

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, 2018

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)

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 (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post 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. (Check one):

Large accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Emerging growth company

Accelerated filer

Smaller reporting company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of November 2, 2018, the issuer had 72,780,549 shares of common stock issued and 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)

	<u>September 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,972	\$ 7,839
Accounts receivable, net	1,194	1,831
Inventories, net	3,604	2,700
Prepaid expenses and other current assets	507	795
Total current assets	10,277	13,165
Property and equipment, net	1,114	1,299
Deposits and other assets	29	33
Total assets	<u>\$ 11,420</u>	<u>\$ 14,497</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,546	\$ 752
Accrued expenses	1,975	2,425
Accrued compensation expense	2,962	2,611
Accrued clinical trial expenses	934	779
Contract liabilities	111	48
Total current liabilities	7,528	6,615
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, no par value, 10,000 shares authorized; none outstanding	—	—
Common stock, no par value; 200,000 shares authorized; shares issued and outstanding: 70,312 and 57,630 as of September 30, 2018 and December 31, 2017, respectively	221,774	202,156
Common stock issuable	—	153
Additional paid-in capital	43,311	40,522
Accumulated other comprehensive loss	(580)	(572)
Accumulated deficit	(260,613)	(234,377)
Total stockholders' equity	3,892	7,882
Total liabilities and stockholders' equity	<u>\$ 11,420</u>	<u>\$ 14,497</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,	
	2018	2017	2018	2017
Net sales	\$ 2,246	\$ 1,610	\$ 5,129	\$ 4,855
Cost of sales	1,784	1,001	3,287	3,255
Gross profit	<u>462</u>	<u>609</u>	<u>1,842</u>	<u>1,600</u>
Operating expenses:				
Research and development, net of grants	2,672	1,826	7,567	5,622
Clinical and regulatory	964	629	3,439	1,927
Selling and marketing	3,040	2,375	8,931	7,057
General and administrative	2,332	2,528	8,208	8,170
Total operating expenses	<u>9,008</u>	<u>7,358</u>	<u>28,145</u>	<u>22,776</u>
Loss from operations	(8,546)	(6,749)	(26,303)	(21,176)
Interest income	<u>24</u>	<u>33</u>	<u>67</u>	<u>69</u>
Net loss	<u>\$ (8,522)</u>	<u>\$ (6,716)</u>	<u>\$ (26,236)</u>	<u>\$ (21,107)</u>
Net loss per common share – basic and diluted	<u>\$ (0.12)</u>	<u>\$ (0.12)</u>	<u>\$ (0.41)</u>	<u>\$ (0.40)</u>
Weighted average common shares outstanding – basic and diluted	<u>68,763</u>	<u>56,799</u>	<u>64,113</u>	<u>53,206</u>

See accompanying notes.

SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	\$ (8,522)	\$ (6,716)	\$ (26,236)	\$ (21,107)
Other comprehensive income (loss):				
Foreign currency translation adjustments	24	(86)	(8)	36
Comprehensive loss	<u>\$ (8,498)</u>	<u>\$ (6,802)</u>	<u>\$ (26,244)</u>	<u>\$ (21,071)</u>

See accompanying notes.

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

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

	Common Stock		Common Stock Issuable		Additional Paid-in Capital	Notes Receivable for Stock Option Exercises	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount					
Balance, December 31, 2016	42,701	\$ 186,769	77	\$ 153	\$ 30,697	\$ (2)	\$ (608)	\$ (205,861)	\$ 11,148
Issuance of shares of common stock and warrants, net of issuance costs	13,653	13,647	—	—	6,021	—	—	—	19,668
Fair value of stock options issued for services	—	—	—	—	20	—	—	—	20
Common stock issuance for services	—	—	88	65	—	—	—	—	65
Release of restricted stock units	12	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	981	—	—	—	981
Repayment of notes receivable for stock option exercises	—	—	—	—	—	1	—	—	1
Net loss	—	—	—	—	—	—	—	(7,548)	(7,548)
Foreign currency translation adjustment	—	—	—	—	—	—	30	—	30
Balance, March 31, 2017	56,366	\$ 200,416	165	\$ 218	\$ 37,719	\$ (1)	\$ (578)	\$ (213,409)	\$ 24,365
Issuance of shares of common stock in connection with employee stock purchase plan	193	189	—	—	—	—	—	—	189
Common stock issuance for services	223	262	(147)	(197)	—	—	—	—	65
Release of restricted stock units	12	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	935	—	—	—	935
Net loss	—	—	—	—	—	—	—	(6,843)	(6,843)
Foreign currency translation adjustment	—	—	—	—	—	—	92	—	92
Balance, June 30, 2017	56,794	\$ 200,867	18	\$ 21	\$ 38,654	\$ (1)	\$ (486)	\$ (220,252)	\$ 18,803
Common stock issuance for services	—	—	57	65	—	—	—	—	65
Release of restricted stock units	12	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	905	—	—	—	905
Repayment of notes receivable for stock option exercises	—	—	—	—	—	1	—	—	1

Net loss	—	—	—	—	—	—	—	(6,716)	(6,716)
Foreign currency translation adjustment	—	—	—	—	—	—	—	(86)	(86)
Balance, September 30, 2017	56,806	\$ 200,867	75	\$ 86	\$ 39,559	\$ —	\$ (572)	\$ (226,968)	\$ 12,972

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	Common Stock		Common Stock Issuable		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
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
Common stock issuance for services	—	—	34	65	—	—	—	65
Release of restricted stock units	12	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	1,285	—	—	1,285
Warrants exercise	5	7	—	—	—	—	—	7
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	70,312	\$ 221,774	—	\$ —	\$ 43,311	\$ (580)	\$ (260,613)	\$ 3,892

See accompanying notes.

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

Condensed Consolidated Statements of Cash Flows
(in thousands)

	Nine Months Ended September 30,	
	2018	2017
	(unaudited)	
Cash flows from operating activities:		
Net loss	\$ (26,236)	\$ (21,107)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	329	345
Stock-based compensation	2,789	2,821
Bad debt recovery	(6)	(128)
Inventory reserve	171	(1,731)
Common stock issuance for services	109	195
Changes in operating assets and liabilities:		
Accounts receivable	639	(311)
Inventories	(1,082)	1,955
Prepaid expenses and other assets	291	261
Accounts payable	795	(299)
Accrued expenses	(447)	233
Accrued compensation expenses	351	668
Accrued clinical trial expenses	155	(6)
Contract liabilities	63	(25)
Deferred grant revenue	—	(104)
Net cash used in operating activities	<u>(22,079)</u>	<u>(17,233)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(144)	(181)
Net cash used in investing activities	<u>(144)</u>	<u>(181)</u>
Cash flows from financing activities:		
Net proceeds from rights offering	—	19,688
Net proceeds from sale of common stock	18,939	—
Proceeds from repayment of note receivable	—	2
Proceeds from exercise of options, warrants and employee stock purchase plan	417	189
Net cash provided by financing activities	<u>19,356</u>	<u>19,879</u>
Effect of exchange rate changes on cash and cash equivalents	—	4
Cash and cash equivalents:		
Net increase (decrease)	(2,867)	2,469
Balance at beginning of period	7,839	10,875
Balance at end of period	<u>\$ 4,972</u>	<u>\$ 13,344</u>
Supplemental cash flow information:		
Non-cash financing and investing activities:		
Fair value of stock options issued for services	<u>\$ —</u>	<u>\$ 20</u>

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 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, 2018. 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.

