

**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 23, 2016

**SECOND SIGHT MEDICAL PRODUCTS, INC.**

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(Exact Name of Registrant as Specified in Its Charter)

**California**

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(State or Other Jurisdiction of Incorporation)

**333-198073**

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(Commission File Number)

**02-0692322**

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(IRS Employer Identification No.)

**12744 San Fernando Road, Suite 400  
Sylmar, California 91342**

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(Address of Principal Executive Offices)

**(818) 833-5000**

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(Registrant's Telephone Number, Including Area Code)

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(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 February 24, 2016, James T. Handa, MD, Robert Bond Welch Professor of Ophthalmology at the Johns Hopkins University Wilmer Eye Institute, presented data of a five-year post-implant study of Argus<sup>®</sup> II Retinal Prosthesis System ("Argus II") at the 39th Annual Macula Society Meeting held in Miami Beach, Florida. The purpose of this study was to evaluate the safety, reliability, and benefit of the Argus II in restoring some visual function to subjects completely blind from Retinitis Pigmentosa (RP).

Dr. Handa presented long-term safety and performance results from an ongoing clinical trial (NCT00407602), funded by the company, assessing 30 individuals from 10 clinical centers blinded (i.e., with bare light perception or worse) from RP or similar disorders who were implanted with the Argus II. The data represents over 200 cumulative patient-years of clinical trial follow-up and demonstrates the ability for the retinal prosthesis to improve visual function over an extended duration.

A copy of the slide presentation delivered by Dr. Handa at the 39th Annual Macula Society Meeting, entitled "Safety and Performance Results of the Argus II Retinal Prosthesis System Five Years Post Implant" is attached to this Current Report as Exhibit 99.1. On February 23, 2016 the company issued a press release entitled "Second Sight to Announce Five-Year Data from Argus II Clinical Trial Program." A copy of that release is attached to this Current Report as Exhibit 99.2.

### **Item 9.01 Data Presentation And Exhibits**

#### **Exhibit No. Description**

- 99.1 Safety and Performance Results of the Argus II<sup>®</sup> Retinal Prosthesis System Five Years Post-Implant
- 99.2 Press release entitled "Second Sight to Announce Five-Year Data from Argus II Clinical Trial Program"

#### **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 25, 2016

**SECOND SIGHT MEDICAL PRODUCTS, INC.**

/s/ Thomas B. Miller

By: Thomas B. Miller  
Chief Financial Officer

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# Safety and Performance Results of the Argus<sup>®</sup> II Retinal Prosthesis System Five Years Post-Implant

James T. Handa, MD

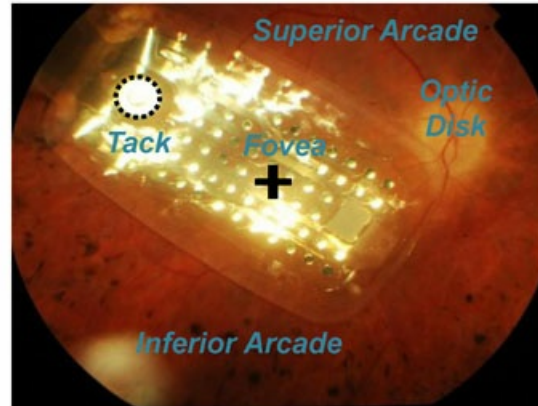
Handa, JT<sup>1</sup>, daCruz L.<sup>2</sup>, Dagnelie G.<sup>3</sup>, Stanga P.<sup>4</sup>, Olmos L.<sup>5</sup>, Greenberg R.<sup>6</sup>, Birch D.<sup>7</sup>, Duncan J.<sup>8</sup>,  
Sahel J.<sup>9</sup>, Thumann G.<sup>10</sup>, Argus II Study Group

<sup>1</sup>Johns Hopkins Hospital, <sup>2</sup>Moorfields Eye Hospital, <sup>3</sup>Johns Hopkins University, <sup>4</sup>Manchester Royal Eye Hospital, <sup>5</sup>University of Southern California, <sup>6</sup>Second Sight Medical Products, Inc., <sup>7</sup>Retina Foundation of the Southwest, <sup>8</sup>University of California, San Francisco, <sup>9</sup>Centre Hospitalier National d'Ophtalmologie des Quinze-Vingts, <sup>10</sup>Hôpitaux Universitaires de Genève

