

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 13, 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))

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 Exchange 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 March 13, 2019, 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, 2018. A copy of the Company’s press release entitled “Second Sight Reports Fourth Quarter and Full Year 2018 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 13, 2019, 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	<u>Press Release issued March 13, 2019 “Second Sight Reports Fourth Quarter and Full Year 2018 Financial Results”</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: March 13, 2019

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 2018 Financial Results

Los Angeles, CA – March 13, 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 months and year ended December 31, 2018.

Recent Financial and Corporate Highlights:

- Implanted 16 Argus® II Retinal Prosthesis Systems (Argus II) worldwide in the fourth quarter of 2018 for a total of 69 implants in 2018;
- Reported net sales of \$6.9 million in 2018;
- Cleared fifth subject for home use as part of the Orion® Visual Cortical Prosthesis System (Orion) early feasibility study and implanted a sixth subject;
- The Centers for Medicare & Medicaid Services (CMS) granted an average 2019 Medicare outpatient payment rate of \$152,500 for the Argus II and associated surgical procedure, the highest rate ever approved for Argus II; CMS created a new rate-setting methodology for extremely low-volume procedures that now considers multiple years of data;
- Completed development work for the Argus 2s next-generation externals and initiated a clinical evaluation with current Argus II users in December 2018;
- Restructured commercial operations outside of North America to align with the Company’s overall corporate strategy; this restructuring is expected to save \$3 million per year in operating expenses; and
- Raised aggregate gross proceeds of approximately \$34.6 million through a rights offering in February 2019.

“In 2018, we advanced our Orion development and clinical programs, and are encouraged by the performance we are seeing with our first six subjects. The data we are collecting will continue to inform the design of a larger pivotal study and our regulatory path with the FDA. Orion is truly a breakthrough technology, bringing us closer to our ultimate goal of delivering useful artificial vision to virtually all blind individuals,” stated Will McGuire, President and CEO of Second Sight.

“To provide the capital required to support our clinical research and R&D efforts, we completed a \$34.6 million rights offering and restructured our commercial operations outside of North America. These actions will provide us with the necessary runway to execute our strategic initiatives into 2020. We continue to be excited about the progress with Orion as well as its potential to create meaningful shareholder value for Second Sight,” concluded McGuire.

Fourth Quarter 2018 Financial Results

Net sales on a GAAP basis were \$1.8 million for the fourth quarter of 2018 compared to \$3.1 million in the fourth quarter of 2017. Revenue was recognized for 16 units in the fourth quarter of 2018 compared to 26 units in the prior year quarter. This decrease is mainly due to lower international sales as the Company restructured its international commercial activities, and a lower average revenue per implant in 2018 due to a lower reimbursement rate set by CMS. On a GAAP basis, revenue recognized per implant was approximately \$112,000 in the fourth quarter of 2018 and \$120,000 in the same period of 2017.

Gross profit for the fourth quarter of 2018 was \$0.2 million compared to a gross profit of \$1.2 million in the fourth quarter of 2017. Cost of sales in the fourth quarter of 2018 was \$1.6 million as compared to \$1.9 million in the fourth quarter of 2017. The decrease was driven primarily by lower unit volume and an increase in the Company’s inventory reserve of \$0.4 million. Cost of sales in the fourth quarter of 2017 included a decrease in the inventory reserve of \$1.4 million.

Research and development expense, net of funding received from grants, increased to \$2.4 million during the fourth quarter of 2018 compared to \$2.3 million in the fourth quarter of 2017. 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, partially offset by \$0.5 million of costs deferred, which are expected to be funded by an NIH grant.

Clinical and regulatory expense was \$1.2 million during the fourth quarter of 2018 compared to \$1.1 million in the fourth quarter of 2017. The increase of \$0.1 million primarily related to costs associated with the Orion feasibility study. The Company expects clinical and regulatory costs to increase in the future as it conducts additional clinical trials to assess new products such as Orion and enhancements to existing products.

Selling and marketing expense was \$2.4 million during the fourth quarter of 2018 compared to \$2.5 million in the fourth quarter of 2017. The decrease of \$0.1 million is attributable to decreased market development activities, including compensation expenses.

General and administrative expense was \$2.5 million in the fourth quarter of 2018 compared to \$2.8 million in the fourth quarter of 2017. The decrease of \$0.3 million is primarily due to lower outside service costs.

