

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): October 5, 2018

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.)

120/121 Baggot Street Lower
Dublin 2 Ireland

(Address of Principal Executive Offices)(Zip Code)

+353 (1) 659 9446
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 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange 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.

Item 8.01. Other Events.

Presbia PLC (the “Company”) disclosed in its Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2018, as filed with the Securities and Exchange Commission on August 10, 2018, that the Company had submitted to the U.S. Food and Drug Administration (the “FDA”) its final pre-market approval application (“PMA”) module containing 24-month data with respect to its microlens ophthalmic device. In the same Form 10-Q, the Company disclosed that it was targeting PMA approval during the fourth quarter of 2018 and was targeting the submission of a final report containing 36-month data on all enrolled subjects in the first quarter of 2019. On October 5, 2018, the Company received notification from the FDA that 36-month data on all subjects enrolled in the Company’s staged pivotal clinical trial, including additional safety and efficacy related information, is required before the FDA can complete its review of the Company’s PMA. The Company must respond by April 3, 2019, otherwise it must amend the PMA within the 180-day period to request an extension of time to respond. In light of the FDA’s typical 180-day review period following the Company’s anticipated response date of April 3, 2019, the Company does not anticipate PMA approval prior to the fourth quarter 2019. The foregoing targeted milestones and associated estimated timeframes could be delayed by further interactions with the FDA or by a variety of other factors, including requests for further safety and efficacy related information pertaining to our microlens ophthalmic device. In addition, no assurance can be given that the FDA will grant us PMA approval or, if granted, that it will be granted in accordance with our anticipated time schedule. Also, the FDA may require us to conduct post-approval studies as a condition of approval.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “objective,” “ongoing,” “plan,” “predict,” “project,” “potential,” “should,” “will,” or “would,” and or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Current Report on Form 8-K, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. The forward-looking statements in this Current Report on Form 8-K include, among other things, statements about the timing, progress and results of our U.S. staged pivotal clinical trial and our regulatory submissions, our ability to advance our microlens and successfully complete our U.S. staged pivotal clinical trial, our ability to obtain pre-market approvals, and the targeted timeframe thereof, and the timing or likelihood of regulatory filings and approvals. You should refer to “Part I, Item 1A. Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the Securities and Exchange Commission (“SEC”) on March 30, 2018, as well as our Quarterly Reports on Form 10-Q filed since such time, and our other filings from time to time with the Securities and Exchange Commission, for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Current Report on Form 8-K will prove to be accurate. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider any such list to be a complete discussion of all potential risks or uncertainties that may substantially impact our business. Moreover, we operate in a competitive and rapidly changing environment. New factors emerge from time to time and it is not possible to predict the impact of all of these factors on our business, financial condition or results of operations. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by 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/ Richard T. Fogarty

Name: Richard T. Fogarty

Title: Chief Accounting Officer

Dated: October 12, 2018