PRESBIA PLC

FORM 8-K
(Current report filing)

Filed 11/30/15 for the Period Ending 11/30/15

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U N ITED STATES
SE CURI T IE S A N D E X CHAN G E COMMI S S I O N
Wa s h i n g t on, D . C . 20549

F O RM 8 - K

C URREN T R E P O RT P u r s u a n t t o S ec t i on 1 3 o r 15 (d)
of t h e S e c u ri t ies E xc h a n ge Act of 1934

Da t e of R e p o r t (D a t e of earli e s t eve n t r e p o r t e d) : November 30, 2015

P R E S B I A P L C
(Exa c t N a m e of R e g i s t r a n t as Sp e c i f i e d i n Ch a r t e r)

Ireland	001-36824	98-1162329
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

120 / 121 Ba g got S t r e e t Lo w e r
D u b l i n 2 I r e l and
(A d d re ss of P r i n c i p a l E xec u t i v e O ff i c e s)(Z i p C o d e)

+353 (1) 659 9446
R e g i s t r a n t's T e l e p h o n e N u m b e r

Ch e c k t he a p p ropr i a t e box b e l ow i f t he F orm 8-K f i l i ng i s i n t e nd e d t o s i m u l t a n e ou s l y s a t i s fy t he f i l i ng ob l i g a t i on of t he r e g i s t r a nt und e r a ny of t h e fo l l o w i ng pr o v i s i o n s :

- ☐ 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 Piper Jaffray Healthcare Conference on December 1, 2015, a slide presentation. The slide presentation is attached hereto as Exhibit 99.1. The Company undertakes no obligation to update, supplement or amend the slide presentation 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 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 shall be expressly set forth by reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Number	Exhibit
99.1	Investor Presentation, dated November 30, 2015 (furnished herewith)

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: November 30, 2015

PRESBIA
freedom in sight

Investor Presentation

Piper Jaffray Healthcare Conference
December 2015

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

Disclosure

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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 31, 2015 and those risks discussed under "Risk Factors" in our Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission on May 15, 2015, August 4, 2015 and November 13, 3015.

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.

Business Highlights

PRESBIA

Best-in-Class Microlens Technology	• Refractive corneal inlay restores reading vision—average 6 lines of improvement • Wide range of lens size refractive powers to offer patients a customized therapy • Compatible with other ophthalmic surgical procedures (e.g. cataract surgery)
Clear FDA Pathway	• CE-marked with over 1000 lenses safely implanted globally • FDA two-stage clinical trial: 421 U.S. patients received Presbia Flexivue Microlens™ • 24-month follow-up expected to lead to FDA approval Q4 2018
Large, Underserved Presbyopia Opportunity	• 114 million presbyopes in the U.S.; 1.8 billion worldwide (2014)* • 4,000+ ophthalmic surgery centers with no effective treatment of presbyopia • Ophthalmic 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 time, leverage large installed base of femtosecond lasers
Commercial Strategy	• Two beach-heads • Now: Asia Pacific—South Korea (18.3 million presbyopes)* • Next: Europe—Germany (37.3 million presbyopes)*

*Source: 2014 Market Scope.

Presbyopia Surgery is the Missing Piece in Refractive Surgery

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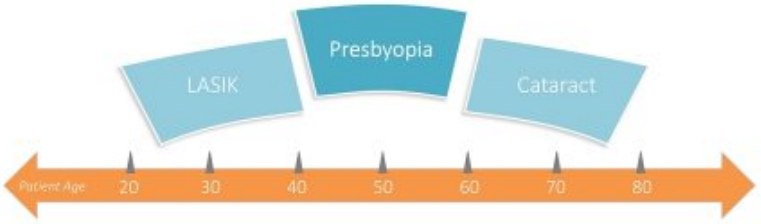
Currently There is No Established Surgical Market for the 40–60 Year Old Patient Pool



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 leaning curve
- 100% private pay; ~10 minute procedure

Presbyopia

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A Loss of Near Vision Affecting the Majority of People over the Age of 40