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# Second Sight

## Argus II Retinal Prosthesis



- Equivalent to visual field of  $\sim 20^\circ$
  - Each electrode individually programmable
  - Epiretinal placement using standard vitreoretinal surgical techniques
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## Long-Term Results from an Epiretinal Prosthesis to Restore Sight to the Blind

Allen C. Ho, MD,<sup>1</sup> Mark S. Humayun, MD, PhD,<sup>2</sup> Jessy D. Dorn, PhD,<sup>3</sup> Lyndon da Cruz, MD,<sup>4,5</sup> Gislain Dagnelie, PhD,<sup>6</sup> James Handa, MD,<sup>7</sup> Pierre-Olivier Baraké, MD,<sup>7</sup> José-Alain Sahel, MD,<sup>7,12</sup> Paulo E. Stangs, MD,<sup>8,9,13</sup> Farhad Hafezi, MD, PhD,<sup>1,11,12</sup> Avinash B. Sofran, MD,<sup>11,13</sup> Joel Salzmann, MD,<sup>11</sup> Arnau Santos, MD, PhD,<sup>14,15</sup> David Birch, PhD,<sup>16</sup> Rand Spencer, MD,<sup>17</sup> Amir V. Cideciyan, PhD,<sup>18</sup> Eugène de Juan, MD,<sup>19</sup> Jacques L. Duncan, MD,<sup>20</sup> Dean Elliott, MD,<sup>21</sup> Amrout Fawzi, MD,<sup>22,23</sup> Liza C. Olmos de Koo, MD,<sup>2</sup> Gary C. Brown, MD,<sup>2</sup> Julia A. Haller, MD,<sup>1,8</sup> Carl D. Regillo, MD,<sup>2</sup> Lucian V. Del Priore, MD,<sup>22,24</sup> Aris Avner, PhD,<sup>21,25</sup> Duane R. Gieruskar, PhD,<sup>2</sup> Robert J. Greenberg, MD, PhD,<sup>2</sup> for the Argus II Study Group<sup>8</sup>

**Purpose:** Retinitis pigmentosa (RP) is a group of inherited retinal degenerations leading to blindness due to photoreceptor loss. Retinitis pigmentosa is a rare disease, affecting only approximately 100 000 people in the United States. There is no cure and no approved medical therapy to slow or reverse RP. The purpose of this clinical trial was to evaluate the safety, reliability, and benefit of the Argus II Retinal Prosthesis System (Second Sight Medical Products, Inc, Sylmar, CA) in restoring some visual function to subjects completely blind from RP. We report clinical trial results at 1 and 3 years after implantation.

**Design:** The study is a multicenter, single-arm, prospective clinical trial.

**Participants:** There were 30 subjects in 10 centers in the United States and Europe. Subjects served as their own controls, that is, implanted eye versus fellow eye, and system on versus system off (native residual vision).

**Methods:** The Argus II System was implanted on and in a single eye (typically the worse-seeing eye) of blind subjects. Subjects wore glasses mounted with a small camera and a video processor that converted images into stimulation patterns sent to the electrode array on the retina.

**Main Outcome Measures:** The primary outcome measures were safety (the number, seriousness, and relatedness of adverse events) and visual function, as measured by 3 computer-based, objective tests.

**Results:** A total of 29 of 30 subjects had functioning Argus II Systems implants 3 years after implantation. Eleven subjects experienced a total of 23 serious device- or surgery-related adverse events. All were treated with standard ophthalmic care. As a group, subjects performed significantly better with the system on than off on all visual function tests and functional vision assessments.

**Conclusions:** The 3-year results of the Argus II trial support the long-term safety profile and benefit of the Argus II System for patients blind from RP. Earlier results from this trial were used to gain approval of the Argus II by the Food and Drug Administration and a CE mark in Europe. The Argus II System is the first and only retinal implant to have both approvals. *Ophthalmology* 2015;•1–8 © 2015 by the American Academy of Ophthalmology.

