

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, 2018

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))

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 8.01 Other Events

On November 2, 2018, the Centers for Medicare & Medicaid Services (CMS) published the final rule and related final rates for the calendar year (CY) 2019, Medicare Hospital Outpatient Prospective Payment System (OPPS) and the CY 2019 Ambulatory Surgical Center (ASC) payment systems. In these postings, CMS finalized a Medicare hospital average outpatient rate for CY 2019 of approximately \$152,500 for the Argus® II Retinal Prosthesis System (Argus II) and the associated surgical implantation procedure, and a proposed ASC average rate of approximately \$134,051 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) 1904, with a CY 2018 Medicare payment rate of approximately \$122,500, to APC 1908, with a CY 2019 payment rate of approximately \$152,500. 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. CMS acknowledged the difficulty presented by variation in the CMS payment rate for Argus II, and the need to mitigate these variations. It presented three methodologies of calculating the rate based on data from multiple years. The Secretary used the equitable adjustment authority to set the new payment rate. The likely result is that the payment rate will stabilize at this level for the foreseeable future.

Payment for Argus II has been reduced in some cases when packaged with a J1 coded procedure. To address this issue and help ensure that there is sufficient claims data for services assigned to New Technology APCs, in the CY 2019 OPPS/ASC proposed rule, CMS has proposed to exclude payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a “J1” service assigned to a C-APC.

In addition, the CMS postings address CY 2019 payments for the codes for initial programming and 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). CMS finalized its proposed APC assignments for these codes. As such, the CY 2019 national average hospital outpatient payment rates for the initial programming (CPT code 0472T) and for the reprogramming (CPT code 0473T) are \$280.41 and \$117.54, 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, 2019. They do not directly alter payment from Medicare Advantage, private U.S. health insurance and non-U.S. reimbursement.

Second Sight Medical Products, Inc. issued a press release entitled “Second Sight Announces Final 2019 Medicare Hospital Outpatient Payment Rate 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
99.1	Press Release issued November 6, 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 6, 2018

SECOND SIGHT MEDICAL PRODUCTS, INC.

/s/ John T. Blake

By: John T. Blake
Chief Financial Officer



For Immediate Release

Second Sight Announces Final 2019 Medicare Hospital Outpatient Payment Rate for the Argus II Retinal Prosthesis System

Los Angeles, CA, November 6, 2018 – 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 announced that the Centers for Medicare & Medicaid Services (CMS) has finalized its Medicare hospital outpatient payment rate of \$152,500 for the Argus[®] II Retinal Prosthesis System (Argus II) and the associated surgical implantation procedure for calendar year 2019.

“We are delighted to have received CMS’ final 2019 outpatient payment rate, which provides Medicare patients continued access to our life changing technology. We are also happy to see the change in methodology that considers multiple years of historic data when setting a rate for a low volume device such as Argus. We believe this change will temper future year-to-year fluctuations in the reimbursement rate,” said Will McGuire, President and Chief Executive Officer of Second Sight.

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.

Second Sight’s Argus[®] II Retinal Prosthesis System is the only FDA and CE Mark approved device for treating retinitis pigmentosa, with proven implant durability of multiple years. In 2016, the Company published five year results. Today, several Argus II devices have been implanted and continue to be operational in humans for more than 10 years. The Company is developing the Orion[®] Visual Cortical Prosthesis which is intended to provide useful artificial vision to individuals who are blind due to various causes. The Company’s U.S. headquarters are in Los Angeles, and European headquarters are in Lausanne, Switzerland. More information is available at 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,” “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 20, 2018 and Form 10-Q, filed on August 7, 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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