

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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): April 16, 2019

PRESBIA PLC

(Exact Name of Registrant as Specified in Charter)

Ireland
(State or Other Jurisdiction
of Incorporation)

001-36824
(Commission
File Number)

98-1162329
(IRS Employer
Identification No.)

Suite 7, Sandycroft Office Centre, 17 Corrig Road, Sandycroft
Dublin 18 Ireland
(Address of Principal Executive Offices)(Zip Code)

+353 (1) 551 1487
Registrant's Telephone Number

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:

- 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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).
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 1.01 Entry into a Material Definitive Agreement

On April 22, 2019, Presbia USA, Inc., a subsidiary of Presbia PLC (the “*Company*,” “*we*” or “*us*”) amended its secured promissory note with Richard Ressler to increase the outstanding principal amount in respect of an advance by Mr. Ressler of [\$470,000.00] [in order to pay for certain enumerated expenses of the Company.]

Item 2.05. Costs Associated with Exit or Disposal Activities.

Based on recent conversations and correspondence with the FDA, the Company has determined that the U.S. Food and Drug Administration (“*FDA*”) will not be willing to grant the Company’s pending application for premarket approval (“*PMA*”) for the Company’s microlens product based on the Company’s current FDA staged pivotal clinical trial for its microlens product, but is likely to require that a new, additional (albeit potentially abbreviated) clinical trial to be undertaken and completed prior to issuing any approval of our PMA. In light of the foregoing, on April 18, 2019, the Board of Directors (the “*Board*”) of the Company approved a reduction of staffing and efforts by the Company in connection with its pursuit of the PMA. As previously disclosed, earlier this month, the FDA granted an extension of time through September 30, 2019 to complete the Company’s 36-month Clinical Study Report and provide additional safety and efficacy related information relating to the Company’s PMA application. Given our limited cash position, together with our lack of sources of additional capital, the Company has determined that it will need an investor or strategic partner in order to continue pursuit of the trial and the PMA application.

In connection with the above determination, the Board of Directors has approved a partial reduction of scope of the business of the Company in the United States, with such process to commence immediately. Approximately three employees or contractors will be retained at our Irvine location to assist with the efforts to locate an investor or strategic partner and maintain the assets of the business and the rest will be terminated. The Company is in discussion with creditors and vendors, and is making efforts to, among other things, preserve and maximize the value of its assets including all of its intellectual property and clinical data. In Europe, the Company intends to provide the requisite notice under applicable law with respect to our employees in Germany and Ireland, and operations in Europe will continue for approximately three months. During the three month period, the Company will pursue and evaluate opportunities to identify an investor or strategic partner in order to continue pursuit of the trial and the PMA application, or to otherwise monetize its intellectual property and related assets, including data collected in the FDA trial and other studies, CE marks and related microlens and other inventory, manufacturing and other equipment, patents and trade secrets, through a potential sale or partnering arrangement. No assurances can be provided that the Company will be able to locate any interested party (or enter into any transaction) for a potential sale or partnering arrangement.

As we cannot yet determine whether our efforts to find an investor or strategic partner will be successful, or what the nature of any such transaction will be, we cannot at this time estimate any charges associated with the foregoing process.

This Item 2.05 contains forward-looking statements, including, but not limited to, statements related to the financial impact of the reduction in our activities, including expected costs associated with employee termination benefits, and the Company’s intentions regarding efforts to maximize the value of and potentially monetize the Company’s assets. These forward-looking statements are based on the Company’s current expectations and inherently involve significant risks and uncertainties. The Company’s actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to the wind-down process, the actions undertaken in connection therewith and the costs thereof and expenses associated therewith. In addition, the Company’s costs, expenses and charges may be greater than anticipated and the suspension of the trial and PMA application, and the wind-down process including the associated termination of employees and other related actions, may have an adverse impact on the Company’s ability to monetize its assets. The Company undertakes no duty or obligation to update any forward-looking statements contained in this Item 2.05 as a result of new information, future events, changes in its expectations or otherwise, except as may be required by law.

Item 2.06. Material Impairments.

The information set forth under Item 2.05 of this Current Report on Form 8-K regarding the reduction in the Company affairs is incorporated by reference in response to this Item 2.06. As noted above, the Company cannot estimate the charges associated with these activities at this time.

Item 3.01. Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On April 16, 2019, the Company received a Staff Determination letter from the Listing Qualifications division of the Nasdaq Stock Market notifying the Company that the Company is not in compliance with Nasdaq Listing Rule 5250(f) which requires the Company to pay all applicable fees associated with its Nasdaq listing. As noted by Nasdaq in the letter, the Company has not paid \$55,000 representing certain past due listing fees. The letter provides that, unless the Company resolves the deficiency noted in the letter or appeals Nasdaq's determination, the Company will be delisted from Nasdaq, with trading in the Company's ordinary shares suspended at the opening of business on April 25, 2019. Nasdaq also notes in its letter that, as previously disclosed by the Company, on November 19, 2018, Nasdaq notified the Company that it did not comply with the minimum stockholders' equity required by Nasdaq Listing Rule 5550(b). Noting that Nasdaq granted the Company an extension until May 20, 2019 to comply with the minimum stockholders' equity requirement, Nasdaq states in the letter that since the Company is currently under review by an Adjudicatory Body for the listing fee delinquency, the Nasdaq Staff may no longer consider the Company's compliance plan for the stockholders' equity deficiency and accordingly, this matter serves as an additional basis for delisting the Company's securities from Nasdaq and any Company appeal of the delisting determination would need to address the additional concern presented by the continuing stockholders' equity deficiency. As previously disclosed, the Company has an additional continuing listing deficiency insofar as the Company remains in noncompliance with Nasdaq's \$1.00 minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2).

