

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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 September 30, 2019

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 001-36747

Second Sight Medical Products, Inc.

(Exact name of Registrant as specified in its charter)

California
*(State or other jurisdiction of
incorporation or organization)*

02-0692322
(I.R.S. Employer Identification No.)

12744 San Fernando Road, Suite 400, Sylmar, CA 91342
(Address of principal executive offices, including zip code)

(818) 833-5000
(Registrant's telephone number, including area code)

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock	EYES	NASDAQ
Warrants	EYESW	NASDAQ

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 (§232.405 of this chapter) 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 the 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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 Exchange Act).

Yes No

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes No

As of November 12, 2019, the registrant had 124,598,198 shares of common stock, \$0 par value per share and 61,459,657 warrants, outstanding.

**SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY**

**FORM 10-Q
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PART I. FINANCIAL STATEMENTS

Item 1. Financial Statements

**SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY**

Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2019	December 31, 2018
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 18,462	\$ 4,471
Accounts receivable, net	264	504
Inventories, net	1,264	3,250
Prepaid expenses and other current assets	366	1,395
Total current assets	20,356	9,620
Property and equipment, net	1,125	1,025
Right-of-use assets	2,399	—
Deposits and other assets	18	37
Total assets	<u>\$ 23,898</u>	<u>\$ 10,682</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,126	\$ 1,305
Accrued expenses	2,082	2,503
Accrued compensation expense	2,461	2,690
Accrued clinical trial expenses	734	933
Current operating lease liabilities	228	—
Contract liabilities	554	167
Total current liabilities	7,185	7,598
Long term operating lease liabilities	2,427	—
Total liabilities	<u>9,612</u>	<u>7,598</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, no par value, 10,000 shares authorized; none outstanding	—	—
Common stock, no par value; 300,000 shares authorized; shares issued and outstanding: 124,598 and 76,336 as of September 30, 2019 and December 31, 2018, respectively	263,656	229,019
Additional paid-in capital	48,131	44,111
Accumulated other comprehensive loss	(585)	(575)
Accumulated deficit	(296,916)	(269,471)
Total stockholders' equity	<u>14,286</u>	<u>3,084</u>
Total liabilities and stockholders' equity	<u>\$ 23,898</u>	<u>\$ 10,682</u>

See accompanying notes.

**SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY**

Condensed Consolidated Statements of Operations (unaudited)
(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net sales	\$ 472	\$ 2,246	\$ 2,882	\$ 5,129
Cost of sales	364	1,784	2,028	3,287
Gross profit	<u>108</u>	<u>462</u>	<u>854</u>	<u>1,842</u>
Operating expenses:				
Research and development, net of grants	3,379	2,672	8,998	7,567
Clinical and regulatory, net of grants	862	964	2,404	3,439
Selling and marketing	1,308	3,040	5,100	8,931
General and administrative	2,178	2,332	6,883	8,208
Restructuring charges	—	—	3,297	—
Total operating expenses	<u>7,727</u>	<u>9,008</u>	<u>26,682</u>	<u>28,145</u>
Loss from operations	(7,619)	(8,546)	(25,828)	(26,303)
Interest income	<u>35</u>	<u>24</u>	<u>104</u>	<u>67</u>
Net loss	<u>\$ (7,584)</u>	<u>\$ (8,522)</u>	<u>\$ (25,724)</u>	<u>\$ (26,236)</u>
Net loss per common share – basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.12)</u>	<u>\$ (0.22)</u>	<u>\$ (0.41)</u>
Weighted average common shares outstanding – basic and diluted	<u>124,592</u>	<u>68,763</u>	<u>115,266</u>	<u>64,113</u>

See accompanying notes.

**SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY**

Condensed Consolidated Statements of Comprehensive Loss (unaudited)
(in thousands)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Net loss	\$ (7,584)	\$ (8,522)	\$ (25,724)	\$ (26,236)
Other comprehensive income (loss):				
Foreign currency translation adjustments	(11)	24	(10)	(8)
Comprehensive loss	<u>\$ (7,595)</u>	<u>\$ (8,498)</u>	<u>\$ (25,734)</u>	<u>\$ (26,244)</u>

See accompanying notes.

**SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY**

Condensed Consolidated Statements of Stockholders' Equity (unaudited)
(in thousands)

	<u>Common Stock</u>		<u>Common Stock Issuable</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Other Comprehensive Loss</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>				
Balance, December 31, 2017	57,630	\$ 202,156	82	\$ 153	\$ 40,522	\$ (572)	\$ (234,377)	\$ 7,882
Issuance of shares of common stock, net of issuance costs	2,224	3,992	—	—	—	—	—	3,992
Warrants exercise	5	7	—	—	—	—	—	7
Common stock issuance for services	—	—	34	65	—	—	—	65
Release of restricted stock units	12	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	1,285	—	—	1,285
Exercise of common stock options	5	8	—	—	—	—	—	8
Net loss	—	—	—	—	—	—	(9,753)	(9,753)
Foreign currency translation adjustment	—	—	—	—	—	45	—	45
Balance, March 31, 2018	59,876	206,163	116	218	41,807	(527)	(244,130)	3,531
Issuance of shares of common stock, net of issuance costs	6,757	9,978	—	—	—	—	—	9,978
Issuance of common stock in connection with employee stock purchase plan	226	261	—	—	—	—	—	261
Common stock issued or issuable for services	133	262	(116)	(218)	—	—	—	44
Release of restricted stock units	12	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	627	—	—	627
Exercise of common stock options	71	141	—	—	—	—	—	141
Net loss	—	—	—	—	—	—	(7,961)	(7,961)
Foreign currency translation adjustment	—	—	—	—	—	(77)	—	(77)
Balance, June 30, 2018	67,075	216,805	—	—	42,434	(604)	(252,091)	6,544
Issuance of shares of common stock, net of issuance costs	3,225	4,969	—	—	—	—	—	4,969
Release of restricted stock units	12	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	877	—	—	877
Net loss	—	—	—	—	—	—	(8,522)	(8,522)
Foreign currency translation adjustment	—	—	—	—	—	24	—	24
Balance, September 30, 2018	<u>70,312</u>	<u>\$ 221,774</u>	<u>—</u>	<u>\$ —</u>	<u>\$ 43,311</u>	<u>\$ (580)</u>	<u>\$ (260,613)</u>	<u>\$ 3,892</u>

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2018	76,336	\$ 229,019	\$ 44,111	\$ (575)	\$ (269,471)	\$ 3,084
Adoption of ASC Topic 842-Leases (see note 2)	—	—	—	—	(144)	(144)
Issuance of shares of common stock and warrants in connection with rights offering, net of issuance costs	47,812	34,399	—	—	—	34,399
Release of restricted stock units	50	—	—	—	—	—
Warrants modification (see note 7)	—	—	1,577	—	(1,577)	—
Stock-based compensation expense	—	—	898	—	—	898
Net loss	—	—	—	—	(9,700)	(9,700)
Foreign currency translation adjustment	—	—	—	(8)	—	(8)
Balance, March 31, 2019	124,198	263,418	46,586	(583)	(280,892)	28,529
Release of restricted stock units	12	—	—	—	—	—
Issuance of common stock in connection with employee stock purchase plan	376	238	—	—	—	238
Stock-based compensation expense	—	—	859	—	—	859
Net loss	—	—	—	—	(8,440)	(8,440)
Foreign currency translation adjustment	—	—	—	9	—	9
Balance, June 30, 2019	124,586	263,656	47,445	(574)	(289,332)	21,195
Release of restricted stock units	12	—	—	—	—	—
Stock-based compensation expense	—	—	686	—	—	686
Net loss	—	—	—	—	(7,584)	(7,584)
Foreign currency translation adjustment	—	—	—	(11)	—	(11)
Balance, September 30, 2019	124,598	\$ 263,656	\$ 48,131	\$ (585)	\$ (296,916)	\$ 14,286

See accompanying notes.

**SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY**

Condensed Consolidated Statements of Cash Flows
(in thousands)

	Nine Months Ended September 30,	
	2019	2018
	(unaudited)	
Cash flows from operating activities:		
Net loss	\$ (25,724)	\$ (26,236)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	293	329
Stock-based compensation	2,443	2,789
Bad debt recovery	—	(6)
Non-cash lease expense	13	—
Inventory reserve	(793)	171
Restructuring charges-inventory impairment	2,587	—
Common stock issuance for services	—	109
Changes in operating assets and liabilities:		
Accounts receivable	240	639
Inventories	186	(1,082)
Prepaid expenses and other assets	1,010	291
Accounts payable	(178)	795
Accrued expenses	(282)	(447)
Accrued compensation expenses	(227)	351
Accrued clinical trial expenses	(199)	155
Contract liabilities	388	63
Net cash used in operating activities	(20,243)	(22,079)
Cash flows from investing activities:		
Purchases of property and equipment	(394)	(144)
Net cash used in investing activities	(394)	(144)
Cash flows from financing activities:		
Net proceeds from sale of common stock and warrants	34,399	18,939
Proceeds from exercise of options, warrants and employee stock purchase plan options	238	417
Net cash provided by financing activities	34,637	19,356
Effect of exchange rate changes on cash and cash equivalents	(9)	—
Cash and cash equivalents:		
Net increase (decrease)	13,991	(2,867)
Balance at beginning of period	4,471	7,839
Balance at end of period	\$ 18,462	\$ 4,972

See accompanying notes.

SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Organization and Business Operations

Second Sight Medical Products, Inc. (“Second Sight,” “we,” “us,” or “the Company”) was incorporated in the State of California in 2003. Second Sight develops, manufactures and markets implantable visual prosthetics to potentially enable blind individuals to achieve greater independence.

In 2007, Second Sight formed Second Sight Medical Products (Switzerland) Sàrl, initially to manage clinical trials for its products in Europe, and later to manage sales and marketing in Europe, the Middle East and Asia-Pacific. As the laws of Switzerland require at least two corporate stockholders, Second Sight Medical Products (Switzerland) Sàrl is 99.5% owned directly by us and 0.5% owned by an executive of Second Sight as of September 30, 2019. Accordingly, Second Sight Medical Products (Switzerland) Sàrl is considered 100% owned for financial statement purposes and is consolidated with Second Sight for all periods presented.

We are currently developing the Orion® Visual Cortical Prosthesis System (“Orion”), an implanted cortical stimulation device intended to provide useful artificial vision to individuals who are blind due to a wide range of causes including retinitis pigmentosa (RP), glaucoma, diabetic retinopathy, optic nerve injury or disease, or forms of cancer and trauma. A feasibility study of the Orion device is currently underway at the Ronald Reagan UCLA Medical Center in Los Angeles (“UCLA”) and Baylor College of Medicine in Houston (“Baylor”).

Our commercially approved product, the Argus® II retinal prosthesis system (“Argus II”), entered clinical trials in 2006, received CE Mark approval for marketing and sales in the European Union (“EU”) in 2011, and received approval by the United States Food and Drug Administration (“FDA”) for marketing and sales in the United States in 2013. We began selling the Argus II in Europe at the end of 2011, Saudi Arabia in 2012, the United States and Canada in 2014, Turkey in 2015, Iran, Taiwan, South Korea and Russia in 2017, and Singapore in 2018. Given the limited addressable market of Argus II, we have made the decision to maximize capital efficiency with our Argus commercial and clinical activities and increase our investment of resources with our Orion clinical and R&D programs. See Note 2 for discussion of Discontinued Operations.

