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 26, 2021

SECOND SIGHT MEDICAL PRODUCTS, INC.
(Exact Name of Registrant as Specified in Its Charter)
California
(State or Other Jurisdiction of Incorporation)

001-36747	**02-0692322**
(Commission File Number)	(IRS Employer Identification No.)

13170 Telfair Ave
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 8.01 Other Events

By letter dated February 26, 2021, the Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration (FDA) approved the Argus 2s Retinal Prosthesis System developed by Second Sight Medical Products, Inc. (the "Company"). Argus 2s is a redesigned set of external hardware (glasses and video processing unit) to be used in combination with previously implanted Argus II systems for the treatment of retinitis pigmentosa (RP). The Company issued a press release on March 5, entitled *Second Sight Medical Products, Inc. Receives FDA Approval for the Argus 2s Retinal Prosthesis System*, which is attached hereto as Exhibit 99.1. Argus II, and now Argus 2s, are approved under a humanitarian device exemption (HDE). The approval is contingent upon the Company filing periodic reports with CDRH, use only under prescription, under the supervision of an institutional review board (IRB), and taking all other required actions under FDA rules. The Company expects that the Argus 2s will be adapted to be the external system for the next generation Orion Visual Cortical Prosthesis System currently under development.

A decision on when or if to begin production of the newly approved hardware is pending completion of the Company's planned business combination with Pixium Vision, which currently is in progress. Should the business combination be completed, the new management team will then evaluate how best to proceed with the Argus 2s Retinal Prosthesis System, as well as all other products in development.

The company announced the approval in a press lease date March 5, 2021. A copy of the release is attached as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release "*Second Sight Medical Products, Inc. Receives FDA Approval for the Argus 2s Retinal Prosthesis System*" dated March 5, 2021

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: March 5, 2021

SECOND SIGHT MEDICAL PRODUCTS, INC.

/s/ Matthew Pfeffer
By: Matthew Pfeffer
Acting Chief Executive Officer

SECONDSIGHT

FOR IMMEDIATE RELEASE

Second Sight Medical Products, Inc. Receives FDA Approval for the Argus 2s Retinal Prosthesis System

Los Angeles – (Business Wire) – March 5, 2021, Second Sight Medical Products (NASDAQ:EYES) a leading developer and marketer of implantable visual prosthetics that are intended to create an artificial form of useful vision for blind individuals, today announced U.S. Food and Drug Administration (FDA) has approved the Argus 2s Retinal Prosthesis System, a redesigned set of external hardware (glasses and video processing unit) initially for use in combination with previously implanted Argus II systems for the treatment of retinitis pigmentosa (RP). The Company expects that the Argus 2s will be adapted to be the external system for the next generation Orion Visual Cortical Prosthesis System currently under development.

In addition to ergonomic improvements, the Argus 2s system offers significantly more processing power, potentially allowing for improved video processing.

“We are very pleased to have received this approval, as it presents an opportunity to offer external hardware that we believe enhance comfort and aesthetics compared with the legacy Argus II system” said Matthew Pfeffer, acting CEO of Second Sight.

A decision on when or if to begin production of the newly approved hardware is pending completion of Second Sight’s planned business combination with Pixium Vision, which currently is in progress. Should the business combination be completed, the new management team will then evaluate how best to proceed with the Argus 2s Retinal Prosthesis System, as well as all other products in development.

About Second Sight Medical Products Inc.
Second Sight Medical Products, Inc. (NASDAQ: EYES) develops 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 headquarters are in Los Angeles, California. More information is available at https://secondsight.com.

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 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 stimulate the retina's remaining cells, intending to result in the perception of patterns of light in the brain. The patient must learn to interpret these visual patterns, having the potential to regain some visual function. The Argus II was the first artificial retina to receive widespread commercial approval. Second Sight has discontinued new implants of the Argus II system. Further information on the long-term benefits and risks can be found in the peer reviewed paper at:
http://www.sciencedirect.com/science/article/pii/S0161642016305796

About the Orion Visual Cortical Prosthesis System

Leveraging Second Sight's 20 years of experience in neuromodulation for vision, the Orion 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.

Non-Solicitation

This press release does not constitute a solicitation of a proxy, consent or authorization with respect to any securities or in respect of the proposed transaction. This press release also does not constitute an offer to sell or the solicitation of an offer to buy any securities, nor will there be any sale of securities in any states or jurisdictions in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities will be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended, or an exemption therefrom.

