SECOND SIGHT MEDICAL PRODUCTS INC

FORM 8-K
(Current report filing)

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Address	12744 SAN FERNANDO ROAD, BLDG. 3 SYLMAR, CA, 91342
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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 2, 2017

SECOND SIGHT MEDICAL PRODUCTS, INC.

(Exact Name of Registrant as Specified in Its Charter)

California

(State or Other Jurisdiction of Incorporation)

333-198073	**02-0692322**
(Commission File Number)	(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))

ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION

On November 2, 2017, Second Sight Medical Products, Inc. (the " ***Company*** ") issued a press release announcing its financial and operating results for the three and nine month periods ended September 30, 2017. A copy of the Company's press release entitled "Second Sight Reports Third Quarter 2017 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 November 2, 2017, 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.

The Company conducted a conference call to discuss these results on November 2, 2017, that was accessible live over the telephone by dialing 1- (800) 954-0586 (or dialing 1- (212) 271-4657 from outside the U.S.) . As described in the press release, all statements in the teleconference other than historical financial information, may be deemed to be forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act. Although the Company believes the expectations expressed in such forward-looking statements are based on reasonable assumptions, such statements are not guarantees of future performance and actual results or developments may differ materially from those in the forward-looking statements. The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

The conference call was broadcast live and was made available shortly after completion of the call for replay for two weeks. The replay can be accessed by dialing (800) 633-8284 (U.S.) or (402) 977-9140 (International). The conference ID for the replay is 21861643. The archived webcast will be available for 30 days following the call via www.secondsight.com under the 'Investor Relations' section

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 entitled "Second Sight Reports Third Quarter 2017 Financial Results" issued November 2, 2017

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 7, 2017

SECOND SIGHT MEDICAL PRODUCTS, INC.
/s/ Thomas B. Miller
By: Thomas B. Miller
Chief Financial Officer

Exhibit 99.1

Second Sight Reports Third Quarter 2017 Financial Results

Sylmar, CA, November 2, 2017 – 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 to blind patients, today reported financial results for the three- and nine-month periods ended September 30, 2017.

Recent Company Highlights:

- Generated net sales of $1.6 million in the third quarter of 2017, compared to $1.2 million in the third quarter of 2016;
- Implanted 12 Argus ® II Retinal Prosthesis Systems (Argus II) during the third quarter of 2017, compared to 19 in the second quarter of 2017, and 14 in the third quarter of 2016;
- The Company anticipates a strong fourth quarter of 2017, with over 20 Argus II surgeries completed or scheduled to date;
- Received full approval from the U.S. Food and Drug Administration (FDA) to begin the Orion™ Cortical Visual Prosthesis System (Orion) feasibility clinical study, allowing two U.S. sites, the University of California at Los Angeles (UCLA) and Baylor College of Medicine (Baylor) in Houston, to enroll up to five total patients;
- Appointed Frank Vandeputte as Vice President and General Manager, EMEA and Asia Pacific, who will lead all commercial activities outside North America and focus on the Company's direct and indirect market strategies, and Gregoire Cosendai as Vice President, Clinical Affairs, who will focus on expanding the population of patients treatable by the Argus II and the Orion clinical program, targeting millions of additional patients who today have no other treatment option;
- Received approval from Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), the German competent authority, to begin a ten-patient study in Germany to implant and evaluate the Argus II in better sighted retinitis pigmentosa (RP) patients; and,
- The Centers for Medicare Services (CMS) issued a final Medicare outpatient payment rate for 2018 of $122,500 for Argus II and the associated surgical implantation procedure.

" We are making excellent progress against all of our 2017 stated goals. Our Centers of Excellence model in North America is gaining traction and we are seeing an increasing number of centers perform Argus II cases on a regular basis. In the third quarter, we continued building our base of accounts and added two new centers in the large New York market. We expect to continue this expansion and plan to add another two new North American centers in the fourth quarter," stated Will McGuire, President and Chief Executive Officer of Second Sight.

"We also made significant clinical progress on the R&D front. German authorities approved the protocol we submitted for a clinical trial to treat better sighted RP patients with our Argus technology. We are moving forward with the clinical trial and are beginning to recruit subjects. Importantly, the FDA granted us full approval to conduct a clinical feasibility study for the Orion cortical visual prosthesis; we anticipate our first implant in the U.S. before the end of the year. We are also pursuing participation in the FDA's Breakthrough Devices Program for Orion, which if accepted, could significantly reduce the time and cost to move from development to commercialization," concluded McGuire.

Third Quarter 2017 Financial Results

Total revenue was $1.6 million for the third quarter of 2017, compared with $1.2 million in the third quarter of 2016. The Company received a higher revenue per implant due to the higher CMS reimbursement rate in 2017, and the collection of some deferred revenue.

Gross profit was $609,000 in the third quarter of 2017, compared to a $1.4 million gross loss in the third quarter of 2016. Gross profit in the third quarter of 2017, included a credit of $275,000 to partially reverse a previously established reserve for slow-moving inventory. The gross loss for the third quarter of 2016, included a reserve for slow-moving inventory of $1.0 million.

