inventions and Licensor Know-how related to the Product in the Territory, always subject to the limitations of Articles 2.1 and 2.2. Licensee shall not be required to pay any additional License Fee related to such updated Invention or Licensor Know-how. Licensee shall keep confidential such disclosed updates and improvements of Licensor Inventions and Licensor Know-how provided to it. Licensee agrees that none of the information provided in application of the present Article 9.2 may be used by Licensee for a Licensee Invention, nor for any application for a Licensee Patent with regard to the Products as long as such information does not fall into the public domain and is not known by Licensee prior to the execution of this Agreement or is obtained or developed by Licensee itself, as demonstrated by contemporaneous written evidence.

9.3 Patent License Filing and Technology Import Registration. Both Parties agree that promptly after the conclusion of this Agreement, the license of Licensor Patents under this Agreement shall complete filing formalities in accordance with the *Circular on the Measures for the Filing of Patent Exploitation License Contracts*, the license of Product Marks as listed in Exhibit G shall complete filing formalities in accordance with the *Measures for Record-filing of Trademark License Contracts*, and the license of Licensor IP and Licensor Know-how shall complete technology import registration formalities in accordance with the *Measures for the Administration of Registration of the Contracts for Import or export of Technologies* at competent Governmental Authorities. This formality can be taken in the form of template contracts or summarized version instead of whole agreement for the purpose of confidentiality, if possible.

9.4 Patent Prosecution

(a) **Licensee Invention Patents**. Licensee shall have the first right, but not the obligation, to prepare, file, prosecute and maintain patents for Licensee Inventions in the Territory, including any related interference, re-issuance, re-examination and opposition proceedings with respect thereto. If Licensee fails to timely exercise such right, Licensor shall be permitted, but shall not have the obligation, to exercise such right on Licensee's behalf.

(b) **Licensor Patents**. Licensor shall have the sole right, but not the obligation, to prepare, file, prosecute and maintain Licensor Patents outside the Territory. Licensor shall be responsible for preparation, filing, prosecution, and maintenance of Licensor Patents which are necessary for Commercialization of the Products in the Territory during the Term of this Agreement. During the Term, Licensee shall cooperate, at Licensor's cost, in connection with the prosecution of any patent applications included within such Licensor Patents, including without limitation, periodically providing assistance and advice to Licensor regarding the status of applications, and all material steps and developments with regard to the preparation, filing, prosecution and maintenance of the Licensor Patents in the Territory.

(c) **Collaboration.** Each Party shall provide the other Party all reasonable assistance and cooperation in the patent prosecution efforts provided in this Article 9.4, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

9.5 Patent Enforcement

(a) **Notification Regarding Licensor Patents**. If Licensee becomes aware of any existing or threatened infringement of any Licensor Patent in the Territory ("**Infringement**"), it shall promptly notify Licensor in writing to that effect and the Parties will consult with each other regarding any actions to be taken with respect to such Infringement.

(b) **Licensor Patents Enforcement Rights.** Each Party shall share with the other Party all Information available to it regarding each alleged Infringement. Licensor shall have the sole right, but not the obligation, to bring an appropriate suit or other action against any person or entity engaged in such Infringement (including as part of any enforcement action against infringement of any Licensor Patent globally), at Licensor's cost and expense and subject to Licensor's control.

(c) **Licensee Invention Patents**. As between the Parties, Licensee shall have the first right, but not the obligation, to attempt to resolve any Third Party activity that infringes or threatens to infringe an Licensee Invention Patent, including the filing of an infringement suit to enforce the Licensee Invention Patent, at its own expense using counsel of its own choice.

9.6 Third Party Infringement Claims

(a) **Third Party IP Action**. During the Term, each Party shall promptly notify the other Party in writing upon becoming aware of any allegation by a Third Party that the Localization, Manufacture or Commercialization of any Products in the Field in the Territory infringes or misappropriates or may infringe or misappropriate the intellectual property rights (for the purpose of this Article 9.6 the such intellectual property rights include patents, inventions, trademarks, copyrights, domain names, databases, data, know-how, trade secrets and confidential information, and all other intellectual or industrial property and other proprietary rights) of such Third Party in the Territory (a "**Third Party IP Action**"). To the maximum extent permitted under Applicable Law, Licensor shall defend the Third Party IP Action, and unless otherwise agreed in writing by the Parties, Licensor shall have control of the defense of any such Third Party IP Action by counsel of its own choice; provided, however, that Licensor may not settle or compromise any Third Party IP Action, or knowingly take any other action in the course thereof, in a manner that materially adversely affects Licensee's rights or interests, without the written consent of Licensee (such consent not to be unreasonably withheld, conditioned or delayed). Licensor shall keep the Licensee reasonably informed of all material developments in connection with any Third Party IP Action. This Article 9.6 shall not be interpreted as placing on either Party a duty of inquiry regarding Third Party intellectual property rights. Licensor shall hold Licensee harmless from any damage that may be caused by Licensee due to the Third Party IP Action and indemnify Licensee of any losses that it may suffer due to the Third Party IP Action for the Localization, Manufacture or Commercialization of any Products by using the Licensor IP, so long as such use is within the scope permitted by the licenses granted by Licensor to Licensee hereunder.

9.7 Trademarks.

(a) **Product Mark**

(1) Licensor hereby grants, and Licensee hereby accepts, an exclusive and royalty-free license to use the Product Mark(s) solely for the purpose of Localization, registration, Manufacture and Commercialization of Products in the Territory.

