

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT PURSUANT
TO SECTION 13 OR 15(D) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): November 14, 2019

SECOND SIGHT MEDICAL PRODUCTS, INC.
(Exact Name of Registrant as Specified in Its Charter)
California
(State or Other Jurisdiction of Incorporation)

001-36747

(Commission File Number)

02-0692322

(IRS Employer Identification No.)

12744 San Fernando Road, Suite 400
Sylmar, California 91342

(Address of Principal Executive Offices)

(818) 833-5000

(Registrant's Telephone Number, Including Area Code)
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	EYES	Nasdaq
Warrants	EYESW	Nasdaq

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION

On November 14, 2019, Second Sight Medical Products, Inc. (the “*Company*”) announced financial results for the three-month period, and nine-month period, ended September 30, 2019, in the earnings release attached hereto as Exhibit 99.1.

The information in this Item 2.02 including Exhibit 99.1 hereto is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the “*Exchange Act*”), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS

Exhibit No.	Description
99.1	<u>Earnings Release of Second Sight Medical Products, Inc. dated November 14, 2019</u>

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 14, 2019

SECOND SIGHT MEDICAL PRODUCTS, INC.

/s/ John T. Blake

By: John T. Blake
Chief Financial Officer

FOR IMMEDIATE RELEASE

Second Sight Reports Third Quarter 2019 Financial Results

-- Reached agreement with FDA regarding the primary efficacy endpoint for the Orion pivotal trial --

LOS ANGELES – November 14, 2019 – Second Sight Medical Products, Inc. (NASDAQ: EYES) (“Second Sight” or the “Company”), a developer, manufacturer and marketer of implantable visual prosthetics that are intended to create an artificial form of useful vision for blind individuals, today reported financial results for the three and nine months ended September 30, 2019.

Recent Corporate Highlights:

- Reached agreement with the U.S. Food and Drug Administration (“FDA”) regarding the primary efficacy endpoint to be used in the Orion® Visual Cortical Prosthesis System (“Orion”) pivotal trial;
- Presented additional positive data from the Company’s Early Feasibility Study of Orion at three scientific conferences in October: the American Academy of Ophthalmology (AAO), the Congress of Neurological Surgeons (CNS), and the Society for Neuroscience (SfN);
- Met with Centers for Medicare and Medicaid Services (“CMS”) to discuss future reimbursement for artificial vision to include the critically important post-surgical training and rehabilitation; and
- Received a \$2.4 million, four-year grant from the National Institutes of Health (NIH) to develop spatial localization and mapping technology (SLAM) in collaboration with the Johns Hopkins University Applied Physics Laboratory (APL).

“Our ongoing discussions with the FDA are proceeding well, and we are pleased to have reached agreement on the primary efficacy endpoint for the Orion pivotal trial. This endpoint is a new version of the FLORA assessment tool used in the Argus II trial and is designed to measure the technology’s impact to orientation, mobility and activities of daily living. Our efforts are currently focused on finalizing agreement with the FDA on the primary safety endpoint by year end. We are also engaged in productive dialogue with CMS about reimbursement for the critically important post-surgical training for Orion users, in an effort to ensure that patients are able to achieve the greatest benefit from the device,” stated Will McGuire, President and Chief Executive Officer of Second Sight.

“Orion has received some excellent coverage in the media recently, as awareness and excitement builds for this innovative, life-changing device. R&D efforts continue to focus on enhancements to Orion that are required for a pivotal trial and ultimately for commercialization. Most

importantly, the Orion subjects in our feasibility study are doing well, and we look forward to advancing this important technology and making it available to the large population of blind individuals who can benefit,” concluded McGuire.

Third Quarter 2019 Financial Results

Net sales on a GAAP basis were \$0.5 million for the third quarter of 2019 compared to \$2.2 million in the third quarter of 2018. Revenue was recognized for four implants on a GAAP basis with an average selling price of \$118,000 in the third quarter of 2019 compared to 22 implants with an average selling price of \$102,000 in the same period of 2018.