Liquidity and Going Concern

From inception, our operations have been funded primarily through the sales of our common stock and warrants, as well as from the issuance of convertible debt, research and clinical grants, and limited product revenue generated from the sale of our Argus II product. Funding of our business since 2017 has been primarily provided by:

- Revenue of \$2.9 million for the nine months ended September 30, 2019 and \$6.9 million for the year ended December 31, 2018 generated by sales of our Argus II product.
- Issuance of common stock and warrants in a rights offering in February 2019, which provided net cash proceeds of \$34.4 million.
- Issuance of common stock in securities purchase agreements in May, August, October and December 2018, which provided net cash proceeds of \$22.0 million.
- Issuance of common stock through our At Market Issuance Sales Agreement (the “Sales Agreement”) during the first quarter of 2018 which provided net cash proceeds of \$4.0 million.

On September 17, 2019, we received a \$2.4 million, four-year grant from the National Institutes of Health (NIH) to develop spatial localization and mapping technology (“SLAM”). This grant involves a joint collaboration with the Johns Hopkins University Applied Physics Laboratory, and is intended to speed the integration of SLAM into future generations of Orion. The goal is to give Orion users the ability to localize objects and navigate landmarks in unfamiliar surroundings in real time.

In a rights offering completed on February 22, 2019, we sold approximately 47.8 million units, each priced at \$0.724 for gross proceeds of approximately \$34.6 million. Each unit consisted of one share and one immediately exercisable warrant having an exercise price of \$1.47 per share. Entities controlled by Gregg Williams, our Chairman of the Board of Directors, acquired approximately 41.4 million units in the offering for an aggregate investment of approximately \$30 million.

In November 2017, we entered into an At Market Issuance Sales Agreement with B. Riley FBR Inc. and H.C. Wainwright & Co., LLC, as agents (“Agents”) pursuant to which we may offer and sell, from time to time through either of the Agents, shares of our common stock having an aggregate offering price as set forth in the Sales Agreement and a related prospectus supplement filed with the SEC. We agreed to pay the Agents a cash commission of 3.0% of the aggregate gross proceeds from each sale of shares under the Sales Agreement. During January and February 2018, we sold 2.2 million shares of common stock which provided net proceeds of \$4.0 million under the Sales Agreement. No shares have been sold since February 2018 under the Sales Agreement.

On January 25, 2019, we received a letter from The Nasdaq Stock Market advising us that for 30 consecutive trading days preceding the date of the letter, the bid price of our common stock had closed below the \$1.00 per share minimum required for continued listing on The Nasdaq Capital Market pursuant to listing rules, and therefore we could become subject to delisting if we did not regain compliance within the compliance period. Nasdaq has extended the compliance period for an additional 180 days through January 20, 2020 and we continue to monitor and evaluate our options including, if necessary, effecting a reverse stock split to cure this deficiency within this extended compliance period.

Our financial statements have been presented on the basis that our business is a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We are subject to the risks and uncertainties associated with a business with one product line and limited commercial product revenues, including limitations on our operating capital resources and uncertain demand for our product. We have incurred recurring operating losses and negative operating cash flows since inception, and we expect to continue to incur operating losses and negative operating cash flows for the foreseeable future.

We do not have sufficient funds to support our operations for the next 12 months from the date of issuance of these financial statements. Accordingly, these and other related factors raise substantial doubt about our ability to continue as a going concern. We anticipate that we will seek to additionally fund our operations through public or private equity or debt financings, grants, collaborations, strategic partnerships or other sources. However, we may be unable to raise additional capital or enter into such other arrangements when needed on favorable terms or at all. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or any other approved product candidates, or we may be unable to expand our operations, maintain our current organization and employee base or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations. The accompanying financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

2. Basis of Presentation, Significant Accounting Policies and Recent Accounting Pronouncements

Basis of Presentation

These unaudited interim financial statements have been prepared in accordance with United States generally accepted accounting principles (“GAAP”) and following the requirements of the United States Securities and Exchange Commission (“SEC”) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP can be condensed or omitted. In our opinion, the unaudited interim financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of our financial position and our results of operations and cash flows for periods presented. These statements do not include all disclosures required by GAAP and should be read in conjunction with our financial statements and accompanying notes for the fiscal year ended December 31, 2018, contained in our Annual Report on Form 10-K filed with the SEC on March 19, 2019. The results of the interim periods are not necessarily indicative of the results expected for the full fiscal year or any other interim period or any future year or period.

Significant Accounting Policies

Discontinued operations

Based upon our decision on May 10, 2019 to accelerate our transition to the Orion platform, we evaluated our accounting policies related to the disposition in accordance with ASC 205-20 *Discontinued Operations*, and assessed our long-lived assets for any indications that their carrying values may not be recoverable in accordance with ASC 360, *Property, Plant, and Equipment*, for any impairment. Based upon these reviews we recorded impairment charges of \$2.6 million related to inventory of Argus II in the nine months ended September 30, 2019, based on our plans to suspend production of Argus II. As part of this transition we commenced a corporate restructuring plan to focus on development of Orion and other key research projects. Specifically, we reduced expenses and personnel related to commercial activities and production for the Argus II. We recognized approximately \$0.7 million of pre-tax restructuring charges in the second quarter of fiscal year 2019 in connection with this restructuring, consisting of severance and other employee termination benefits, \$0.4 million of which we have settled at September 30, 2019 with substantially all of the remainder expected to be settled in cash by the end of 2019. Until Argus II operations cease, we continue to present it as part of continuing

operations. Based upon our review of the applicable accounting standards, we determined that there was no impairment of any other assets.

Our significant accounting policies are set forth in Note 2 of the financial statements in our Annual Report on Form 10-K for the year ended December 31, 2018.

Recently Adopted Accounting Pronouncements

We adopted ASU No. 2016-02—*Leases (Topic 842)*, as amended, as of January 1, 2019, using the modified retrospective approach. The modified retrospective approach provides a method for recording existing leases at the period of adoption without restating prior comparative periods which is the method we have chosen. In addition, we elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed us to carry forward the historical lease classification. Adoption of the new standard resulted in the recording of right-of-use assets and operating lease liabilities of approximately \$2.6 million and \$2.8 million respectively, as of January 1, 2019. The difference of \$0.2 million between the right-of-use assets and operating lease liabilities, net of the deferred tax impact, was recorded as an adjustment to accumulated deficit at January 1, 2019. The standard did not materially impact our consolidated net earnings and had no impact on cash flows.

We do not believe that any other recently issued, but not yet effective, accounting standards, if adopted, will have a material effect on the financial statements.

3. Concentration of Risk

Credit Risk

Financial instruments that subject us to concentrations of credit risk consist primarily of cash, money market funds, and trade accounts receivable. We maintain cash and money market funds with financial institutions that we deem reputable. We extend differing levels of credit to our customers, and typically do not require collateral.

Customer Concentration

The following tables provide information about disaggregated revenue by service type, customer and geographical market.

The following table shows our revenues by customer type during the three and nine months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Direct customers	\$ 412	\$ 1,921	\$ 2,364	\$ 4,378
Indirect customers (distributors)	60	325	518	751
Total	\$ 472	\$ 2,246	\$ 2,882	\$ 5,129

During the three and nine months ended September 30, 2019 and 2018, the following customers each comprised greater than 10% of our total revenues

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Customer 1	44%	6%	23%	11%
Customer 2	29%	4%	12%	4%
Customer 3	28%	—%	6%	—%
Customer 4	—%	—%	12%	5%
Customer 5	—%	6%	11%	3%
Customer 6	—%	12%	5%	5%
Customer 7	—%	10%	9%	6%
Customer 8	—%	10%	—%	4%

As of September 30, 2019 and December 31, 2018, the following customers each comprised greater than 10% of our total accountsreceivable:

	September 30, 2019	December 31, 2018
Customer 1	97%	—%
Customer 2	—%	55%
Customer 3	—%	22%
Customer 4	—%	21%

Geographic Concentration

During the three and nine months ended September 30, 2019 and 2018, regional revenue based on customer locations which each comprised greater than 10% of our total revenues, consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Italy	44%	6%	23%	11%
China	29%	4%	12%	4%
United States	27%	47%	60%	51%
France	—%	15%	—%	14%
Canada	—%	10%	—%	4%

Foreign Operations

The accompanying condensed consolidated financial statements as of September 30, 2019 and December 31, 2018 include assets amounting to \$1.8 million and \$1.5 million, respectively, relating to operations of our subsidiary based in Switzerland. It is possible that unanticipated events in foreign countries could disrupt our operations.

4. Fair Value Measurements

The authoritative guidance with respect to fair value establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three levels, and requires that assets and liabilities carried at fair value be classified and disclosed in one of three categories, as presented below. Disclosure as to transfers in and out of Levels 1 and 2, and activity in Level 3 fair value measurements, is also required.

Level 1. Observable inputs such as quoted prices in active markets for an identical asset or liability that we have the ability to access as of the measurement date. Financial assets and liabilities utilizing Level 1 inputs include active-exchange traded securities and exchange-based derivatives.

Level 2. Inputs, other than quoted prices included within Level 1, which are directly observable for the asset or liability or indirectly observable through corroboration with observable market data. Financial assets and liabilities utilizing Level 2 inputs include fixed income securities, non-exchange based derivatives, mutual funds, and fair-value hedges.

Level 3. Unobservable inputs in which there is little or no market data for the asset or liability which requires the reporting entity to develop its own assumptions. Financial assets and liabilities utilizing Level 3 inputs include infrequently-traded non-exchange-based derivatives and commingled investment funds, and are measured using present value pricing models.

Cash equivalents, which includes money market funds, are the only financial instrument measured and recorded at fair value on our consolidated balance sheet, and they are valued using Level 1 inputs.

Assets measured at fair value on a recurring basis are as follows (in thousands):

	Total	Level 1	Level 2	Level 3
September 30, 2019 (unaudited):				
Money market funds	<u>\$ 18,266</u>	<u>\$ 18,266</u>	<u>\$ —</u>	<u>\$ —</u>
December 31, 2018:				
Money market funds	<u>\$ 4,156</u>	<u>\$ 4,156</u>	<u>\$ —</u>	<u>\$ —</u>

As of September 30, 2019 and December 31, 2018, the money market funds include \$0.1 million and \$0.2 million, respectively, held in a deposit account in Switzerland as security for the performance of contracts.

5. Selected Balance Sheet Detail

Inventories, net

Inventories consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Raw materials	\$ 807	\$ 791
Work in process	1,854	3,055
Finished goods	2,174	2,089
	<u>4,835</u>	<u>5,935</u>
Allowance for excess and obsolete inventory and impairment charge	(3,571)	(2,685)
Inventories, net	<u>\$ 1,264</u>	<u>\$ 3,250</u>

We recorded \$2.6 million as an impairment charge during the nine months ended September 30, 2019, related to our plans to suspend Argus II production. See note 2 for further details.

