

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): February 12, 2019

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

Orion Early Feasibility Study

Second Sight Medical Products, Inc. (the “Company”) has completed enrollment of the sixth subject at Baylor College of Medicine in Houston (“Baylor”) in the Company’s Early Feasibility Study of the Orion Visual Cortical Prosthesis. 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, or forms of cancer and trauma. As previously expected, the sixth subject was implanted at Baylor in January 2019, with no adverse events noted during the surgery.

Risk Factor Update

The following risk factor is provided to update the Risk Factors previously disclosed in the Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 (the “Q3 Form 10-Q”) filed with the U.S. Securities and Exchange Commission. Capitalized terms not otherwise defined herein have the meanings ascribed to them in the Q3 Form 10-Q.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

In order to obtain marketing approval for Orion we must demonstrate the safety and efficacy of Orion through clinical trials as well as additional supporting data. If Orion is associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to interrupt, delay or abandon Orion’s development, cause it to have reduced functionality, or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. We are conducting at UCLA and Baylor a six subject initial feasibility clinical study of Orion, but we cannot guarantee that any positive results in this limited trial will successfully translate to a pivotal clinical trial. It is not uncommon to observe results in human clinical trials that are unexpected based on limited trials testing, and many product candidates fail in large clinical trials despite promising limited clinical trial results. Moreover, clinical data is often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products. No assurance can be given that we will not encounter similar results in our Orion trials. Human subjects in our clinical trials may suffer significant adverse events, tolerability issues or other side effects associated with the surgical implantation, chronic implantation, and chronic use of the Orion device. These events include, but are not limited to, the following (events that are also anticipated during or following explantation of the Orion device are identified with an asterisk (*)): intracranial hemorrhage*; subcutaneous hematoma*; vascular injury causing stroke or hemorrhage (e.g. injury to the superior sagittal sinus or posterior cerebral artery perforators)*; hydrocephalus*; intracranial hypotension or cerebrospinal fluid (CSF) leak*; headache or pain in the head, including deep pain*; tingling at the implant site*; brain edema*; infection*; meningitis*; implant site pain, swelling, discharge or effusion*; suture-related complications or stitch abscess*; skin erosion on and/or around the implant site; adverse tissue reaction to the implant; tissue damage at the implant/explant site*; cranial defect/bone damage*; decline in residual vision*; dizziness/syncope*; foreign body sensation at the implant site*; activation of motor or sensory neurons (e.g., muscle twitch); clinically symptomatic seizure*; development of epilepsy; coma*; death*; psychiatric events, including but not limited to mood changes, depression, suicidality, and psychosis*; neurological deficit, including but not limited to language (dysphemia), dysesthesias, paresis, parathesias, visual field, motor deficit (including apraxia), and memory impairment*; drug hypersensitivity, adverse drug reaction, or therapeutic agent toxicity*; events related to any surgery and general anesthesia including cardiac risks, including stroke/transient ischemic attack, arrhythmia, cardiac arrest, and myocardial infarction*, venous thromboembolic (VTE) disease*; pneumonia*, urinary tract infection*, post-operative delirium*, postoperative constipation*, post-operative vomiting or nausea*, or post-operative fever*; injuries due to falls or bumps; skin irritation or burns; Orion system failure or malfunction; array migration; damage to the Orion electronics case; device interaction including the Orion device may interfere with the proper functioning of other electronic devices and emissions from other electronic equipment may interfere with the proper functioning of the Orion device; and (explant only) inability to remove all or part of the Orion device due to fibrosis or other reason.

No assurance can be given that we will not encounter adverse events in our Orion trials. The observed efficacy and extent of light perception and vision restoration for subjects implanted with Orion in our feasibility study may not be observed in a larger pivotal clinical trial. If general clinical trials of Orion fail to demonstrate efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of Orion.

For example, in June 2018, one subject in our Early Feasibility Study for Orion (“EFS”) experienced a seizure while in the clinic when we were evaluating a specific video stimulation algorithm. The seizure resolved quickly with medication and the subject was released from the clinic without need for hospitalization or further treatment. The subject was allowed to continue using the Orion device after the serious adverse event was reviewed by a safety committee for the study and clinicians at the implanting institution.

In addition, for example, in January 2019 we observed higher impedance levels on 11 of 60 electrodes with the first EFS subject implanted with the Orion device in January 2018. As a result, some of these electrodes no longer generate a phosphene, or observable spot of light, for the subject. The subject continues to use the device and is continuing to participate in the clinical study. Mechanical and software safeguards are built into the device to avoid excessive electrical stimulation and, as a result, the higher impedance levels do not pose any known safety risks to the subject. We are currently investigating the possible cause(s) for the higher impedance levels, including any combination of the following: potential manufacturing defects, damage due to improper or excessive handling of the device, materials chosen for the design, and related processes. While our first subject has been implanted with the device for 12 months and 5 subjects have been implanted for 10 months or less, we currently have no indication that the issue exists with any of the Orion devices implanted in each of the other five EFS subjects. Prior to initiation of EFS, we subjected six Orion implants to accelerated aging tests and had no failures for what was the equivalent of up to 6.5 years. We cannot provide any assurance that we will not experience similar or other issues with any of the implanted Orion devices, be able to determine the root cause of the issue or to ascertain whether the issue is isolated or systemic in nature. Additional testing, investigation, design changes or mitigation activities may delay our plans to conduct additional clinical studies for Orion and/or our marketing approval and may have a material adverse effect on our business.

If device defects, significant adverse events or other side effects are observed in any of our future clinical trials, we may have difficulty recruiting subjects to the clinical trial, subjects may drop out of our trial, or we may be required to abandon the trial or our development efforts of that product candidate altogether. We, the FDA or other applicable regulatory authorities may suspend clinical trials of Orion at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks. Devices developed in the prosthesis industry that initially showed promise in early-stage studies have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude Orion from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its actual or perceived safety and tolerability profile. Any of these developments could materially harm our business, financial condition and prospects.

Should Orion obtain marketing approval, adverse effects associated with it may also develop after such approval and could lead to requirements for conducting additional clinical safety trials, placing additional warnings in the labeling, imposing significant restrictions on Orion, or withdrawing the Orion from the market while further incurring attendant costs of explants and exposure to litigation. We cannot predict whether Orion will cause significant adverse effects in humans that would preclude or lead to the revocation of regulatory approval. However, any such event, were it to occur, would cause substantial harm to our business and financial condition and would result in the diversion of our management’s attention.

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: February 12, 2019

SECOND SIGHT MEDICAL PRODUCTS, INC.

/s/ John T. Blake

By: John T. Blake
Chief Financial Officer