Today's presentation of 5 year data confirms that performance is maintained, with no additional SAE's

# Argus II Clinical Trial Sites

<b>Europe and Mexico</b>	<b>United States</b>
CHNO des Quinze-Vingts (Paris, France)	Columbia University (New York, NY)
Hôpitaux Universitaires de Genève (Geneva, Switzerland)	Doheny Eye Institute/University of Southern California (Los Angeles, CA)
Manchester Royal Eye Hospital (Manchester, UK)	Johns Hopkins University (Baltimore, MD)
Moorfields Eye Hospital (London, UK)	Lighthouse International (New York, NY)
Puerto de Hierro (Guadalajara, Mexico) – prototype feasibility	Retina Foundation of the Southwest (Dallas, TX)
	Scheie Eye Institute (Philadelphia, PA)
	UC San Francisco (San Francisco, CA)
	Wills Eye Hospital (Philadelphia, PA)

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# Study Design

- Prospective single-arm, non-randomized trial
- 3 years minimum follow-up
  - extended follow-up to 10 years
- Key inclusion Criteria
  - Severe to profound outer retinal degeneration
  - Remaining visual acuity worse than 2.3 logMAR in both eyes
  - US Label: Retinitis Pigmentosa with remaining visual acuity of bare light perception or worse in both eyes

<http://clinicaltrials.gov/show/NCT00407602>

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## Study Demographics

Subjects (n)	30
Age at Time of Implant (years)	58 ± 10 (range 28 – 77)
Females : Males	9 : 21
Diagnosis Retinitis pigmentosa Choroideremia	97% (n=29) 3% (n=1)
Baseline Vision Bare light perception* No light perception	97% (n=29) 3% (n=1)
Median Surgery Time (hours)	4:04 (range 1:53 – 8:32)

\* Defined as vision worse than 2.9 logMAR and the ability to detect a photographic flash

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# Implant Duration & Long-Term Reliability

## As of January 1, 2016

Subjects (n)	30
# <u>Years</u> Implanted (Ave.)	6.9 (range 1.2– 8.6)
Cumulative Implant Time	207 subject-years

Range of implant functionality (not including explants)	3.9 – 8.6 years
# Subjects with device explant	3
# Subjects with device failure	2

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## Total Serious Adverse Events Five Years Post-Implant

Serious Adverse Event Type	N subjects with SAE	% subjects with SAE	95% Confidence Interval
Conjunctival erosion	4	13.3%	3.1 - 30.7%
Hypotony	4	13.3%	3.1 - 30.7%
Conjunctival dehiscence	3	10.0%	2.1 - 26.5%
Presumed endophthalmitis	3	10.0%	2.1 - 26.5%
Re-tack	2	6.7%	0.8 - 22.1%
Retinal Detachment - Rhegmatogenous	2	6.7%	0.8 - 22.1%
Retinal detachment - tractional and serous	1	3.3%	0.1 - 17.2%
Retinal Tear	1	3.3%	0.1 - 17.2%
Uveitis	1	3.3%	0.1 - 17.2%
Keratitis - infective	1	3.3%	0.1 - 17.2%
Corneal Melt	1	3.3%	0.1 - 17.2%
Corneal Opacity	1	3.3%	0.1 - 17.2%

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# Safety Profile Improving in the Commercial Setting

## SAEs in Year 1: Clinical Trial vs. Commercial\*

	Clinical Trial	All Commercial
<b>n patients</b>	<b>30</b>	<b>111</b>
Conjunctival dehiscence	10.0%	1.3%
Conjunctival erosion	10.0%	5.1%
Corneal opacity	3.3%	0.0%
Endophthalmitis - infective	10.0%	0.0%
Epiretinal membrane	3.3%	0.0%
Scleritis	0.0%	1.3%
Hyphema	0.0%	1.3%
Hypotony	6.7%	2.5%
Inflammation - ocular	0.0%	1.3%
Re-tack	6.7%	0.0%
Retinal detachment	6.7%	2.5%
Retinal Tear	3.3%	0.0%
Sclerotomy Leak	0.0%	1.3%
Uveitis	3.3%	0.0%
Vitreous hemorrhage	0.0%	1.3%

\* Kaplan-Meier  
Estimates of  
Cumulative SAE  
rates (As of July  
2015)

