

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): March 19, 2020

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))

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.

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

ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION

On March 19, 2020, Second Sight Medical Products, Inc. (the “*Company*”) issued a press release announcing its financial and operating results for the three-months and year ended December 31, 2019. A copy of the Company’s press release entitled “Second Sight Reports Fourth Quarter and Full Year 2019 Financial Results” is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”), nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such filing.

ITEM 7.01. REGULATION FD DISCLOSURE

On March 19, 2020, the Company issued the press release described above in Item 2.02 of this Current Report on Form 8-K. A copy of the press release is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item shall not be deemed “filed” for the purpose of Section 18 of the Exchange Act, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, 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	Press Release issued March 19, 2020 ‘ Second Sight Reports Fourth Quarter and Full Year 2019 Financial Results ’

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: March 19, 2020

SECOND SIGHT MEDICAL PRODUCTS, INC.

/s/ John T. Blake

By: John T. Blake

Chief Financial Officer

FOR IMMEDIATE RELEASE

Second Sight Reports Fourth Quarter and Full Year 2019 Financial Results

-- Received CE Mark Certification and U.S. Food and Drug Administration conditional approval for Argus 2s, next-generation wearables --

Los Angeles, CA – March 19, 2020 – 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 months and full year ended December 31, 2019.

Recent Financial and Corporate Highlights:

- Received CE Mark Certification and U.S. Food and Drug Administration (“FDA”) conditional approval for Argus 2s, the Company’s next-generation wearables. Enhancements include a more powerful video processing unit, an improved camera and more ergonomic glasses;
 - Completed the 12-month testing for the sixth subject in the Orion® Visual Cortical Prosthesis System (“Orion”) Early Feasibility Study, with continued positive overall safety and efficacy results across key measures;
 - Commenced validation of a new version of the Functional Low Vision Observer Rated Assessment (“FLORA 20”), which will serve as the primary efficacy endpoint for the Orion pivotal trial. This process has been suspended due to the implementation of COVID-19 social distancing protocols;
 - Held in-person discussions with Centers for Medicare and Medicaid Services (“CMS”) regarding reimbursement pathways available for Orion; and
 - Effected a 1:8 reverse split of the Company’s common stock.
-

“We are pleased that our development work on the Argus 2s has been completed, and that we received both FDA conditional approval and CE Mark Certification for these new wearables. The improved technology will serve as an important base for the next generation Orion system that will be used in the U.S. pivotal study. Our discussions with FDA around the primary safety endpoint for the pivotal trial are ongoing, as we work together to determine the appropriate parameters for a first-in-class technology like Orion,” stated Pat Ryan, Chief Operating Officer of Second Sight.

“Now that the last subject enrolled in our Early Feasibility Study has reached the 12-month mark, we are pleased to report that overall safety and efficacy metrics remain positive and support moving forward with a pivotal study. It is gratifying to know that this device can help profoundly blind individuals gain some independence and participate once again in certain activities of daily life. We look forward to making continued strides in advancing this breakthrough technology,” concluded Ryan.

Fourth Quarter 2019 Financial Results

Net sales on a GAAP basis were \$0.5 million for the fourth quarter of 2019 compared to \$1.8 million in the fourth quarter of 2018. Revenue was recognized for three units in the fourth quarter of 2019 as compared to 16 units in the prior year quarter. On a GAAP basis, revenue recognized per implant was approximately \$166,000 in the fourth quarter of 2019 and \$110,000 in the same period of 2018, reflecting an average higher reimbursement rate set by CMS in 2019 in the US.

Gross profit for the fourth quarter of 2019 was \$0.4 million compared to \$0.2 million in the fourth quarter of 2018. Cost of sales in the fourth quarter of 2019 was \$0.1 million as compared to \$1.6 million in the fourth quarter of 2018. During the fourth quarter of 2019, costs previously reported as cost of sales are reported in research and development expense in connection with the Company’s changeover in production from Argus II commercial units to Orion prototypes.