(2) Under Importation Paradigm, the Licensee shall use the Product Mark(s) upon or in relation to or in connection with the Imported Products and in accordance with the directions and specifications given by Licensor from time to time. Licensee is also entitled to use Licensee's Product Mark(s) for Commercialization of the Imported Products in case of specific requirements of clients, as for example with respect to the need for translation into Chinese for certain clients and/or the Licensee will make reasonable efforts to allow for dual marking. Licensee is also entitled to use dual brands for the Commercialization of the Imported Products, while dual brands include both the brands of Avinger and Zylox-Tonbridge. In the afore-mentioned cases, Licensor agrees to change its instruction for use and labels to comply with the requirements of the Licensee it being understood that all costs relating to the same shall be borne by Licensee.

(3) Under Localization Paradigm, Licensee shall be entitled to register and maintain in its own or Designated Parties' name the applicable Licensee's Product Mark(s) for Commercialization of the Domestic Products in the Territory, and shall be entitled to determine whether to use the Product Mark(s) of the Licensor upon or in relation to or in connection with the Domestic Product and in accordance with the directions and specifications given by Licensor from time to time. If the Licensee decides to use the Product Mark(s) of the Licensor upon or in relation to or in connection with the Domestic Product, it shall be entitled to grant such use of Product Mark(s) to its entrusted manufacturer (if any) for the sole purpose of Manufacturing the Domestic Products.

(4) Licensee hereby covenants and undertakes that, during the Term and thereafter, (i) it shall not directly or indirectly use the Product Mark(s) in any manner whatsoever which may jeopardize the significance, distinctiveness or validity of the said Product Mark(s) and shall use the said Product Mark(s) in accordance with the terms of the Agreement; (ii) without prior written consent of Licensor, it shall not register or caused to be registered or use or permit the use of any mark or any combined mark or its Chinese transliteration which are identical or similar to the Product Mark(s) whether in relation to goods in the same class or in any other class.

(5) Licensee shall, and shall require that its Affiliates will, use the Product Marks solely in connection with the Localization and Commercialization of Products in the Field in the Territory. Licensor shall maintain the validity of the Product Marks registered or to be registered by Licensor in the Territory.

(6) **Cooperation**. Each Party shall provide to the other Party prompt written notice of any actual or threatened infringement of the Product Marks in the Territory and shall cooperate in good faith fully with the other Party with respect to any enforcement action or defense taken in connection with the same.

The Licensor shall have the sole right but not the obligation to manage and control the enforcement action or defense for any actual or threatened infringement of the Product Marks while the Licensee has the right to fully participate in any such action or proceeding and to retain its own counsel, at its own expense. In case the Licensor chooses not to manage and control the enforcement action or defense for any actual or threatened infringement of the Product Marks, the Licensee is entitled to take the initiative to carry out such enforcement action or defense on its own at its own expense and all the relevant damages shall belong to Licensee and the Licensor shall provide all support reasonably necessary for the Licensee at its request. However, if the Product Marks infringe the trademark of any third party in the Territory, Licensor shall manage and control the defense at the Licensor's own costs and the Licensee has the right to fully participate in any such action or proceeding at its own expenses. All goodwill and other value related to the Product Marks shall be the sole property of Licensor.

ARTICLE 10
REPRESENTATIONS AND WARRANTIES; COVENANTS

10.1 Mutual Representations and Warranties

Each Party hereby represents and warrants to the other Party as follows as of the Effective Date:

(a) **Corporate Existence**. It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated.

(b) **Corporate Power, Authority and Binding Agreement** . (i) It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and similar laws affecting creditors' rights and remedies generally.

10.2 Additional Representations and Warranties of Licensor

Except as would not have a material adverse effect on the rights or interests of Licensee under this Agreement, Licensor hereby represents and warrants to Licensee as follows as of the Effective Date:

(a) **Sole Ownership; Encumbrances.** It is the sole owner of, or otherwise has the right to grant the licenses granted to Licensee hereunder of, the Licensor IP existing as of the Effective Date.

(b) **No Conflicting Agreements.** Neither it nor, to its knowledge, any of its Affiliates has entered into any agreement or any other transaction with any Third Party or Affiliate that conflicts with Licensor’s undertakings under this Agreement or granted any right, interest or claim in or to, any Licensor IP that would conflict with the licenses to Licensee as purported to be granted pursuant to this Agreement.

(c) **No Assignment.** Other than security interests granted to the lenders under the Company’s Term Loan Agreement dated as of September 22, 2015, as amended, no matter whether or not such security interests granted to the lenders have been already subject to any pledge or mortgage registration with the China National Intellectual Property Administration or other competent authorities in the Territory in charge of pledge or mortgage registration of Licensor IP, it has not assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the Licensor IP existing as of the Effective Date in the Territory. The Parties acknowledge that the lenders and Licensee will contemporaneously with the execution of this Agreement enter into a “Non-Disturbance Agreement” to the satisfaction and sole benefits of the Licensee by which the lenders or any of their successors or other parties who are or will become directly or indirectly the beneficiary owner of the security interests described in this Section 10.2(c) or who are or will become directly or indirectly the beneficiary owner or the owner of the Licensor IP will ensure that Licensee’s rights under this Agreement are not curtailed by any foreclosure on the security interests described in this Section 10.2(c).

(d) **Notice of Infringement or Misappropriation.** Neither it nor, to its knowledge, any of its Affiliates has received any written notice from any Third Party asserting or alleging that the Localization, Manufacture, Commercialization or other Business related to the Imported Products or the practice of the Licensor IP in the Field in the Territory or in any other relevant jurisdiction, in connection with the Commercialization of the Imported Products, or the Domestic Products as they are anticipated to be Manufactured and Commercialized, would infringe, misappropriate or otherwise violate any intellectual property rights owned or controlled by a Third Party.

