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

Ireland
(State or Other Jurisdiction of Incorporation) 001-36824 98-1162329
(Commission File Number) (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))

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 other conferences, including the Needham & Co. Healthcare Conference on April 12, 2016, 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>
</tr>
</thead>
<tbody>
<tr>
<td>99.1</td>
<td>Investor Presentation (furnished herewith)</td>
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</table>
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

Date: April 11, 2016

By: /s/ Richard Fogarty

Richard Fogarty
Chief Accounting Officer
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 28, 2016 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.

Caution: Investigational Device. Limited by Federal (or United States) law to investigational use.
## Business Highlights

### Best-in-Class Near Vision Microlens
- Refractive corneal inlay restores reading vision, multiple lines of improvement
- Wide range of lens refractive powers to offer patients a customized therapy
- Compatible with other refractive surgical procedures - LASIK and cataract surgery
- CE-marked with over 1000 lenses safely implanted globally

### Clear FDA Pathway
- Second and final FDA two-stage clinical trial enrollment completed: 421 U.S. patients received Presbia Flexivue Microlens™
- 18 months into 36-month follow-up; submission of final PMA module in Q4 2017 expected to lead to FDA approval Q4 2018
- + 5 lines of uncorrected near visual acuity in treated eyes (90% of 6 month US study cohort)

### Large, Underserved Presbyopia Opportunity
- 113 million presbyopes in the U.S.; 1.8 billion worldwide (2014)*
- 4,000+ ophthalmic surgery centers with no effective treatment of presbyopia
- Refractive surgeons are highly motivated to develop this market to replace lost LASIK volumes and utilize installed base of expensive femtosecond lasers
- Compelling surgery center economics: 100% private pay, ~10 minute procedure

### Commercial Strategy
- Two beachheads
- Now: Asia Pacific – South Korea
- Next: Europe – Germany
- Ongoing: Centers of Excellence – Ireland, Netherlands, Canada, Australia

*Source: 2013 Market Scope

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Presbyopia Surgery is the Missing Piece in Refractive Surgery

Currently There is No Established Surgical Market for the 40–60 Year Old Patient Pool

<table>
<thead>
<tr>
<th>Patient Age</th>
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<td>80</td>
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</tbody>
</table>

**Presbyopia**

**LASIK**

**Cataract**

**Refractive Surgery Centers**
- Hit hard by flat-to-declining LASIK procedure volumes, overcapacity, and LASIK procedure price erosion
- Highly receptive to new private pay presbyopia procedure requiring no capital outlay

**Presbia Flexivue MicroLens™ Procedure**
- No capital expenditure required
- Simple surgical procedure, short learning curve
- 100% private pay; ~10 minute procedure

Caution: Investigational Device. Limited by Federal (or United States) law to Investigational use.
A Loss of Near Vision Affecting the Majority of People over the Age of 40

Presbia and related research shows:

- **The Inconvenience of Presbyopia**
  - “I can never find my glasses”**
  - “Can’t read using my iPhone”**
  - “The hassle of my glasses on and off all day”**

- **Freedom and Confidence**
  - Reading glasses are one of the most ubiquitous signs of aging
  - Recent Bausch & Lomb survey found “almost half of women over the age of 40 admit to feeling embarrassed, frumpy, or annoyed when reaching for reading glasses” *
  - “I feel younger”**
  - “My friends notice I don’t have reading glasses”*
  - “I feel free now that I don’t need them”**

* Focus Groups, February, 2015, Dublin, Ireland
U.S. Pivotal Trial

**Sept 2015:** Completion of 2nd stage enrollment (a total of 346 subjects)

**Throughout 2016 into 2017:** Focus is on compliance – constant subject follow through

**Q4, 2017:** Submit clinical data in final PMA Module to FDA (300 subjects, 2 year data)

**Q4, 2018:** Anticipate approval

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**2015**
- 421st subject treated 9/11/15
- Submit annual safety report to FDA 4Q15

**2016**
- 379th subject 12M visit 9/16
- Submit annual safety report to FDA 4Q16

**2017**
- 300 Intent To Treat 24M visit early 3Q17
- Submit final PMA module 4Q17
- Submit annual safety report to FDA 4Q17

**2018**
- Submit final report to FDA 4Q18

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Safety Data (March 25, 2016)
- 89 adverse events reported in operated eyes to date; majority easily treated
- No unanticipated adverse device effects reported to date

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U.S. Pivotal Trial

- Through March 31, 2016, 421 subjects have undergone insertion of the Company’s Microlens during the staged pivotal clinical trial to obtain pre-market approval from the FDA.

