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): September 8, 2017

PRESBIA PLC
(Exact Name of Registrant as Specified in Charter)

Ireland
(State or Other Jurisdiction
001-36824
(Commission
of Incorporation)
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 (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 7.01 Regulation FD Disclosure.**

Presbia PLC (the “Company”) intends, from time to time, to present and/or distribute to the investment community and utilize at various industry and investor conferences a slide presentation. The slide presentation is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by reference in such a filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<table>
<thead>
<tr>
<th>Number</th>
<th>Exhibit</th>
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<tbody>
<tr>
<td>99.1</td>
<td>Investor Presentation (furnished herewith)</td>
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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/ Todd Cooper
Name: Todd Cooper
Title: Chief Executive Officer

Dated: September 8, 2017
CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use.
Disclosure

To the extent statements contained in this presentation are not descriptions of historical facts regarding Presbia PLC and its subsidiaries (collectively “Presbia,” “we,” “us,” or “our”), they are forward-looking statements reflecting management’s current beliefs and expectations. Forward-looking statements are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry’s actual results, levels of activity, performance, or achievements to be materially different from those anticipated by such statements. You can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “intends,” or “continue,” or the negative of these terms or other comparable terminology.

Forward-looking statements contained in this presentation include, but are not limited to, statements regarding: (i) the initiation, timing, progress and results of our clinical trials, our regulatory submissions and our research and development programs; (ii) our ability to advance our products into, and successfully complete, clinical trials; (iii) our ability to obtain pre-market approvals; (iv) the commercialization of our products; (v) the implementation of our business model, strategic plans for our business, products and technology; (vi) the scope of protection we are able to establish and maintain for intellectual property rights covering our products and technology; (vii) estimates of our expenses, future revenues, growth of operations, capital requirements and our needs for additional financing; (viii) the timing or likelihood of regulatory filings and approvals; (ix) our financial performance; (x) developments relating to our competitors and our industry; and (xi) statements regarding our markets, including the estimated size and anticipated growth in those markets. Various factors may cause differences between our expectations and actual results, including those risks discussed under “Risk Factors” in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 29, 2017 and those risks discussed under “Risk Factors” in other reports we may file with the Securities and Exchange Commission.

Except as required by law, we assume no obligation to update these forward-looking statements publicly or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

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Presbia Restores Near Vision

Presbia has developed a solution for presbyopia, an age related condition affecting people from approximately 40 years of age, to help restore near vision

- Safe, effective and minimally invasive surgical procedure
- Currently marketed in certain markets outside the United States
- Marketed to people with presbyopia who need reading glasses or contact lenses
Large, Underserved and Growing Commercial/Market Opportunity

1.9 Billion Presbyopes

Source: 2016 Market Scope Refractive Surgery Report

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The Presbia Flexivue Microlens™

- The Presbia Flexivue Microlens™ is a best in class treatment option for presbyopia
- A powered corneal inlay is implanted in the non-dominant eye, with minimal impact to binocular distance vision

Presbia has unique competitive advantages

- A refractive lens like reading glasses
- Designed to be removable
- The only option that is adjustable as you age (replace to a higher power)
- Can easily be done before or after LASIK or cataract surgery
The Presbia Procedure

10-Minute Procedure Utilizing Existing Femtosecond Laser

- True “Microlens” with 3.2 mm diameter and edge thickness of 0.015 mm
- Hydrophilic acrylic material similar to that used in IOLs for > 20 years
- Invisible to the naked eye once implanted
- Can be done concurrently or pre/post LASIK or cataract surgery
- Offered in a wide range of powers ranging from +1.5 diopter to +3.5 diopter, in 0.25 diopter increments

Femtosecond Laser
- Creates a pocket in patient’s cornea

Lens Insert
- Surgeon uses inserter to implant lens in patient’s cornea

Self-Sealing Pocket
- Pocket self-seals, holding lens in place at center of visual axis

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Competitive Landscape

Corneal inlays are an exciting surgical treatment for presbyopia. There are two primary competitors in the corneal inlay space:

**AcuFocus - KAMRA**
- Non-powered “disc” implanted in the non-dominant eye
- Utilizes the “pinhole effect” to focus light to enhance near vision
- The disc is visible to naked eye in light colored eyes
- Difficult for patient in low light environments
- Obstructs the view of the retina in diagnostic exams and cataract surgery
- Requires capital outlay from physician for “centration” equipment