The Company made the determination not to pay the \$55,000 in listing fees based on its current circumstances and outlook, which include the previously disclosed and ongoing listing deficiencies resulting from noncompliance with Nasdaq's minimum stockholders' equity and minimum bid price requirements, as to which the Company does not believe that it will be able to regain compliance prior to the end of the applicable grace periods, which are May 20, 2019 for the minimum stockholders' equity requirement and June 10, 2019 for the minimum bid price requirement. With regard to the latter listing deficiency, in order to be eligible for additional time to regain compliance with the minimum bid price requirement, the Company would be required to meet the continued listing requirement for minimum stockholders' equity (which as noted above) the Company does not believe it will be able to do prior to the May 20, 2019 deadline) and all other initial listing standards for the Nasdaq Capital Market.

In light of the listing deficiencies described in the preceding paragraph, together with the current status and prospects of the Company's business given the plan to significantly reduce its activities which has been adopted and is being implemented as described in Item 2.05 of this Current Report on Form 8-K, the Company has determined not to appeal Nasdaq's decision and, as such, it is expected that the Company will be delisted from Nasdaq and trading of its ordinary shares will be suspended at the opening of business on April 25, 2019, and Nasdaq will file a Form 25-NSE with the Securities and Exchange Commission (the "*SEC*"), which will remove the Company's securities from listing and registration on the Nasdaq Stock Market.

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On April 18, 2019, Mark Yung, our Executive Chairman of the Board and Chief Executive Officer, notified the Board of his resignation as an officer of the Company and its subsidiaries, effective as of the close of business on April 30, 2019. Mr. Yung will continue as a director of the Company and, in that role, will assist in the wind down of its business described in Item 2.05.

On April 18, 2019, the Board appointed Zohar Loshitzer as Executive Chairman of the Board and Chief Executive Officer effective May 1, 2019.

Zohar Loshitzer has served as a director of the Company since February 2014. He served as a director of Presbia Holdings from May 2007 until its liquidation in 2015. He served as the Company's Chief Executive Officer from February 2014 to October 2014, served as the Company's President from February 2014 to January 2015, served as

the Company's Chief Business Development Officer from January 2015 to September 2015, and has also provided management consulting services to the Company. Since 2016, Mr. Loshitzer has served as principal at OCV. Since January 2005, Mr. Loshitzer has served as a principal at Orchard Capital. OCV and Orchard Capital are majority owned by Richard Ressler (one of our directors and the beneficial owner of the majority of the ordinary shares of our Company), where he supports the portfolio companies of Orchard Capital by designing operational efficiencies and cost reductions, and he has served since August 2000 as the President and Chief Executive Officer of Universal Telecom Services, Inc., a provider of telecommunications services and solutions to emerging markets. He has served as Executive Vice President of Corporate Strategy of j2 Global since June 2001 and from July 1997 through June 2001 he served as the Chief Information Officer at j2 Global. Mr. Loshitzer was the founder and President of MTP Consulting, Inc., a business consulting firm, from January 2011 to August 2013, and he was the founder and President of Imali, Inc., another business consulting firm, from January 2007 to December 2010. Since 1995, he has been a Managing Director at Orchard Telecom, a provider of telecommunications products. He previously served as a consultant to MAI Systems Corporation, a provider of information technology solutions, and as a General Manager and Managing Director at Life Alert Emergency Response, Inc., a provider of security services for the elderly, which Mr. Loshitzer co-founded. He was a director of the publicly-traded OCATA Therapeutics (formerly Advanced Cell Technology Inc.) from December 2011 to February 2016, when the company was sold to a Japanese private company. He was also a director of publicly-traded Environmental Solutions Worldwide, Inc. from January 2011 to December 2015. He graduated from Tel Aviv ORT Yad Singalovsky with a degree in Electronics Engineering.

Mr. Loshitzer will not be compensated directly by the Company for his services and will provide his services pursuant to the terms of the existing services agreement between the Company and OCV.

Forward-Looking Statements

This Current Report on Form 8-K contains "forward-looking statements" for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements regarding the wind-down of the Company's business and the resulting effects thereof including costs, expenses and financial statement charges, the Company's intentions regarding any potential maximization and monetization of its assets, and the effects of the delisting of the Company's ordinary shares from Nasdaq, including any resulting impairment in respect of the liquidity and market price of the ordinary shares. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation, the risks and uncertainties described in the Company's periodic public filings with the SEC. The forward-looking statements contained in this Current Report on Form 8-K are made as of this date, and the Company undertakes no obligation to revise or update any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent that it is required to do so under applicable law.

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.

PRESBIA PLC

By: /s/ Mark Yung

Name: Mark Yung

Title: Chief Executive Officer

Dated: April 22, 2019