Property and equipment

Property and equipment consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Laboratory equipment	\$ 2,723	\$ 2,482
Computer hardware and software	1,590	1,456
Leasehold improvements	304	298
Furniture, fixtures and equipment	58	46
	<u>4,675</u>	<u>4,282</u>
Accumulated depreciation and amortization	(3,550)	(3,257)
Property and equipment, net	<u>\$ 1,125</u>	<u>\$ 1,025</u>

Contract Liabilities

Contract liabilities consisted of the following (in thousands):

Beginning balance as of December 31, 2018	\$ 167
Consideration received in advance of revenue recognition	387
Revenue recognized	—
Ending balance as of September 30, 2019	<u>\$ 554</u>

Allowance for Doubtful Accounts

Allowance for doubtful accounts consisted of the following (in thousands):

Beginning balance as of December 31, 2018	\$ 181
Additions	—
Write-offs	(64)
Ending balance as of September 30, 2019	<u>\$ 117</u>

Right-of-use assets and operating lease liabilities

We lease certain office space and equipment for our use. Leases with an initial term of 12 months or less are not recorded on the balance sheet. Lease costs are recognized in the income statement over the lease term on a straight-line basis. Depreciation is computed using the straight-line method over the estimated useful life of the respective assets. Our operating lease for office space includes one option to renew, with a five year renewal term that can extend the lease term to 2027. The exercise of this lease renewal option is at our sole discretion. The depreciable life of assets and leasehold improvements are limited by the expected lease term. Our

lease agreements do not contain any material residual value guarantees or restrictive covenants. As most of our leases do not provide an implicit rate, we used our estimated incremental borrowing rate of 10% based on the information available at commencement date in determining the present value of lease payments.

Lease assets and liabilities consisted of the following (in thousands):

Assets	Classification	September 30, 2019
Non-current assets	Right-of-use assets	\$ 2,399
Liabilities		
Current	Current operating lease liabilities	\$ 228
Long term	Long term operating lease liabilities	\$ 2,427

The components of lease expense for the three and nine months ended September 30, 2019 were as follows (unaudited):

	For the nine months ended September 30, 2019	
	September 30, 2019	2019
Lease expense:		
Operating lease expense	\$ 123	\$ 370
Short-term lease expense	—	—
Total lease expense	\$ 123	\$ 370

Other information:

Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	\$ 357
For operating lease:	
Weighted average remaining lease term (in years)	7.3
Weighted average discount rate	10%

Minimum future payments under the Company's leases at September 30, 2019 and their application to the corresponding lease liabilities are as follows (unaudited):

	Discounted lease liability payments	Payments due under lease agreements
2019 (remaining three months)	\$ 53	\$ 120
2020	237	491
2021	278	505
2022	322	521
2023	352	516
Thereafter	1,413	1,704
Total	\$ 2,655	\$ 3,857

6. Equity Securities

Increase in Authorized Shares of Common Stock

On June 4, 2019, our shareholders approved an amendment to our restated articles of incorporation increasing our authorized no par value shares of common stock from 200 million to 300 million shares.

Potentially Dilutive Common Stock Equivalents

As of September 30, 2019 and 2018, we excluded the potentially dilutive securities summarized below, which entitle the holders thereof to potentially acquire shares of common stock, from our calculations of net loss per share and weighted average common shares outstanding, as their effect would have been anti-dilutive (in thousands).

	September 30,	
	2019	2018
Common stock warrants issued to underwriter of initial public offering	802	802
Common stock warrants issued in connection with March 2017 rights offering	13,647	13,647
Common stock warrants issued in connection with February 2019 rights offering	47,812	—
Common stock options	8,680	7,581
Restricted stock units	488	47
Employee stock purchase plan	456	191
	<u>71,885</u>	<u>22,268</u>

7. Warrants

Warrants to purchase 47,812,371 shares of common stock with an exercise price of \$1.47 per share were issued in the rights offering completed in February 2019. The warrants are listed for trading under the symbol “EYESW” on the NASDAQ Capital Market and expire on March 14, 2024.

At the Company’s discretion, the warrants are redeemable on 30 days’ notice (i) if, after March 14, 2019, the shares of the Company’s common stock are trading at \$2.94 for 15 consecutive trading days and (ii) if all of the independent directors vote in favor of redeeming the warrants. Holders may be able to sell or exercise warrants prior to any announced redemption date and the Company will redeem outstanding warrants not exercised by the announced redemption date for a nominal amount of \$0.01 per Warrant.

The net cash proceeds were allocated to the relative fair values of the common stock and warrants on the date of issuance resulting in an allocation of \$0.47 per share to the common stock and \$0.25 per share to the warrants. In calculating the fair value of the warrants using the Black-Scholes model, the assumptions included a risk free interest rate of 2.49%, expected volatility of 82% and expected life of 5.08 years, and a 0% dividend yield.

We extended the term of 13,647,286 warrants issued in our March 2017 rights offering (“March 2017 Warrants”) by approximately two years effective as of February 15, 2019 as part of our February 2019 rights offering. We determined the fair value of the March 2017 Warrants immediately before and after the modification. The fair value of the March 2017 Warrants after the modification was increased by approximately \$1.6 million, resulting in an accounting adjustment to additional paid-in capital and accumulated deficit in the consolidated statements of shareholders’ equity. The assumptions used in the determination of fair value of the warrants before and after the extension included a risk free interest rate of 2.50% and 2.49%, expected volatility of 81% and 82%, and expected lives of 3.08 years and 5.08 years, respectively and 0% dividend yields for both.

A summary of warrants activity for the nine months ended September 30, 2019 is presented below (in thousands, except per share and contractual life data).

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (in Years)
Warrants outstanding as of December 31, 2018	14,449	\$ 2.01	3.10
Issued	47,812	1.47	
Exercised	—		
Forfeited or expired	—		
Warrants outstanding as of September 30, 2019	<u>62,261</u>	\$ 1.60	4.40
Warrants exercisable as of September 30, 2019	<u>62,261</u>	\$ 1.60	4.40

The warrants outstanding as of September 30, 2019 had no intrinsic value.

8. Stock-Based Compensation

A summary of stock option activity under our 2011 Equity Incentive Plan (“2011 Plan”) for the nine months ended September 30, 2019 is presented below (in thousands, except per share and contractual life data).

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (in Years)
Options outstanding as of December 31, 2018	7,120	\$ 3.83	6.81
Granted	2,600	\$ 0.77	
Exercised	—	\$	
Forfeited or expired	(1,040)	\$ 2.89	
Options outstanding as of September 30, 2019	<u>8,680</u>	\$ 3.03	7.28
Options exercisable as of September 30, 2019	<u>4,385</u>	\$ 4.62	5.88

The estimated aggregate intrinsic value of stock options exercisable as of September 30, 2019 was approximately \$14,000. As of September 30, 2019, there was \$3.2 million of total unrecognized compensation cost related to outstanding stock options that will be recognized over a weighted average period of 2.51 years.

During the nine months ended September 30, 2019, we granted stock options to purchase 2,600,042 shares of common stock to certain employees and directors. The options are exercisable for a period of ten years from the date of grant at prices ranging from \$0.69 to \$1.00 per share, which was the fair value of our common stock on the respective grant dates. The options generally vest over a period of four years with the exception of options issued in connection with director compensation which vest in approximately one year. The fair value of these options, calculated using the Black-Scholes option-pricing model, was determined to be \$1.3 million (\$0.44 to \$0.65 per share) using the following assumptions: expected term of 5.5 to 6.08 years, volatility of 72.0%, risk-free interest rate of 1.63% to 2.63%, and expected dividend rate of 0.0%.

The following table summarizes restricted stock unit (“RSU”) activity for the nine months ended September 30, 2019 (in thousands, except per share data):

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Outstanding as of December 31, 2018	35	\$ 12.43
Awarded	527	0.75
Vested and released	(74)	6.51
Forfeited/canceled	—	—
Outstanding as of September 30, 2019	<u>488</u>	<u>\$ 0.74</u>

As of September 30, 2019, there was \$0.3 million of total unrecognized compensation cost related to the outstanding RSUs that will be recognized over a weighted average period of 3.39 years.

During the nine months ended September 30, 2019, we awarded RSUs of 526,500 to certain employees. The fair value of these RSUs totaled \$0.4 million. The RSUs generally vest over a four year period, and were awarded at the fair value of our common stock on the respective award dates.

We adopted an employee stock purchase plan in June 2015 for all eligible employees. At September 30, 2019 the maximum number of shares that may be issued under the plan is 2,050,000.

Stock-based compensation expense recognized for stock-based awards in the condensed consolidated statements of operations for the three and nine months ended September 30, 2019 and 2018 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Cost of sales	\$ 43	\$ 74	\$ 133	\$ 201
Research and development	119	110	440	321
Clinical and regulatory	19	19	84	122
Selling and marketing	118	165	379	380
General and administrative	387	509	1,407	1,765
Total	<u>\$ 686</u>	<u>\$ 877</u>	<u>\$ 2,443</u>	<u>\$ 2,789</u>

9. Litigation, Claims and Assessments

Twenty-two oppositions have been filed by third-parties in the European Patent Office each challenging the validity of a European patent owned or exclusively licensed by us. The outcome of the challenges is not certain. However, if successful, they may affect our ability to block competitors from utilizing some of our patented technology in Europe. We do not believe a successful challenge will have a material effect on our ability to manufacture and sell our products, or otherwise have a material effect on our operations.

On August 22, 2019, Second Sight and Pixium Vision SA concluded a settlement agreement resolving all advertising disputes between the companies. The agreement provides that all litigation is withdrawn and costs are shared. The settlement does not address the patent opposition proceedings, between the companies, in the European Patent Office.

We are party to litigation arising in the ordinary course of business. It is our opinion that the outcome of such matters will not have a material effect on our results of operations, however, the results of litigation and claims are inherently unpredictable. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited condensed financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q as well as our audited 2018 financial statements and related notes included in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission (“SEC”) on March 19, 2019. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our products, plans and strategy for our business and related financing, contains forward-looking statements that involve risks and uncertainties, including statements regarding our expected financial results in future periods. The words “anticipates,” “believes,” “could,” “estimates,” “expects,” “intends,” “may,” “might,” “plans,” “projects,” “will,” “would,” “strategy” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Examples of forward-looking statements include, among others, statements we make regarding expectations for revenues, liquidity, cash flows and financial performance, the anticipated results of our development efforts and the timing for receipt of required regulatory approvals, insurance reimbursements and product launches. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. You should read “Risk Factors” in Part II, Item 1A of this Quarterly Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. We assume no obligations to update these forward-looking statements to reflect events or circumstances after the date of this Quarterly Report or to reflect actual outcomes.

Second Sight Medical Products, Inc. (NASDAQ: EYES) develops, manufactures and markets implantable visual prosthetics that are intended to deliver useful artificial vision to blind individuals. We are a recognized global leader in neuromodulation devices for blindness, and are committed to developing new technologies to treat the broadest populations of sight-impaired individuals.