**Revision Optics - Raindrop**
- Hydrogel placed under a LASIK-like flap in the non-dominant eye
- Changes the curvature of the cornea by adding volume under the flap
- Non-powered
- Challenging to remove
The Physician Appeal

No established surgical market for the 40–60 year old patient pool

LASIK

Presbyopia

Cataract

Incremental revenue driver
No capital expenditure required
Short 10-minute procedure, short learning curve
Private pay

Presbia provides ophthalmologist with an exciting new option to treat patients with presbyopia

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Confidential
Commercial Opportunity - LASIK as a Market Benchmark

Corneal inlay has the potential to impact the Presbyopia market similar to LASIK’s impact on vision correction in younger patients.

- Grew **1230%** in the first 5 years of US commercialization – to over **1.2 million** procedures annually.
- Steady state is about **2.8 million** procedures per year in North America, Europe and Asia.
- Internal survey of 143 LASIK patients indicate **75%** would use a surgical solution to eliminate reading glasses.

Positive takeaways from LASIK market:

Rapid commercial acceptance of cash pay medical procedure to eliminate glasses.

Serves early adult demographic, which is now approaching the age at which near vision deteriorates.

Presbia Flexixe MicroLens™ requires a less invasive procedure.

About 1.5x more people suffer from presbyopia than the conditions that LASIK treats (myopia, astigmatism, and hyperopia).

* Market Scope, 2024.
Focused Commercial Strategy

- Build global KOL acceptance carrying momentum into US commercial launch
- Registered to commercialize in 42 different countries
- Clinics implanting in South Korea, Germany, Ireland, UK, Netherlands, Australia/NZ, and Canada
- Gain FDA approval and begin marketing in the United States
- Adjust marketing strategy to differentiate Presbia Flexivue Microlens™ from corneal inlay competitors
Compelling Results

Subjects can perform almost **all near vision tasks** without glasses.

For example, an improvement from reading a **subhead** in the newspaper (12pt font) to reading the **content label** (4pt font) on a medicine bottle.
Improvement in Uncorrected Near Visual Acuity in Operated Eyes

Average Uncorrected Near Visual Acuity in Operated Eyes
US Data (100% of Cohort up to Month 18)

+5 line improvement in Uncorrected Near Visual Acuity in treated eyes compared to preoperative visual acuity

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No change in Binocular Uncorrected Distance Visual Acuity

≥ 96% of Subjects with Uncorrected Distance Visual Acuity Preoperatively and at Month 18 between 20/16 and 20/25

Uncorrected Distance Visual Acuity in Both Eyes
US Data (100% of Cohort up to Month 18)

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US Registration Timeline

- Complete 24 Month follow up for 300 subjects
- Complete 24 Month follow up for ALL subjects
- Complete documents for PMA Module 4 (study report, labeling)

**Timeline:**
- Q4 2017
- Q1 2018
- Q2 2018
- Q3/4 2018

**US PMA**

- Submit PMA
- Anticipate Approval
Business Highlights

Large, Underserved Presbyopia Opportunity
- 118 million presbyopes in the U.S.; 1.9 billion presbyopes worldwide (2016)*

Developed Ophthalmic Surgery Market
- Over 4,000 global ophthalmic surgery centers with no effective treatment of presbyopia†
- We believe ophthalmic surgeons are highly motivated to develop this market to replace lost LASIK volumes and utilize installed base of expensive femtosecond lasers
- Refractive corneal inlay restores reading vision—on average 5 lines of improvement which is the highest reported UNVA change‡
- Wide range of lens size refractive powers to offer patients a customized therapy—competitors offer single size
- Compatible with additional diagnostic and surgical procedures (e.g., cataract surgery)—competitors are not§

Best-in-Class Microlens Technology
- CE-marked, 1000+ lenses implanted globally
- Ongoing U.S. pivotal trial targeting FDA approval Q3 2018

FDA Pathway
- Senior ophthalmic and global medical device experience: major KOLs worldwide supporting Presbia
- Compelling surgery center economics: 100% private pay, ~10 minute procedure time, leverage large installed base of femtosecond lasers
- Irish domicile

*Source: Market Scope 2016
†Source: Market Scope 2013
‡FDA Submission data
§OUS Data non-concurrent

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