Total operating expenses in the third quarter of 2017 were $7.4 million, compared to $7.1 million in the third quarter of 2016, reflecting higher personnel and consulting costs related to the Company's development and commercial efforts, offset by lower spending on prototype development as the design of the Orion neared finalization. Grant revenue, which is used to offset research and development costs, declined to $107,000 in the third quarter of 2017, compared to $713,000 in the third quarter of 2016, due to a grant that was fully utilized by the end of the first quarter of 2017 and provided no benefit in the third quarter of 2017.

Net loss for the third quarter of 2017 was $6.7 million, or $0.12 per share, compared to a net loss of $8.5 million, or $0.20 per share, in the prior year quarter.

The non-GAAP adjusted net loss for the third quarter of 2017, excluding non-cash charges, was $6.0 million, or $0.11 per share, compared with a non-GAAP adjusted net loss of $6.5 million, or $0.15 per share in the third quarter of 2016.

Nine Months Ended September 30, 2017 and 2016 Financial Results

For the nine months ended September 30, 2017, total revenue was $4.9 million compared to $3.3 million in 2016. This increase is mainly due to the higher number of implants and a higher average revenue per implant in 2017 compared to the prior year.

Gross profit in first nine months of 2017 was $1.6 million, versus a gross loss of $3.5 million in the comparable 2016 period. Gross profit for the first nine months of 2017 included a credit of $1.7 million to partially reverse for a previously established reserve for slow-moving inventory. The gross loss for the first nine months of 2016 included a reserve for slow-moving inventory of $2.6 million.

Total operating expenses during the first nine months of 2017 were $22.8 million versus $19.3 million during the same period in 2016. This increase is primarily due to higher costs for compensation and outside consultants as the Company increased its commercial and development activities. Grant revenue, which is used to offset research and development costs, also declined by $1.8 million in the first nine months of 2017, and provided minimal expense offset in the first nine months of 2017 compared to the prior year period.

Operating loss in the first nine months of 2017 was $21.2 million, compared to an operating loss of $22.8 million in the comparable 2016 period.

Net loss for the nine months ended September 30, 2017 was $21.1 million, or $0.40 per share, compared with a net loss of $22.8 million, or $0.57 per share in the prior year period. The non-GAAP adjusted net loss for the nine months ended September 30, 2017, excluding non-cash expenses, was $19.8 million, or a loss of $0.37 per share, compared with a non-GAAP adjusted net loss of $17.4 million, or $0.44 per share in the prior year period.

2017 Key Objectives

- Validate revised Centers of Excellence commercial model in North America in order to demonstrate adoption
- Implant Orion in humans, creating the opportunity to treat up to six million blind individuals worldwide who today have no options
- Demonstrate the ability to treat better-sighted Retinitis Pigmentosa (RP) patients in order to expand our treatable population beyond bare light RP

Conference Call

As previously announced, Second Sight management will host its third quarter 2017 conference call as follows:

Date	Thursday, November 2, 2017
Time	4:30 PM EDT
Telephone U.S:	(800) 954-0586
International:	(212) 271-4657
Webcast (live and archive)	www.secondsight.com under the ‘Investor Relations’ 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 21861643. The archived webcast will be available for 30 days via the aforementioned URL.

About the Orion Visual Cortical Prosthesis System

Second Sight, the manufacturer of the Argus II ® Retinal Prosthesis System (Argus II), has developed a new device, the Orion. A proof-of-concept clinical trial at UCLA demonstrating the viability of stimulation of the human visual cortex with a commercially available device from a different manufacturer was announced in Q4 2016. First-in-human clinical studies with the Orion are planned to begin in 2017. Like the Argus II, the idea behind Second Sight's Orion is to convert images captured by a miniature video camera mounted on the patient's glasses into a series of small electrical pulses. The Orion is designed to transmit these electrical pulses wirelessly to an array of electrodes implanted on the surface of the visual cortex, intended to result in the perception of patterns of light. By bypassing the retina and optic nerve and directly stimulating the visual cortex, a cortical prosthesis system has the potential to restore useful vision to patients completely blinded due to many reasons, including glaucoma, diabetic retinopathy, or forms of cancer and trauma – many fold more patients than for the current Argus II indications. No clinical data is yet available for the Orion.

About the Argus II Retinal Prosthesis System

Second Sight's Argus II System provides electrical stimulation that bypasses the defunct retinal cells and stimulates remaining viable cells inducing visual perception in individuals with severe to profound Retinitis Pigmentosa. The Argus II works by converting images captured by a miniature video camera mounted on the patient's 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, intending to result in the perception of patterns of light in the brain. The patient must learn to interpret these visual patterns, having the potential to regain some visual function. The Argus II was the first artificial retina to receive widespread commercial approval, and is offered at approved centers in Canada, France, Germany, Italy, Russia, Saudi Arabia, South Korea, Spain, Taiwan, Turkey, the United Kingdom, and the United States. Further information on the benefits and risks can be found in the peer reviewed paper at:
http://www.sciencedirect.com/science/article/pii/S0161642016305796