Leveraging our 20 years of experience in neuromodulation for vision, we are developing the Orion® Visual Cortical Prosthesis System (“Orion”), an implanted cortical stimulation device intended to provide useful artificial vision to individuals who are blind due to a wide range of causes, including RP, glaucoma, diabetic retinopathy, optic nerve injury or disease and eye injury. Orion is intended to convert images captured by a miniature video camera mounted on glasses into a series of small electrical pulses. The device is designed to bypass diseased or injured eye anatomy and to transmit these electrical pulses wirelessly to an array of electrodes implanted on the surface of the brain’s visual cortex, where it is intended to provide the perception of patterns of light. A six-subject Early Feasibility Study of the Orion device is currently underway at the Ronald Reagan UCLA Medical Center in Los Angeles (“UCLA”) and Baylor College of Medicine in Houston (“Baylor”). Our 12 month results for five of the six subjects and six month results for the sixth subject (who will reach his 12 month mark in January 2020) indicate to us that:

- We have a good safety profile. Two subjects experienced a total of six adverse events (AEs) over this time period related to the device or to the surgery. One was considered a serious adverse event (SAE), and all of the adverse events were in the expected category. The one SAE was resolved quickly and did not require a hospital stay.
- The efficacy data is encouraging. We measure efficacy by looking at three measures of visual function: The first is square localization, where Orion subjects sit in front of a touch screen and are asked to touch within the boundaries of a square when it appears. The second is direction of motion, where subjects are asked to identify the direction and motion of lines on a screen. The third is grating visual acuity, a measure of visual acuity that is adapted for very low vision. On square localization, five of the six subjects in our feasibility study performed significantly better with the system on than off. On direction of motion, all six performed better on than off; and on grating visual acuity, three had measurable visual acuity on the scale of this test (versus none who can do it with the device off). Another efficacy measurement of day-to-day functionality and benefit is FLORA, which stands for Functional Low-Vision Observer Rated Assessment. FLORA is an assessment performed by an independent, third-party low vision orientation and mobility specialist who spends time with each of the subjects in their homes. The specialist asks each of the subjects a series of questions and also observes them performing 15 or more daily living tasks, such as finding light sources, following a sidewalk, or sorting laundry. The specialist then determines if the system is providing a benefit, if it is neutral, or if it is actually hurting the abilities of subjects to perform these tasks. Our FLORA results show that for five of the six subjects, the Orion system is providing benefit. No peer-reviewed data is available yet for the Orion system. We reached agreement with the FDA in the fourth quarter of 2019 to utilize a revised version of FLORA as our primary efficacy endpoint in our pivotal trial for Orion, pending successful validation of the instrument in the first half of 2020.

Our principal offices are located in Los Angeles, California. We also have an office in Lausanne, Switzerland, that manages our commercial and clinical operations in Europe, the Middle East and Asia.

Our current commercially approved product, the Argus® II Retinal Prosthesis System (“Argus II”), treats outer retinal degenerations, such as retinitis pigmentosa, also referred to as RP. RP is a hereditary disease, affecting an estimated 1.5 million people worldwide including about 100,000 people in the United States, that causes a progressive degeneration of the light-sensitive cells of the retina, leading to significant visual impairment and ultimately blindness. The Argus II is the only retinal prosthesis approved in the United States by the Food and Drug Administration (“FDA”), and was the first approved retinal prosthesis in the world. A subset of these patients would be eligible for the Argus II since the approved baseline vision for the Argus II is worse than legally blind (20/200). We commissioned 3rd party market research to estimate the size of the RP market that resulted in an estimate of approximately 1,500 patients in the US with advanced RP that could be treated with the Argus II given the eligibility criteria of our label.

The Argus II system provides an artificial form of vision that differs from the vision of people with normal sight. It does not restore normal vision and there is no evidence that it can slow or reverse the progression of the disease. The majority of patients receive a significant benefit from the Argus II, however results can vary and some patients report receiving little or no benefit. By creating an artificial form of useful vision in patients who otherwise have total sight loss, the Argus II can provide benefits that include:

- restoring independence through a renewed ability to navigate independently in unfamiliar environments;
- improving patients’ orientation and mobility, such as locating doors and windows, avoiding obstacles, and following the lines of a crosswalk;
- allowing patients to feel more connected with people in their surroundings, such as seeing when someone is approaching or moving away;
- providing patients with enjoyment from being “visual” again, such as locating the moon, tracking groups of players as they move around a field, and watching moving streams of lights from fireworks;
- enabling some patients to re-enter the workforce through multiple vocations that become possible because of Argus II; and
- improving patients’ well-being and ability to perform activities of daily living.

We began selling the Argus II System in Europe at the end of 2011, Saudi Arabia in 2012, the United States and Canada in 2014, Turkey in 2015, Iran, Taiwan, South Korea and Russia in 2017, and Singapore in 2018. Given the limited addressable market of Argus II, we made the decision in 2018 to maximize capital efficiency with our Argus commercial and clinical activities and increase our investment of resources with our Orion clinical and R&D programs. In October 2018, we announced a restructuring of our international commercial activities and personnel. This restructuring resulted in a decision to no longer support new implants of Argus II in Turkey, Iran, Singapore and Russia. We retained a team that continues to support existing Argus II patients and Centers of Excellence in all markets. We recognized approximately \$0.6 million of pre-tax restructuring charges in the fourth quarter of fiscal year 2018 in connection with this restructuring, consisting of severance and other employee termination benefits, substantially all of which were settled in cash during the fourth quarter of 2018.

Based on assessments of the development of our Orion technology and Orion's positive results in our Early Feasibility Study of the six subjects implanted with the Orion at UCLA and Baylor, on May 10, 2019 our Board approved an acceleration of our transition from the Argus II to the Orion platform so we may more rapidly implement our strategy of treating blindness domestically and worldwide with the Orion technology. As a result, we have or will:

- accelerate the changeover to, and upgrades of, our supply chain, manufacturing and quality assurance processes, as well as our facilities and talent pool to the Orion program and suspend production of Argus II systems;
- plan for the manufacture of the relatively large number of additional Orion devices that we will require to support FDA approval of the Orion as an approved commercial product;
- seek to expand our Early Feasibility Study and/or conduct a pivotal clinical trial with the intent of seeking regulatory approval for marketing Orion in the U.S.;
- reduce our commercial activities and other costs associated with expanding or maintaining Argus II sales domestically and outside the United States;
- limit future sales and implants of the Argus II to finished units and inventory on hand;
- incurred non-cash impairment charges of our inventory of approximately \$2.6 million in the nine months ended September 30, 2019;
- incurred cash severance and related expenses of approximately \$700,000 in the nine months ended September 30, 2019 covering employees associated with Argus II operations; and
- continue to support our existing and future Argus II users, which includes our commitment to bring the Argus 2s enhanced software and peripherals, following regulatory approval, to market in a limited manner which may improve the current user experience.

We expect to realize selling and marketing expense savings of approximately \$5.3 million for the year ended December 31, 2019 as compared to the same period in 2018. We also expect revenue to decline as we sell through our existing inventory. We expect approximately \$4.9 million of annual expense related to our manufacturing capacity to be reported as additional R&D expense in future quarters.

We are actively developing multiple technologies that we believe to be complimentary to artificial vision and could potentially provide significant enhancements to the Argus II or Orion user experience. In most cases, we collaborate with 3rd party firms to advance and integrate these innovative technologies with our artificial vision systems. Examples of technologies that we are currently researching include: eye tracking, object recognition and localization, thermal imaging and depth-based decluttering. We expect to advance several of these technologies to the point of having prototype eyewear suitable for clinical testing in 2019.

As of September 30, 2019, after more than 20 years of research and development, more than \$250 million of investment and over \$37 million of grants awarded in support of our technology development, we employ over 105 people in the development (research, engineering and clinical), manufacture, and commercialization of the Argus II System and future products such as Orion.

Capital Funding

From inception, our operations have been funded primarily through the sales of our common stock and warrants, as well as from the issuance of convertible debt, research and clinical grants, and limited product revenue generated by the sale of our Argus II System. Funding of our business since 2017 has been primarily provided by:

- Revenue of \$2.9 million for the nine months ended September 30, 2019 and \$6.9 million for the year ended December 31, 2018 generated by sales of our Argus II product.

- Issuance of common stock and warrants in a rights offering in February 2019, which provided net cash proceeds of \$34.4 million.
- Issuance of common stock in securities purchase agreements in May, August, October and December 2018, which provided net cash proceeds of \$22.0 million.
- Issuance of common stock through our At Market Issuance Sales Agreement (the “Sales Agreement”) during the first quarter of 2018 which provided net cash proceeds of \$4.0 million.

On September 17, 2019, we received a \$2.4 million, four-year grant from the National Institutes of Health (NIH) to develop spatial localization and mapping technology (“SLAM”). This grant involves a joint collaboration with the Johns Hopkins University Applied Physics Laboratory, and is intended to speed the integration of SLAM into future generations of Orion. The goal is to give Orion users the ability to localize objects and navigate landmarks in unfamiliar surroundings in real time.

In a rights offering completed on February 22, 2019 we sold approximately 47.8 million units, each priced at \$0.724 for net cash proceeds of approximately \$34.4 million. Each unit consisted of one share and one immediately exercisable warrant having an exercise price of \$1.47 per share. Entities controlled by Gregg Williams, our Chairman of the Board of Directors, acquired approximately 41.4 million units in the offering for an aggregate investment of approximately \$30 million.

In November 2017, we entered into an At Market Issuance Sales Agreement (the “Sales Agreement”) with B. Riley FBR Inc. and H.C. Wainwright & Co., LLC, as agents (“Agents”) pursuant to which we may offer and sell, from time to time through either of the Agents, shares of our common stock having an aggregate offering price as set forth in the Sales Agreement and a related prospectus supplement filed with the SEC. We agreed to pay the Agents a cash commission of 3.0% of the aggregate gross proceeds from each sale of shares under the Sales Agreement. During January and February 2018, we sold 2.2 million shares of common stock for additional net proceeds of \$4.0 million under the Sales Agreement. No shares have been sold since February 2018 under the Sales Agreement. We utilized these proceeds to further develop and enhance our products, support operations and for general corporate purposes.

We are subject to the risks and uncertainties associated with a business with one product line and diminishing commercial product revenues, including limitations on our operating capital resources and uncertain demand for our product. We have incurred recurring operating losses and negative operating cash flows since inception, and we expect to continue to incur operating losses and negative operating cash flows for the foreseeable future. Based on our current plans, we do not have sufficient funds to continue operating our business at current levels for at least twelve months from the date of issuance of this report. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity offerings or debt financings, grants, collaborations, strategic partnerships or other sources. However, we may be unable to raise additional capital or enter into such other arrangements when needed on favorable terms or at all. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or any other approved product candidates, or we may be unable to expand our operations, maintain our current organization and employee base or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Insurance Reimbursement

Obtaining reimbursement from governmental and private insurance companies is critical to our commercial success. Due to the price of the Argus II system, our sales would be limited without the availability of third party reimbursement. In the US, coding, coverage, and payment are necessary for the surgical procedure and Argus II system to be reimbursed by payers. Coding has been established for the device and the surgical procedure. The same will be required for Orion. Coverage and payment vary by payer. The majority of Argus II patients are eligible for Medicare, and coverage is primarily provided through traditional Medicare, sometimes referred to as Medicare Fee-for-Service (“FFS”) or Medicare Advantage. A small percentage of patients are covered by commercial insurers.