Gross profit for the third quarter of 2019 was \$0.1 million compared to a gross profit of \$0.5 million in the third quarter of 2018. Cost of sales was \$0.4 million in the third quarter of 2019 compared to \$1.8 million in the prior year period. In the third quarter of 2019, cost of sales included approximately \$0.2 million for the cost of products implanted and unabsorbed production costs of \$0.2 million. The Company expects to record cost of sales for any remaining Argus II inventory that is sold and a majority of the expenses related to production capabilities and fixed overhead to be reported as research and development expense in future periods.

Research and development expense increased to \$3.4 million during the third quarter of 2019 from \$2.7 million in the third quarter of 2018. The increase primarily reflects costs to produce Orion prototypes. The Company expects research and development expenses to increase in future periods as it accelerates the transition to the Orion platform, including costs previously related to production activities such as facilities and personnel that will be transitioning to Orion development activities.

Clinical and regulatory expense was \$0.9 million during the third quarter of 2019 compared to \$1.0 million in the third quarter of 2018. The decrease is attributable to lower costs from the Orion Early Feasibility Study. The Company expects clinical and regulatory costs to increase in the future as it conducts additional clinical trials to assess Orion and related enhancements to the user experience.

Selling and marketing expense was \$1.3 million during the third quarter of 2019 compared to \$3.0 million in the third quarter of 2018. The decrease of \$1.7 million is primarily driven by reduced commercial activities related to Argus II. The Company expects selling and marketing expense to decrease as it reduces Argus II commercial activities and sells through existing inventory.

General and administrative expense was \$2.2 million in the third quarter of 2019 compared to \$2.3 million in the third quarter of 2018. The decrease is primarily attributable to lower compensation costs. The Company expects general and administrative expense to remain consistent for the remainder of 2019.

Net loss for the third quarter of 2019 was \$7.6 million, or a loss of \$0.06 per share, compared to a net loss of \$8.5 million, or a net loss of \$0.12 per share, in the third quarter of 2018.

The non-GAAP net loss for the third quarter of 2019, excluding certain non-cash items, was \$6.9 million, or \$0.06 per share, compared to a non-GAAP net loss of \$7.5 million, or \$0.11 per share, in the third quarter of 2018.

As of September 30, 2019, Second Sight had \$18.5 million in cash and cash equivalents. The Company continues to expect its cash to fund operations into the second quarter of 2020.

For a full reconciliation of non-GAAP financial measures to the most comparable GAAP financial measures, please refer to the tables included with this press release.

2019 Key Objectives

- Advance Orion R&D implant and externals projects;
- Finalize agreement with the FDA regarding Orion's clinical and regulatory path;
- Engage and expand discussions with CMS and private payors while developing a comprehensive reimbursement strategy for Orion in the U.S.;
- Submit Argus 2s, our next-gen externals, to the FDA for U.S. regulatory approval by year end; and
- Add key talent to support our Orion programs and develop a plan for high-volume manufacturing.

Conference Call

As previously announced, Second Sight management will host its third quarter 2019 conference call as follows:

Date	Thursday, November 14, 2019
Time	4:30 PM EST
Telephone	U.S.: (800) 771-6759
	International: (212) 231-2937
Webcast (live and archive)	www.secondsight.com under the 'Investors' section.

A replay of the conference call will be available for two weeks after the call's completion by dialing (800) 633-8284 (U.S.) or (402) 977-9140 (International). The conference ID for the replay is 21933121. The archived webcast will be available for 30 days via the aforementioned URL.

About Second Sight

Second Sight Medical Products, Inc. (NASDAQ: EYES) develops, manufactures and markets implantable visual prosthetics that are intended to deliver useful artificial vision to blind individuals. A recognized global leader in neuromodulation devices for blindness, the Company is committed to developing new technologies to treat the broadest population of sight-impaired individuals. The Company's U.S. headquarters are in Los Angeles, California, and European headquarters are in Lausanne, Switzerland. More information is available at www.secondsight.com.

