

SECOND SIGHT MEDICAL PRODUCTS INC

FORM 8-K (Current report filing)

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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 1, 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 1, 2017, the Centers for Medicare & Medicaid Services (CMS) published the final rule and related final rates for the calendar year (CY) 2018, Medicare Hospital Outpatient Prospective Payment System (OPPS) and the CY 2018 Ambulatory Surgical Center (ASC) payment systems. In these postings, CMS finalized a Medicare hospital outpatient rate for CY 2018 of approximately \$122,500 for the Argus[®] II Retinal Prosthesis System (Argus II) and the associated surgical implantation procedure, and a proposed ASC rate of approximately \$117,501 for the Argus II and related implantation procedure. CMS also reassigned Current Procedural Terminology (CPT) code 0100T (Placement of subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) from Ambulatory Payment Classification (APC) 1906, with a 2017 Medicare payment rate of approximately \$150,000, to APC 1904, with a CY2018 payment rate of approximately \$122,500. The final hospital outpatient and ASC rates include both the Argus II, reported with HCPCS code C1841 (Retinal prosthesis, includes all internal and external components), and the surgical implantation procedure, reported with CPT code 0100T.

Additionally, CMS finalized the CY 2018 payment rates for the recently created codes for the initial programming and the reprogramming services related to Argus II – CPT codes 0472T (Device evaluation, interrogation, and initial programming of intra-ocular retinal electrode array (e.g., retinal prosthesis), in person, with iterative adjustment of the implantable device to test functionality, select optimal permanent programmed values with analysis, including visual training, with review and report by a qualified health care professional) and 0473T (Device evaluation and interrogation of intra-ocular retinal electrode array (e.g., retinal prosthesis), in person, including reprogramming and visual training, when performed, with review and report by a qualified health care professional). The final CY 2018 hospital outpatient payment rates for the initial programming (CPT code 0472T) and for the reprogramming (0473T) are \$261.87 and \$115.17, respectively.

This final rule and related files affect Medicare payment to the hospital outpatient departments and ambulatory surgical centers that are paid under the OPPS and ASC prospective payment system for services rendered on or after January 1, 2018. They do not directly alter payment from Medicare Advantage, private U.S. health insurance and non-U.S. business.

Second Sight Medical Products, Inc. issued a press release entitled “Second Sight Announces Final Medicare Hospital Outpatient Payment Rate for 2018 for the Argus II retinal Prosthesis System”, a copy of which 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
<u>99.1</u>	<u>Press Release issued November 2, 2017</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 5, 2017

SECOND SIGHT MEDICAL PRODUCTS, INC.

/s/ Thomas B. Miller

By: Thomas B. Miller
Chief Financial Officer



Second Sight Announces Final Medicare Hospital Outpatient Payment Rate for 2018 for the Argus II Retinal Prosthesis System

SYLMAR, Calif.--(BUSINESS WIRE)- Second Sight Medical Products, Inc. (NASDAQ:EYES) (“Second Sight”), 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 Centers for Medicare & Medicaid Services (CMS) finalized its Medicare hospital outpatient payment rate of \$122,500 for the Argus[®] II Retinal Prosthesis System (Argus II) procedure for calendar year 2018. The payment for the surgical procedure includes the cost of the Argus II.

“We sincerely appreciate CMS’ decision to establish the 2018 outpatient payment rate using their equitable adjustment authority. This payment rate will facilitate ongoing Medicare patient access to this life changing treatment, while we work to drive adoption at our Centers of Excellence. We look forward to continuing to work with CMS to establish a long-term stable payment rate for the Argus II procedure,” said Will McGuire, President and Chief Executive Officer of Second Sight.

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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