Our current 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.

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 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”).

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. From 2016, we have funded our business primarily through:

- Issuance of common stock in our rights offering in June 2016, which provided net cash proceeds of \$19.5 million.
- Issuance of common stock and warrants in our rights offering in March 2017, which provided net cash proceeds of \$19.7 million.
- Issuance of common stock through our At Market Issuance Sales Agreement during the fourth quarter of 2017 and first quarter of 2018, which provided \$5.1 million of net cash proceeds.
- Issuance of common stock in a securities purchase agreement in May 2018, which provided net cash proceeds of \$10.0 million.
- Issuance of common stock in a securities purchase agreement in August 2018, which provided net cash proceeds of \$5.0 million.
- Issuance of common stock in a securities purchase agreement in October 2018, which provided net cash proceeds of \$4.0 million.
- Revenue of \$5.1 million in the first nine months of 2018, and \$8.0 million and \$4.0 million, for the years ended December 31, 2017 and 2016, respectively, generated by sales of our Argus II product.

We entered into stock purchase agreements on October 18, 2018, August 14, 2018 and May 3, 2018 with entities beneficially owned by Gregg Williams for the purchase of 2,467,727, 3,225,807 and 6,756,757 shares respectively of common stock priced at \$1.62, \$1.55 and \$1.48 per share respectively, the last reported sale price of our common stock on each purchase date. Gregg Williams is the Chairman of our Board of Directors. These placements of common stock provided net proceeds of \$4.0 million, \$5.0 million and \$10.0 million respectively.

No warrants or discounts were provided and no placement agent or investment banking fees were incurred in connection with these transactions. The shares issuable to the purchasers under the Securities Purchase Agreements were also issued pursuant to the exemption from registration under Rule 506 of Regulation D. We relied on this exemption from registration based in part on representations made by the purchasers.

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 which provided net proceeds of \$4.0 million under the Sales Agreement. No shares have been sold since February 2018 under the Sales Agreement.

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. Management has concluded that there is substantial doubt about our ability to continue as a going concern, and our independent registered public accounting firm, in its report on our 2017 consolidated financial statements, has raised substantial doubt about our ability to continue as a going concern.

We do not have sufficient funds to support our operations for the next 12 months from the date of issuance of these financial statements. 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. 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 the commercialization Argus II 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.

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. Certain prior year amounts have been reclassified to conform to the current year presentation. 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, 2017, contained in our Annual Report on Form 10-K filed with the SEC on March 20, 2018. 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

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, 2017.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, *Revenue from Contracts with Customers (Topic 606)*. This ASU is a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services. We adopted this ASU on January 1, 2018 retrospectively, and the cumulative effect of the initial application on our accumulated deficit on that date was immaterial.

We generate our revenue from the sale of our Argus II retinal prosthesis systems, which include the implant and external components. Our product sales generally consist of the implant and related surgical supplies and may include a performance obligation related to post-surgical support.

We sell our products through two main sales channels: 1) directly to customers who use our products (the “Direct Channel”) and 2) to distribution partners who resell our products (the “Indirect Channel”).

Under the Direct Channel, we sell our systems to and we receive payment directly from customers who implant our products. Under our Indirect Channel, we have entered into distribution agreements that allow the distributors to sell our systems and fulfill performance obligations for surgical support and post-surgical support.

We determine revenue recognition through the following steps:

- Identification of the contract, or contracts, with a customer
- Identification of the performance obligations in the contract
- Determination of the transaction price
- Allocation of the transaction price to the performance obligations in the contract
- Recognition of revenue when, or as, we satisfy a performance obligation

Revenue is generally recognized upon surgical implant, unless we have a significant performance obligation for post-surgical support. We recognize revenue when a material reversal is no longer probable. Conditions that preclude us from recognizing revenue generally involve new customers with no reimbursement or reimbursement history, and depends on third-party behavior beyond our control, uncertain payment cycles over an extended period of time, and our limited historical experience with these arrangements.

Management does 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 management deems 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, 2018 and 2017:

Three Months Ended September 30,		Nine Months Ended September 30,	
2018	2017	2018	2017

Direct customers	\$	1,921	\$	1,383	\$	4,378	\$	4,087
Distributors		<u>325</u>		<u>227</u>		<u>751</u>		<u>768</u>
Total	\$	<u>2,246</u>	\$	<u>1,610</u>	\$	<u>5,129</u>	\$	<u>4,855</u>

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During the three and nine months ended September 30, 2018 and 2017, the following customers each comprised greater than 10% of our total revenues:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Customer 1	12%	—%	5%	—%
Customer 2	10%	18%	6%	8%
Customer 3	10%	—%	4%	4%
Customer 4	6%	9%	11%	11%
Customer 5	6%	18%	3%	6%
Customer 6	5%	18%	2%	6%
Customer 7	—%	10%	5%	3%

As of September 30, 2018 and December 31, 2017, the following customers each comprised greater than 10% of our total accounts receivable:

	September 30,	December 31,
	2018	2017
Customer 1	18%	—%
Customer 2	14%	—%
Customer 3	12%	—%
Customer 4	11%	—%
Customer 5	—%	17%
Customer 6	—%	16%
Customer 7	—%	11%

Geographic Concentration

During the three and nine months ended September 30, 2018 and 2017, 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,	
	2018	2017	2018	2017
United States	47%	72%	51%	59%
France	15%	—%	14%	7%
Canada	10%	—%	4%	4%
Italy	6%	9%	11%	11%

Foreign Operations

The accompanying condensed consolidated financial statements as of September 30, 2018 and December 31, 2017 include assets amounting to \$1.7 million and \$2.7 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):

	<u>Total</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
September 30, 2018 (unaudited):				
Money market funds	\$ 4,857	\$ 4,857	\$ —	\$ —
December 31, 2017:				
Money market funds	\$ 7,235	\$ 7,235	\$ —	\$ —