(e) **Compliance with Law.** Licensor and its Affiliates, and its subcontractors, and their respective consultants and agents, have conducted all research and development of the Imported Products for its registration in the Territory prior to the Effective Date in compliance with all Applicable Laws, including GCP as applicable. The development and manufacturing of the Imported Products by Licensor and/or its Affiliates or subcontractors comply with the Applicable Law at the place of the development and manufacturing of the Imported Products. And the Licensor IP as licensed to the Licensee hereunder constitutes all of the Intellectual Property used or held for use in the Business and is sufficient for the Licensee to, exclusive of applicable Regulatory Approvals, conduct the Business after the execution of Agreement in or for the Territory. Licensor shall inform Licensee in advance of any change of the Applicable Law at the place of manufacturing of the Imported Products which may be related to or have impact on the Regulatory Approval of the Imported Products in the Territory.

(f) **No Proceeding.** There is no pending, and, to its knowledge, no threatened, investigation, inquiry, action, suit or proceeding against Licensor or its Affiliates in the Territory involving the Imported Products or relating to the transactions contemplated by this Agreement.

10.3 Additional Representations and Warranties of Licensee

Except as would not have a material adverse effect on the rights or interests of Licensor under this Agreement, Licensee hereby represents and warrants to Licensor as follows as of the Effective Date:

(a) **No Conflicting Agreements.** Neither it nor, to its knowledge, any of its Affiliates has entered into any agreement or any other transaction with any Third Party or Affiliate that conflicts with its undertakings under this Agreement.

(b) **No Suits or Proceedings.** There are no suits, claims, or proceedings pending, or, to its knowledge, threatened against it or any of its Affiliates in any court or by or before any governmental body or agency which to its knowledge would have a material adverse effect on its ability to perform its obligations under this Agreement.

(c) **Requisite Approvals and Expertise.** It has, and will at all times throughout the Term have, the requisite approvals, permits, licenses, expertise, resources, experience and skill reasonably required to perform its obligations hereunder.

10.4 No Other Representations or Warranties

TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

10.5 Other Covenants

(a) **Regulatory Compliance.** Licensee shall comply with all Applicable Laws in the Territory, including without limitation those in relation to hygiene, safety, packaging, transportation, storage, sale, labeling, advertising, promotion, vigilance, recall, adverse event reporting of the Product, and protection of the environment.

(b) **Data Protection.** All data which may be obtained by Licensee shall be collected according to the Applicable Laws of the Territory, and the collection, storage and transmission of such data shall comply with the Applicable Laws of the Territory including without limitation those regarding data safety, health data protection, personal information protection.

(c) **Anti-corruption Compliance.** Licensee and its Affiliates and Designated Parties, including their directors, officers, employees, agents, agree to comply with all Applicable Laws with respect to anti-corruption in the Territory.

ARTICLE 11
INDEMNIFICATION

11.1 Indemnification by Licensor

Without prejudice to other rights of the Licensee under this Agreement, Licensor shall defend, indemnify, and hold Licensee and its Affiliates and their respective officers, directors, employees, and agents (the "**Licensee Indemnitees**") harmless from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") arising out of or occurring as a result of or in connection with (a) the breach by Licensor or its Affiliates, or where applicable, its or their respective representatives of any representations, warranties, undertakings or obligations pursuant to or under this Agreement, or (b) the willful misconduct, gross negligence or violations of Applicable Laws of Licensor, its Affiliates, or the officers, directors, employees, or agents of Licensor or its Affiliates. The foregoing indemnity obligation shall not apply to the extent that those Losses arise from, are based on, or result from any activity or occurrence for which Licensee is obligated to indemnify the Licensor Indemnitees under Article 11.2.

11.2 Indemnification by Licensee

Without prejudice to other rights of the Licensor under this Agreement, Licensee shall defend, indemnify, and hold Licensor and its Affiliates and their respective officers, directors, employees, and agents (the "**Licensor Indemnitees**") harmless from and against any and all Losses arising out of or occurring as a result of or in connection with (a) the breach of any of Licensee's or its Affiliates' or Designated Party's, or where applicable, its or their respective representatives of any representations, warranties, undertakings or obligations under this Agreement, or (b) the willful misconduct, gross negligence or violations of Applicable Laws of Licensee, its Affiliates or Designated Party, or the officers, directors, employees, or agents of Licensee or its Affiliates or Designated Party. The foregoing indemnity obligation shall not apply to the extent that the Losses arise from, are based on, or result from any activity or occurrence for which Licensor is obligated to indemnify the Licensee Indemnitees under Article 11.1.

11.3 Indemnification Procedures

The Party claiming indemnity under this Article 11 (the " **Indemnified Party**") shall give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of such Losses. The Indemnified Party shall furnish promptly to the Indemnifying Party copies of all papers and official documents received in respect of any Losses and, to the extent any indemnification claims are arising from or occurring as a result of, or in connection with any and all suits, investigations, claims or demands of a Person other than a Party (collectively, "**Third Party Claims**"), in respect of such Third Party Claims, and shall offer control of the defense of such Third Party Claim to the Indemnifying Party. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Third Party Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, however, the Indemnifying Party shall have the right to assume and conduct the defense of the Third Party Claim with counsel of its choice. The Indemnifying Party shall not settle any Third Party Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money, in which case consent is not required. The Indemnified Party shall not settle or compromise any such Third Party Claim without the prior written consent of the Indemnifying Party, and the Indemnifying Party shall have no obligation to indemnify the Indemnified Party with respect to any Third Party Claim settled or compromised without the Indemnifying Party's consent.

