

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): June 25, 2019

SECOND SIGHT MEDICAL PRODUCTS, INC.

(Exact Name of Registrant as Specified in Its Charter)

California

(State or Other Jurisdiction of Incorporation)

001-36747

(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Act of 1934 (§240.12b-2 of this chapter).

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.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	EYES	NASDAQ
Warrants	EYESW	NASDAQ

ITEM 7.01. REGULATION FD DISCLOSURE

A copy of a slide presentation that Nader Pouratian, MD, Ph.D. a researcher in the study of the Orion Cortical Visual Prosthesis from Second Sight Medical Products, Inc. ("**Second Sight**") intends to use during a presentation at the World Society for Stereotactic and Functional Neurosurgery (WSSFN) Conference in New York City on June 25, 2019 (the "Presentation Materials") is attached to this Current Report on Form 8-K as Exhibit 99.2, and is incorporated by reference herein. The Presentation Materials speak as of the date of this Current Report on Form 8-K. While Second Sight may elect to update the Presentation Materials in the future or reflect events and circumstances occurring or existing after the date of this Current Report on Form 8-K, Second Sight specifically disclaims any obligation to do so. The information contained in this Item 7.01 and Exhibit 99.1 hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by reference in such a filing.

ITEM 8.01 OTHER EVENTS

On June 25, 2019, Second Sight issued a press release entitled "Researchers Present Latest Positive Results of Second Sight's Orion Visual Cortical Prosthesis Feasibility Study". In the release, Second Sight stated that the study's principal investigators, Nader Pouratian, MD, Ph.D. of Ronald Reagan UCLA Medical Center and Daniel Yoshor, MD of Baylor College of Medicine 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. A copy of the press release is attached to this current report on Form 8-K as exhibit 99.1 and incorporated herein by this reference.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

Exhibit No. Description

- 99.1 Press Release titled "Researchers Present Latest Positive Results of Second Sight's Orion Visual Cortical Prosthesis Feasibility Study", dated June 25, 2019.
99.2 Presentation titled "Development of a Visual Prosthesis: The Orion Visual Prosthesis System", dated June 25, 2019.

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: June 25, 2019

SECOND SIGHT MEDICAL PRODUCTS, INC.

/s/ John T. Blake

By: John T. Blake
Chief Financial Officer

FOR IMMEDIATE RELEASE

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

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

LOS ANGELES and NEW YORK- June 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® 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 the Company's website under Investors/Events and Presentations and 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.

About the Orion Visual Cortical Prosthesis System

Leveraging Second Sight's 20 years of experience in neuromodulation for vision, the Orio® 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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Development of a Visual Prosthesis: The Orion Visual Prosthesis System

Ex 99.2

Nader Pouratian, M.D., Ph.D.
Daniel Yoshor, M.D., Ph.D.