5. Selected Balance Sheet Detail

Inventories, net

Inventories consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Raw materials	\$ 771	\$ 485
Work in process	2,362	2,620
Finished goods	2,707	1,660
	5,840	4,765
Allowance for excess and obsolete inventory	(2,236)	(2,065)
Inventories, net	\$ 3,604	\$ 2,700

[Table of Contents](#)*Property and equipment*

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

	September 30, 2018	December 31, 2017
Laboratory equipment	\$ 2,469	\$ 2,450
Computer hardware and software	1,453	1,329
Leasehold improvements	298	298
Furniture, fixtures and equipment	46	46
	<u>4,266</u>	<u>4,123</u>
Accumulated depreciation and amortization	<u>(3,152)</u>	<u>(2,824)</u>
Property and equipment, net	<u>\$ 1,114</u>	<u>\$ 1,299</u>

Contract Liabilities

Contract liabilities consisted of the following (in thousands):

Beginning balance, December 31, 2017	\$ 48
Consideration received in advance of revenue recognition	437
Revenue recognized	<u>(374)</u>
Ending Balance, September 30, 2018	<u>\$ 111</u>

6. Equity Securities*Common Stock Issuable*

Non-employee members of our Board of Directors have been paid for their services in common stock on June 1 of each year based on the average closing prices for the immediately preceding twenty trading days. During the nine months ended September 30, 2018, we issued a total of 132,996 shares of common stock for annual service through May 31, 2018 to the board members. Our Director Compensation Policy was amended in December 2017 and board members receive compensation in cash and stock options, effective with the annual period commencing June 1, 2018.

Potentially Dilutive Common Stock Equivalents

As of September 30, 2018 and 2017, 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,	
	2018	2017
Common stock warrants issued to underwriter of initial public offering	802	802
Common stock warrants issued in connection with convertible debt	—	676
Common stock warrants issued in connection with March 2017 rights offering	13,647	13,652
Common stock options	7,581	5,530
Common stock issuable	—	75
Restricted stock units	47	95
Employee stock purchase plan	<u>191</u>	<u>220</u>
Total	<u>22,268</u>	<u>21,050</u>

7. Warrants

A summary of warrants activity for the nine months ended September 30, 2018 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, 2017	15,130	\$ 2.15	3.90
Issued	—		
Exercised	(5)	1.47	
Forfeited or expired	(676)	5.00	
Warrants outstanding as of September 30, 2018	<u>14,449</u>	\$ 2.01	3.35
Warrants exercisable as of September 30, 2018	<u>14,449</u>	\$ 2.01	3.35

The intrinsic value of warrants outstanding as of September 30, 2018 was \$5.9 million.

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, 2018 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, 2017	5,675	\$ 4.87	7.40
Granted	3,139	\$ 1.94	
Exercised	(76)	\$ 1.95	
Forfeited or expired	(1,157)	\$ 4.15	
Options outstanding as of September 30, 2018	<u>7,581</u>	\$ 3.80	7.04
Options exercisable as of September 30, 2018	<u>2,943</u>	\$ 6.06	4.34

The estimated aggregate intrinsic value of stock options exercisable as of September 30, 2018 was \$0.1 million. As of September 30, 2018, there was \$4.9 million of total unrecognized compensation cost related to outstanding stock options that will be recognized over a weighted average period of 2.82 years.

During the nine months ended September 30, 2018, we granted stock options to purchase 3,138,752 shares of common stock to certain employees, board members and a contractor. The options are exercisable for a period of ten years from the date of grant at prices ranging from \$1.69 to \$2.07 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. The fair value of these options, calculated using the Black-Scholes option-pricing model, was determined to be \$3.8 million (\$0.96 to \$1.30 per share) using the following assumptions: expected term of 5.50 to 6.11 years, volatility of 48.0% to 67.0%, risk-free interest rate of 2.3% to 3.0%, and expected dividend rate of 0.0%.

During the nine months ended September 30, 2018, we recorded \$0.4 million of stock-based compensation expense related to stock option modifications for executive transitions.

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The following table summarizes restricted stock unit (“RSU”) activity for the nine months ended September 30, 2018 (in thousands, except per share data):

	<u>Number of Shares</u>	<u>Weighted Average Grant Date Fair Value Per Share</u>
Outstanding as of December 31, 2017	83	\$ 12.43
Awarded	—	—
Vested and released	(36)	12.43
Forfeited/canceled	—	—
Outstanding as of September 30, 2018	<u>47</u>	<u>\$ 12.43</u>

As of September 30, 2018, there was \$0.5 million of total unrecognized compensation cost related to the outstanding RSUs that will be recognized over a weighted average period of 0.9 years.

We adopted an employee stock purchase plan in June 2015 for all eligible employees. At September 30, 2018 the maximum number of shares that may be issued under the plan is 1,550,000. During the nine months ended September 30, 2018, 225,887 shares were issued under the stock purchase plan.

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, 2018 and 2017 was as follows (in thousands):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Cost of sales	\$ 74	\$ 36	\$ 201	\$ 184
Research and development	110	71	321	203
Clinical and regulatory	19	42	122	135
Selling and marketing	165	116	380	321
General and administrative	509	640	1,765	1,978
Total	<u>\$ 877</u>	<u>\$ 905</u>	<u>\$ 2,789</u>	<u>\$ 2,821</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.

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.

10. Subsequent Event

On October 9, 2018, we implemented a corporate restructuring plan to rebalance our operations to more closely align operating expenses with our long-term strategic plan to focus on development of Orion and other key research projects. Specifically, we will reduce expenses and personnel by 8 employees related to international commercial operations for the Argus II and focus on the markets and centers of excellence with the highest potential return on investment and limit expansion to new markets. We will maintain a team that will continue support of existing Argus II patients and centers of excellence.

We recorded 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 are expected to be settled in cash during the fourth quarter of 2018.

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 in conjunction with the unaudited condensed financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q as well as our audited 2017 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 20, 2018. In addition to historical information, the discussion and analysis here and throughout this Quarterly Report contains forward-looking statements that are based upon current beliefs, plans and expectations and involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including, but not limited, to those set forth under "Risk Factors" in Part II, Item 1A of this Quarterly Report. We undertake 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 was founded in 1998 with a mission to develop, manufacture, and market prosthetic devices that are intended to create an artificial form of useful vision for blind individuals. Our principal offices are located in Los Angeles, California. We also have an office in Lausanne, Switzerland that manages our commercial operations and supports clinical activities in Europe, the Middle East, and Asia-Pacific.

Our current product, the Argus[®] II 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. 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 the 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.

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 clear evidence that it can slow or reverse the progression of RP. 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.