11.4 Product Liability

Each Party shall promptly notify the other Party of any Third Party Claim for Product Liability about which it becomes aware, and each Party shall discuss in good faith who should have exclusive control over the defense thereof and which Party shall have the right to select counsel; provided, however, that the Party that does not have exclusive control of the defense shall have the right to fully participate in any such action or proceeding and to retain its own counsel, at its own expense.

ARTICLE 12
CONFIDENTIALITY

12.1 Confidentiality

Each Party agrees that, during the Term and for a period of sixty (60) months thereafter (or, with respect to Licensor Know-How and Licensee Information that constitutes a trade secret under Applicable Laws, for so long as such Licensor Know-How or Licensee Information continues to constitute a trade secret under Applicable Laws), it shall keep strictly confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any Confidential Information furnished to it by the other Party pursuant to this Agreement, except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties. The foregoing confidentiality and non-use obligations shall not apply to any portion of the other Party's Confidential Information that the receiving Party can demonstrate by competent written proof:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was disclosed to the receiving Party or its Affiliate by a Third Party who had a legal right to make such disclosure and who did not obtain such information directly or indirectly from the other Party; or

(e) was independently discovered or developed by the receiving Party or its Affiliate without access to or aid, application, use of the other Party's Confidential Information, as evidenced by a contemporaneous writing.

12.2 Authorized Disclosure

Notwithstanding the obligations set forth in Article 12.1, a Party may disclose the other Party's Confidential Information and the terms of this Agreement to the extent:

(a) such disclosure is reasonably necessary (i) for the filing or prosecuting Patent rights as contemplated by this Agreement subject to written prior approval the other Party which shall not be unreasonably withheld; (ii) to comply with the requirements of Regulatory Authorities or Applicable Laws with respect to obtaining and maintaining Regulatory Approval of the Products; or (iii) for the prosecuting or defending litigation as contemplated by this Agreement; in all such cases, reasonable efforts shall be made to limit any further disclosure beyond that directly required under subsections (i)-(iii).

(b) such disclosure is reasonably necessary to its Affiliates, employees, agents, consultants, contractors, and actual and potential licensees or sublicensees (but, in the case of disclosures by Licensee, subject to Article 12.3) on a need-to-know basis for the purpose of performing its obligations or exercising its rights under this Agreement including, with respect to Licensor, for the purpose of development, Localization, Manufacture, Commercialization or other exploitation of the Products outside the Territory during the Term and worldwide after termination of this Agreement; provided that in each case, the disclosees are bound by written obligations of confidentiality and non-use consistent with those contained in this Agreement;

(c) such disclosure is reasonably necessary to any bona fide potential or actual investor, acquiror, merger partner, or other financial or commercial partner for the sole purpose of evaluating or carrying out an actual or potential investment, acquisition or other business relationship; provided that in connection with such disclosure, such Party shall first obtain a prior written consent for the disclosure from the other Party and inform each disclosee of the confidential nature of such Confidential Information and require each disclosee to treat such Confidential Information as confidential; or

(d) such disclosure is reasonably necessary to comply with Applicable Laws, including regulations promulgated by applicable security exchanges, court or arbitration tribunal orders, administrative subpoenas or orders.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Article 12.2 (a) or 12.2 (d), such Party shall promptly notify the other Party of such required disclosure and shall use reasonable efforts to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the required disclosure.

12.3 Publicity

(a) The Parties agree that the terms of this Agreement apply to the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in this Article 12.3.

(b) If either Party desires to make a public disclosure concerning the terms or fact of signature of this Agreement, such Party shall give prior advance written notice of at least three (3) Business Day of the proposed text of such disclosure to the other Party for its prior review (except as otherwise provided herein). A Party commenting on such a proposed disclosure shall provide its comments, if any, within three (3) Business Days after receiving the proposed disclosure for review. In addition, where required by Applicable Laws, including regulations promulgated by applicable security exchanges, such Party shall have the right to make a press release or other public disclosure regarding the achievements of Regulatory Approval, including product pricing and reimbursement, in the Territory as applicable and as they occur, or the occurrence of other events that affect either Party's rights or obligations under this Agreement, in each case subject only to the review procedure set forth in the preceding sentences. In relation to the other Party's review of such an announcement, such other Party may make specific, reasonable comments on such proposed press release within the prescribed time for commentary, but such other Party's approval shall not be required. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement that has already been publicly disclosed by such Party, or by the other Party, in accordance with this Article 12.3.

(c) The Parties acknowledge that either or both Parties or their Affiliates may be obligated to file under Applicable Laws a copy of this Agreement with the applicable stock exchange or other Governmental Authorities. Each Party and its Affiliates shall be entitled to make such a required filing, provided that it requests confidential treatment of the commercial terms and sensitive technical terms hereof to the extent such confidential treatment is reasonably available. In the event of any such filing, each Party will provide the other Party with a copy of this Agreement marked to show provisions for which such Party or its Affiliate intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's timely comments thereon to the extent consistent with the legal requirements, with respect to the filing Party or Affiliate, governing disclosure of material agreements and material information that must be publicly filed.

12.4 Equitable Relief

Each Party acknowledges that its breach of this Article 12 will cause irreparable harm to the other Party, which cannot be reasonably or adequately compensated in damages in an action at law. By reasons thereof, each Party agrees that the other Party shall be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to preliminary and permanent injunctive and other equitable relief to prevent or curtail any actual or threatened breach of the obligations relating to Confidential Information set forth in this Article 12 by the other Party without the filing of any bond or security with court under Applicable Laws.

