

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
Telephone	818-833-5000
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Industry	Medical Equipment, Supplies & Distribution
Sector	Healthcare
Fiscal Year	12/31

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 8, 2017

SECOND SIGHT MEDICAL PRODUCTS, INC.
(Exact Name of Registrant as Specified in Its Charter)

California
(State or Other Jurisdiction of Incorporation)

333-198073
(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))
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Item 8.01 Other Events

On November 8, 2017, Second Sight Medical Products, Inc. (the “Company” or “we”) issued a press release announcing that the U.S. Food and Drug Administration (FDA) has granted Expedited Access Pathway designation for the Orion™ Cortical Visual Prosthesis System (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 Orion converts images captured by a miniature video camera mounted on the patient's glasses into a series of small electrical pulses that are transmitted wirelessly to an array of electrodes implanted on the surface of the visual cortex of the brain, intended to result in the perception of patterns of light. We believe that Orion, by bypassing the retina and optic nerve and directly stimulating the visual cortex, 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.

The Company has approval for a feasibility study for two U.S. sites to enroll up to five total patients. The Company has designated the University of California, Los Angeles and Baylor College of Medicine in Houston as the U.S. clinical trial sites.

A copy of our press release entitled “Second Sight Receives FDA Expedited Access Pathway Designation for the Orion Cortical Visual Prosthesis System” is attached as Exhibit 99.1 to this Current Report on Form 8-K, and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued November 8, 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 10, 2017

SECOND SIGHT MEDICAL PRODUCTS, INC.

/s/ Thomas B. Miller

By: Thomas B. Miller
Chief Financial Officer



Second Sight Receives FDA Expedited Access Pathway Designation for the Orion Cortical Visual Prosthesis System

-- Allows patients to have more timely access to medical devices by expediting their development, assessment, and review --

SYLMAR, Calif.--(BUSINESS WIRE)-- 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 announced that the U.S. Food and Drug Administration (FDA) has granted Expedited Access Pathway designation for the Orion™ Cortical Visual Prosthesis System (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. FDA has indicated that all devices which have EAP designation will gain Breakthrough Device designation when the guidance document is finalized.

With this designation, 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

"These advantages potentially allow the FDA to approve Orion with fewer patients and with a shorter follow-up timeline, thus facilitating a faster entry of Orion into the commercial market. We are delighted about the opportunity for patients to have expedited access to Orion, once approved," stated Will McGuire, President and Chief Executive Officer of Second Sight.

Dr. Robert Greenberg, Chairman of Second Sight stated, "FDA's Expedited Access Pathway is a game changer for nearly all blind individuals in the U.S. who currently have no treatment options. We look forward to moving the program ahead and working with the FDA in the coming months to map out the most efficient path to market for this therapy, which has the potential to treat most causes of blindness."

Blind patients interested in the Orion clinical trial can contact Second Sight customer service at 1-855-756-3703 for further information or referral to one of our clinical trial sites.

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, 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, 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.

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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