Study partly funded by NIH BRAIN Initiative grant: UH3NS103442

Disclosures

Second Sight – Grant Support for this project
Consultant

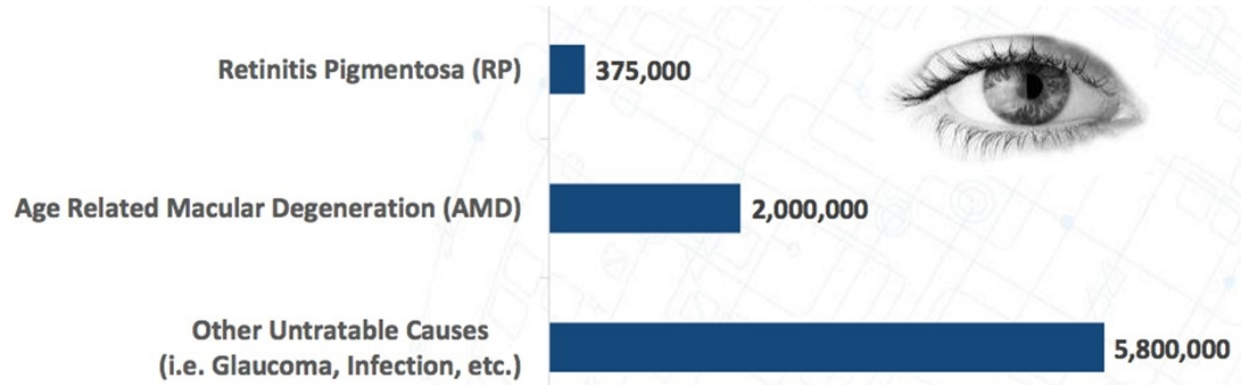
BrainLab – Grant Support

Medtronic – Fellowship Support

Boston Scientific – Consultant, DSMB

39 million people worldwide are legally blind

8 million patients globally are legally blind due to unpreventable causes



Overall Goal: Cortical Prosthesis for Previously Sighted Patients with No or Bare Light Perception

Safe – Implant-related concerns (infection)
Seizures

Practical – Surgically Practical and Adoptable
(microarray “tiles” vs ECoG)

Clinically Useful – Perceptions
Shadows
Edges

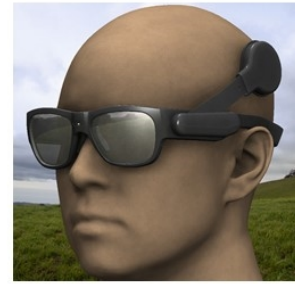
Visual Cortical Prosthesis: Orion I Implant

- Leverages existing Argus II technology
- Bypasses the eyes and optic nerve and directly stimulates the visual cortex
- Designated a Breakthrough Device by FDA
- Early Feasibility Study underway in U.S.
- In planning stages for next phase (pivotal or feasibility study)



Orion I Implant

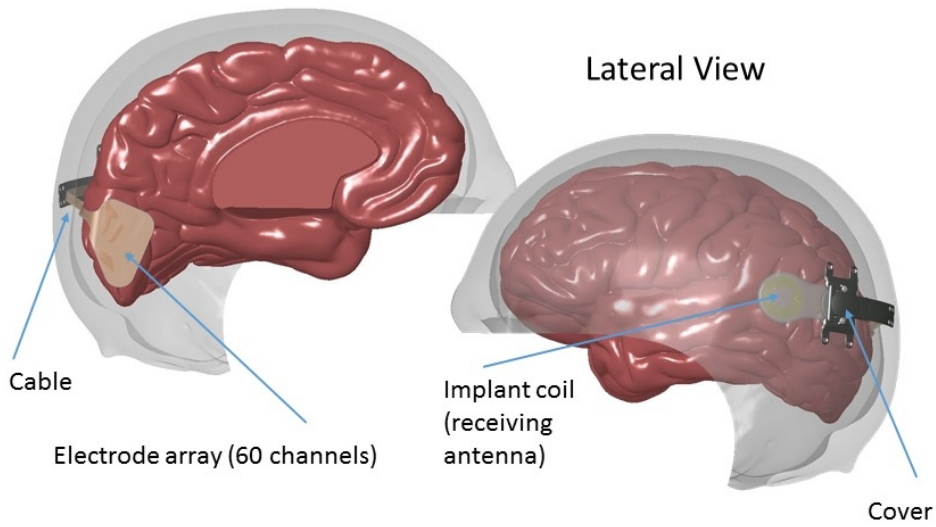
Glasses & Antenna



Video Processing Unit

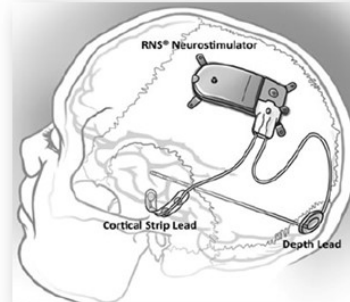
Medial View

Lateral View



Early Testing in a Blind Subject with “Off the shelf” Device

30 year old with an 8 year history of bare light perception blindness due to Vogt-Koaynagi-Harada Syndrome



Implantation of a Neuropace responsive neurostimulation device with 2 parallel 4-contact leads implanted over the right medial occipital lobe via a posterior interhemispheric approach.