About Second Sight
Second Sight's mission is to develop, manufacture and market innovative implantable visual prosthetics to enable blind individuals to achieve greater independence. Second Sight has developed, and now manufactures and markets, the Argus® II Retinal Prosthesis System. Enrollment has been completed in a feasibility trial to test the safety and utility of the Argus II in individuals with Dry Age-Related Macular Degeneration. New hardware and software to improve the quality of the vision produced is underway. A clinical trial to study the Argus II in better-sighted subjects earlier in the disease was recently approved in Germany. Second Sight is also developing the Orion™ Visual Cortical Prosthesis to restore some vision to individuals who are blind due to causes other than preventable or treatable conditions. U.S. Headquarters are in Sylmar, California, and European Headquarters are in Lausanne, Switzerland. For more information, visit www.secondsight.com.

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," 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 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 as filed on March 16, 2017, 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.

Reconciliation to Non-GAAP Financial Measures

In addition to reporting all financial information required in accordance with generally accepted accounting principles (GAAP), the Company is also reporting Non-GAAP net loss and Non-GAAP net loss per share which are non-GAAP financial measures. Non-GAAP net loss and Non-GAAP net loss per share are not measurements of financial performance under GAAP and should not be used in isolation or as a substitute or alternative to net income, operating income or any other performance measure derived in accordance with GAAP, or as a substitute or alternative to cash flow from operating activities or a measure of the Company's liquidity. In addition, the Company's definition of Non-GAAP net loss and Non-GAAP net loss per share may not be comparable to similarly titled non-GAAP financial measures reported by other companies. Non-GAAP net loss and Non-GAAP net loss per share, as defined by the Company, represent net loss adjusted for non-cash stock-based compensation and a reserve for excess inventory. Management believes that these non-GAAP financial measures provide useful supplemental information regarding the performance of the Company's business operations and facilitates comparisons to the Company's historical operating results. For a full reconciliation of Non-GAAP net loss to the most comparable GAAP financial measures, please see the tables at the end of this press release.

Investor Relations:

Institutional Investors
In-Site Communications, Inc.
Lisa Wilson, President
212-452-2793
lwilson@insitecony.com
or
Individual Investors
MZ North America
Greg Falesnik, Managing Director
949-385-6449
greg.falesnik@mzgroup.us

Source: Second Sight Medical Products, Inc.

Financial Tables Follow

SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY

Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2017 (unaudited)	December 31, 2016
ASSETS		
Current assets:		
Cash	$ 639	$ 539
Money market funds	12,705	10,336
Accounts receivable, net	668	274
Inventories, net	3,245	3,416
Prepaid expenses and other current assets	462	717
Total current assets	17,719	15,282
Property and equipment, net	1,327	1,489
Deposits and other assets	35	39
Total assets	$ 19,081	$ 16,810
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 826	$ 1,156
Accrued expenses	2,330	2,088
Accrued compensation expenses	2,266	1,600
Accrued clinical trial expenses	623	629
Deferred revenue	64	85
Deferred grant revenue	—	104
Total current liabilities	6,109	5,662
Commitments and contingencies		
Stockholders' equity	12,972	11,148
Total liabilities and stockholders' equity	$ 19,081	$ 16,810

SECOND SIGHT MEDICAL PRODUCTS, INC.
AND SUBSIDIARY

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Net sales	$ 1,610	$ 1,180	$ 4,855	$ 3,270
Cost of sales	1,001	2,615	3,255	6,768
Gross profit (loss)	609	(1,435)	1,600	(3,498)
Operating expenses:				
Research and development, net of grants	1,826	1,588	5,622	3,266
Clinical and regulatory	629	609	1,927	1,955
Selling and marketing	2,375	2,262	7,057	6,473
General and administrative	2,528	2,605	8,170	7,635
Total operating expenses	7,358	7,064	22,776	19,329
Loss from operations	(6,749)	(8,499)	(21,176)	(22,827)
Interest and other income, net	33	10	69	18
Net loss	$ (6,716)	$ (8,489)	$ (21,107)	$ (22,809)
Net loss per common share – basic and diluted	$ (0.12)	$ (0.20)	$ (0.40)	$ (0.57)
Weighted average shares outstanding – basic and diluted	56,799	42,220	53,206	39,929

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 September 30,		Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Net loss	$ (6,716)	$ (8,489)	$ (21,107)	$ (22,809)
Add back non-cash charges:				
Stock-based compensation	970	964	3,016	2,787
Excess inventory reserve	(275)	1,044	(1,731)	2,611
Non GAAP net loss	$ (6,021)	$ (6,481)	$ (19,822)	$ (17,411)
Net loss per share	$ (0.12)	$ (0.20)	$ (0.40)	$ (0.57)
Add back non-cash charges:				
Stock-based compensation	0.01	0.02	0.06	0.07
Excess inventory reserve	(0.00)	0.03	(0.03)	0.06
Non GAAP net loss per share	$ (0.11)	$ (0.15)	$ (0.37)	$ (0.44)