About the Orion Visual Cortical Prosthesis System

Leveraging Second Sight's 20 years of experience in neuromodulation for vision, the Orion Visual Cortical Prosthesis System (Orion) is 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, and eye injury. Orion is intended to convert images captured by a miniature video camera mounted on glasses into a series of small electrical pulses. The device is designed to bypass diseased or injured eye anatomy and to transmit these electrical pulses wirelessly to an array of electrodes implanted on the surface of the brain's visual cortex, where it is intended to provide the perception of patterns of light. A six-subject early feasibility study of the Orion is currently underway at the Ronald Reagan UCLA Medical Center in Los Angeles and the Baylor College of Medicine in Houston. No peer-reviewed data is available yet for the Orion system. The Company anticipates negotiating the clinical and regulatory pathway to commercialization with the FDA as part of the Breakthrough Devices Program.

Safe Harbor

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are intended to be covered by the "safe harbor" created by those sections. All statements in this release that are not based on historical fact are "forward looking statements." These statements may be identified by words such as "estimates," "anticipates," "projects," "plans," "strategy," "goal," or "planned," "seeks," "may," "will," "expects," "intends," "believes," "should," and similar expressions, or the negative versions thereof, and which also may be identified by their context. All statements that address operating performance or events or developments that Second Sight expects or anticipates will occur in the future, such as stated objectives or goals, our refinement of strategy, or that are not otherwise historical facts, are forward-looking statements. While management has based any forward-looking statements included in this release on its current expectations, the information on which such expectations were based may change. Forward-looking statements involve inherent risks and uncertainties which could cause actual results to differ materially from those in the forward-looking statements as a result of various factors, including those risks and uncertainties described in or implied by the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of our Annual Report on Form 10-K, filed on March 19, 2019, our Form 10-Q to be filed on or about November 14, 2019, and our other reports filed from time to time with the Securities and Exchange Commission. We urge you to consider those risks and uncertainties in evaluating our forward-looking statements. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, we disclaim any obligation or undertaking to publicly release any updates or revisions to any forward-looking statement contained herein (or elsewhere) to reflect any change in our expectations with regard thereto, or any change in events, conditions, or circumstances on which any such statement is based.

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Financial Tables Follow

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

Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2019 (unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 18,462	\$ 4,471
Accounts receivable, net	264	504
Inventories, net	1,264	3,250
Prepaid expenses and other current assets	366	1,395
Total current assets	20,356	9,620
Property and equipment, net	1,125	1,025
Right-of-use assets	2,399	-
Deposits and other assets	18	37
Total assets	\$ 23,898	\$ 10,682
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	\$ 1,126	\$ 1,305
Accrued expenses	2,082	2,503
Accrued compensation expense	2,461	2,690
Accrued clinical trial expenses	734	933
Current operating lease liabilities	228	-
Contract liabilities	554	167
Total current liabilities	7,185	7,598
Long term operating lease liabilities	2,427	-
Total liabilities	9,612	7,598
Commitments and contingencies		
Stockholders' equity	14,286	3,084
Total liabilities and stockholders' equity	\$ 23,898	\$ 10,682

SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY

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

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

SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY

Reconciliation of Non-GAAP Information to Most Comparable GAAP Measures

(in thousands, except per share data)

(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
Net loss	\$ (7,584)	\$ (8,522)	\$ (25,724)	\$ (26,236)
Add back non-cash charges:				
Stock-based compensation	686	877	2,443	2,898
Excess inventory reserve	-	110	(793)	171
Restructuring charges/inventory impairment	-	-	2,587	-
Non GAAP net loss	<u>\$ (6,898)</u>	<u>\$ (7,535)</u>	<u>\$ (21,487)</u>	<u>\$ (23,167)</u>
Net loss per share	\$ (0.06)	\$ (0.12)	\$ (0.22)	\$ (0.41)
Add back non-cash charge:				
Stock-based compensation	-	0.01	0.02	0.05
Excess inventory reserve	-	-	(0.01)	-
Restructuring charges/inventory impairment	-	-	0.02	-
Non GAAP net loss per share	<u>\$ (0.06)</u>	<u>\$ (0.11)</u>	<u>\$ (0.19)</u>	<u>\$ (0.36)</u>