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 glaucoma, diabetic retinopathy, optic nerve injury or disease, or forms of cancer and trauma. The Orion System leverages hardware from the Argus II and 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-patient feasibility study of the Orion I device is currently underway at UCLA and Baylor. No published in-human data is available yet for the Orion system. Depending on the results of this first in-human testing of the Orion cortical stimulation device, we anticipate initiation of the next study in 2019.

Our major corporate, clinical and regulatory milestones include:

- In 1998, Second Sight was founded.
- In 2002, we commenced clinical trials in the U.S. for our prototype product, the Argus I retinal prosthesis.
- In 2007, we commenced clinical trials in the U.S. for the Argus II, which later became our first commercial product.
- In 2011, we received marketing approval in Europe (CE Mark) for the Argus II.
- In 2013, we received marketing approval from the FDA in the U.S. for the Argus II.
- In 2014, we launched the Argus II in the U.S., completed our initial public offering ("IPO"), and began trading on NASDAQ under the symbol "EYES."
- In January 2016, we successfully implanted and activated a wireless cortical visual prosthesis in a human.
- In November 2017, the FDA granted Expedited Access Pathway Designation for the Orion.
- In the first quarter of 2018, first-in-human Orion was successfully implanted, activated and tested at UCLA.
- In September 2018, we were awarded a \$1.6 million grant from National Institutes of Health to support Orion clinical development (with the intent to fund \$6.3 million over five years subject to annual review and approval).

Currently, we have approximately 120 employees involved in the development (research, engineering and clinical), manufacture, and commercialization of the Argus II, Orion and future products.

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Financing

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. From 2016, we have funded our business primarily through:

- Issuance of common stock in our rights offering in June 2016, which provided net cash proceeds of \$19.5 million.
- Issuance of common stock and warrants in our rights offering in March 2017, which provided net cash proceeds of \$19.7 million.
- Issuance of common stock through our At Market Issuance Sales Agreement during the fourth quarter of 2017 and first quarter of 2018, which has provided \$5.1 million of net cash proceeds.
- Issuance of common stock in a securities purchase agreement in May 2018, which provided net proceeds of \$10.0 million.
- Issuance of common stock in a securities purchase agreement in August 2018, which provided net proceeds of \$5.0 million.
- Issuance of common stock in a securities purchase agreement in October 2018, which provided net proceeds of \$4.0 million.
- Revenue of \$5.1 million in the first nine months of 2018, and \$8.0 million and \$4.0 million, for the years ended December 31, 2017 and 2016, respectively, generated by sales of our Argus II product.

We entered into stock purchase agreements on October 18, 2018, August 14, 2018 and May 3, 2018 with entities beneficially owned by Gregg Williams for the purchase of 2,467,727, 3,225,807 and 6,756,757 shares, respectively of common stock priced at \$1.62, \$1.55 and \$1.48 per share, respectively, the last reported sale price of the common stock on each purchase date. Gregg Williams is the Chairman of our Board of Directors. These placements of common stock provided net proceeds of \$4.0 million, \$5.0 million and \$10.0 million, respectively.

No warrants or discounts were provided and no placement agent or investment banking fees were incurred in connection with these transactions. The shares issuable to the purchasers under the Securities Purchase Agreements were also issued pursuant to the exemption from registration under Rule 506 of Regulation D. We relied on this exemption from registration based in part on representations made by the purchasers.

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 are utilizing these proceeds to further develop and enhance our products, support operations and for general corporate purposes.

Going concern

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. Management has concluded that there is substantial doubt about our ability to continue as a going concern, and our independent registered public accounting firm, in its report on our 2017 consolidated financial statements, has raised substantial doubt about our ability to continue as a going concern.

We believe our current cash and cash equivalents will fund our operations into January 2019. We do not have sufficient funds to support our operations for the next 12 months from the date of issuance of these financial statements. 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 our 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. Furthermore, we continue to generate significant operating losses related to our Argus II product.

Until such time, if ever, as 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. 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.

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 the commercialization of Argus II or of 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.

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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 U.S., 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. 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.

- **Medicare FFS patients** – Coverage is determined by Medicare Administrative Contractors (“MACs”) that administer various geographic regions of the U.S. The Argus II is authorized for coverage, when medically necessary in eight of 12 MAC jurisdictions (comprising 31 states). Effective January 1, 2018, the Centers for Medicare and Medicaid Services (“CMS”) established a 2018 national average payment rate of \$122,500 for both the procedure and the Argus II retinal prosthesis system when furnished in a hospital outpatient department. On November 2, 2018 CMS posted the final rule and related rates for the calendar year (“CY”) 2019 for the Medicare Hospital Outpatient Prospective Payment Systems (“OPPS”) and the CY 2019 Ambulatory Surgical Center (“ASC”) payment system. In these postings, CMS established a national average Medicare hospital outpatient rate for CY 2019 of \$155,500 for Argus II and the associated surgical implantation procedure, and a national average ASC rate of approximately \$134,051 for the Argus II and related implantation procedure.
- **Medicare Advantage patients** – Medicare Advantage plans are required to cover the same benefits as those covered by the MAC in that jurisdiction. For example, if a MAC in a jurisdiction has favorable coverage for the Argus II, then all Medicare Advantage plans in that MAC jurisdiction are required to offer the same coverage for the Argus II. Individual hospitals and ASCs may negotiate contracts specific to that individual facility, which may include additional separate payment for the Argus II implant system. In addition, procedural payment is variable and can be based on a percentage of billed charges, payment groupings or other individually negotiated payment methodologies. Medicare Advantage plans may allow providers to confirm coverage and payment for the Argus II procedure in advance of implantation. Since 2015 a large majority of all Medicare Advantage pre-authorization requests for Argus II procedures were granted.
- **Commercial insurer patients** – Commercial insurance plans make coverage and payment rate decisions independent of Medicare, and contracts are individually negotiated with facility and physician providers.

We retain employees and utilize consultants with insurance reimbursement expertise dedicated to expand and enhance coverage decisions. Currently, eight of 12 Medicare jurisdictions authorize coverage of the Argus II in 31 states, two territories and the District of Columbia when medically necessary, including:

- CGS (J15 -- Ohio and Kentucky),
- Palmetto GBA (JM -- Virginia, (excluding Part B for Arlington and Fairfax counties), West Virginia, North Carolina and South Carolina),
- Palmetto GBA (JJ -- Alabama, Georgia and Tennessee),
- NGS (J6 -- Minnesota, Illinois and Wisconsin),
- NGS (JK -- Connecticut, New York, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont),
- FCSO (JN -- Florida, Puerto Rico and the U.S. Virgin Islands),
- Novitas (JH-- Arkansas, Colorado, Louisiana, Mississippi, New Mexico, Oklahoma, and Texas) and
- Novitas (JL -- Delaware, District of Columbia, Maryland, New Jersey and Pennsylvania)

We are actively engaged with the remaining MACs and are committed to supporting their requests for additional information and clinical evidence. We expect that additional positive coverage decisions will be issued over time but cannot predict timing or ultimate success with each MAC.