- The Inconvenience of Presbyopia
  - Glasses off / on; lost glasses (can't find them when you need them), etc.
  - Hassle of daily maintenance of contact lenses, especially among active people
  - Difficulty seeing text/images on personal electronic devices such as cell phones, tablets
- The Vanity Factor
  - 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"
- Clinical Advantages of the Presbia Flexivue Microlens™
  - Presbia Flexivue Microlens™ is tailorable to a patient's specific, desired near visual acuity reading distance
  - Crystal clear material that is not visible to the naked eye
  - Outstanding safety profile and compatible with other ophthalmic procedures
  - Average of 6 lines improvement

Large, Underserved And Growing Market Opportunity

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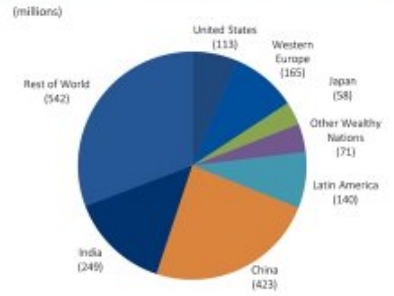
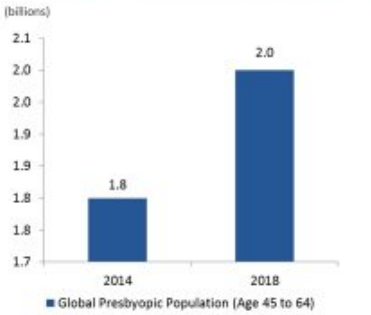
1.8 Billion Presbyopes



Demographic-Driven Market Growth



Source: 2013 Market Scope.

Clear U.S. Regulatory Pathway

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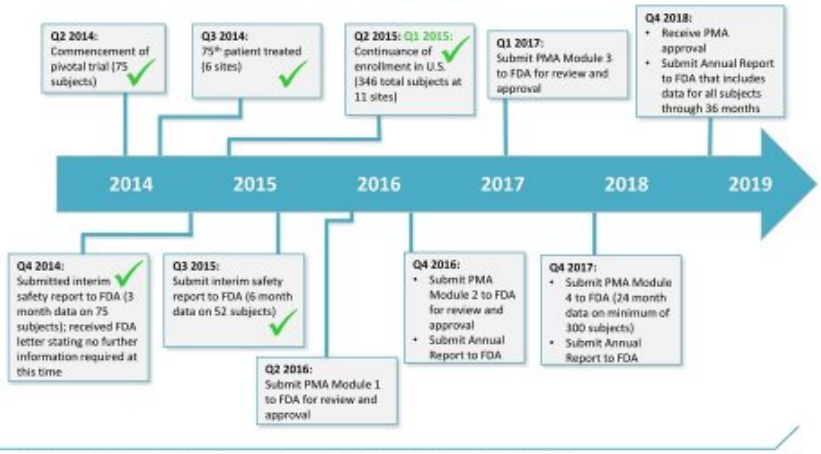
Targeted U.S. IDE Regulatory Pathway – Presbia Flexivue Microlens™



U.S. Pivotal Trial

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U.S. Staged Pivotal Clinical Trial Timeline

- **January 2015:**
  - Submitted interim safety report to FDA, which included 6-month data on 52 subjects (a total of 75 subjects were implanted at six investigational sites in the first stage of this trial)
- **February 2015:**
  - Approved to begin 2nd stage enrollment; we were permitted to enroll at 15 investigational sites, and we used 11 of 15 to complete 2nd stage enrollment
  - Enrollment started and first surgery performed
- **September 2015:**
  - Completion of 2nd stage enrollment (a total of 346 subjects)
- **Q4 2017:**
  - Submit clinical data in Final PMA Module to FDA (300 subjects, 2 year data)

Safety Data
(Total of 421 Subjects 9/11/2015)

- No unanticipated adverse device effects reported to date
- 71 adverse events reported in operated eyes to date; majority easily treated