Systematic manipulation of stimulation intensity, pulse width, frequency, and site of stimulation over 10 months.

Results: Retinotopic Localization and Reproducibility Over Time

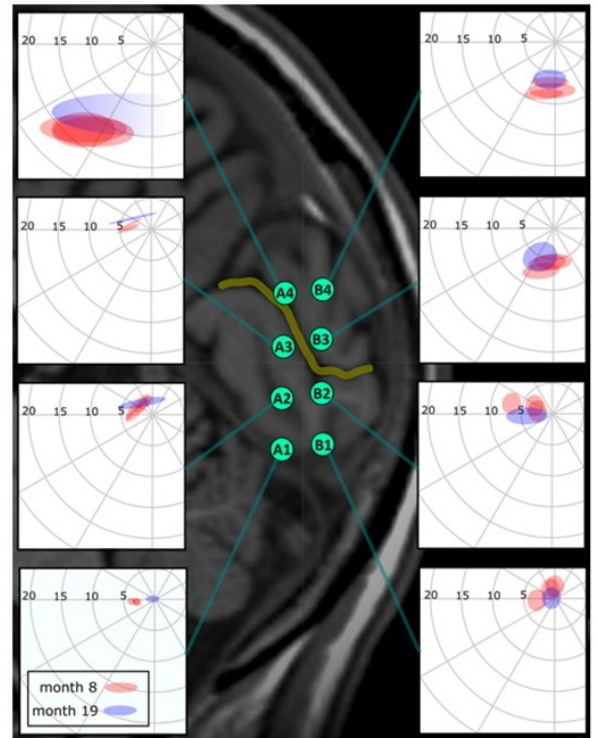
Different shapes and sizes

Consistent Localization

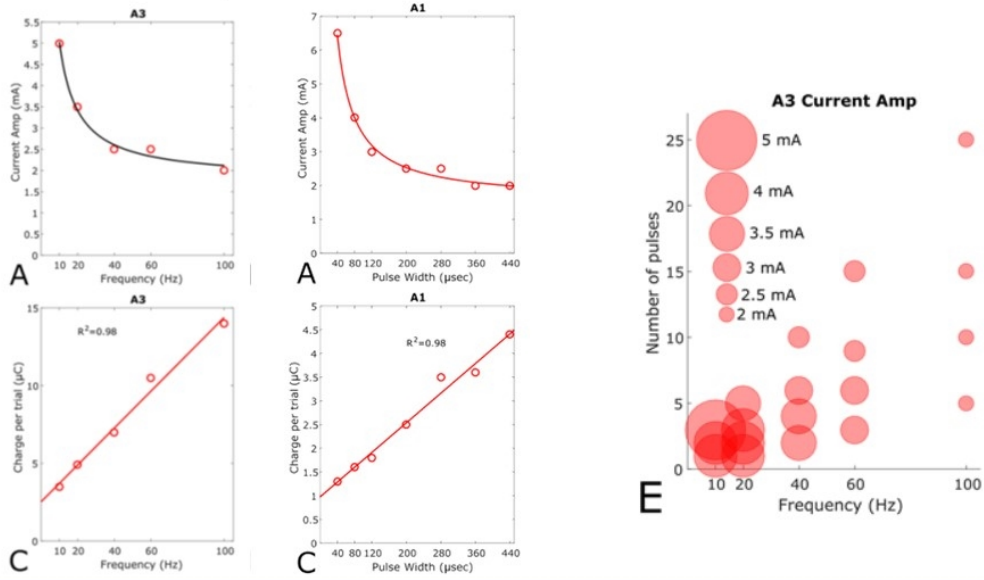
JNS CASE REPORT

Phosphene perceptions and safety of chronic visual cortex stimulation in a blind subject