Research and development expense, net of funding received from grants, increased to \$4.1 million during the fourth quarter of 2019 compared to \$2.4 million in the fourth quarter of 2018. The increase primarily reflects costs to produce Orion prototypes. The Company expects research and development expenses to increase in future periods reflecting additional personnel and verification and validation testing of Orion prototypes, including costs previously related to production activities such as facilities and personnel that have transitioned to Orion development activities.

Clinical and regulatory expense was \$1.0 million during the fourth quarter of 2019 compared to \$1.2 million in the fourth 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 \$1.0 million during the fourth quarter of 2019 compared to \$2.4 million in the fourth quarter of 2018. The decrease of \$1.4 million is the result of the Company’s de-emphasis of commercial activities for Argus II.

General and administrative expense was \$2.3 million in the fourth quarter of 2019 compared to \$2.5 million in the fourth quarter of 2018. The decrease of \$0.2 million is primarily due to lower non-cash stock compensation costs from executive transitions.

Net loss for the fourth quarter of 2019 was \$7.9 million, or a loss of \$0.50 per share, compared to a net loss of \$8.9 million, or a net loss of \$0.96 per share, in the fourth quarter of 2018.

The non-GAAP net loss for the fourth quarter of 2019, excluding certain non-cash items, was \$7.4 million, or \$0.47 per share, compared to a non-GAAP net loss of \$7.6 million, or \$0.83 per share in the fourth quarter of 2018.

Full Year 2019 Financial Results

Net sales on a GAAP basis were \$3.4 million in 2019 compared to \$6.9 million in 2018. This decrease is mainly due to lower implant volumes as the Company restructured its commercial activities to transition from the Argus II to the Orion platform. In 2019, there were 26 implants recognized compared to 64 in 2018.

On a GAAP basis, revenue recognized per implant was approximately \$130,000 in 2019 and \$108,000 in 2018, reflecting an average higher reimbursement rate set by CMS in 2019 in the U.S.

Gross profit in 2019 was \$1.2 million, compared to \$2.0 million in 2018. Cost of sales decreased to \$2.2 million in 2019 from \$4.9 million in 2018, a decrease of \$2.7 million. In 2019, cost of sales was impacted by decreased production volumes. In 2019, the Company ceased production of Argus II. A significant portion of the Company's manufacturing activity related to Argus 2s and Orion prototypes and thus were reported in research and development expenses.

Research and development expense increased from \$10.0 million in 2018 to \$13.1 million in 2019, an increase of \$3.1 million, or 31%. The increase from the prior year was primarily due to increased headcount, outside services, and costs for internally produced prototypes related to the Orion platform.

Clinical and regulatory expense decreased from \$4.6 million in 2018 to \$3.4 million in 2019, a decrease of \$1.2 million, or 27%. The decrease of \$1.2 million primarily related to costs associated with the Orion feasibility study, which were higher in 2018 driven by the costs of the surgeries and devices in the early phases of the study, and \$0.5 million of grant revenue received in 2019. The Company expects clinical and regulatory costs to increase in the future as it conducts additional clinical trials, such as a future pivotal study with Orion and if the Company enrolls additional subjects in the Early Feasibility Study.

Selling and marketing expense was \$6.1 million in 2019 compared to \$11.3 million in 2018. The decrease of \$5.2 million is the result of the Company's de-emphasis of commercial activities for Argus II.

General and administrative expense was \$9.2 million in 2019 compared to \$10.7 million in 2018. The decrease is primarily related to reduced personnel costs of \$1.0 million that includes

a reduction in non-cash stock compensation expense of \$0.7 million primarily due to executive transitions, patent costs and outside services.

The Company incurred \$3.4 million in restructuring charges in 2019, consisting of a non-cash restructuring charge of \$2.6 million to reserve for Argus II inventory, and \$0.8 million for severance and other employee termination benefits, substantially all of which were settled in cash during 2019.