Focused Commercialization Strategy

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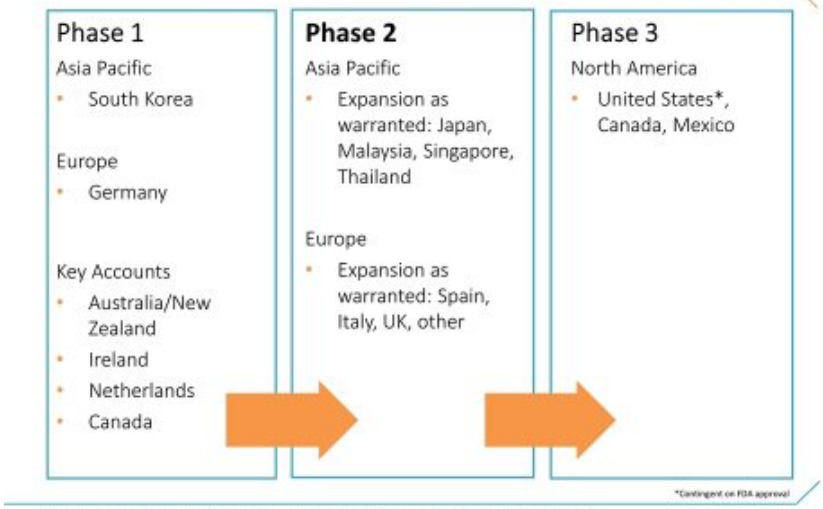

Phase 1 Focus Markets
Asia Pacific & Europe

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Country Selection Criteria

- Initially create beach head in two most developed ophthalmology regions of the world outside of US: Asia Pacific and Europe
- Countries with several 1 million+ metro areas
- Large presbyopia population, high presbyopia per capita
- Ability to buy: household income
- Desire to buy: high LASIK penetration
- Ability to do procedure: high number of refractive surgeons, laser centers and number of lasers
- Direct response marketing permitted

Phase 1 Focus Markets
South Korea & Germany

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Sustained Resource Concentration – Few countries, more clinics and more customers

- Multiple refractive practices per metro area to create competition
- Start lead generation marketing and PR in each metro area
- Go deep – hands-on with clinic

Saturate each city: surgical trainer, clinical applications specialist, business development director, sales account manager & marketing

South Korea

Germany

Surgeon Demand Creation

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Patient Demand Creation

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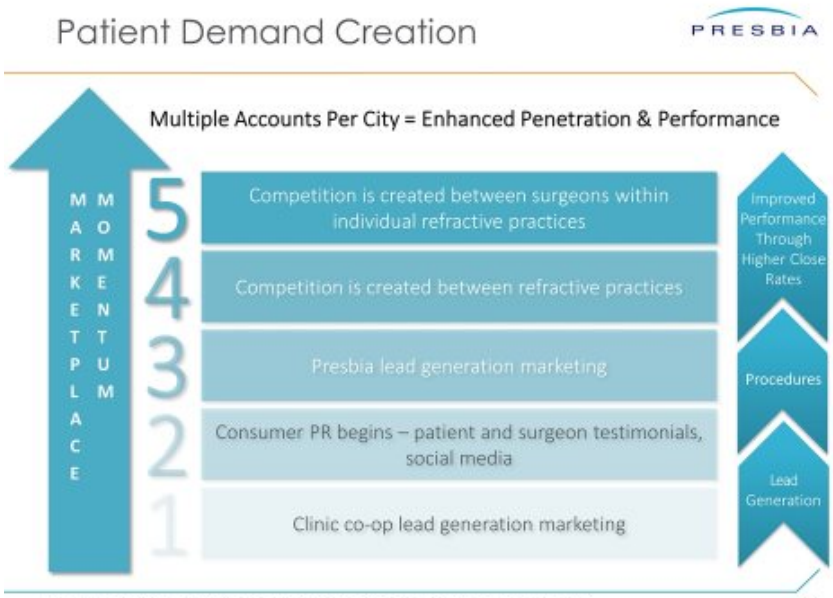

The LASIK Perspective

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LASIK MARKET

Country	Population	LASIK Cases (2013 Units)	LASIK Penetration of Population
South Korea	49,000,000	139,000	0.28%
Germany	81,000,000	135,000	0.17%

LASIK is a procedure to eliminate the need for distance glasses.

