
**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): February 6, 2015

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))
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Item 8.01. Other Events

On February 6, 2015, Presbia PLC (the “Company”) issued a press release announcing that it received approval from the United States Food and Drug Administration (FDA) to commence second stage enrollment in the Company’s staged pivotal clinical trial of the Presbia Flexivue Microlens™. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Presbia PLC dated February 6, 2015.

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 Fogarty

Name: Richard Fogarty

Title: Chief Accounting Officer

Dated: February 9, 2015



Feb 6, 2015

Presbia PLC Receives Approval to Begin Second Stage Enrollment In US FDA Pivotal Trial

DUBLIN, Ireland—(BUSINESS WIRE)— Presbia PLC (NASDAQ:LENS), an ophthalmic device company that has developed and is currently marketing the Presbia Flexivue Microlens™, a proprietary optical lens implant for treating presbyopia, announced today that it received approval from the United States Food and Drug Administration (FDA) to commence second stage enrollment in the pivotal trial of the Presbia Flexivue Microlens™. Subjects in stage one of the pivotal trial continue with the Microlens, and are actively being followed.

“With this approval, we will continue enrollment in our pivotal trial taking us one step closer towards gaining FDA approval of our product in the U.S.,” said Todd Cooper, President and CEO of Presbia. “Pending FDA approval, we intend to make the Presbia Flexivue Microlens™ commercially available to U.S. presbyopic patients to improve their near vision, and to reduce their dependency on reading glasses.”

Forward-Looking Statements

Information provided and statements contained in this press release that are not purely historical are forward-looking statements. Such forward-looking statements only speak as of the date of this press release and Presbia assumes no obligation to update the information included in this press release. Statements made in this press release that are forward-looking in nature may involve risks and uncertainties. Accordingly, readers are cautioned that any such forward-looking statements are not guarantees and are subject to certain risks, uncertainties and assumptions that are difficult to predict. Although Presbia believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking

statements. Unless otherwise required by law, Presbia also disclaims any obligation to update its view of any such risks or uncertainties or to announce publicly the result of any revisions to the forward-looking statements made in this press release.

About Presbia

Presbia PLC (NASDAQ:LENS) is an ophthalmic device company that has developed and is currently marketing the presbyopia-correcting Presbia Flexivue Microlens™, a miniature lens that is implanted in a corneal pocket created by a femtosecond laser. The Presbia Flexivue Microlens™ has received a CE mark for the European Economic Area, allowing the lens to be marketed in over 30 countries across Europe. A staged pivotal U.S. clinical trial for the Presbia Flexivue Microlens™ commenced in 2014.

Presbia PLC

Monica Yamada, 323-860-4903
monica@presbia.com

Source: Presbia PLC

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