Net loss for the fourth quarter of 2018 was \$8.9 million, or a loss of \$0.12 per share, compared to a net loss of \$7.4 million, or a net loss of \$0.13 per share, in the fourth quarter of 2017.

The non-GAAP net loss for the fourth quarter of 2018, excluding certain non-cash items, was \$7.6 million, or \$0.10 per share, compared to a non-GAAP net loss of \$7.8 million, or \$0.14 per share in the fourth quarter of 2017.

Full Year 2018 Financial Results

Net sales on a GAAP basis were \$6.9 million in 2018 compared to \$8.0 million in 2017. This decrease is mainly due to lower international sales as the Company restructured its international commercial activities, and a lower average revenue per implant in 2018 due to a lower reimbursement rate set by CMS. On a GAAP basis, revenue recognized per implant was approximately \$108,000 in 2018 and \$119,000 in 2017. The Company expects its average revenue recognized per implant unit for 2019 to be in a range of \$120,000 to \$130,000, depending on the geographic mix of implants.

Gross profit in 2018 was \$2.0 million, compared to gross profit of \$2.8 million in 2017. Cost of sales decreased to \$4.9 million in 2018 from \$5.1 million in 2017, a decrease of \$0.2 million. In 2018, cost of sales were impacted by decreased production volumes which increased per unit production costs. In 2017, cost of sales included a \$3.1 million decrease in the inventory reserve for slow-moving inventory and a \$2.8 million charge related to unabsorbed overhead costs.

Research and development expense, net of funding received from grants, increased to \$10.0 million in 2018 compared to \$7.9 million in 2017. 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 partially offset by \$0.5 million of costs deferred that are expected to be funded by an NIH grant.

Clinical and regulatory expense was \$4.6 million in 2018 compared to \$3.1 million in 2017. The increase of \$1.5 million primarily related to costs associated with the Orion feasibility study. The Company expects clinical and regulatory costs to increase in the future as it conducts additional clinical trials to assess new products such as Orion and enhancements to existing products.

Selling and marketing expense was \$11.3 million in 2018 compared to \$9.6 million in 2017. The increase of \$1.7 million is attributable to increased personnel related costs, such as salaries, benefits, outside services, travel and stock-based compensation.

General and administrative expense was \$10.7 million in 2018 compared to \$10.9 million in 2017. The decrease is primarily related to non-cash stock compensation expense due to executive transitions.

The Company incurred \$0.6 million in restructuring charges in 2018, consisting of severance and other employee termination benefits, substantially all of which were settled in cash during the fourth quarter of 2018.

Net loss in 2018 was \$35.1 million, or \$0.53 per share, compared with a net loss of \$28.5 million, or \$0.53 per share in 2017. The non-GAAP adjusted net loss in 2018, excluding non-cash expenses, was \$30.8 million, or a loss of \$0.46 per share, compared with a non-GAAP adjusted net loss of \$27.6 million, or \$0.51 per share in 2017.

As of December 31, 2018, Second Sight had \$4.5 million in cash and cash equivalents. In February 2019, the Company completed a rights offering that provided approximately \$34.6 million of gross proceeds. The Company expects 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

- Complete analysis of 12 month data from the first five Orion early feasibility study subjects;
- Enroll additional subjects in the Orion US early feasibility study to gather incremental safety and performance data;
- Reach agreement with the FDA concerning the clinical and regulatory pathway to commercialization for Orion; and
- Advance research projects intended to enhance the overall user experience, including the delivery of prototype eyewear suitable for patient testing with eye tracking technology, distance filtering/decluttering or thermal imaging.

Conference Call

As previously announced, Second Sight management will host its fourth quarter and year-end 2018 conference call as follows:

Date	Wednesday, March 13, 2019
Time	4:30 PM EDT
Telephone	U.S: (888) 221-1887
	International: (303) 223-4366
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 21918961. 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 Baylor College of Medicine in Houston. No published in-human data is available yet for the Orion system. The Company anticipates enrolling additional feasibility subjects in 2019 while simultaneously negotiating the clinical and regulatory pathway to commercialization with the FDA as part of the Breakthrough Devices Program.