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

Source: 2012 Market Scope.

Clearly Differentiated Microlens Technology

Microlens Surgical Procedure

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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

Proprietary Reusable Insertion Tools

Single Use Inserter
Disposable

Presbia Flexivue Microlens™ Best In Class Solution

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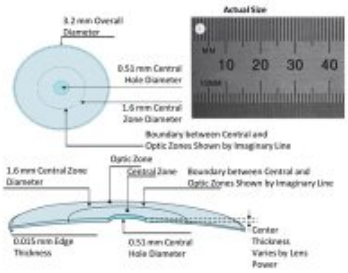
Presbia Flexivue Microlens™
Designed to Eliminate Need for Reading Glasses

- **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 "Microlens"** 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**



Presbia's Microlens Clinical Results

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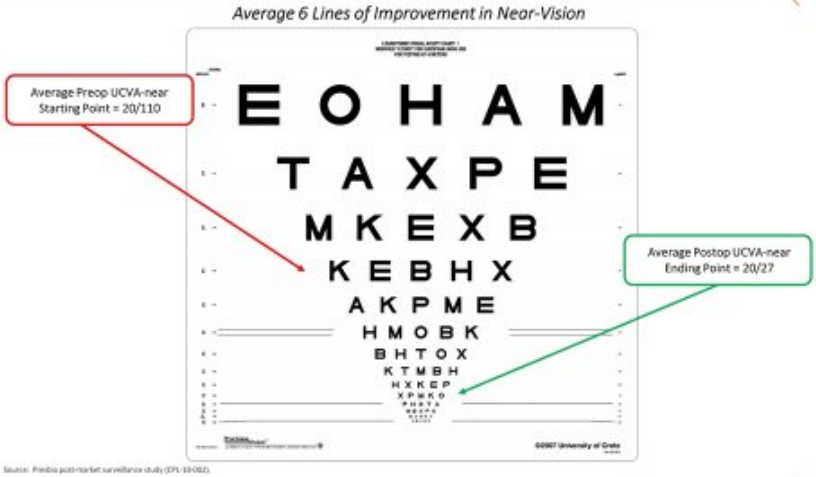
Average 6 Lines of Improvement in Near-Vision



Source: Presbia post-market surveillance study (CPS-10-002).

Intellectual Property

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U.S. Patents

- Five patents issued:
  - Lens Holder Apparatus and System Method (US 8,888,975 B2)
  - Lens Inserter Apparatus and Method (US 9,017,403 B2)
  - Lens Injector Apparatus and Method (US 8,454,687 B2)
  - Lens Injector Apparatus System and Method (US 9,010,817 B2)
  - Method for Laser Cutting a Corneal Pocket (US 9,168,175 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

Clearly Differentiated Microlens Technology

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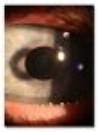
	Presbia FlexivueMicrolens™	**AcuFocus KAMRA**	**ReVision Optics Raindrop**
	Intracorneal Refractive Lens; Implanted in a Pocket	**Creates a Pinhole Effect; Implanted in a Pocket**	**Adds Bulk to Cornea; Implanted under a LASIK-like Flap**
			
Wide Range of Refractive Powers	✓	X	X
Aesthetically Appealing	✓	X	✓
Designed to be Replaced	✓	X	X
Tissue Sparing Procedure	✓	X (Is if placed in pocket and patient is -0.75 D)	X

Manufacturing

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Irvine, CA Manufacturing Facility

- Completed construction of 4,000 square-foot, two-part (wet/dry) manufacturing facility in Q3 2013
- 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

Experienced Leadership Team & Board

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*Source: 2014 Market Scope.

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