- Currently, the Company is 18 months into its 3-year pivotal study and anticipates submitting data to the FDA in Q4 2017. To date, 90% of the subjects have passed through the 6-month post-operative visit.

- Data made available to the Company indicates that:
  - Subjects gained an average of 5 lines of uncorrected near visual acuity (the ability to see close objects without prescription enhancement) in treated eyes.

*Presbia dataset represents 90% of study cohort at 6M; excludes explant subjects to date.

Notwithstanding these results, we cannot assure you when, if ever, the Company will obtain pre-market approval, or what expenditures the Company will incur, whether or not we obtain such approval, given the many significant risks associated with seeking such approval from the FDA. Furthermore, certain adverse events have been reported as part of the ongoing pivotal clinical trial. For a discussion of previously reported adverse events please see the risk factors, including the risks factors titled "Factors Regarding side effects from presbyopia correction surgery generally, or our product specifically, cover, including as a result of medical studies and publications, questions, risks or operations and financial condition will be materially and adversely affected," in the Company’s annual report on form 10-K for the year ended December 31, 2013. The Company requires FDA approval in order to market its product in the United States.

Caution: Investigational Device. Limited by Federal (or United States) law to investigational use.
U.S. Pivotal Trial

- 82% of subjects achieved 20/40 or better uncorrected distance vision in treated eyes (Figure A) and there was little to no change in binocular uncorrected distance vision (Figure B)
U.S. Pivotal Trial

- 99% of subjects achieved 20/40 or better best corrected distance vision in treated eyes (Figure C) and there was little to no change in binocular best corrected distance vision (Figure D). Presbia Flexivue Microlens is designed to take advantage of binocular vision as most patients fuse both images in the brain. The brain filters bad images, thus, resulting in accepting the best images. This process is known as “neuroadaptation.”
Focused Commercialization Strategy

South Korea
Start to build clinical credibility in Germany

Germany

Q4: North America* launch

Asia:
- TBD: Japan, Malaysia, Singapore, Thailand
- Europe:
  - TBD: Spain, Italy, Other

Centers of Excellence: Ireland/UK, Netherlands, Australia/NZ, Canada

* Contingent on FDA approval
## Two Pronged Approach in Country

<table>
<thead>
<tr>
<th>Clinical</th>
<th>Commercial</th>
</tr>
</thead>
</table>
| - Local data  
- Local key opinion leader (KOL)  
- Increase global data  
- Local reference site (peer-to-peer education)  
- PR driven by clinical data (positive clinical outcomes result in a believable and newsworthy campaign) | - Local experience  
- Acceptance  
- Competition  
- Increased awareness drives more patients |

*Contingent FDA approval*

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Focus Market
South Korea

- Launch Symposium in Q4 2015
- Wet labs completed
- Currently engaging top hospitals to participate in local Korean/Asian clinical studies
- Initial KOLs targeted to increase surgeon confidence and expedite adoption
- Lead generation marketing and PR in each metro area
  - Go deep – hands-on with clinic
- Target largest metro areas and saturate each city:
  - surgical trainer, clinical applications specialist
  - business development director, sales account manager & marketing
- Sustained Resource Concentration – multiple refractive practices per metro area to create competition
The LASIK Perspective

<table>
<thead>
<tr>
<th>Country</th>
<th>Population</th>
<th>LASIK Cases (2013 Units)</th>
</tr>
</thead>
<tbody>
<tr>
<td>South Korea</td>
<td>49,000,000</td>
<td>139,000</td>
</tr>
<tr>
<td>Germany</td>
<td>81,000,000</td>
<td>135,000</td>
</tr>
</tbody>
</table>

The presbyopia market is approximately 1.6 times the size of the LASIK market.