Within Europe, Argus II obtained reimbursement approval or funding in Germany (NUB Innovation Funding Program), France (Forfait Innovation Funding Program), and one region of Italy (Regional Funding). We were in the process of obtaining reimbursement through the Commissioning through Evaluation (“CtE”) program in England and discontinued these efforts in connection with our restructuring of the Argus II program. If Argus II was still available, the Forfait Innovation Funding Program and CtE program could have resulted in permanent national funding for Argus II assuming positive outcomes in the program, especially in France where we were in the final stages of reimbursement review process.

Currently, we are in process of evaluating potential reimbursement pathways for Orion in the US market. Compared to Argus II, which is largely catering to the Medicare patient population, Orion is expected to address a patient population with diverse and more balanced payer mix due to our potential indications profile and expected younger patient population, on average. As Orion is a part of the FDA’s Breakthrough Devices program, we are closely evaluating a variety of fast track reimbursement programs, including recent encouraging announcements from CMS proposing modernization of payment policies for medical devices that meet FDA’s

Breakthrough Devices designation. During the second half of 2019, we also approached some commercial payers and CMS to get their feedback to ensure our overall reimbursement strategy for Orion therapy will cater to their key data requirements.

Product and Clinical Development Plans

Orion. By further developing our visual cortical prosthesis, Orion, we believe we will significantly expand our market to include nearly all profoundly blind individuals. The only notable exceptions for potential use of the Orion are those who are blind due to otherwise currently treatable diseases, individuals who are born blind, or blindness due to direct damage of the visual cortex, which is rare. However, of the estimated 36 million blind people worldwide, there are approximately 5.8 million people who are legally blind due to causes that are not otherwise treatable (including RP) or age-related macular degeneration (“AMD”). We continue to develop and refine our estimates of the potential addressable market size as we evaluate the commercial prospects for Orion using a combination of published sources, 3rd party market research, and physician feedback. We currently estimate over 500,000 individuals in the US are legally blind due to retinitis pigmentosa, glaucoma, diabetic retinopathy, optic nerve disease and eye injury. Of this population, we estimate the potential US addressable market is between 50,000 and 100,000 individuals with bi-lateral blindness at the light-perception level or worse. Our marketing approvals by the FDA and other regulatory agencies will ultimately determine the subset of these patients who are eligible for the Orion based on our clinical trials and the associated results.

Our objective in designing and developing the Orion visual prosthesis system is to bypass the optic nerve and directly stimulate the part of the brain responsible for human vision. A six-subject Early Feasibility Study of the Orion device is currently underway at UCLA and Baylor. Our 12 month results for five of the six subjects and six month results for the sixth subject show a good safety profile with encouraging efficacy data and benefits in helping subjects perform their daily living tasks. Early promising results are not necessarily indicative of results which may be obtained in large clinical trials. No assurance can be given that we will achieve similar results in our larger Orion clinical trials. See Risk Factors in Item 1A below. No peer-reviewed data is available yet for the Orion system.

In November 2017, the FDA granted Breakthrough Devices Program designation for the Orion. This designation is given to a few select medical devices in order to provide more effective treatment of life-threatening or irreversibly debilitating diseases or conditions. This program is intended to help patients have more timely access to these medical devices by expediting their development, assessment, and review. With this designation, we believe the Orion will have the following advantages during the FDA review process:

- Greater interactive review both for the Investigational Device Exemption and Premarket Approval application;
- Greater reliance on post-market vs. pre-market data collection and greater acceptance of uncertainty in the benefit-risk profile at the time of approval;
- Priority review (i.e., review of the submission is placed at the top of the review queue and receives additional review resources); and,
- Senior FDA management involvement and assignment of a cross-disciplinary case manager.

We expect that inclusion in the Breakthrough Devices Program may shorten the timeline required to bring the Orion to market as a commercial product. We also are currently evaluating our pivotal trial design for Orion and expect to reach consensus with the FDA on design specifics during 2019. Major elements of our clinical trial design include the number of patients, study duration, and the endpoints suitable for assessing visual function, functional vision and quality of life. We have reached agreement with FDA on the primary effectiveness endpoint, pending validation of an assessment we have developed for the purpose. We anticipate completing the validation study in the first half of 2020. We are currently working with FDA on alignment on a primary safety endpoint and confirmation of a sample size. While negotiations with the FDA are ongoing, we are evaluating two different paths for Orion. The first path is a Premarket Approval, or PMA, track. The projected start of the pivotal trial is still not determined pending resolution of various aspects of the pivotal study and post approval requirements. Depending on the timing of the pivotal study, it is possible that we would expand our Early Feasibility Study in order to collect additional data before proceeding to a pivotal trial. The second path would involve first obtaining a Humanitarian Device Exemption approval, or HDE, followed by a PMA. This path would become preferable if the PMA requirements push the start of the pivotal study too far into the future. Given that an HDE approval requires the demonstration of probable benefit rather than the PMA standard of effectiveness, we believe that we could start a study to support HDE approval much sooner than a pivotal study. In parallel to seeking an HDE approval, we would continue negotiations with the Agency as well as preparations to start a pivotal study.

Argus II. The Argus II is currently approved for RP patients with bare or no light perception in the US, and in Europe for severe to profound vision loss due to outer retinal degeneration, such as from RP, choroideremia, and other similar conditions. The number of people who are legally blind due to RP is estimated to be about 25,000 in the US, 42,000 in Europe, and about 375,000 total worldwide. A subset of these patients would be eligible for the Argus II since the approved baseline vision for the Argus II is worse

than legally blind (20/200). We commissioned 3rd party market research for the size of the RP market that resulted in an estimate of approximately 1,500 patients in the US with advanced RP that could be treated with the Argus II given the eligibility criteria of our label.

Given the limited addressable market of Argus II, we made the decision to maximize capital efficiency with our Argus II commercial and clinical activities and increase our investment of resources with our Orion clinical and R&D programs. As a result, we expect to suspend production activities related to Argus II, sell through our remaining inventory and reduce our commercial activities related to Argus II. We remain committed to supporting existing Argus II users and intend to pursue regulatory approvals for our new externals, Argus 2s.

Critical Accounting Policies

The preparation of our condensed consolidated financial statements in conformity with generally accepted accounting principles in the United States (“GAAP”) and the requirements of the United States Securities and Exchange Commission require management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions. A summary of our critical accounting policies is presented in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2018.

We adopted ASU No. 2016-02—*Leases (Topic 842)*, as amended, as of January 1, 2019, using the modified retrospective approach. The modified retrospective approach provides a method for recording existing leases at adoption and in comparative periods that approximates the results of a full retrospective approach. In addition, we elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed us to carry forward the historical lease classification.

Adoption of the new standard resulted in the recording of right-of-use assets and operating lease liabilities of approximately \$2.6 million and \$2.8 million respectively, as of January 1, 2019. The difference of \$0.2 million between the right-of-use assets and operating lease liabilities, net of the deferred tax impact, was recorded as an adjustment to accumulated deficit at January 1, 2019. The standard did not materially impact our consolidated net loss and had no impact on cash flows.

Based upon our decision on May 10, 2019 to accelerate our transition to the Orion platform, we evaluated our accounting policies related to the disposition in accordance with ASC 205-20 *Discontinued Operations*, and assessed our long-lived assets for any indications that their carrying values may not be recoverable in accordance with ASC 360, *Property, Plant, and Equipment*, for any impairment. Based upon these reviews we recorded in the nine months ended September 30, 2019 impairment charges of \$2.6 million related to inventory of Argus II based on our plans to suspend production of Argus II. Specifically, we reduced expenses and personnel related to commercial activities and production for the Argus II. We recognized approximately \$0.7 million of pre-tax restructuring charges in the second quarter of fiscal year 2019 in connection with this restructuring, consisting of severance and other employee termination benefits, \$0.4 million of which has been settled at September 30, 2019 with substantially all of the remainder expected to be settled in cash by the end of 2019. Based upon our review of the applicable accounting standards we determined that there was no impairment of any other assets.

There have been no other material changes to our critical accounting policies during the nine months ended September 30, 2019.

Results of Operations

Net sales. Our net sales are derived primarily from the sale of our Argus II product. We began selling the Argus II in Europe at the end of 2011, Saudi Arabia in 2012, the United States and Canada in 2014, Turkey in 2015, Iran, Taiwan, South Korea and Russia in 2017, and Singapore in 2018. In May 2019, we decided to accelerate our transition to the Orion platform. As a result, we expect to suspend production related to Argus II and sell through our remaining inventory.

Cost of sales. Cost of sales includes the salaries, benefits, material, overhead, third party costs, warranty, charges for excess and obsolete inventory, and other costs required to make the Argus II system at our Los Angeles, California facility. Our product involves technologically complex materials and processes. We expect to record cost of sales for any remaining Argus II inventory that we sell and a majority of our expenses related to our production capabilities and fixed overhead to be reported as research and development expense in future periods. We record cost of sales when products are implanted, which may differ from the period we are able to record revenue. Such timing differences may cause our reported results of operations to be difficult to compare from period to period.

Operating Expenses. We generally recognize our operating expenses as incurred in four general operational categories: research and development, clinical and regulatory, sales and marketing, and general and administrative. Our operating expenses also include a non-cash component related to the amortization of stock-based compensation for research and development, clinical and regulatory, sales and marketing, and general and administrative personnel. From time to time we have received grants from institutions or agencies, such as the National Institutes of Health, to help fund the some of the cost of our development efforts. We have recorded the amount of funding received from these grants as reductions to operating expenses.

- Research and development expenses consist primarily of employee compensation and consulting costs related to the design, development, and enhancements of our current and potential future products, offset by grant revenue received in support of specific research projects. We expense our research and development costs as they are incurred. We expect research and development expenses to increase in the future as we pursue further enhancements of our existing product and develop technology for our potential future products, such as Orion. We also expect to receive additional grants in the future that will be offset primarily against research and development costs.
- Clinical and regulatory expenses consist primarily of salaries, travel and related expenses for personnel engaged in clinical and regulatory functions, as well as internal and external costs associated with conducting clinical trials and maintaining relationships with regulatory agencies. We expect clinical and regulatory expenses to increase as we assess the safety and efficacy of enhancements to our current Argus II and conduct clinical studies of potential future products such as Orion.
- Sales and marketing expenses consist primarily of salaries, commissions, travel and related expenses for personnel engaged in sales, marketing and business development functions, as well as costs associated with promotional and other marketing activities including the cost of units consumed as demos or samples. We expect sales and marketing expenses to decrease as we reduce our Argus II commercial activities and sell through our existing inventory.
- General and administrative expenses consist primarily of salaries and related expenses for executive, legal, finance, human resources, information technology and administrative personnel, as well as recruiting and professional fees, patent filing and annuity costs, insurance costs and other general corporate expenses, including rent. We expect general and administrative expenses to remain consistent through 2019 but increase in future years as we add personnel and incur additional costs related to the growth of our business and operate as a public company.

