



## Researchers Present Latest Positive Results of Second Sight's Orion Visual Cortical Prosthesis Feasibility Study

June 25, 2019

*Study Investigators from UCLA and Baylor Provide Latest Study Update at the World Society for Stereotactic and Functional Neurosurgery Annual Meeting*

LOS ANGELES & NEW YORK--(BUSINESS WIRE)--Jun. 25, 2019--

Second Sight Medical Products, Inc. (NASDAQ:EYES) ("Second Sight" or the "Company"), a developer, manufacturer and marketer of implantable visual prosthetics intended to create an artificial form of useful vision for blind individuals, announced that 12-month results from the Company's Early Feasibility Study of the Orion<sup>®</sup> Visual Cortical Prosthesis System ("Orion") will be presented today at the World Society for Stereotactic and Functional Neurosurgery Annual Meeting in New York City. On both the primary and secondary outcome measures, latest results at 12 months have been positive.

The study's principal investigators, Nader Pouratian, MD, Ph.D. of Ronald Reagan UCLA Medical Center ("UCLA"), and Daniel Yoshor, MD of Baylor College of Medicine ("Baylor"), are presenting the topline data. Orion is a breakthrough technology 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, and eye injury. Orion converts images captured by a miniature video camera mounted on glasses into a series of small electrical pulses transmitted wirelessly to electrodes implanted directly on the visual cortex of the individual subject's brain.

The first human subject was implanted with Orion in January 2018. A total of six subjects have been implanted in the Orion Early Feasibility Study, including four subjects at the UCLA site in Los Angeles and two subjects at the Baylor site in Houston. There are five male subjects and one female subject, with a median age of 48 and an average of 13 months since implant. Study subjects are completely bilaterally blind. Causes of vision loss among participants include congenital glaucoma, head trauma, endophthalmitis and optic neuropathy.

The primary outcome measure of the Orion Early Feasibility Study is safety. Secondary outcome measures include the ability to produce phosphenes, assess the long-term functionality of the device and evaluate the benefit to patients in terms of visual function, functional vision and quality of life.

"We are pleased with the continued favorable progress being made in the Orion Early Feasibility Study among the six study participants. The first four subjects have now reached 12 months post-implant, and participants appear to be making steady improvements in their ability to perform everyday tasks and successfully meet the study's functional vision endpoint goals. It is also encouraging to see that when compared with similar Argus II feasibility study results at the 12-month mark, the Orion study participants are doing as well as or better than Argus II participants in most measurements, such as the Functional Low-Vision Observer Rated Assessment (FLORA). We look forward to continued collaboration with our study investigators and to advancing our Orion technology platform," said Will McGuire, President and Chief Executive Officer of Second Sight.

### Study Results

Safety outcomes as of the last independent medical safety monitor review:

- Only two out of six study participants have experienced an adverse device event (ADE), which, as of May 3, 2019, included one serious adverse event (seizure), five non-serious adverse events such as headache, and no unanticipated adverse device events.

Ability to see phosphenes demonstrated for all patients:

- The perception threshold measurements, which is the energy required to produce a spot of light, for all participants have remained generally consistent over time.

Preliminary performance assessment of ability to locate objects and detect motion at 12 months post-implant (four subjects measured as of June 25, 2019):

- Three out of four Orion subjects at 12 months demonstrated the ability to locate a high-contrast target significantly better with the System ON than with the System OFF (t-test,  $p < 0.05$ ) as measured by Square Localization.
- Three out of four Orion subjects at 12 months demonstrated the ability to determine the direction of motion of a high-contrast target significantly better with the System ON than with the System OFF (t-test,  $p < 0.05$ ).

Overview of real-world use of Orion:

- Four out of four Orion subjects at 12 months were rated by certified Orientation and Mobility specialists as having received positive or mild positive benefit from Orion in terms of functional vision and well-being on the FLORA.

The presentation is available on Form 8-K as filed with the U.S. Securities and Exchange Commission.

### 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. The Company's U.S. headquarters are in Los Angeles, California, and European headquarters are in Lausanne, Switzerland. More information is available at [www.secondsight.com](http://www.secondsight.com).

### **About the Orion Visual Cortical Prosthesis System**

Leveraging Second Sight's 20 years of experience in neuromodulation for vision, the Orion<sup>®</sup> Visual Cortical Prosthesis System (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, and eye injury. Orion is intended to convert images captured by a miniature video camera mounted on glasses into a series of small electrical pulses. The device is designed to bypass diseased or injured eye anatomy and to transmit these electrical pulses wirelessly to an array of electrodes implanted on the surface of the brain's visual cortex, where it is intended to provide the perception of patterns of light. A six-subject early feasibility study of the Orion is currently underway at the Ronald Reagan UCLA Medical Center in Los Angeles and the Baylor College of Medicine in Houston. No peer-reviewed data is available yet for the Orion system. The Company anticipates enrolling additional feasibility subjects in 2019 while simultaneously negotiating the clinical and regulatory pathway to commercialization with the FDA as part of the Breakthrough Devices Program.

### **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 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," "appears," "projects," "plans," "goal," "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 19, 2019, our Quarterly Report, on Form 10-Q, filed on May 15, 2019, 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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