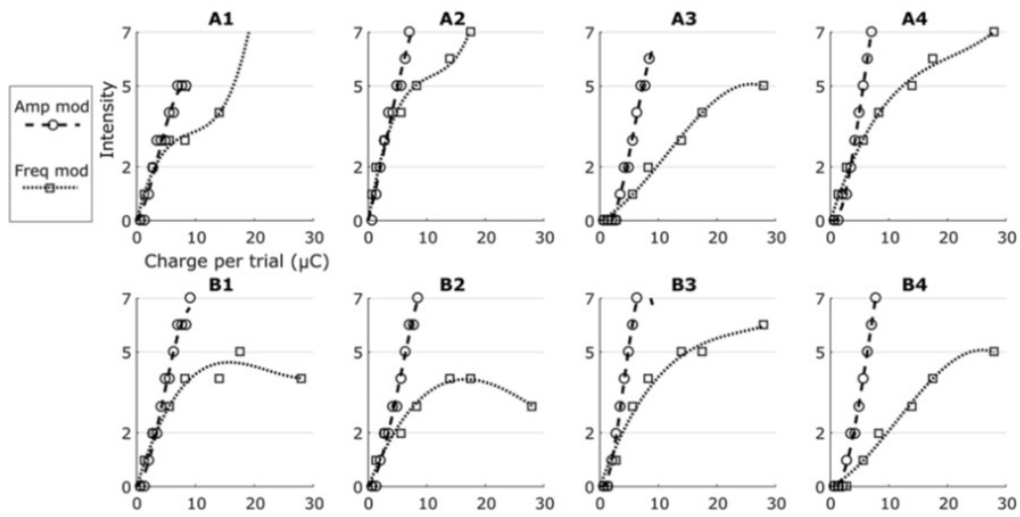
Soroush Niketeghad, MS,¹ Abirami Muralidharan, PhD,² Uday Patel, PhD,² Jessy D. Dorn, PhD,² Laura Bonelli, MD,³ Robert J. Greenberg, MD, PhD,² and Nader Pouratian, MD, PhD^{1,4}



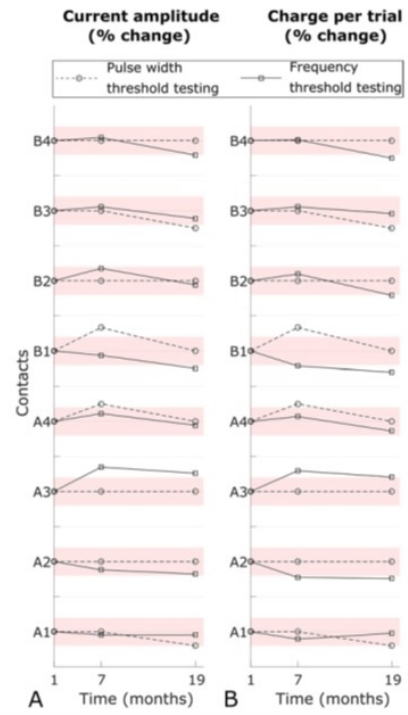
Current Thresholds: Relationship to Stimulus Parameters



Differential phosphene modulation with modulation of distinct simulation parameters



Stimulation thresholds are stable over 19 months



Orion Early Feasibility Study: 6 subjects

- **Eligibility:** Subjects are completely bilaterally blind due to any cause other than damage to the visual cortex
 - May include trauma to eyes or optic nerve, diabetic retinopathy, glaucoma, or other etiology
- **Primary outcome:** safety (adverse events)
- **Secondary outcome:** ability to produce phosphenes, long-term functionality of the device, and benefit in terms of visual function, functional vision, quality of life
- Two centers: UCLA and Baylor College of Medicine