ARTICLE 13
TERM AND TERMINATION

13.1 Term

This Agreement shall commence on the Effective Date and shall continue in force and effect for twenty (20) years (the " **Initial Term**") and shall be further automatically extended for additional twenty (20) years provided the operation term of Licensee shall have been extended before that date and unless terminated earlier by mutual written agreement of the Parties or pursuant to Articles 13.2, 13.3, 13.4, 13.5 or 15.2 of this Agreement (all such additional terms extended, together with the Initial Term, the "**Term**"). Accordingly, the Licensee shall be responsible for extending its current business term which is to expire on November 4th 2032.

13.2 Termination Breach

Neither Party is entitled to terminate this Agreement unless otherwise stipulated in this Agreement.

(a) Despite the above, a Party (the "**Non-Breaching Party**") shall have the right to claim against the other Party (the " **Breaching Party**") for all losses of the Non-Breaching Party arising out of or in connection to the act of breach of contract by the Breaching Party, without prejudice to any other rights stipulated under this Agreement. The right to terminate under this Article 13.2 arises only for uncured material breach, as follows.

For more clarity, the material breach of obligations includes especially:

- on the part of Licensee:

  (1) its material breach of (i) the Products purchase payment obligation provided for in this Agreement, (ii) the limitations on its rights under Article 2.1 and/or 2.4, (iii) its obligations under Article 2.3, (iv) its regulatory obligations under Articles 5 and 7, or (v) its obligations under Articles 11 and 12;

If any of the above breaches by Licensee are not cured to Licensor's reasonable satisfaction within six months, Licensor shall have the right but not the obligation, to terminate this Agreement unilaterally.

- on the part of the Licensor:

(1) failure to comply with obligations of granting exclusive rights to Licensee under Article 2.1 and Article 2.2 hereof.

(2) failure to supply the Imported Products within the [***] lead time, such that Licensor has still failed to supply the Imported Products within another three (3) months grace period, provided that Licensee has placed Purchase Order(s) in accordance with this Agreement (for example, within the Lead Time and Rolling Forecast limits) and there is no act of Material Breach by Licensee as defined Article 13.2 hereof.

(3) material failure to comply with transfer obligations under Article 5.2 (b), 5.2 (c) or 5.2 (j) hereof, especially failure to provide Licensor Know-how, and the technical data set forth in Exhibit D to the Licensee for the Manufacturing of the Domestic Products within 2 months of execution of this Agreement.

(4) material failure to provide technical support under the agreed terms and conditions which causes Licensee to be unable to manufacture the Domestic Products.

(5) violation of Article 13.5(a) hereof that causes material harm to Licensee that cannot be remedied by damages.

(c) If the above breach of the Licensor described in paragraphs (1)-(4) of this Article 13.2 cannot be remedied within six months,

1) In case such breach occurs before the obtaining the Regulatory Approvals of Domestic Products, Licensor shall reimburse all documented, out-of-pocket costs actually paid to a Third Party (i.e., excluding any Licensee Affiliates) incurred by the Licensee related to the registration of the Imported Products and all costs incurred by the Licensee related to the registration of the Domestic Products in the Territory;

2) the Licensor shall pay damages equivalent to demonstrated lost profits from loss of sales of the Imported and/or Domestic Products in the Territory, if any, during such period; and

3) Licensor agrees that all licenses granted under Licensor's Intellectual Property Rights, including Licensor IP, Licensor Inventions, Licensor Know-How, Licensor Patents licensed to Licensee under this Agreement within the Territory shall become perpetual, irrevocable, and fully paid up without need to pay any further consideration or price or License Fee, so that Licensee can continue to develop, register, Manufacture and Commercialize the Domestic Products in the Territory;

4) Licensee shall have the right but not the obligation, to terminate this Agreement unilaterally; but the license rights set forth in the paragraph immediately above shall not be operative unless the Licensee elects to terminate this Agreement or as otherwise stipulated in the above paragraph.

13.3 Termination for Insolvency

Any Party may terminate this Agreement effective immediately by written notice to the other Party if the other Party is subject to an Insolvency Event.

Despite the above, in case of an Insolvency Event of the Licensor described in Article 1.26 that is not resolved as provided for in that Article, Licensor agrees that, to the extent permitted by law, including without limitation, section 365(n) of Title 11 of the United States Code (the "Bankruptcy Code"), Licensee shall have the right to continue to use those licensed Licensor's Intellectual Property Rights under this Agreement, including Licensor IP, Licensor Inventions, Licensor Know-How, Licensor Patents licensed to Licensee under this Agreement, and such licenses shall become perpetual, irrevocable, and fully paid up, so that Licensee can continue to develop, register, Manufacture and Commercialize the Domestic Products in the Territory. Furthermore, to the extent any Licensor IP is sold during the course of an Insolvency Event, whether pursuant to Section 363 of the Bankruptcy Code or otherwise, Licensee does not consent to such sale being free and clear of its licenses, and Licensee's rights to use the Licensor IP shall remain in place.

13.4 Change of Control

Despite the above, each Party agrees that a Change of Control does not lead to the termination of this Agreement.

The Licensor shall make sure that the Change of Control event shall not affect the Localization, registration, importation and Commercialization of the Imported Products and the Localization, registration, Manufacturing and Commercialization of the Domestic Products in the Territory by the Licensee and that all the terms and conditions under this Agreement and relevant agreements shall remain unchanged after the Change of Control event. Especially that, Change of Control events shall not lead to the effect that any local Chinese competitor of Licensee in the field of vascular intervention becomes directly or indirectly a shareholder or actual controller of Licensor. The Parties understand that such restriction does not apply to cases where any multinational company headquartered outside the Territory becomes directly or indirectly a shareholder or actual controller of Licensor.