Comparison of the Three Months Ended September 30, 2019 and 2018

We implanted a total of four Argus II products during the third quarter of 2019 and 20 in the third quarter of 2018. All four implants were in Europe, the Middle East and Asia (collectively, "EMEA") in the third quarter of 2019 while eleven implants were in EMEA in the third quarter of 2018.

In North America, there were no implants in the third quarter of 2019 while there were nine implants in the third quarter of the prior year. Of these, there were seven implants in the U.S. and two implants in Canada in the third quarter of 2018.

Net Sales. Net sales were \$0.5 million in the third quarter of 2019 as compared to \$2.2 million in the same period in 2018, a decrease of \$1.7 million or 79%. Revenue was recognized for four units in the third quarter of 2019 while 22 units were recognized in the third quarter of 2018. Revenue recognized per implant was approximately \$118,000 in the third quarter of 2019 and was \$102,000 in same period of 2018. We expect our net sales to decline as we sell through our existing inventory of Argus II.

Cost of sales. Cost of sales was \$0.4 million in the third quarter of 2019 as compared to \$1.8 million in the third quarter of 2018. Cost of sales in the third quarter of 2019 consists primarily of the cost of products implanted of \$0.2 million and unabsorbed production costs of approximately \$0.2 million. In the third quarter of 2018, the cost of sales included approximately \$1.7 million for the cost of products implanted and unabsorbed production costs plus an adjustment of \$0.1 million for an increase in the reserve for

excess inventory. We expect to record cost of sales for any remaining Argus II inventory that we sell and a majority of our expenses related to our production capabilities and fixed overhead to be reported as research and development expense in future periods.

Research and development expense. Research and development expense increased by \$0.7 million, or 26%, from \$2.7 million in the third quarter of 2018 to \$3.4 million in the third quarter of 2019. The costs increased from the prior year due primarily to costs incurred for internally produced prototypes. We expect our research and development expenses to increase in future periods as we accelerate our transition to the Orion platform, including costs previously related to production activities such as facilities and personnel that will be transitioning to Orion development activities.

Clinical and regulatory expense. Clinical and regulatory expense decreased \$0.1 million, or 11%, from \$1.0 million in the third quarter of 2018 to \$0.9 million in the third quarter of 2019. This decrease is attributable to decreased costs associated with the Orion feasibility study. We expect clinical and regulatory costs to increase in the future as we conduct additional clinical trials to assess new products such as Orion and related enhancements to our user experience.

Selling and marketing expense. Selling and marketing expense decreased \$1.7 million, or 57%, from \$3.0 million in the third quarter of 2018 to \$1.3 million in the third quarter of 2019. This decrease in costs was primarily driven by our reduced commercial activities related to Argus II and the resulting decreased use of outside services, supplies, reduced headcount and related compensation expense. We expect selling and marketing expense to decrease as we reduce our Argus II commercial activities and sell through our existing inventory.

General and administrative expense. General and administrative expense decreased \$0.1 million, or 7%, from \$2.3 million in the third quarter of 2018 to \$2.2 million in the same period of 2019. This decrease is primarily attributable to \$0.1 million in lower compensation costs primarily due to reduced staffing. We expect general and administrative expenses to remain consistent during the remainder of 2019.

Comparison of the Nine Months Ended September 30, 2019 and 2018

We implanted a total of 25 Argus II products during the first nine months of 2019 and 53 in the first nine months of 2018. Of these, twelve implants were in Europe, the Middle East and Asia (collectively, "EMEA") in the first nine months of 2019 while 25 implants were in EMEA in the first nine months of 2018.

In North America, there were 13 implants in the first nine months of 2019 while there were 28 implants in the first nine months of the prior year. Of these, all the implants were in the U.S. in the first nine months of 2019 while 24 were in the U.S. in the first nine months of 2018 along with four implants in Canada.

Net Sales. Net sales were \$2.9 million in the first nine months of 2019 as compared to \$5.1 million in the same period in 2018, a decrease of \$2.2 million or 44%. Revenue was recognized for 23 units in the first nine months of 2019 as compared to 48 units in the first nine months of 2018. Revenue recognized per implant was approximately \$125,000 in the first nine months of 2019 and was \$107,000 in same period of 2018. We expect our net sales to decline as we sell through our existing inventory of Argus II.

Cost of sales. Cost of sales was \$2.0 million in the first nine months of 2019 as compared to \$3.3 million in the first nine months of 2018. Cost of sales in the first nine months of 2019 consists primarily of the cost of products implanted of \$1.3 million and unabsorbed production costs of \$0.7 million. In the first nine months of 2018, the cost of sales included approximately \$3.1 million for the cost of products implanted and unabsorbed production costs plus an increase of \$0.2 million in the reserve for excess inventory. We expect to record cost of sales for any remaining Argus II inventory that we sell and a majority of our expenses related to our production capabilities and fixed overhead to be reported as research and development expense in future periods.

Research and development expense. Research and development expense, net of funding received from grants, increased by \$1.4 million, or 19%, from \$7.6 million in the first nine months of 2018 to \$9.0 million in the first nine months of 2019. In the first nine months of 2019 we utilized \$0.4 million of grant funds to offset costs as compared to \$0.2 million in 2018. The costs before the grant revenue offset increased from the prior year primarily due to increased headcount and costs for internally produced prototypes. We expect our research and development expenses to increase in future periods as we accelerate our transition to the Orion platform, including costs previously related to production activities such as facilities and personnel that will be transitioning to Orion development activities.

Clinical and regulatory expense. Clinical and regulatory expense, net of funding received from grants, decreased \$1.0 million, or 30%, from \$3.4 million in the first nine months of 2018 to \$2.4 million in the first nine months of 2019. This decrease is primarily attributable to decreased costs associated with the Orion feasibility study of \$0.7 million and offset costs from grants of \$0.5 million. We expect clinical and regulatory costs to increase in the future as we conduct additional clinical trials to assess new products such as Orion and related enhancements to our user experience.

Selling and marketing expense. Selling and marketing expense decreased \$3.8 million, or 43%, from \$8.9 million in the first nine months of 2018 to \$5.1 million in the first nine months of 2019. This decrease in costs was primarily driven by our reduced

commercial activities related to Argus II and the resulting decreased use of outside services, reduced headcount and related compensation expenses. We expect selling and marketing expense to decrease as we reduce our Argus II commercial activities and sell through our existing inventory.

General and administrative expense. General and administrative expense decreased \$1.3 million, or 16%, from \$8.2 million in the first nine months of 2018 to \$6.9 million in the same period of 2019. This decrease is primarily attributable to \$0.7 million in lower compensation costs primarily due to cancelled stock option grants and reduced staffing. Outside service costs and patent costs were both reduced by \$0.2 million and travel costs were reduced by \$0.1 million. We expect general and administrative expenses to remain consistent during the remainder of 2019.

Restructuring charges. We recorded a non-cash restructuring charge of \$2.6 million in the first nine months of 2019 to our reserve for excess and obsolete inventory in connection with our plans to suspend Argus II production. In addition, we recognized \$0.7 million of pre-tax restructuring charges in the second quarter of fiscal year 2019 consisting of severance and other employee termination benefits, \$0.4 million of which was settled at September 30, 2019, with substantially all of the remainder expected to be settled in cash during the last quarter of 2019.

Liquidity and Capital Resources

Our financial statements have been presented on the basis that our business is a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We are subject to the risks and uncertainties associated with a business with one product line and limited commercial product revenues, including limitations on our operating capital resources and uncertain demand for our products. We have incurred recurring operating losses and negative operating cash flows since inception, and we expect to continue to incur operating losses and negative operating cash flows for the foreseeable future.

In a rights offering completed on February 22, 2019, we sold approximately 47.8 million units, each priced at \$0.724 for net cash proceeds of approximately \$34.4 million. Each unit consisted of one share and one immediately exercisable warrant having an exercise price of \$1.47 per share. Entities controlled by Gregg Williams, our Chairman of the Board of Directors, acquired approximately 41.4 million units in the offering for an aggregate investment of approximately \$30 million. The expiration date of the warrants issued pursuant to this rights offering is March 14, 2024, and the expiration date of all previously outstanding warrants listed for trading under the symbol "EYESW" were extended to March 14, 2024.

We do not have sufficient funds to support our operations for the next 12 months from the date of issuance of this report. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. Conducting clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete and we may never generate the necessary data or results required to obtain marketing approval. We expect revenues for Argus II to decrease as we sell through our remaining inventory and expenses to increase in connection with our ongoing activities, particularly as we continue clinical trials of Orion, initiate new research and development projects and seek marketing approval for any product candidates that we successfully develop. In addition, if we obtain marketing approval for Orion, we expect to incur significant additional expenses related to sales, marketing, distribution and other commercial infrastructure to commercialize such product. In addition, our product candidates, if approved, may not achieve commercial success. We incur significant costs associated with operating as a public company in a regulated industry.

Until such time, if ever, we can generate substantial product revenues, we anticipate that we will seek to fund our operations through public or private equity or debt financings, grants, collaborations, strategic partnerships or other sources. Accordingly, these factors among others raise substantial doubt about our ability to continue as a going concern. However, we may be unable to raise additional capital or enter into such other arrangements when needed on favorable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or to grant licenses on terms that may not be favorable to us.

Cash and cash equivalents increased by \$14.0 million from \$4.5 million as of December 31, 2018 to \$18.5 million as of September 30, 2019. Working capital was \$13.2 million as of September 30, 2019, as compared to \$2.0 million as of December 31, 2018, an increase of \$11.2 million. We use our cash and cash equivalents and working capital to fund our operating activities.

Cash Flows from Operating Activities

During the first nine months of 2019, we used \$20.2 million of cash in operating activities, consisting primarily of a net loss of \$25.7 million, offset by non-cash charges which provided cash of \$4.5 million for depreciation and amortization of property and equipment, stock-based compensation, change in right of use assets, excess inventory reserve, impairment charge and by a net change

in operating assets and liabilities which provided cash of \$1.0 million. During the first nine months of 2018, we used \$22.1 million of cash in operating activities, consisting primarily of a net loss of \$26.2 million, offset by non-cash charges which provided cash of \$3.4 million for depreciation and amortization of property and equipment, stock-based compensation, bad debt recovery, excess inventory reserve and common stock issuable and by a net change in operating assets and liabilities which provided cash of \$0.7 million.

Cash Flows from Investing Activities

Cash used for investing activities in the first nine months of 2019 was \$394,000 and was \$144,000 in the first nine months of 2018 both for the purchase of property and equipment.

Cash Flows from Financing Activities

Financing activities provided \$34.6 million of cash in the first nine months of 2019 consisting of \$34.4 million of net proceeds from the rights offering and \$0.2 million from employee stock plan purchases. Financing activities provided \$19.4 million of cash in the first nine months of 2018 consisting of \$19.0 million in net proceeds from the sale of common stock and \$0.4 million from the exercise of options and warrants and employee stock plan purchases.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk*Interest Rate Sensitivity*

The primary objective of our investment activities is to maintain the safety of principal and preserve liquidity without incurring significant risk. We invest cash in excess of our current needs in money market funds. As of September 30, 2019, our investments consisted solely of money market funds.