Orion Early Feasibility Study – Enrollment

Site	Subject	Implant Date	Age at time of implant	Gender	Reason for Vision Loss	Implant Duration as of 6/28/19 (months)
UCLA	S1	01/30/2018	56	Male	Optic neuropathy secondary to burn/trauma	17
UCLA	S2	03/29/2018	29	Male	Head Trauma – motor vehicle accident	15
UCLA	S3	04/26/2018	64	Female	Endophthalmitis secondary to liver abscess	14
Baylor	S4	04/27/2018	34	Male	Congenital glaucoma	14
UCLA	S5	05/31/2018	52	Male	Congenital glaucoma	13
Baylor	S6	01/17/2019	57	Male	Head Trauma–gunshot wound	5

Mean ± Std Dev
48.7 ± 13.9

Ratio F:M
1 : 5

Mean ± Std Dev
13.0 ± 4.0

UCLA

Neurosurgical and **BRAIN** Mapping Restoration Lab

Primary Endpoint - Safety

- **6** adverse device or procedure-related adverse events (ADEs) in 2 (out of 6) subjects
 - **1** serious ADE
 - **5** non-serious ADEs
- Four out of 6 subjects have not experienced any device- or procedure-related AEs
- Data as of last independent medical safety monitor meeting of May 3, 2019

Event	# Subjects	# Events
Serious Adverse Events	1	1
Seizure	1	1
Non-serious Adverse Event	2	5
Hand Twitch-Bilateral	1	1
Headache	2	2
Visual Aura	1	1
Visual phenomenon	1	1
Grand Total	2	6

Orion System Programming and Home Use

- After implantation, subjects undergo “programming” process to customize settings for use of the system in video mode (with stimulation driven by the camera image)
 - No earlier than 3 months, subjects are cleared to use the system outside the clinic
 - Visual rehabilitation begins immediately thereafter
 - In the study, a suite of assessments to measure performance is administered at multiple time points
 - Visual function – objective, controlled, artificial
 - Functional vision – subjective, real-world, more meaningful
 - Well-being & quality of life – patient-reported
-

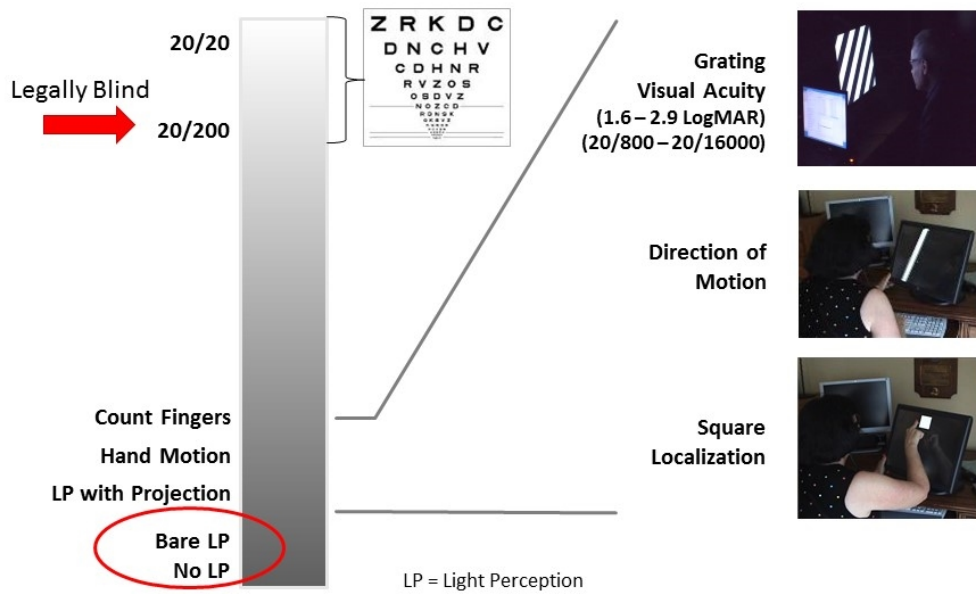
First Threshold Measurement

- Thresholds amount of current required for subject to see phosphene 50% of the time on a single electrode
- Thresholds have been mostly stable over time