13.5 Fundamental Change Event

(a) Licensor undertakes that:

- until the earlier of the date the Licensee has obtained the Market Authorization for Imported Products or November 30, 2026, Licensor shall maintain its current manufacturing site and shall not make changes to the manufacturing site, Licensor shall not sell or dispose of the assets or facilities related to the manufacturing of the Imported Products to a Third Party, or change its subcontractors related to the manufacturing of the Imported Products, change place of manufacturing or manufacturing lines or manufacturing quality system of the Imported Products or change any other items as mentioned on Exhibit I (except with respect to any of the foregoing, (i) as required by a regulator or to address any failure that might be of significance to a regulator, or (ii) if parts or components become unavailable for reasons outside Licensor's control), nor shall Licensor transfer or dispose of any of the Licensor IP, based on which the Regulatory Approval of the Imported Products has been applied for;

- until the earlier of the date the Licensee has obtained the Market Authorization of the Domestic Products and has initiated First Commercial Sale of Domestic Products or November 30, 2026 ("**Lock-up Term**"), unless a prior written consent is given by Licensee to Licensor after a 6 months prior notice is sent to Licensee, Licensor shall not sell or dispose of, to a Third Party, its assets or facilities related to the manufacturing of the Imported Products, or change its subcontractors related to the manufacturing of the Imported Products, change place of manufacturing or manufacturing lines or manufacturing quality system of the Imported Products, or change any other items as mentioned on the Exhibit I (except with respect to any of the foregoing, (i) as required by a regulator or to address any failure that might be of significance to a regulator, or (ii) if parts or components become unavailable for reasons outside Licensor's control), nor shall Licensor transfer or dispose of any of the Licensor IP, based on which the Regulatory Approval of the Imported Products or Domestic Products is applied ("**Fundamental Change Event**").

(b) After the Lock-up Term, if Licensor intends to sell its assets or facilities related to the manufacturing of the Imported Products, Licensor shall give an 60 days' prior written notice to Licensee, and Licensee shall have the first right to make an offer to purchase the said assets. If the Licensee determines not to follow through with the purchase after giving a formal notice of an offer to the Licensor, or if the Licensee does not make an offer to the Licensor, Licensor may sell the assets to a Third Party of its choosing. The Licensor shall make best efforts to ensure that the party which acquires such assets continues to perform all the obligations of the Licensor under this Agreement so that the rights and obligations of the Licensee remain unaffected.

In case of violation of this Article 13.5 by the Licensor, the Licensor shall reimburse all documented, out-of-pocket costs actually paid to a Third Party (i.e., excluding any Licensee Affiliates) by the Licensee related to the application and obtaining of the Regulatory Approval and Market Authorization of the Imported Products in the Territory.

13.6 Effects of Termination

13.6.1 General Effects of Termination. Upon the termination of this Agreement in its entirety or, if applicable, on a Product-by-Product basis, the following shall apply (in addition to any other rights and obligations under this Agreement with respect to such termination), without prejudice to the rights of Licensee under Article 13.2 and Article 13.3:

(a) **Licenses.** On the effective date of termination, all licenses and other rights granted by Licensor to Licensee under this Agreement (or with respect to the terminated Product(s), as applicable) shall terminate. Upon termination of this Agreement in its entirety, all licenses and other rights granted by Licensor to Licensee under this Agreement terminate as provided in the preceding sentence, except rights under Articles 13.2 and 13.3.

(b) **Inventory; Wholesalers.** Upon termination of this Agreement, Licensee will have the continued right to sell such terminated Products in its inventory after the date of termination until such inventory has been cleared but for a maximum period of 1 year; provided, however, that Licensee's obligations under this Agreement with respect to all such Products that Licensee sells shall continue in full force and effect. However, if such termination is made by Licensee due to the fact that the Imported Products do not comply with the Regulatory Approvals due to Licensor's fault, Licensee has the right to return all the said unsold stocks to Licensor and Licensor shall pay the supply price paid by the Licensee.

(c) **Product Mark**. If this Agreement is terminated in its entirety, then on the effective date of termination, Licensee and its Affiliates shall no longer have any right to use the Product Marks in the Territory except for the sale of the inventory in the Territory.

(d) **Survival**. Notwithstanding anything to the contrary, the following provisions shall survive any termination of this Agreement as described in this Article 13, Article 10, Article 11, Article 12, Article 13.6, Article 13.7, Article 14, Article 15.3, and Article 15.9.

(e) **Rights due to Articles 13.2 and 13.3:** For the purpose of clarify, the termination of this Agreement does not affect any rights that may be obtained by Licensee in case of termination due to Article 13.2 or Article 13.3, under which Licensee may have the full right to continue to Localize, register, Manufacture, Commercialize the Products in the Territory.

13.7 Accrued Rights and Obligations

Termination of this Agreement shall not affect rights or obligations of the Parties under this Agreement or other agreements between the Parties that have accrued prior to the date of termination. Liabilities under this Agreement shall not affect liabilities of the Parties under other agreements between the Parties regarding the event triggering such liabilities.

13.8 Termination Not Sole Remedy

Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies shall remain available except as otherwise agreed upon and set forth herein.

ARTICLE 14
DISPUTE RESOLUTION

14.1 Dispute

The Parties recognize that disputes as to certain matters may from time to time arise that relate to either Party's rights or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation. To accomplish this objective, the Parties agree that, if a dispute arises under this Agreement, including any alleged breach of this Agreement or any issue relating to the due execution, interpretation, validity, performance or application of this Agreement (" **Dispute**"), and the Parties are unable to resolve such Dispute within thirty (30) days after such Dispute is first identified by either Party in writing to the other, the Parties shall refer such Dispute the Executive Officers for attempted resolution by good faith negotiations within thirty (30) days after such notice is received. If the negotiations by the Executive Officers fail to achieve a mutually acceptable resolution, the Dispute shall be submitted to the Singapore International Arbitration Center ("**SIAC**") for arbitration in accordance with its arbitration rules then in force at the time of application. The place of arbitration shall be Singapore. The number of arbitrators shall be three (3).