Net loss in 2019 was \$33.6 million, or \$2.28 per share, compared with a net loss of \$35.1 million, or \$4.23 per share in 2018. The non-GAAP adjusted net loss in 2019, excluding non-cash expenses, was \$28.1 million, or a loss of \$1.91 per share, compared with a non-GAAP adjusted net loss of \$30.8 million, or \$3.71 per share in 2018.

As of December 31, 2019, Second Sight had \$11.3 million in cash and cash equivalents. The Company expects its cash and cash equivalents 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.

Conference Call

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

Date	Thursday, March 19, 2020
Time	4:30 PM ET
Telephone	U.S: (800) 710-8126
	International: (720) 634-2491
Webcast (live and archive)	www.secondsight.com under the 'Investor Relations' section.

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 and 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," "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, 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 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, 2020, 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)

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 11,327	\$ 4,471
Accounts receivable, net	455	504
Inventories, net	1,029	3,250
Prepaid expenses and other current assets	299	1,395
Total current assets	13,110	9,620
Property and equipment, net	1,122	1,025
Right-of-use asset	2,342	-
Deposits and other assets	25	37
Total assets	<u>\$ 16,599</u>	<u>\$ 10,682</u>
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	\$ 1,093	\$ 1,305
Accrued expenses	1,889	2,503
Accrued compensation expenses	2,698	2,690
Accrued clinical trial expenses	707	933
Current operating lease liabilities	237	-
Contract liabilities	335	167
Total current liabilities	6,959	7,598
Long term operating lease liabilities	2,365	-
Total liabilities	9,324	7,598
Commitments and contingencies		
Stockholders' equity	7,275	3,084
Total liabilities and stockholders' equity	<u>\$ 16,599</u>	<u>\$ 10,682</u>

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

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
Net sales	\$ 497	\$ 1,767	\$ 3,379	\$ 6,896
Cost of sales	124	1,601	2,152	4,888
Gross profit	373	166	1,227	2,008
Operating expenses:				
Research and development, net of grants	\$ 4,145	\$ 2,438	\$ 13,143	\$ 10,005
Clinical and regulatory, net of grants	950	1,161	3,354	4,600
Selling and marketing	1,001	2,405	6,101	11,336
General and administrative	2,343	2,484	9,226	10,692
Restructuring charges	60	555	3,357	555
Total operating expenses	8,499	9,043	35,181	37,188
Loss from operations	(8,126)	(8,877)	(33,954)	(35,180)
Interest and other income, net	258	19	362	86
Net loss	<u>\$ (7,868)</u>	<u>\$ (8,858)</u>	<u>\$ (33,592)</u>	<u>\$ (35,094)</u>
Net loss per common share – basic and diluted	<u>\$ (0.50)</u>	<u>\$ (0.96)</u>	<u>\$ (2.28)</u>	<u>\$ (4.23)</u>
Weighted average shares outstanding – basic and diluted	<u>15,598</u>	<u>9,203</u>	<u>14,708</u>	<u>8,297</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		Twelve Months Ended	
	December 31,		December 31,	
	2019	2018	2019	2018
Net loss	\$ (7,868)	\$ (8,858)	\$ (33,592)	\$ (35,094)
Add back non-cash charges:				
Stock-based compensation	482	800	2,925	3,698
Excess inventory reserve	-	448	-	619
Restructuring charges/inventory impairment	-	-	2,587	-
Non GAAP net loss	<u>\$ (7,386)</u>	<u>\$ (7,610)</u>	<u>\$ (28,080)</u>	<u>\$ (30,777)</u>
Net loss per share	\$ (0.50)	\$ (0.96)	\$ (2.28)	\$ (4.23)
Add back non-cash charges:				
Stock-based compensation	0.03	0.08	0.20	0.45
Excess inventory reserve	-	0.05	-	0.07
Restructuring charges/inventory impairment	-	-	0.17	-
Non GAAP net loss per share	<u>\$ (0.47)</u>	<u>\$ (0.83)</u>	<u>\$ (1.91)</u>	<u>\$ (3.71)</u>