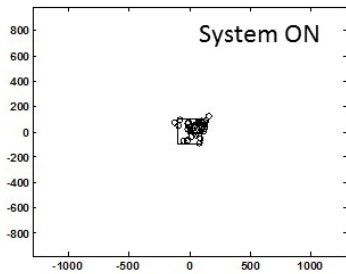
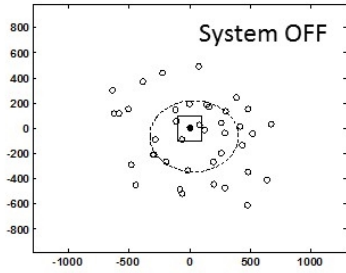
Subject	Average Threshold (μA)	Standard Deviation (μA)	No. of Thresholds
S1	2893	1322	56/60
S2	1645	828	60/60
S3	2194	789	59/59
S4*	3765	1603	54/58
S5	2693	1248	59/59
S6	3730	1170	55/59

* Measured with a modified staircase method

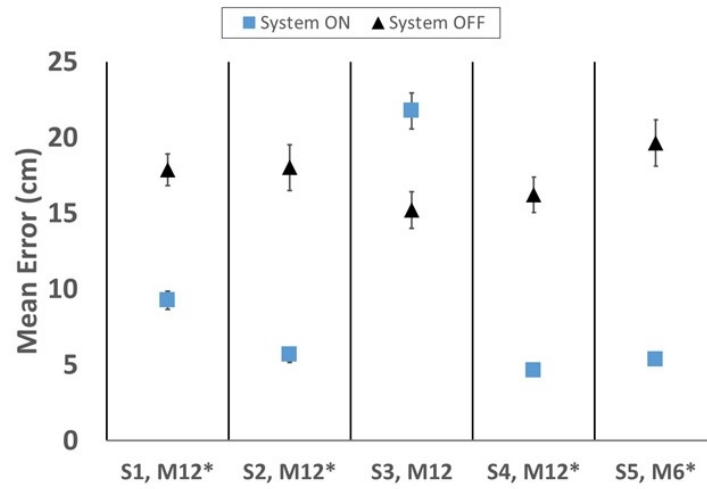
Measuring Ultra-Low Vision Visual Function



Square Localization Performance



Subject S2 at 6 months

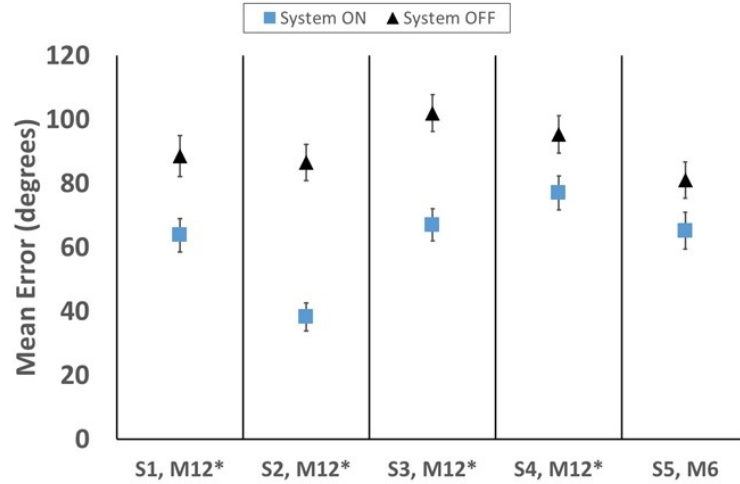
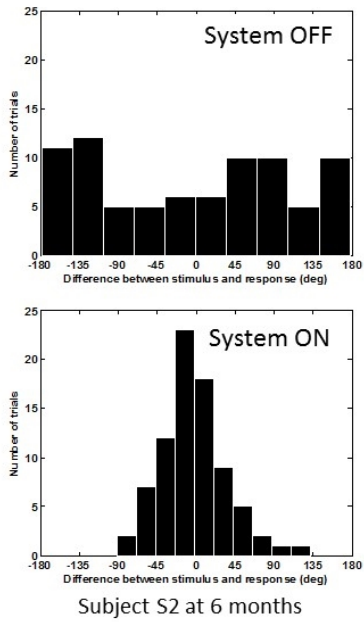