Source: 2012 Market Scope.
Clearly Differentiated Near Vision Solution
Microlens Surgical Procedure

10 Minute Procedure Utilizing Existing Femtosecond Laser

1. Femtosecond Laser
   Creates a pocket in patient’s cornea

2. Proprietary Inserters
   Surgeon uses inserter to implant lens in patient’s cornea

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

Caution: Investigational Device. Limited by Federal (or United States) law to investigational use.
Intracorneal Refractive Lens implanted in a pocket in cornea of non-dominant eye

Hydrophilic Acrylic Material similar to that used in IOLs for > 20 years

A True "Micro lens" with 3.2 mm diameter and edge thickness of 0.015 mm

Offered in a Wide Range of Powers ranging from +1.5 diopter to +3.5 diopter, in 0.25 diopter increments

Invisible to the Naked Eye once implanted

Compatible with other ophthalmic diseases (e.g., cataract)

Platform for Future Technologies
# Not All Inlays are the Same

<table>
<thead>
<tr>
<th>Presbia FlexivueMicroLens™</th>
<th>AcuFocus KAMRA</th>
<th>ReVision Optics Raindrop</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intracorneal Refractive Lens; Implied in a Pocket</td>
<td>Creates a Pinhole Effect; Implied in a Pocket</td>
<td>Adds Bulk to Cornea; Implanted under a LASIK-like Flap</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Feature</th>
<th>Presbia</th>
<th>AcuFocus</th>
<th>ReVision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wide Range of Refractive Powers</td>
<td>✔️</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Aesthetically Appealing</td>
<td>✔️</td>
<td>✗</td>
<td>✔️</td>
</tr>
<tr>
<td>Designed to be Replaced if Needed</td>
<td>✔️</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Tissue Sparing Procedure</td>
<td>✔️</td>
<td>✗ (Is placed in pocket and patient is -0.75 D)</td>
<td>✗</td>
</tr>
<tr>
<td>No Additional Capital Expenditure</td>
<td>✔️</td>
<td>✗ (AcuTarget for centration)</td>
<td>✔️</td>
</tr>
</tbody>
</table>

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## Intellectual Property

### U.S. Patents

- Five patents issued:
  - Lens Holder Apparatus and System Method (US 8,869,975 B2)
  - Lens Inserter Apparatus and Method (US 9,017,421 B2)
  - Lens Injector Apparatus and Method (US 8,454,687 B2)
  - Lens Injector Apparatus System and Method (US 9,010,827 B2)

- Two patents pending (patent applications):
  - Lens Inserter Assembly
  - System for Monitoring and Tracking Patient Outcomes After Surgical Implantation of an Intracorneal Lens

### Foreign Patents

- Lens Holder Apparatus and System Method
  - Issued: Canada
  - Allowed, waiting for issue: China
  - Awaiting Examination: Australia, Europe, Israel, Japan, Korea, Russia, India, Brazil

- Lens Inserter Apparatus and Method
  - Issued: Japan, China, Australia
  - Allowed, waiting for issue: Israel
  - Pending: Canada, Europe, Korea

- Lens Injector Apparatus and Method
  - Pending: Japan, Korea
  - Method for Laser Cutting a Corneal Pocket
    - Pending: Australia, Canada, China, Europe, Hong Kong, Israel, Japan, Korea

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Manufacturing

Irvine, CA Manufacturing Facility

- 4,000 square-foot, two-part (wet/dry) manufacturing facility
- Approved to manufacture devices for U.S. IDE by State of California FDA in 2013
- Sufficient capacity to handle projected Presbia Flexivue Microlens™ volume through U.S. launch
- Approved to manufacture devices for OUS sale by Intertek (ISO 13485:2012 certified)
- Additional third-party manufacturing facility in Israel supplies product for all current OUS requirements
- Distribution facilities in Ireland and the Netherlands

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*Source: 2013 Market Scope.

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"Corneal inlays are an exciting new approach to the treatment of presbyopia. In my opinion, the Presbia Microlens represents the most robust corneal inlay platform to date!"  

Dean Smith, MD (Canada)

"Presbia offers a unique technology that provides the patient with correction for nearsightedness while allowing the dominant eye to continue to provide effective distance vision. Most importantly, this is a very simple and reversible procedure. Long-time research and follow-up has proven the highest level of biocompatibility of this miniature intracorneal lens."

Prof. Ioannis Pallikaris (Greece)

"It (Presbia Microlens) marks a new era in the treatment of this natural part of the ageing process, and in a sense it allows you to turn back the clock and regain the vision you enjoyed when younger."

Wayne Crewe-Brown, MD (Ireland/UK)

"We’re looking for a solution that’s safe, that’s simple, that’s effective, that’s customizable to the patient, that’s reversible and I think the Presbia Flexivue Microlens™ is the solution for the future."

Mickey Gordon, MD (USA)

"Thank you for enabling us to implant an invisible product into a transparent organ, with dogma-defying outcomes and joyous recipients. It is these inspiring experiences that make medicine fun."

Kerry Assel, MD (USA)

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