Exchange Rate Sensitivity

During the nine months ended September 30, 2019, approximately 63% of our revenue was denominated in U.S. dollars and 37% in Euros. The majority of our operating expenses were denominated in U.S. dollars. We have not entered into foreign currency forward contracts to hedge our operating expense exposure to foreign currencies, but we may do so in the future.

Item 4. Controls and Procedures*Evaluation of Disclosure Controls and Procedures*

Our management, including our Chief Executive Officer (“CEO”) and our Chief Financial Officer (“CFO”), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2019. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. As of September 30, 2019, based on the evaluation of these disclosure controls and procedures, our CEO and CFO have concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended September 30, 2019 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PART II-OTHER INFORMATION

Item 1. Legal Proceedings

Twenty-two oppositions have been filed by third parties in the European Patent Office each challenging the validity of a European patent owned or exclusively licensed by us. The outcome of the challenges is not certain. However, if successful, they may affect our ability to block competitors from utilizing some of its patented technology in Europe. We do not believe a successful challenge will have a material effect on our ability to manufacture and sell our products, or otherwise have a material effect on our operations.

On August 22, 2019, Second Sight and Pixium Vision SA concluded a settlement agreement resolving all advertising disputes between the companies. The agreement provides that all litigation is withdrawn and costs are shared. The settlement does not address the patent opposition proceedings, between the companies, in the European Patent Office.

We are party to litigation arising in the ordinary course of business. It is our opinion that the outcome of such matters will not have a material effect on our results of operations, however, the results of litigation and claims are inherently unpredictable. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

Although we believe that our strategy to (i) leverage proven Argus II technology to develop the Orion visual cortical prosthesis and (ii) significantly expand our addressable market to include a portion of the almost 6 million patients who are blind from eye trauma, optic nerve disease and injury, diabetic retinopathy, glaucoma and other untreatable causes is more likely to address a better and faster way to treat many causes of blindness, including the Retinitis Pigmentosa population, we will incur material near term losses, market uncertainty and our stock may experience significant fluctuations as we make the transition from the Argus II to Orion.

Based on assessments of the development of our Orion technology and the positive results in an early feasibility study of the six subjects implanted with the Orion at UCLA Medical Center and Baylor College of Medicine, in May 2019, our Board approved an acceleration of our transition from the Argus II to the Orion platform so we may more rapidly implement our strategy of treating blindness domestically and worldwide. As a result, we will or have:

- accelerate the changeover to, and upgrades of, our supply chain, manufacturing and quality assurance processes, as well as our facilities and talent pool to the Orion program and suspend production of Argus II systems;
- plan for the manufacture of Orion devices that we will require to support FDA approval of the Orion commercial product;
- seek to expand our early feasibility study and/or conduct a pivotal clinical trial with the intent of seeking regulatory approval for marketing Orion in the U.S.;
- continue to reduce our commercial activities and other costs associated with expanding or maintaining Argus II sales domestically and outside the United States;
- limit future sales and implants of the Argus II to finished units and inventory on hand;
- incurred non-cash impairment charges of approximately \$2.6 million relating to Argus II inventory in the nine months ended September 30, 2019;
- incurred cash severance and related expenses of approximately \$700,000 in the nine months ended September 30, 2019 covering employees associated with Argus II operations; and
- continue to support our existing and future Argus II patient population, which includes our commitment to bring the Argus 2s enhanced software and peripherals, following regulatory approval, to market in a limited manner which may improve the current patient experience.

Our decision to accelerate Orion development will likely cause physicians or individuals who are eligible for Argus II to delay implantation of Argus II in favor of Orion which will adversely affect our Argus II sales and results of operations.

As a result of this transition from Argus II, our future success will depend on the further development, regulatory approval and commercialization of the Orion product. Although we believe this more rapid changeover and implementation of our long term strategy for treating blindness by Orion will provide us a sizable, commercially sustainable domestic and worldwide market for our products, in the near term we will incur significant losses, market volatility and regulatory uncertainty, including uncertainty associated with pricing and reimbursement coverage with no current assurance of market acceptance. No assurance can be given that this strategy will achieve domestic and regulatory approvals or result in commercial viability of our products or our company.

If our development activity, regulatory efforts and substantial investments related to Orion do not result in a commercial product or if our company never achieves profitability or positive free cash flow, our stock price will decline, we will not be able to sustain operations and our stockholders may incur a complete loss of their investment in our company.

Our revenues for Argus II have decreased and we expect that they will continue to decrease as we sell through our remaining inventory and that our expenses will increase in connection with our ongoing activities, particularly as we expand and continue clinical trials of Orion, initiate new research and development projects and seek marketing approval for the Orion and any product candidates that we successfully develop. In addition, if we obtain marketing approval for Orion, we expect to continue incurring significant additional expenses related to sales, marketing, distribution and other commercial infrastructure to commercialize that product. Nevertheless no assurance can be given that Orion will achieve commercial success or result in profitable operations, in which case investors may lose all or substantially all of their investment in our company.

The CE marking regulations in the European Union are subject to a significant effort to strengthen the regulatory regime for medical devices which, if adopted, will make the approval process more time consuming and costly for us to obtain access to and continue to market within the European markets.

We are subject to an annual audit of compliance with the rules necessary to support our CE Mark. In April 2017 the European Commission published a new regulatory scheme that imposes significant additional obligations on medical device companies. As such, devices with a current CE marking, such as the Argus II, will have to comply with additional, more challenging regulatory obligations. The changes being made to the regulations include stricter requirements for clinical evidence and pre-market assessment of safety and performance, new classifications to indicate risk levels, requirements for third party testing by government accredited groups for some types of medical devices, and tightened and streamlined quality management system assessment procedures. With the additional provisions adopted by the European Parliament, the European Medicines Agency (EMA) may be involved in regulation of some types of medical devices in the qualification and monitoring of notified bodies (NBs), and enhancing the roles of other bodies, including a new Medical Devices Coordination Group (MDCG). The European Parliament's revisions also impose enhanced competence requirements for NBs and "special notified bodies" (SNBs) for specific categories of devices, such as implantable devices. These changes are anticipated to result in stricter conformity assessment procedures. The medical device industry anticipates that there will be significant changes under these initiatives to the regulation of medical devices which will increase the time and costs for obtaining CE marking after May 2020. A grace period of four years provides medical device companies the opportunity to be compliant with the new standard before May 2024. We anticipate being audited to this new standard by 2024.

Our CE Mark registration must be renewed on a periodic basis. Our CE Mark registration for the Argus II system expired on September 1, 2019. We commenced our recertification audit in June 2019 and expect to receive a recertification through May 2024. No assurance can be made that we will receive recertification. We currently have limited inventory of Argus II placed in the EU market prior to September 1, 2019, and anticipate being able to maintain our Argus II support outside the United States. Further, the Medical Device Single Audit Program (MDSAP) is a new multi-national standard adopted by Australia, Brazil, Canada, Japan and the United States. MDSAP may impose a higher compliance burden than CE Mark through more rigorous audit requirements. In connection with our strategic decision to accelerate Orion development, we decided not to pursue MDSAP compliance during 2019 and will suspend our commercial activities for Argus II in Canada until further notice. We believe we are able to support current Argus II users through Health Canada's special access program, but no assurance of approval can be made.

We are increasingly dependent on sophisticated information technology systems, including systems from third parties, and if we fail to properly maintain the integrity of our data or if our products do not operate as intended, our business could be materially and adversely affected.

We are increasingly dependent on sophisticated information technology systems for our products and infrastructure, and we rely on these information technology systems, including technology from third party vendors, to process, transmit and store electronic information in our day-to-day operations. We continuously monitor, upgrade and expand the systems we operate to improve information systems capabilities. Our information systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop or contract new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards, and the increasing need to protect patient and customer information. In addition, third parties may attempt to hack into our products or systems and may obtain data relating to patients with our products or proprietary information. If we fail to maintain or protect our information systems and data integrity with cyber security effectively, we could lose existing customers, have difficulty attracting new customers, have problems in determining product cost estimates and establishing appropriate pricing, have difficulty preventing, detecting, and controlling fraud, have disputes with customers, physicians, and other health care professionals, have regulatory sanctions, fines, or penalties imposed, have increases in operating expenses, incur expenses or lose revenues as a result of a data privacy breach, or suffer other adverse consequences. There can be no assurance that our process of upgrading and expanding our information systems capabilities, protecting and enhancing our systems including cyber security methods, and developing new systems to keep pace with continuing changes in information processing technology will be successful or that additional systems issues will not arise in the future. Our products contain hardware and software protections which are intended to prevent unauthorized access or control of our implanted device. However, if an unauthorized user is able to breach our controls and gain access to one of our devices implanted in a patient, serious harm, injury and/or death may result. Any significant breakdown, intrusion, interruption, corruption, or destruction of these systems, as well as any data breaches, could have a material adverse effect on our business.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

In order to obtain marketing approval for Orion we must demonstrate the safety and efficacy of Orion through clinical trials as well as additional supporting data. If Orion is associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to interrupt, delay or abandon Orion's development, cause it to have reduced functionality, or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. We are conducting at UCLA and Baylor a six subject initial feasibility clinical study of Orion, but we cannot guarantee that any positive results in this limited trial will successfully translate to a pivotal clinical trial. It is not uncommon to observe results in human clinical trials that are unexpected based on limited trials testing, and many product candidates fail in large clinical trials despite promising limited clinical trial results. Moreover, clinical data is often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain marketing approval for their products. No assurance can be given that we will not encounter similar results in our Orion trials.

Human subjects in our clinical trials may suffer significant adverse events, tolerability issues or other side effects associated with the surgical implantation, chronic implantation, and chronic use of the Orion device. These events include, but are not limited to, the following (events that are also anticipated during or following explantation of the Orion device are identified with an asterisk (*)): intracranial hemorrhage*; subcutaneous hematoma*; vascular injury causing stroke or hemorrhage (e.g. injury to the superior sagittal sinus or posterior cerebral artery perforators)*; hydrocephalus*; intracranial hypotension or cerebrospinal fluid (CSF) leak*; headache or pain in the head, including deep pain*; tingling at the implant site*; brain edema*; infection*; meningitis*; implant site pain, swelling, discharge or effusion*; suture-related complications or stitch abscess*; skin erosion on and/or around the implant site; adverse tissue reaction to the implant; tissue damage at the implant/explant site*; cranial defect/bone damage*; decline in residual vision*; dizziness/syncope*; foreign body sensation at the implant site*; activation of motor or sensory neurons (e.g., muscle twitch); clinically symptomatic seizure*; development of epilepsy; coma*; death*; psychiatric events, including but not limited to mood changes, depression, suicidality, and psychosis*; neurological deficit, including but not limited to language (dysphemia), dysesthesias, paresis, paresthesia, visual field, motor deficit (including apraxia), and memory impairment*; drug hypersensitivity, adverse drug reaction, or therapeutic agent toxicity*; events related to any surgery and general anesthesia including cardiac risks, including stroke/transient ischemic attack, arrhythmia, cardiac arrest, and myocardial infarction*, venous thromboembolic (VTE) disease*, pneumonia*, urinary tract infection*, post-operative delirium*, postoperative constipation*, post-operative vomiting or nausea*, or post-operative fever*; injuries due to falls or bumps; skin irritation or burns; Orion system failure or malfunction; array migration; damage to the Orion electronics case; device interaction including the Orion device may interfere with the proper functioning of other electronic devices and emissions from other electronic equipment may interfere with the proper functioning of the Orion device; and (explant only) inability to remove all or part of the Orion device due to fibrosis or other reason.