# **Probable Benefit**

## **5 Year Results**

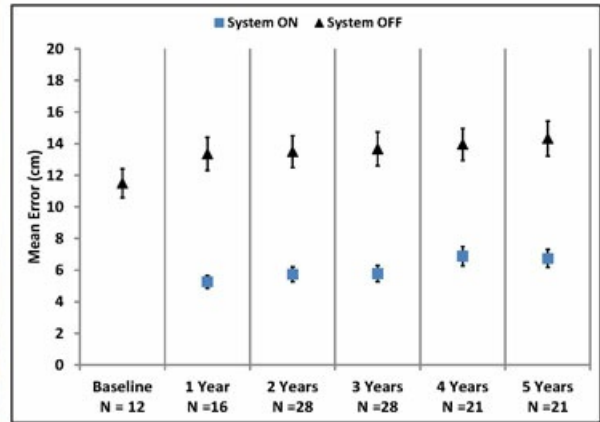
### **Visual Function**

- Object Localization
- Motion Discrimination
- Visual Acuity Testing

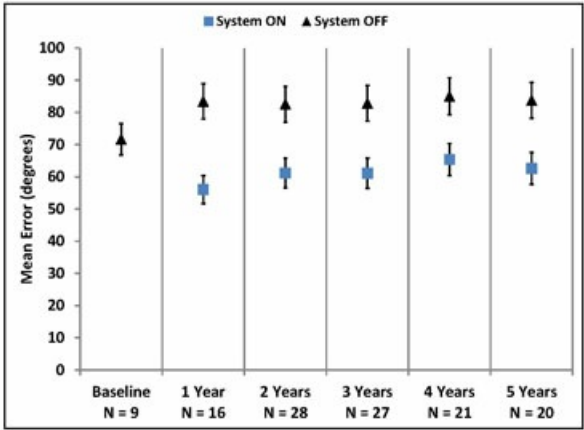
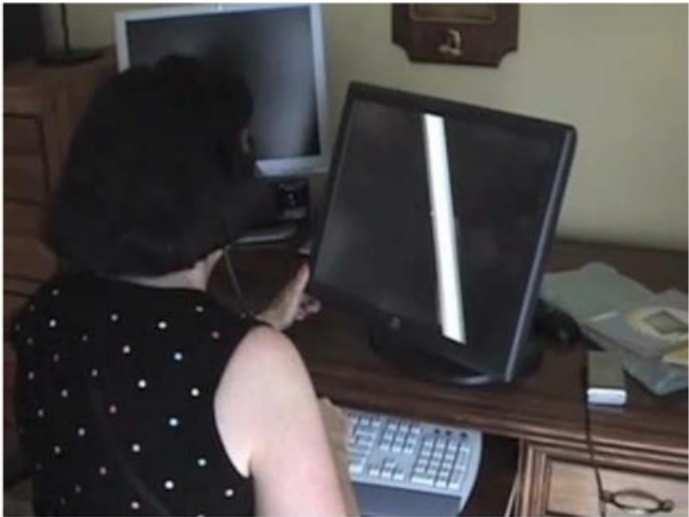
### **Functional Vision and Quality of Life**

- Orientation and Mobility
  - Functional Low-Vision Observer Rated Assessment (FLORA)
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# Visual Function Square Localization