About the Argus II Retinal Prosthesis System

The Argus® II Retinal Prosthesis System (Argus II) is an established, FDA and CE mark approved retinal implant that delivers a useful form of artificial vision to individuals who are blind due to severe to profound retinitis pigmentosa (RP). The Argus II works in place of lost photoreceptor cells and sends electrical pulses to remaining viable retinal cells to induce visual perception. The system works by converting images captured by a miniature video camera mounted on glasses into a series of small electrical pulses, which are transmitted wirelessly to an array of electrodes implanted on the surface of the retina. These pulses stimulate the retina's remaining cells, enabling the perception of patterns of light in the brain. The user learns to interpret these visual patterns in order to regain some visual function. The Argus platform, which leverages the unique, patented design of its 60-contact array, has been implanted in over 300 patients worldwide, is supported by more than 10 years of clinical experience and has been evaluated in multiple peer reviewed publications. Argus II was also the first retinal neuromodulation prosthesis to receive widespread commercial approval and is presently available at more than 50 leading medical centers in North America, Europe, the Middle East and Asia. Further information on the long-term benefits and risks can be found in the peer reviewed paper at: <http://www.sciencedirect.com/science/article/pii/S0161642016305796>

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, expected to be filed on or before March 18, 2019, Form 10-K filed on March 20, 2018, and Form 10-Q filed on November 8, 2018, 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)

	<u>December 31,</u> 2018	<u>December 31,</u> 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,471	\$ 7,839
Accounts receivable, net	504	1,831
Inventories, net	3,250	2,700
Prepaid expenses and other current assets	<u>1,395</u>	<u>795</u>
Total current assets	9,620	13,165
Property and equipment, net	1,025	1,299
Deposits and other assets	<u>37</u>	<u>33</u>
Total assets	<u>\$ 10,682</u>	<u>\$ 14,497</u>
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	\$ 1,305	\$ 752
Accrued expenses	2,503	2,425
Accrued compensation expenses	2,690	2,611
Accrued clinical trial expenses	933	779
Contract liabilities	<u>167</u>	<u>48</u>
Total current liabilities	7,598	6,615
Commitments and contingencies		
Stockholders' equity	<u>3,084</u>	<u>7,882</u>
Total liabilities and stockholders' equity	<u>\$ 10,682</u>	<u>\$ 14,497</u>

SE COND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY

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

	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	2018	2017	2018	2017
Net sales	\$ 1,767	\$ 3,109	\$ 6,896	\$ 7,964
Cost of sales	<u>1,601</u>	<u>1,862</u>	<u>4,888</u>	<u>5,117</u>
Gross profit	166	1,247	2,008	2,847
Operating expenses:				
Research and development, net of grants	\$ 2,438	2,271	\$ 10,005	7,893
Clinical and regulatory	1,161	1,135	4,600	3,062
Selling and marketing	2,405	2,512	11,336	9,569
General and administrative	2,484	2,762	10,692	10,932
Restructuring charges	555	-	555	-
Total operating expenses	<u>9,043</u>	<u>8,680</u>	<u>37,188</u>	<u>31,456</u>
Loss from operations	(8,877)	(7,433)	(35,180)	(28,609)
Interest and other income, net	<u>19</u>	<u>24</u>	<u>86</u>	<u>93</u>
Net loss	\$ (8,858)	\$ (7,409)	\$ (35,094)	\$ (28,516)
Net loss per common share – basic and diluted	\$ (0.12)	\$ (0.13)	\$ (0.53)	\$ (0.53)
Weighted average shares outstanding – basic and diluted	73,623	56,960	66,208	54,152

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,	
	2018	2017	2018	2017
Net loss	\$ (8,858)	\$ (7,409)	\$ (35,094)	\$ (28,516)
Add back non-cash charges:				
Stock-based compensation	800	1,030	3,698	4,046
Excess inventory reserve	448	(1,375)	619	(3,106)
Non GAAP net loss	\$ (7,610)	\$ (7,754)	\$ (30,777)	\$ (27,576)
Net loss per share	\$ (0.12)	\$ (0.13)	\$ (0.53)	\$ (0.53)
Add back non-cash charges:				
Stock-based compensation	0.01	0.01	0.06	0.08
Excess inventory reserve	0.01	(0.02)	0.01	(0.06)
Non GAAP net loss per share	\$ (0.10)	\$ (0.14)	\$ (0.46)	\$ (0.51)