Within Europe, we have obtained reimbursement approval or funding in Germany, France, one region of Italy, and a Commissioning through Evaluation (“CtE”) program in England.

We are seeking additional reimbursement approvals in other countries in Europe and international markets.

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In France, we were selected to receive the first “Forfait Innovation” (Innovation Bundle) from the Ministry of Health, which is a special funding program for breakthrough procedures to be introduced into clinical practice. As part of this program, we are conducting a post-market study in France which has enrolled a total of 18 subjects who are being followed for two years. The French program also funds implantation of up to 18 additional patients that are not part of the post-market study. After review of the study’s results, we expect Argus II therapy to be covered and funded through the standard payment system in France. However, we can provide no assurance that the French government will continue to fund the Argus II after the first 36 implants.

In December 2016, NHS England announced it would cover 10 Argus II implantations as part of their CtE program. The CtE program is especially designed for treatments that show significant promise for the future, while new clinical and patient experience data are collected within a formal evaluation program. This program is similar to the Forfait Innovation program in France. NHS England is known to be under significant financial pressure and also highly selective in adopting innovative technologies which must demonstrate sufficient value for the cost expended. This program is progressing slower than expected and we now believe implants under this program will not begin until late 2018 or early 2019.

To date, our marketing activities have focused on raising awareness of the Argus II with potential patients, implanting physicians, and referring physicians. Our marketing activities include exhibiting, sponsoring symposia, and securing podium presence at professional and trade shows, securing journalist coverage in popular and trade media, attending patient meetings focused on educating patients about existing and future treatments, and sponsoring information sessions for the Argus II. In the United States, our efforts will focus on media advertisements dedicated to RP patients and their families. These advertisements will be placed in geographic areas where we have Centers of Excellence committed to Argus II.

Currently, we are in process of evaluating potential reimbursement pathways for Orion. Compared to Argus II, which is largely catering to Medicare patient population, Orion is expected to address patient population with diverse and more balanced payer mix due to our potential indications profile and expected younger average patient population. As Orion is approved for FDA’s Breakthrough Devices program, we are closely evaluating a variety of fast track reimbursement programs catering to promising breakthrough treatments, including the Coverage with Evidence Development pathway with CMS. We also plan to approach some of the key payers early next year and get their feedback to ensure our pivotal clinical trial design will be able to cater to their key coverage requirements.

Product and Clinical Development Plans

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 U.S. with advanced RP that could be treated with the Argus II given the eligibility criteria of our label.

We believe an opportunity exists to expand the use of our Argus II technology to better sighted individuals with RP who are currently not being treated. To achieve this market expansion, we have taken steps to request US label expansion with FDA and endeavor to improve the technology’s performance, including:

- Development of advanced retina stimulation techniques that we believe can improve the quality or usefulness of the vision provided by Argus II;
- Redesigns of the externals (glasses, camera, and video processing unit) that will provide a next-generation platform capable of supporting the commercial implementation of improved image processing capabilities and advanced retina stimulation techniques in late 2018 or 2019.

Given the limited addressable market of Argus II, we 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. As a result, we evaluate the short-term financial payback to enter new Argus markets or expand geographically; have increased focus on our strongest markets and the top centers of excellence in those markets allowing for more efficient deployment of field resources; and continue our efforts to expand the U.S. label to include better-vision RP patients without conducting a potentially costly U.S. Investigational Device Exemption (“IDE”) trial.

In October 2018, we announced a restructuring of our international commercial activities and personnel. We will maintain a team that will continue support of existing Argus II patients and Centers of Excellence in our international markets. We anticipate that the annual savings from the restructuring will amount to approximately \$3.0 million per year and we plan to reallocate savings to the Orion program and other related projects. We expect to recognize 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 are expected to be settled in cash during the fourth quarter of 2018.

Orion. We believe that we can further expand our market to include nearly all profoundly blind individuals, other than those who are blind due to preventable diseases or due to brain damage, by developing a visual cortical prosthesis. We refer to this product as the Orion[®] Visual Cortical Prosthesis System. We estimate that there are approximately 5.8 million people worldwide who are legally blind due to causes other than preventable conditions, RP or age-related macular degeneration. We commissioned 3rd party market research for the potential market for Orion that resulted in initial estimates of over 500,000 individuals in the U.S. who are legally blind due to glaucoma, diabetic retinopathy, optic nerve disease and eye trauma and a potential U.S. addressable market of more than 70,000 individuals from this population with vision defined as bare light or no light perception. Our marketing approvals by the FDA and other regulatory agencies will ultimately determine the subset of these patients who are eligible for the Orion.

Our objective in designing and developing Orion is to bypass the optic nerve and directly stimulate the part of the brain responsible for vision. In 2017, we submitted and received FDA approval for an IDE application to begin a human feasibility study of Orion. Enrollment began for this study in January 2018, and to date, the five planned subjects have been implanted and had their devices activated; four at UCLA and one at Baylor. In addition, during the second quarter of 2018, we submitted and received approval from the FDA to enroll a sixth subject; we are screening for the sixth subject at Baylor. This study is intended to confirm initial findings in our human pilot study we announced in the fourth quarter of 2016, and provide the first human data of a fully functional wireless visual cortical stimulator system including the external video camera system. This initial study in a small number of subjects, if successful, should also form the basis for an expansion to our next clinical trial in 2019.

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In November 2017, the FDA granted Expedited Access Pathway 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. The FDA has also released a draft guidance document for a Breakthrough Devices Program, which, when finalized, will supersede the Expedited Access Pathway. The FDA has indicated that all devices which have Expedited Access Pathway designation will gain Breakthrough Device designation when the guidance document is finalized. 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.

It is our expectation that inclusion in the Expedited Access Pathway Program (soon-to-be Breakthrough Devices Program) will shorten the timeline required to bring the Orion to market as a commercial product. We are currently evaluating our pivotal trial design for Orion and expect to reach consensus with the FDA on design specifics during early 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. While negotiations with the FDA are ongoing, we believe the study design will require a minimum sample population of 30 subjects with at least 6 months of follow-up data for each patient prior to submittal of a premarket approval (PMA) application.

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 requires 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, 2017.

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, *Revenue from Contracts with Customers (Topic 606)*. This ASU is a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services. We adopted this ASU on January 1, 2018 retrospectively, and the cumulative effect of the initial application on our accumulated deficit on that date was immaterial.

We generate our revenue from the sale of the Argus II which includes the implant and external components. Our product sales generally consist of the implant and related surgical supplies and may include a performance obligation related to post-surgical support.