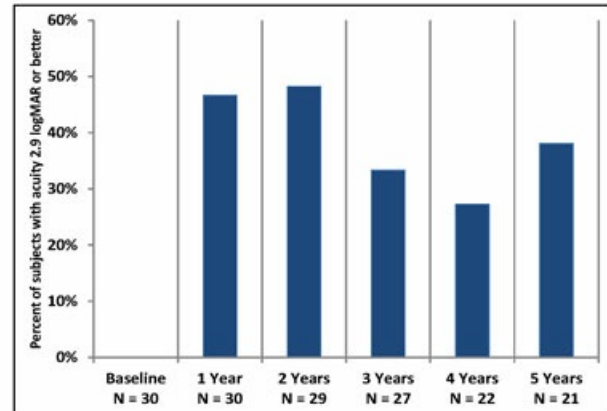


# Visual Function Direction of Motion



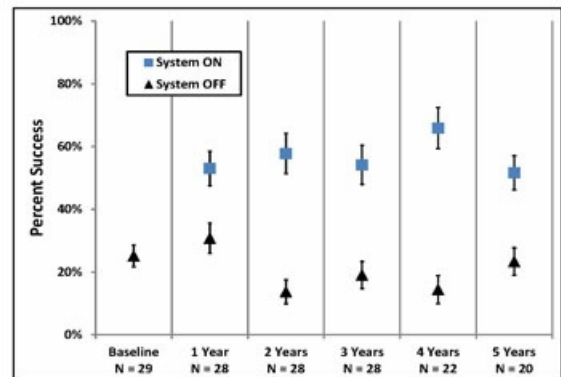
# Visual Function

## Grating Visual Acuity



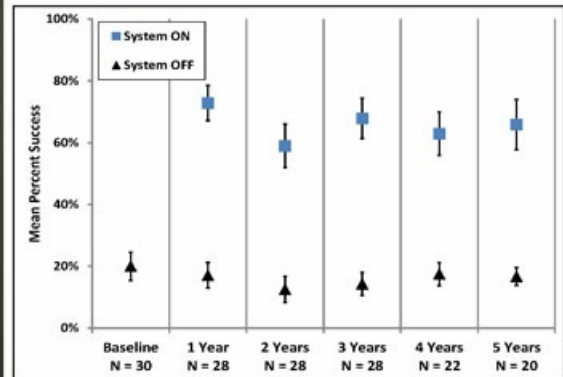
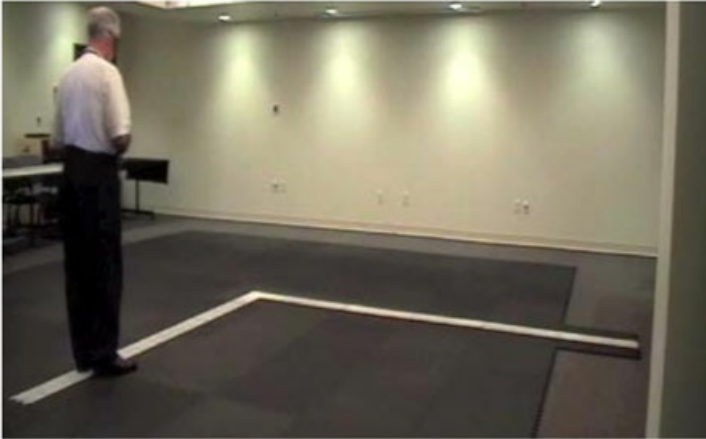
Best acuity in the clinical trial to date is 20/1260 (1.8 logMAR)

# Functional Vision Orientation & Mobility Finding a Door





# Functional Vision Orientation & Mobility Following a Line

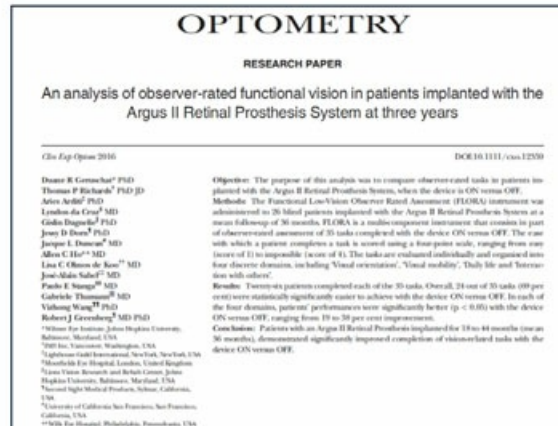


# Benefits of Argus II

- Patient reported advantages
  - Participation in bowling, archery, skiing
  - Locate doors and windows
  - Sort light and dark clothes
  - Stay within a crosswalk
  - Detect and track other people
  - Feel more socially connected
  - Enjoy being “visual” again
  - Tracking players on a field
  - Watching fireworks



# Benefits of the Argus II System Through FLORA (Functional Low Vision Observer Rated Assessment)



- Self-report section
- Functional visual tasks
- Tasks rated at impossible, difficult, moderate, easy
- 75% judged “vision only” during tasks with system “ON”
- 29% judged “vision only” with system “OFF”.

# Conclusions

- Argus II has an acceptable safety profile in this blind population.
    - Safety has possibly improved since commercial approval.
  - Visual function performance gains and reliability are maintained through 5 years
  - Subjects report using Argus II in their daily lives and the System has a positive impact on their well-being.
  - The Argus II System is available commercially in the United States, Europe, Canada, and parts of the Middle East
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## Second Sight to Announce Five-Year Data from Argus II Clinical Trial Program

Study Results Will Be Presented at 39<sup>th</sup> Annual Macula Society Meeting

SYLMAR, Calif.—(BUSINESS WIRE) — Second Sight Medical Products, Inc. (EYES) ("Second Sight" or "the Company"), a developer, manufacturer and marketer of implantable visual prosthetics to provide some useful vision to blind patients, announced it will unveil five-year outcomes associated with the Argus<sup>®</sup> II Retinal Prosthesis System ("Argus II") during the 39th Annual Macula Society Meeting, being held February 24-27, 2016, at Eden Roc Miami Beach. James Handa, MD, the Robert Bond Welch Professor of Ophthalmology at the Johns Hopkins University Wilmer Eye Institute, will present the data for the first time during a session on Inherited Retinal Degeneration on Wednesday, February 24th at 6:12 p.m. Eastern Time.