* Mean error significantly different ON vs. OFF, t-test, $p < 0.05$



UCLA

Direction of Motion Performance



* Mean error significantly different ON vs. OFF, t-test, $p < 0.05$

Grating Visual Acuity - Performance



- Grating Visual Acuity is measured between 2.9 – 1.6 logMAR.
- Gratings are presented for only 5 seconds
- **No subjects** (0 of 5) scored on the scale with the System ON or OFF at **6 months** post-implant
- **1 subject** (1 of 4) scored on the scale with the System ON or OFF at **12 months** post-implant (**2.8 logMAR**)
- Training on this task has improved performance considerably

* Available data are reported as of Jun 2019

Functional Low-Vision Observer-Rated Assessment (FLORA)

- Trained observers rate the impact of the Orion implant on patients' well-being and functional vision periodically at specific time points
 - Interview
 - Observer-rated functional vision tasks (System ON and OFF)
 - Final rating of benefit of Orion System on subject's life



Time Point	Positive	Mild Positive	Neutral	Mild Negative	Negative
M6	40% (2/5)	60% (3/5)	0	0	0
M12	75% (3/4)	25% (1/4)	0	0	0

Available data are reported as of Jun 2019

“Real World Use”: observations from rehabilitation sessions

“...He was able to **find the cue ball with no problems on the table**. He was able to tell the cue ball from the blue ten, and also from balls with a stripe vs. the cue ball. He could find the racked balls at the other end of the table too.”

Subjects are finding success with Orion for everyday visual tasks

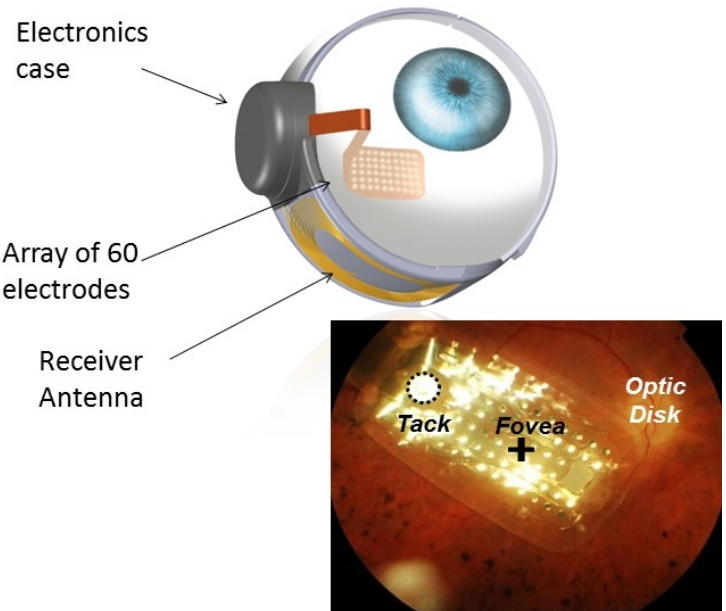
“...we've found that looking forward is where [the Orion] shines better for the user as they can detect upcoming objects... He was **able to see cars parked on the side of the street, openings in the sidewalk up into driveways**, etc.”

“When working throughout her apartment building, she was able to tell where I was located when standing in front of a 10' wide light wall w/out visual clutter. **She was also able to correctly determine whether I was traveling from left to right** or right to left along this wall, 7/10 times.”

“...He was able to **order patterns from small checkers, big checkers, and white cloth**. There's a half inch difference in checker size in the patterns.”