We sell our products through two main sales channels: 1) directly to customers who use our products (the “Direct Channel”) and 2) to distribution partners who resell our products (the “Indirect Channel”).

Under the Direct Channel, we sell our systems to, and we receive payment directly from, customers who implant our products. Under our Indirect Channel, we have entered into distribution agreements that allow the distributors to sell our systems and fulfill performance obligations for surgical support and post-surgical support.

We determine revenue recognition through the following steps:

- Identification of the contract, or contracts, with a customer
- Identification of the performance obligations in the contract
- Determination of the transaction price
- Allocation of the transaction price to the performance obligations in the contract
- Recognition of revenue when, or as, we satisfy a performance obligation

Revenue is generally recognized upon surgical implant, unless we have a significant performance obligation for post-surgical support. We recognize revenue when a material reversal is no longer probable. Conditions that preclude us from recognizing revenue generally involve new customers with no reimbursement or reimbursement history, and depends on third-party behavior beyond our control, uncertain payment cycles over an extended period of time, and our limited historical experience with these arrangements.

There have been no other material changes to our critical accounting policies during the nine months ended September 30, 2018.

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. Our objective is to increase our product revenue over the next several years as we pursue commercialization of our product, as our product becomes more well-known and accepted in the market, and as insurance coverage becomes more widespread.

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 our Argus II system at our Los Angeles, California facility. Our product involves technologically complex materials and processes. While we are currently experiencing low yields on our manufacturing process, we expect that over the next few years we will be able to refine our processes and improve our manufacturing yields. We are also producing at less than our capacity which results in unabsorbed overhead costs. In future years, we expect to produce in greater quantities and improve our manufacturing yields, and we expect that we will more consistently generate positive gross margins. 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 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, seek to expand the indications for the 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 increase as we hire additional sales personnel, initiate additional marketing programs, develop relationships with new distributors, and expand the number of doctors and medical centers that buy and implant our Argus II product and any future products.
- 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 increase 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, 2018 and 2017

We implanted a total of 20 Argus II products during the third quarter of 2018 and 12 in the third quarter of 2017. Of these, 11 implants were in Europe, the Middle East and Asia (collectively, “EMEA”) in the third quarter of 2018 and five implants were in EMEA in the third quarter of 2017.

In North America, there were nine implants in the third quarter of 2018 while there were seven implants in the third quarter of the prior year. Of these, there were seven implants in the U.S. in the third quarter of 2018 and 2017 and two implants in Canada in the third quarter of 2018.

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Net Sales. Net sales were \$2.2 million in the third quarter of 2018 as compared to \$1.6 million in the same period in 2017, an increase of \$0.6 million or 38%. Revenue was recognized for 22 units in the current period while revenue from 12 units was recognized in the prior year quarter. Revenue recognized per implant was approximately \$102,000 in the third quarter of 2018 and was \$133,000 in same period of 2017. We expect our average revenue recognized per implant unit sold for the remainder of 2018 to be in a range of \$100,000 to \$120,000, depending on the geographic mix of implants.

Cost of sales. Cost of sales increased by approximately \$0.8 million, or 80%, from \$1.0 million in the third quarter 2017 to \$1.8 million in the third quarter of 2018. Cost of sales in the third quarter of 2018 consists primarily of the cost of products implanted and unabsorbed production costs in the quarter of \$1.7 million and an increase in the reserve for excess inventory of \$0.1 million. In the third quarter of 2017, the cost of sales included approximately \$1.3 million for the cost of products implanted and unabsorbed production costs less an adjustment of \$0.3 million for a reduction in the reserve for excess inventory. We expect cost of goods on a per-unit basis to stabilize, particularly related to overhead absorption and excess inventory reserve, as we produce more units.

Research and development expense. Research and development expense, net of funding received from grants, increased by \$0.9 million, or 50%, from \$1.8 million in the third quarter of 2017 to \$2.7 million in the third quarter of 2018. The increase from the prior year was primarily due to verification and validation activities related to Argus 2s and consists of increased headcount, outside services, and costs for internally produced prototypes. In both the third quarter of 2018 and 2017, we utilized \$0.1 million of grant funds to offset costs.

Clinical and regulatory expense. Clinical and regulatory expense increased \$0.4 million, or 67%, from \$0.6 million in the third quarter of 2017 to \$1.0 million in the third quarter of 2018. This increase is primarily attributable to increased 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 enhancements to our existing product and enroll more patients in post market clinical studies for Argus II.

Selling and marketing expense. Selling and marketing expense increased \$0.6 million, or 25%, from \$2.4 million in the third quarter of 2017 to \$3.0 million in the third quarter of 2018. This increase in costs was primarily the result of increased market development activities, including headcount and related compensation expenses. We expect selling and marketing expense to decrease over time when expressed as a percentage of product revenue.

General and administrative expense. General and administrative expense decreased \$0.2 million, or 8%, from \$2.5 million in the third quarter of 2017 to \$2.3 million in the same period of 2018. This decrease is primarily attributable to \$0.2 million in lower non-cash stock compensation costs primarily due to cancelled stock option grants.

Comparison of the Nine Months Ended September 30, 2018 and 2017

We implanted a total of 53 Argus II products during the first nine months of 2018 and 45 in the comparable period of 2017. Of these, 25 implants were in EMEA in the first nine months of 2018 as compared to 21 in the first nine months of 2017.

In North America, there were 28 implants in the first nine months of 2018 compared to 24 implants in the first nine months of the prior year. Of these, there were 19 implants in the U.S. and five implants in Canada in the first nine months of 2017 compared to 25 in the U.S. and three in Canada in the first nine months of 2018.

Net Sales. Net sales were \$5.1 million in the first nine months of 2018 as compared to \$4.9 million in 2017, an increase of \$0.2 million or 4%. Revenue was recognized for 48 units in the first nine months of 2018 as compared to 41 units in the first nine months of 2017. Revenue recognized per implant was approximately \$107,000 in the first nine months of 2018 as compared to approximately \$117,000 in the first nine months of 2017. We expect our average revenue recognized per implant unit sold for the remainder of 2018 to be in a range of \$100,000 to \$120,000, depending on the geographic mix of implants.

Cost of sales. Cost of sales were \$3.3 million in the first nine months 2017 and 2018. Cost of sales in the first nine months of 2018 consists primarily of the cost of products implanted and unabsorbed production costs in the period of \$3.1 million and an increase in the reserve for excess inventory of \$0.2 million. In the first nine months of 2017, the cost of sales included approximately \$5.0 million for the cost of products implanted and unabsorbed production costs less an adjustment of \$1.7 million for a reduction in the reserve for excess inventory. We expect cost of goods on a per-unit basis to stabilize, particularly related to overhead absorption and excess inventory reserve, as we produce more units.