14.2 Arbitration

(a) Promptly following receipt of the demand for arbitration (" **Demand**"), the Parties shall each appoint one (1) arbitrator within 30 days of receipt of the Demand. The third arbitrator, who shall act as the presiding arbitrator, shall be appointed by the above two arbitrators within 15 days of when they are appointed. If such third arbitrator or any of the above two arbitrators fails to be appointed with the above deadline, the said arbitrator shall be appointed by the chairman of SIAC. The arbitrators shall have experience with respect to the matter(s) to be arbitrated. The arbitrators shall apply the governing law set forth in Article 14.5. The Parties shall instruct the arbitrators to: (i) conclude the arbitration as soon as practicable (and in any event within six (6) months after selection of the arbitrators), and (ii) deliver a written, reasoned opinion stating the arbitrators' decision within thirty (30) days after the arbitration hearing is concluded.

(b) Each Party shall pay its own attorney's fees incurred in connection with such arbitration; provided however, if the arbitrators specifically determine that one Party prevailed clearly and substantially over the other Party, then the arbitrators may require the non-prevailing Party to pay the prevailing Party's reasonable attorney's fees and expert witness costs and arbitration costs.

(c) Either Party may apply to the arbitrators for, or may seek from any court having jurisdiction, interim injunctive or provisional relief as necessary to protect the rights or property of such Party until the arbitration award is rendered or the controversy is otherwise resolved. Judgment upon the award rendered by the arbitrators shall be binding, final and non-appealable (absent manifest error) and may be entered and enforced in any court having jurisdiction thereof.

14.3 Injunctive Relief

Notwithstanding anything to the contrary in this Article 14, either Party may apply to any court having jurisdiction for interim injunctive relief (including a temporary restraining order or preliminary injunction) to protect a Party's interests or preserve the status quo during the pendency of a dispute between the Parties.

14.4 Intellectual Property Disputes

Notwithstanding Article 14.2, in the event that a Dispute arises with respect to the validity, scope, enforceability or ownership of any Patent or other Intellectual Property Rights, and such Dispute is not resolved in accordance with Article 14.1, such Dispute shall not be submitted to an arbitration proceeding in accordance with Article 14.2, unless otherwise agreed by the Parties in writing, and instead, either Party may initiate litigation in a court of competent jurisdiction in any country in which such rights apply.

14.5 Governing Law

This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the Laws of Hong Kong without giving effect to any choice of law principles that would require the application of the Laws of a different state.

ARTICLE 15
MISCELLANEOUS

15.1 Entire Agreement; Amendment

This Agreement, including the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof (excluding the subject matter of all separate agreements referred to specifically herein) and supersedes, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof; provided, that all information shared by the Parties or their Affiliates pursuant to the Confidentiality Agreement shall be deemed Confidential Information under this Agreement, and the use and disclosure thereof shall be governed by Article 12 hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in this Agreement or in the agreements specifically referenced herein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

15.2 Force Majeure

Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the non-performing Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the reasonable control of the applicable Party, including but not limited to a war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, and destruction of production facilities, equipment or materials by fire, earthquake, storm or like catastrophe. If a force majeure condition persists for more than ninety (90) days, the Party not claiming relief under this force majeure provision shall be entitled to terminate this Agreement upon written notice. Force majeure shall not apply to payment obligations under this Agreement unless it is substantially unfair to continue performance due to the effect of force majeure.

15.3 Notices

Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Article 15.3, and shall be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by a reputable courier service, or (b) five (5) Business Days after mailing, if mailed by first class certified or registered airmail, postage prepaid, return receipt requested. Non-notice copies may be sent by email.

If to Licensor: Avinger

Attention: Jeffrey M. Soinski
Email: [***]
Address: 400 Chesapeake Dr., Redwood City, CA 94063, USA

With copies to (which shall not constitute notice):
Attention: Nabeel Subainati
Email: [***]

Attention: David Marx
Email: v[***]

To Licensee: Zylox-Tonbridge Medical Technology Co., Ltd.

Attention: Jonathon Zhong Zhao
Email: [***]
Address: 270 Shuyun Road, Yuhang District, Hangzhou, Zhejiang Province, China

With copies to (which shall not constitute notice):
Attention: Alan Yuan; Karl Yu
Email: [***]; [***]

15.4 Assignment

Licensee shall notify Licensor of its intention to assign or transfer this Agreement or any rights or obligations hereunder if it considers that such assignment will be conducive to the Business with respect to the Products in or for the Territory, Licensor shall have a right to provide Licensee with reasonable advice for reference. Without the written consent of the Licensor (which shall not be unreasonably withheld, conditioned or delayed), Licensee shall not assign its rights and obligations under the Agreement to a Third Party unless the assignee is an Affiliate of the Licensee.

15.5 Further Actions

Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

15.6 Severability

If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court or arbitration tribunal of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

15.7 No Waiver

Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

15.8 Independent Contractors

Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way except with respect to the limited grant of agency from Licensor to Licensee expressly provided for regarding regulatory compliance. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

15.9 English Language

This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement.

15.10 Counterparts.

This Agreement may be executed in counterparts, all of which taken together shall be regarded as the same instrument. Each Party may execute this Agreement in Adobe™ Portable Document Format (PDF) sent by electronic mail. PDF signatures of authorized signatories of the Parties will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

[Signature Page Follows]

In Witness Whereof, the Parties have executed this License and Distribution Agreement by their duly authorized officers as of the Effective Date.