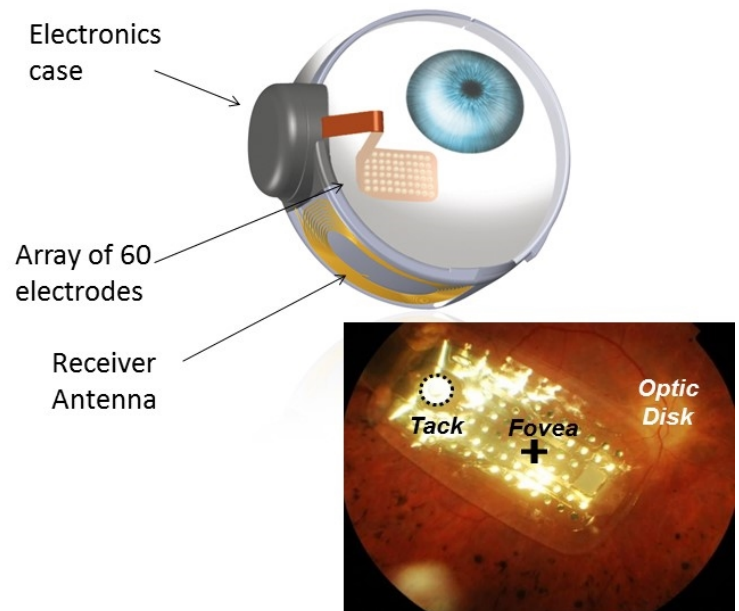
How does the Orion Visual Cortical Prosthesis System compare to the Argus II Retinal Prosthesis System?

- Argus II System: retinal implant for end-stage Retinitis Pigmentosa
- Orion System: potentially treats any cause of profound bilateral blindness other than cortical damage
 - Eye injury, optic nerve disease, glaucoma, retinopathies
 - Excludes reversible conditions such as cataracts
- Different array size, electrode spacing, and neural placement (diseased retina vs. healthy visual cortex)



Argus II System

- Indications for Use (U.S.): Bilaterally blind due to retinitis pigmentosa with bare light or no light perception
 - Implanted in the worse-seeing eye
- Commercial Approval in European Economic Area (CE Mark) in 2011
- Commercial Approval in U.S. (HDE) in 2013
- Over 350 implanted worldwide (EU, US, Canada, Middle East, Asia)
- Only visual prosthesis with market approval in U.S.



Safety Comparison

Rates of Adverse Events due to the Device or Procedure

First 5 Argus II Feasibility Subjects through 1 Year

	# Subjects	# Events
Serious Adverse Events	2	2
Non-serious Adverse Event	4	23
Grand Total	4	25

5 Orion Early Feasibility Study Subjects through 1 Year

	# Subjects	# Events
Serious Adverse Events	1	1
Non-serious Adverse Event	2	5
Grand Total	2	6

Performance Comparison

Percent showing improvement with System ON vs. OFF

	Argus II at 12 months	Orion at 12 months*
Square Localization	94% (N = 16)	80% (4 of 5)
Direction of Motion	63% (N = 16)	80% (4 of 5)
Grating Visual Acuity	48% (N = 29)	20% (1 of 5)
FLORA	80% (N = 15)	100% (5 of 5)

Improvement = significantly better ON than OFF (SL & DOM), on scale @2.9 logMAR or better (GVA), or positive/mild positive (FLORA)
*6 month data used for 1 or 2 subjects (12 months not measured yet)

The logo for SECONDSIGHT, featuring the word "SECONDSIGHT" in white capital letters on a dark blue rectangular background. The letter "O" in "SECONDS" is stylized with a green circle around it.

Conclusions

- Visual Cortical Prostheses are promising.
- Visual cortical prostheses are generally safe.
- Visual cortical stimulation in previously sighted blind subjects results in consistent and reliable thresholds and phosphenes
- Surgery is only the first step.
 - The implant will evolve – Need for penetrating? Greater coverage?
 - Learning to use the device are key.
- Let's not overlook – this is the highest channel count brain stimulation device with multiple independent current sources