Research and development expense. Research and development expense, net of funding received from grants, increased by \$2.0 million, or 36%, from \$5.6 million in the first nine months of 2017 to \$7.6 million in the first nine months of 2018. The increase from the prior year was primarily due to verification and validation activities related to Argus 2s and consists of increased headcount, outside services, costs for internally produced prototypes. In the first nine months of 2018 and 2017, we utilized \$0.2 million of grant funds to offset costs.

Clinical and regulatory expense. Clinical and regulatory expense increased \$1.5 million, or 79%, from \$1.9 million in the first nine months of 2017 to \$3.4 million in the first nine months of 2018. This increase is primarily attributable to increased costs associated with the Orion feasibility study. We expect clinical and regulatory costs to increase in the future as we (i) increase our implant run rate and enroll more patients in post market clinical studies for regulatory authorities, and (ii) conduct additional clinical trials to assess new products such as the Orion I and enhancements to our existing product.

Selling and marketing expense. Selling and marketing expense increased \$1.8 million, or 25%, from \$7.1 million in the first nine months of 2017 to \$8.9 million in the first nine months of 2018. This increase in costs was primarily the result of a \$0.6 million increase for market development activities, increased headcount and related \$0.8 million increase in compensation expense, and a \$0.4 million increase in costs related to additional travel costs. While we expect these costs to increase in the future as we increase our selling and marketing resources to accelerate the commercialization of our product, we expect selling and marketing expense to decrease over time when expressed as a percentage of product revenue.

General and administrative expense. General and administrative expense remained constant at \$8.2 million, in the first nine months of 2017 and 2018.

Liquidity and Capital Resources

Our consolidated financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We have experienced recurring operating losses and negative operating cash flows since inception, and have financed our working capital requirements through the recurring sale of our equity securities in both public and private offerings. As a result, our independent registered public accounting firm, in its report on our 2017 consolidated financial statements, has raised substantial doubt about our ability to continue as a going concern (see “Going Concern” above).

In March 2017, we successfully completed a rights offering to existing shareholders, raising proceeds of approximately \$19.7 million net of offering costs, through the sale of 13,652,341 units at \$1.47 per unit. Each unit consisted of a share of common stock and a five-year warrant with an exercise price of \$1.47 per share.

During the first three months of 2018, we issued 2,224,000 shares of common stock for net proceeds of approximately \$4.0 million as part of our At Market Issuance Sales Agreement with two separate investment banks.

We entered into stock purchase agreements on October 18, 2018, August 14, 2018 and May 3, 2018 with entities beneficially owned by Gregg Williams for the purchase of 2,467,727, 3,225,807 and 6,756,757 shares respectively of common stock priced at \$1.62, \$1.55 and \$1.48 per share respectively, the last reported sale price of the common stock on each purchase date. Gregg Williams is the Chairman of our Board of Directors. These placements of common stock provided net proceeds of \$4.0 million, \$5.0 million and \$10.0 million respectively.

No warrants or discounts were provided and no placement agent or investment banking fees were incurred in connection with these transactions. The shares issuable to the purchasers under the Securities Purchase Agreements were also issued pursuant to the exemption from registration under Rule 506 of Regulation D. We relied on this exemption from registration based in part on representations made by the purchasers.

We believe our current cash and cash equivalents will fund our operations into January 2019. We do not have sufficient funds to support our operations for the next 12 months from the date of issuance of these financial statements. 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 our 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. Furthermore, we continue to generate significant operating losses related to our Argus II product.

Until such time, if ever, as 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. 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 decreased by \$2.8 million, or 36%, from \$7.8 million as of December 31, 2017 to \$5.0 million as of September 30, 2018. Working capital was \$2.8 million as of September 30, 2018, as compared to \$6.6 million as of December 31, 2017, a decrease of \$3.8 million, or 58%. 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 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. During the first nine months of 2017, we used \$17.2 million of cash in operating activities, consisting primarily of a net loss of \$21.1 million, offset by non-cash charges which provided cash of \$1.5 million for depreciation and amortization of property and equipment, stock-based compensation, excess inventory reserve, bad debt recovery and common stock issuable and by a net change in operating assets and liabilities which provided cash of \$2.4 million.

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Cash Flows from Investing Activities

Cash used for investing activities in the first nine months of 2018 was \$0.1 million and was \$0.2 million in the first nine months of 2017 primarily for the purchase of property and equipment.

Cash Flows from Financing Activities

Financing activities provided \$19.4 million of cash in the first nine months of 2018 consisting of \$18.9 million from proceeds of common stock sold during the period and the remainder from the proceeds from exercise of warrants, options and employee stock plan purchases. Financing activities provided \$19.9 million of cash in the first nine months of 2017 consisting of \$19.7 million from the rights offering and the remainder from 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, 2018, our investments consisted solely of money market funds.

Exchange Rate Sensitivity

During the nine months ended September 30, 2018, approximately 62% of our revenue was denominated in U.S. dollars, 35% in Euros, and 4% in Canadian dollars. 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, 2018. 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, 2018, 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.

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Remediation Plan

We identified control deficiencies which constituted material weaknesses in our internal control over financial reporting as noted in our Annual Report on Form 10-K for the year ended December 31, 2017.

In response to the identified weaknesses in our internal control over financial reporting, we continue to remediate the deficiencies that were identified as well as enhance our internal control policies and procedures. We plan to evaluate and test our internal control policies and procedures through the use of internal and external resources, to support management conclusions regarding the effectiveness of our internal controls for the year ended December 31, 2018.

Our CEO and CFO, along with other key members of management, are and will be active participants in the remediation process plan. We believe the steps taken to date have improved the effectiveness of our internal control over financial reporting.

In addition, we have implemented new disclosure controls and procedures with key members of management for the nine month period ended September 30, 2018.

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, 2018 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Our CFO is involved in the operation of key review controls 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.

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 financial statements.

Item 1A. Risk Factors

Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, together with the other information contained in this Quarterly Report and in our other public filings with the SEC. Additional risks and uncertainties that we are unaware of may also become important factors that affect us. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.

Entities controlled by Gregg Williams, our Chairman of the Board, have the ability to influence or control the outcome of matters submitted for stockholder approval and may have interests that differ from those of our other stockholders.

As of October 18, 2018, entities controlled and beneficially owned by Gregg Williams, our Chairman of the Board, own in the aggregate approximately 45.3% of the outstanding shares of our common stock (or 49.9% after giving effect to Mr. Williams' right to acquire beneficial ownership of 6,802,721 shares of common stock upon exercise of options or warrants). As a result, Mr. Williams may be able to exercise substantial influence over all matters requiring stockholder approval, including the election of directors and the approval of significant corporate transactions. Mr. Williams may also have interests that differ from other stockholders and he may vote in a manner that is or could be deemed as adverse to interests of other stockholders. This concentration of voting power may have the effect of deterring, delaying or impeding actions that could be beneficial to other stockholders.