Additional Information and Where to Find it

This communication may be deemed to be solicitation material in respect of the proposed transaction between Second Sight and Pixium Vision. Second Sight intends to file with the SEC preliminary and definitive proxy statements in connection with the proposed business combination and other matters and will mail a definitive proxy statement to its shareholders as of the record date established for voting on the proposed business combination. SECOND SIGHT'S SHAREHOLDERS AND OTHER INTERESTED PERSONS ARE ADVISED TO READ, ONCE AVAILABLE, THE PRELIMINARY PROXY STATEMENT AND ANY AMENDMENTS THERETO AND, ONCE AVAILABLE, THE DEFINITIVE PROXY STATEMENT, IN CONNECTION WITH SECOND SIGHT'S SOLICITATION OF PROXIES FOR ITS SPECIAL MEETING OF STOCKHOLDERS TO BE HELD TO APPROVE, AMONG OTHER THINGS, THE PROPOSED BUSINESS COMBINATION, BECAUSE THESE DOCUMENTS WILL CONTAIN IMPORTANT INFORMATION ABOUT SECOND SIGHT, PIXIUM VISION AND

THE PROPOSED BUSINESS COMBINATION. Second Sight's shareholders may also obtain a copy of the preliminary or definitive proxy statement, once available, as well as other documents filed with the SEC by Second Sight, without charge, at the SEC's website located at www.sec.gov or by directing a request to: Second Sight Medical Products, Inc., 13170 Telfair Avenue, Sylmar CA 91342.

Participants in the Solicitation

Second Sight, Pixium Vision, and their respective directors, executive officers and employees and other persons may be deemed to be participants in the solicitation of proxies from the holders of Second Sight common stock in respect of the proposed transaction described herein. Information about Second Sight's directors and executive officers and their ownership of Second Sight's common stock is set forth in Second Sight's Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC. Other information regarding the interests of the participants in the proxy solicitation will be included in the proxy statement pertaining to the proposed transaction when it becomes available. These documents can be obtained free of charge from the sources indicated above.

Safe Harbor

This press release contains certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the US Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "target," "believe," "expect," "will," "may," "anticipate," "estimate," "would," "positioned," "future," and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. Examples of forward-looking statements include, among others, statements made in this press release regarding the proposed business combination, including the benefits of the proposed business combination, integration plans, expected synergies and opportunities, the expected management and governance of the combined company, and the expected timing of the proposed transactions contemplated by the definitive agreement. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on Second Sight's and Pixium Vision's managements' current beliefs, expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Actual results and outcomes may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward- looking statements. Important factors that could cause actual results and outcomes to differ materially from those indicated in the forward-looking statements include, among others, the following: (1) the occurrence of any event, change or other circumstances that could give rise to the termination of the Memorandum of Understanding or could otherwise cause the business combination to fail to close; (2) the outcome of any legal proceedings that may be instituted against Second Sight or Pixium Vision following the announcement of the Memorandum of Understanding and the business combination; (3) the inability to complete the business combination, including due to failure to obtain approval of the shareholders of Second Sight or Pixium Vision, failure to complete the $25 million financing, or inability to satisfy any of the other conditions to closing in the Memorandum of Understanding; (4) the receipt of an unsolicited offer from another party for an alternative

business transaction that could interfere with the business combination; (5) the inability to obtain the listing of the shares of common stock of the post-acquisition company on the Nasdaq Stock Market following the business combination; (6) the risk that the announcement and consummation of the business combination disrupts current plans and operations; (7) the ability to recognize the anticipated benefits of the business combination, which may be affected by, among other things, competition, the ability of the combined company to grow and manage growth profitably and retain its key employees; (8) costs related to the business combination; (9) changes in applicable laws or regulations; (10) the possibility that Second Sight may be adversely affected by other economic, business, and/or competitive factors; (11) the impact of COVID-19 on the combined company's business; and (12) other risks and uncertainties indicated from time to time in the proxy statement to be filed relating to the business combination, including those under "Risk Factors" therein, and in Second Sight's other filings with the SEC. Some of these risks and uncertainties may in the future be amplified by the COVID-19 outbreak and there may be additional risks that Second Sight considers immaterial or which are unknown. A further list and description of risks and uncertainties can be found in Second Sight's Annual Report on Form 10-K, filed on March 19, 2020, Form 10K/A filed April 28, 2020, Forms 10-Q filed June 26, 2020, August 13, 2020, and November 12, 2020 and in the proxy statement on Schedule 14A that will be filed with the SEC by Second Sight in connection with the proposed transaction, and other documents that the parties may file or furnish with the SEC, which you are encouraged to read. Any forward-looking statement made by us in this press release is based only on information currently available to Second Sight and Pixium Vision and speaks only as of the date on which it is made. Second Sight and Pixium Vision undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise, except as required by law.

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