No assurance can be given that we will not encounter adverse events in our Orion trials. The observed efficacy and extent of light perception and vision restoration for subjects implanted with Orion in our feasibility study may not be maintained over the long term, or may not be observed in a larger pivotal clinical trial. If general clinical trials of Orion fail to demonstrate efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of Orion.

For example, in June 2018, one subject in our Early Feasibility Study for Orion ("EFS") experienced a seizure while in the clinic when we were evaluating a specific video stimulation algorithm. The seizure resolved quickly with medication and the subject was released from the clinic without need for hospitalization or further treatment. The subject was allowed to continue using the Orion device after the serious adverse event was reviewed by a safety committee for the study and clinicians at the implanting institution.

In addition, in January 2019 we observed higher impedance levels on 11 of 60 electrodes with the first EFS subject implanted with the Orion device in January 2018. As a result, some of these electrodes no longer generate a phosphene, or observable spot of light, for the subject. The subject continues to use the device and is continuing to participate in the clinical study. Mechanical and software safeguards are built into the device to avoid excessive electrical stimulation and, as a result, the higher impedance levels do not pose any known safety risks to the subject. Given the pattern of high impedances, we took the precaution of disabling half of the electrodes on the array to ensure that other potentially affected electrodes are not used. Root cause(s) for the higher impedance levels cannot be conclusively determined while the device remains implanted but could include any combination of the following: potential manufacturing defects, damage due to improper or excessive handling of the device, materials chosen for the design, and related processes. The first subject has been implanted with the device for 21 months, four subjects have been implanted for 17-19 months, and one subject for nine months. We currently have no indication that the issue exists with any of the Orion devices implanted in each of the other five EFS subjects. Prior to initiation of EFS, we subjected six Orion implants to accelerated aging tests and had no failures for what was the equivalent of up to 6.5 years.

In October 2019, we also observed changes to impedances (higher and lower) on most electrodes with the sixth EFS subject implanted with the device in January 2019. These impedance changes were coincident with a loss of most perception from the device, though there is no indication of a medical adverse event or a device defect. When examined again in November 2019 this sixth EFS subject showed improved perception and more normal impedances. We are currently investigating the possible root cause(s) for these changes, which may or may not be device related (i.e., may be subject related) and may or may not be permanent.

We cannot provide any assurance that we will not experience similar or other issues with any of the implanted Orion devices, be able to determine the root cause of the issue or to ascertain whether the issue is isolated or systemic in nature. Additional testing, investigation, design changes or mitigation activities may delay our plans to conduct additional clinical studies for Orion and/or our marketing approval and may have a material adverse effect on our business.

If device defects, significant adverse events or other side effects are observed in any of our future clinical trials, we may have difficulty recruiting subjects to the clinical trial, subjects may drop out of our trial, or we may be required to abandon the trial or our development efforts of that product candidate altogether. We, the FDA or other applicable regulatory authorities may suspend clinical trials of Orion at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks. Devices developed in the prosthesis industry that initially showed promise in early-stage studies have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude Orion from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its actual or perceived safety and tolerability profile. Any of these developments could materially harm our business, financial condition and prospects.

Should Orion obtain marketing approval, adverse effects associated with it may also develop after such approval and could lead to requirements for conducting additional clinical safety trials, placing additional warnings in the labeling, imposing significant restrictions on Orion, or withdrawing the Orion from the market while further incurring attendant costs of explants and exposure to litigation. We cannot predict whether Orion will cause significant adverse effects in humans that would preclude or lead to the revocation of regulatory approval. However, any such event, were it to occur, would cause substantial harm to our business and financial condition and would result in the diversion of our management's attention.

If we fail to maintain listing of our common stock on a national securities exchange, the price of our common stock and our ability to access the capital markets may be harmed.

Although we meet all other continued listing requirements, if we cannot demonstrate compliance with Nasdaq's minimum \$1.00 bid price per share requirement by January 20, 2020, Nasdaq will proceed with their process of delisting our securities. While we intend to maintain the listing of our common stock for trading on a national securities exchange, there can be no assurance that we will be able to do so without effecting a reverse split of our common stock.

If our common stock is delisted from a national securities exchange trading in our shares may likely be reduced or impaired, not only in the number of shares which could be purchased and sold, but also through possible delays in the timing of market transactions. We may also experience a reduction in our coverage by security analysts, a more limited following at investor conferences and by the news media, thereby resulting in lower demand for our shares, adverse publicity and a reduced interest in our company from investors, analysts and other market participants.

Securities that delist from national securities exchanges may continue to trade on the over-the-counter market but are generally less liquid than investments in securities trading on a national securities exchange. In addition, the trading of our common shares on the over-the-counter markets could have other negative implications, including the potential loss of confidence in us by suppliers, customers and employees and the loss of institutional investor interest in our common shares. These circumstances could further depress the trading price of our common shares and could also have a long-term adverse effect on our ability to raise capital which could impair our ability to fund Orion development through commercialization.

If shares of our common stock cease to be listed on a national exchange we will not be subject to compliance with rules requiring the adoption of certain corporate governance measures and as a result our stockholders may experience reduced protections.

Each of the New York Stock Exchange and the Nasdaq Stock Market LLC require the implementation of various measures relating to corporate governance for listed companies. These quantitative and qualitative measures are designed to enhance the integrity of corporate management and the securities markets and apply to securities which are listed on those stock exchanges. While we have adopted these measures, we will not be required to comply with many of the corporate governance provisions if our common stock is not listed on a national securities exchange. As a result, if we cease to be listed on national exchange and elect to cease compliance with any of the corporate governance measures required by national exchanges, our stockholders may lose protections afforded to listed companies.

If shares of our common stock cease to be listed on a national exchange they will become subject to the “penny stock” rules of the SEC and the trading market in our securities may become limited, which will make transactions in our stock cumbersome and may reduce the value of an investment in the stock.

Rule 15c-9 under the Exchange Act establishes the definition of a “penny stock,” for the purposes relevant to us, as any equity security that is no longer trading on a national exchange and has a market price of less than \$5.00 per share or with an exercise price of less than \$5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require: (a) that a broker or dealer approve a person’s account for transactions in penny stocks; and (b) the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person’s account for transactions in penny stocks, the broker or dealer must: (a) obtain financial information and investment experience objectives of the person and (b) make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form: (a) sets forth the basis on which the broker or dealer made the suitability determination; and (b) confirms that the broker or dealer received a signed, written agreement from the investor prior to the transaction. Generally, brokers may be less willing to execute transactions in securities subject to the “penny stock” rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our common stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker or dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

If shares of our common stock cease to be listed on a national exchange our securities will not be eligible for federal preemption rights and be subject to state “blue sky” laws which may affect our capabilities of raising capital.

Each state has its own securities laws, often called “blue sky” laws, which (i) limit sales of securities to a state’s residents unless the securities are registered in that state or qualify for an exemption from registration, and (ii) govern the reporting requirements for broker-dealers doing business directly or indirectly in the state. Before a security is sold in a state, there must be a registration in place to cover the transaction, or the transaction must be exempt from registration. The applicable broker must be registered in that state. We do not know whether securities will be registered or exempt from registration under the laws of any state. If our securities cease to be listed on the national exchange, a determination regarding registration will be made by those broker-dealers, if any, who agree to serve as the market-makers for our common stock. Registering or qualifying shares with states can be time consuming. Compliance and regulatory costs may vary from state to state and may adversely affect future financings and our ability to raise capital.

If our common stock is delisted from national exchange some institutional investors may not be allowed to purchase our shares and may be required to liquidate their current positions in our stock which could negatively affect the price and volatility of our shares.

Institutional investors may be restricted by their investment policies from investing in shares of companies that are not listed on a national exchange and may be required to liquidate their positions if our securities are delisted from a national exchange. Liquidations, should they occur, may increase volatility and cause wide fluctuations and further declines in the prices of our securities.

Delisting of our common stock from national exchange can cause material dilution of our stock in future financings which can erode shareholder value.

If we are not able to maintain listing of our securities on Nasdaq, the trading prices of our securities may decline and we may need to sell larger amounts of our securities to obtain needed operating capital, possibly at prices which are at further discounts to the market or upon other terms that are less favorable to us, subjecting our shareholders to material dilution and losses to their investment.

Other Risk Factors

We incorporate herein by reference the risk factors described in our Annual Report on Form 10-K, including those risk factors which are updated, expanded or otherwise modified by this report with respect to our transitioning from a reliance on Argus II to a reliance on our new Orion development program, as filed with the Securities and Exchange Commission on March 19, 2019.

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

None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit No.	Exhibit Description
31.1	<u>Certification of Principal Executive Officer of Second Sight Medical Products, Inc. pursuant to Section 302 of Sarbanes-Oxley Act of 2002.*</u>
31.2	<u>Certification of Principal Financial and Accounting Officer of Second Sight Medical Products, Inc. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*</u>
32.1	<u>Certifications of Principal Executive Officer and Principal Financial and Accounting Officer of Second Sight Medical Products, Inc. pursuant to Rule 13a-14(b) under the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*</u>
101.INS	XBRL Instant Document.*
101.SCH	XBRL Taxonomy Extension Schema Document.*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.*

* Included herein.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Jonathan Will McGuire</u> Jonathan Will McGuire	Chief Executive Officer and Director (Principal Executive Officer)	November 14 , 2019
<u>/s/ John T. Blake</u> John T. Blake	Chief Financial Officer (Principal Financial and Accounting Officer)	November 14 , 2019

**CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT, AS ADOPTED PURSUANT
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jonathan Will McGuire, hereby certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Second Sight Medical Products, 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(s) 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 the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) 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.

Date: November 14, 2019

/s/ Jonathan Will McGuire
Jonathan Will McGuire
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION OF THE CHIEF FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT, AS ADOPTED PURSUANT
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, John T. Blake, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Second Sight Medical Products, 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(s) 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 the 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; and
5. The registrant's other certifying officer(s) 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.

Date: November 14, 2019

/s/ John T. Blake

John T. Blake
Chief Financial Officer
(Principal Financial and Accounting Officer)

Certifications of Principal Executive Officer and Principal Financial Officer
Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant To
Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350), Jonathan Will McGuire, Chief Executive Officer (Principal Executive Officer) and John T. Blake, Chief Financial Officer (Principal Financial and Accounting Officer) of Second Sight Medical Products, Inc. (the "Company"), each hereby certifies that, to the best of his knowledge:

1. The Quarterly Report of the Company on Form 10-Q (the "Report") for the quarter ended September 30, 2019, to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or 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.

Date: November 14, 2019

/s/ Jonathan Will McGuire

Jonathan Will McGuire
Chief Executive Officer
(Principal Executive Officer)

/s/ John T. Blake

John T. Blake
Chief Financial 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 Second Sight Medical Products, Inc. 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.