In addition, Mr. Williams may acquire additional shares of common stock through open market transactions or through future offerings of our common stock that may result in a greater than 50% beneficial ownership of our outstanding shares of common stock. Our equity compensation plans and certain of our executive compensation arrangements contain provisions that accelerate vesting of outstanding equity awards upon a change-in-control and some of our agreements may contain provisions related to change-in-control that may adversely affect our results of operations. Our equity awards are generally structured with four year vesting schedules as long-term incentive compensation. Should equity awards fully vest, our ability to retain key employees may be adversely affected.

We have obtained significant invested amounts from entities affiliated with Mr. Williams, our Chairman of the Board, and if as we seek additional funding to support our business Mr. Williams does not participate in our future offerings we may not be able to raise needed amounts and our operations may be adversely affected.

During 2016 and 2017 and 2018, we funded our business primarily through the issuance and sale of our securities and we received \$9,000,000 in 2016, \$10,000,000 in 2017, \$10,000,000 in May 2018, \$5,000,000 in August 2018 and \$4,000,000 in October 2018 of proceeds from the sale of our securities from entities affiliated with Mr. Williams, our Chairman of the Board, constituting 45.5%, 49.8%, 100%, 100% and 100%, respectively, of amounts received in the offerings we completed. We do not have sufficient funds to support our operations for the next 12 months from the date of issuance of the financial statements included in this Report. 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. No assurance can be given that Mr. Williams or entities affiliated with him will continue to participate in any offerings of our securities or that we will be able to obtain additional capital from him. If we are unable to obtain funding on a timely basis, our business and operations may be materially and adversely affected. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations -*Going Concern*” above.

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 have 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, including, but not limited to, adverse events associated with the surgical implantation, chronic implantation, and chronic use of the Orion device (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, parathesias, 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 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.

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If 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 or adverse side effects. Some potential 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 safety and tolerability profile. Any of these developments could materially harm our business, financial condition and prospects.

Further, if Orion obtains marketing approval, adverse effects associated with it may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional warnings being added to the labeling, significant restrictions on the use of Orion or the withdrawal from the market together with attendant costs of explants and exposure to litigation. We cannot predict whether Orion will cause 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.

Our revenue from sales of Orion will be dependent upon the pricing and reimbursement guidelines adopted in each country and if pricing and reimbursement levels are inadequate to achieve profitability our operations will suffer.

Our financial success is dependent on our ability to price our products in a manner acceptable to government and private payers while still maintaining our profit margins. Numerous factors that may be beyond our control may ultimately impact our pricing of Orion and determine whether we are able to obtain reimbursement or reimbursement at adequate levels from governmental programs and private insurance. If we are unable to obtain reimbursement or our product is not adequately reimbursed, we will experience reduced sales, our revenues likely will be adversely affected, and we may not become profitable.

Obtaining reimbursement approvals is time consuming, requires substantial management attention, and is expensive. Our business will be materially adversely affected if we do not receive approval for reimbursement of Orion under government programs and from private insurers on a timely or satisfactory basis. Limitations on coverage could also be imposed at the local Medicare Administrative Contractor level or by fiscal intermediaries in the US and by regional, or national funding agencies in Europe. Our business could be materially adversely affected if the Medicare program, local Medicare Administrative Contractors or fiscal intermediaries were to make such a determination and deny, restrict or limit the reimbursement of Orion. Similarly in Europe these governmental and other agencies could deny, restrict or limit the reimbursement of Orion at the hospital, regional or national level. Our business also could be adversely affected if surgeons and the facilities within which they operate are not adequately reimbursed by Medicare and other funding agencies for the cost of the procedure in which they implant the Orion on a basis satisfactory to the administering surgeons and their facilities. If the local contractors that administer the Medicare program and other funding agencies are slow to reimburse surgeons or provider facilities for the Argus II System, the surgeons and facilities may delay their payments to us, which would adversely affect our working capital requirements. Also if the funding agencies delay reimbursement payments to the hospitals, any increase to their working capital requirements could reduce their willingness to treat blind patients who wish to have our Orion devices implanted. If reimbursement for our products is unavailable, limited in scope or amount, or if pricing is set at unsatisfactory levels, our business will be materially harmed.

We further incorporate herein by reference the risk factors included in our Annual Report on Form 10-K, which we filed with the Securities and Exchange Commission on March 20, 2018.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

We entered into stock purchase agreements on October 18, 2018, August 14, 2018 and May 3, 2018 with entities beneficially owned by Gregg Williams for the purchase of 2,467,727, 3,225,807 and 6,756,757 shares respectively of common stock priced at \$1.62, \$1.55 and \$1.48 per share respectively, the last reported sale price of the common stock on each purchase date. Gregg Williams is Chairman of our Board of Directors. These placements of common stock provided net proceeds of \$4.0 million, \$5.0 million and \$10.0 million respectively.

No warrants or discounts were provided and no placement agent or investment banking fees were incurred in connection with these transactions. The shares issuable to the purchasers under the Securities Purchase Agreement were issued pursuant to an exemption from registration under Rule 506 of Regulation D. We relied on this exemption from registration based in part on representations made by the purchasers.

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
3.1	Restated Articles of Incorporation of the Registrant.(1)
3.2	Amended and Restated Bylaws of the Registrant, as currently in effect.(1)
10.1	Securities Purchase Agreement by and between the Registrant and each purchaser identified on Exhibit A thereto, dated August 14, 2018.(2)
10.2	Executive Employment Agreement by and between the Registrant and William Patrick Ryan, dated August 28, 2018.(3)
10.3	Securities Purchase Agreement by and between the Registrant and each purchaser identified on Exhibit A thereto, dated October 18, 2018.(4)
31.1	Certification of Principal Executive Officer of Second Sight Medical Products, Inc. pursuant to Section 302 of Sarbanes-Oxley Act of 2002.*
31.2	Certification of Principal Financial and Accounting Officer of Second Sight Medical Products, Inc. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	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.*
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.

(1) Incorporated by reference to the Registrant's registration statement on Form S-1, file no. 333-198073, originally filed with the Securities and Exchange Commission on August 12, 2014, as amended.

(2) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on August 16, 2018.

(3) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on September 4, 2018.

(4) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on October 22, 2018.

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 7, 2018
<u>/s/ John T. Blake</u> John T. Blake	Chief Financial Officer (Principal Financial and Accounting Officer)	November 7, 2018

**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 7, 2018

/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 7, 2018

/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, 2018, 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 7, 2018

/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.