Dr. Handa will present long-term results from an ongoing clinical trial (NCT00407602) assessing 30 individuals from 10 clinical centers blinded (i.e., with bare light perception or worse) from Retinitis Pigmentosa (RP) or similar disorders who were implanted with the Argus II. The data will represent over 200 cumulative patient-years of clinical trial follow-up and will demonstrate the ability for the retinal prosthesis to improve visual function over an extended duration.

"The release of this data represents a milestone in the fight against blindness, given the long-term benefits of the Argus II in restoring some useful vision to individuals blinded by RP. The extended follow-up data clearly demonstrate the utility of the Argus II system, and we have gained considerable knowledge about how best to utilize the device through this trial," said Dr. Handa.

"We are excited about what this long-term follow up represents, both for patients and for our continued development efforts," said Dr. Robert Greenberg, Chairman of Second Sight. "These data are compelling in demonstrating the validity of our approach and the reliability of our implants."

One- and three-year data from the trial were previously published in the peer-reviewed journal *Ophthalmology*. For the study, three types of visual function tests were performed using computer-run assessments: square localization (i.e. object detection), direction of motion (i.e. motion detection) and discrimination of oriented gratings (i.e. visual acuity). Two types of real-world orientation and mobility (O&M) tests were also performed: a test where patients were asked to locate and touch a door, and a test where patients were asked to follow a white line on the floor. The Functional Low-Vision Observer Rated Assessment (FLORA), a multi-part instrument that was developed specifically for use in patients implanted with a retinal prosthesis who suffer from profound loss of vision or blindness, was used to assess the functional visual abilities of patients and how they use the Argus II to complete a series of common activities of daily living. Before the development of the FLORA, there were no accepted, standardized assessments of functional vision or quality of life that could be used to assess the kind of vision that is restored by a retinal prosthesis. Common assessment tools of functional vision that are available such as the National Eye Institute Visual Function Questionnaire (NEI-VFQ-25) or the Massof Activity Inventory have only a few items that can be completed by those with ultra-low vision, with the majority of test items requiring higher levels of spatial vision (ability to read, recognize faces, identify colors).

Earlier results from this trial were used to gain approval of the Argus II by the FDA in addition to CE Mark in Europe. The Argus II System is the first and only retinal implant to have both approvals. Although there are several research efforts in retinal prostheses worldwide, none has demonstrated the same level of reliability and efficacy as the Argus II did in a multi-centered, long-term, controlled clinical trial involving 30 subjects. Today over 180 patients have been treated with the Argus II.

Current research efforts by Second Sight include a feasibility study of the Argus II for individuals with Dry Age-Related Macular Degeneration; hardware and software upgrades for existing and future Argus II patients; and the development of a prosthesis for the primary visual cortex, the Orion<sup>™</sup> I Visual Cortical Prosthesis, suitable for patients with other forms of blindness.

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## **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 (RP). 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 are intended to stimulate the retina's remaining cells, resulting in the perception of patterns of light in the brain. The patient then learns to interpret these visual patterns, thereby regaining some visual function. The system is controlled by software and is upgradeable, which may provide improved performance as new algorithms are developed and tested. The Argus II is the first artificial retina to receive widespread approval, and is offered at approved centers in Austria, Canada, France, Germany, Italy, Netherlands, Saudi Arabia, Spain, Switzerland, Turkey, United Kingdom and the United States.

## **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 manufactures, the Argus® II Retinal Prosthesis intended to provide some useful vision to individuals with outer-retinal degenerations such as Retinitis Pigmentosa (RP). Second Sight is also developing the Orion™ I Visual Cortical Prosthesis to restore some vision to individuals who are blind due to causes other than those currently treated by Argus II or other therapies. U.S. Headquarters are in Sylmar, CA, and European Headquarters are in Lausanne, Switzerland. For more information, visit [www.secondsight.com](http://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 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 17, 2015 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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