Avinger, Inc.

Signature: /s/ Jeffrey M. Soinski

Name: Jeffrey M. Soinski

Title: Chief Executive Officer

Zylox-Tonbridge Medical Technology Co., Ltd.

Signature: /s/ Jonathon Zhong Zhao

Name: Jonathon Zhong Zhao

Title: Chairman

EXHIBIT A
IMPORTED PRODUCT(S) AND WARRANTY UNDER IMPORTATION PARADIGM

The internal names of the current Product portfolio of the Licensor, which may be amended from time to time, are as listed below, and the final and definitive names of the Imported Product shall be subject to the Regulatory Approvals subsequently issued by the competent Regulatory Authorities.

Imported Product:

- OCT imaging console: Lightbox 3 (L300); LightBox (L250). (Avinger is no longer manufacturing new Lightbox L250 imaging consoles. Supply is limited to inventory on hand and refurbished systems.)

The trade name of the Imported Product is Lightbox 3/ LightBox

Indication (anticipated usage):

- Atherectomy: as part of a system, including Pantheris catheters
- CTO Crossing: as part of a system, including Tigereye ST catheter; Ocelot catheters (Ocelot catheters are only compatible with Lightbox L250. Tigereye ST is compatible with both Lightbox L250 and Lightbox 3 L300).

Specification: The Imported Product is composed of (i) Lightbox 3 imaging console, and (ii) Sled (S250) and other accessories.

The consumables of the Imported Products are Pantheris Series (A400/A400X) Pantheris SV (A140-SV), Pantheris LV (A110-LV), Tigereye ST (O350), Ocelot Series (O200, O250) ("**Imported Products Consumables**").

Warranty: The Imported Product comes with a Warranty Period of 12 months starting from the earlier of the date the Imported Product is first used in the field by Licensee on a portable basis or properly installed at the end user in the Territory with installation report. The Warranty Period for the spare parts of the Imported Products shall be 12 months commencing from when the spare parts have been accepted by Licensee. During the Warranty Period Licensor will provide replacement parts free of charge including freight, duties and taxes.

Service Life of Imported Products:

Total Service Life of Imported Product: 5 years

Licensor shall ensure that date of production and service life of the Imported Products delivered to Licensee shall comply with Applicable Laws and regulatory requirements in the Territory, in any case, a minimum service life of 80 % of its label claim is required, at the date of arrival at Licensee's warehouse in the Territory.

Shelf Life of Imported Products Consumables:

Total Shelf-life of Imported Products Consumables' label claim:

Pantheris Series (A400/A400X) – 24 months

Pantheris SV (A140-SV) – 24 months

Pantheris LV (A110-LV) – 24 months

Tigereye ST (O350) – 6 months (anticipated to be extended to 24 months, following completion of shelf-life testing)

Ocelot Series (O200, O250) – 30 months

Licensor shall ensure that the Imported Products Consumables delivered to Licensee will have a minimum remaining shelf-life of at least 80% of its label claim at the date of arrival at Licensee's warehouse in the Territory.

If the remaining shelf life of the delivered Imported Products and Imported Products Consumables is less than the agreed requirements, Licensee or its Designated Party shall be entitled to require Licensor to replace the relevant Imported Products and Imported Products Consumables with other batches of Imported Products and Imported Products Consumables of which the minimum remaining shelf-life complies with the above-mentioned requirements.

EXHIBIT B
DOMESTIC PRODUCT(S) AND WARRANTY UNDER LOCAL IZATION PARADIGM

Reserved.

EXHIBIT C
SUPPLY PRICE

[***]

EXHIBIT D
HAND-OVER LIST OF LICENSOR KNOW-HOW AND TECHNICAL DATA AND TIME SCHEDULE OF DELIVERYEXHIBIT E
LICENSE FEES AND PAYMENT OF LICENSE FEES

[***]

EXHIBIT F
EXISTING LICENSOR PATENTS

[***]

EXHIBIT G
TRADEMARKS (PRODUCT MARKS)

[***]EXHIBIT H
SPARE PARTS PRICE LIST

[***]

EXHIBIT I
LIST OF CHANGES TO REGULATORY APPROVAL REQUIRED ELEMENTS

[***]

EXHIBIT J
QUALITY AGREEMENT

[***]

EXHIBIT K
TIME SCHEDULE OF LOCALIZATION

[***]

EXHIBIT M
BINDING FORECAST OF SAMPLES OF IMPORTED PRODUCTS, AND IMPORTED PRODUCTS FOR CLINICAL/NON-CLINICAL USE

[***]

EXHIBIT N
LIST OF LICENSOR MARKETING SUPPORT DOCUMENTS

[***]

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
Pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a),
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Jeffrey Soinski, hereby certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Avinger, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 15, 2024

/s/ Jeffrey M. Soinski
Jeffrey M. Soinski
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER
Pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a),
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Nabeel Subainati, hereby certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Avinger, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 15, 2024

/s/ Nabeel Subainati
Nabeel Subainati
Vice President, Finance
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER
AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Avinger, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2024, as filed with the Securities and Exchange Commission (the "Report"), Jeffrey Soinski, as Chief Executive Officer of the Company, and Nabeel Subainati, Principal Financial and Accounting Officer of the Company, each hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350), to his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 15th day of May, 2024.

/s/ Jeffrey M. Soinski	/s/ Nabeel Subainati
Jeffrey M. Soinski	Nabeel Subainati
Chief Executive Officer	*Vice President, Finance*
(Principal Executive Officer)	*(Principal Financial and Accounting Officer)*

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.