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**UNITED STATES**  
**SECURITIES and EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 10-Q**

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**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2015

or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number: 001-36824

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**PRESBIA PLC**

(Exact name of registrant as specified in its charter)

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**Ireland**

(State or other jurisdiction of  
incorporation or organization)

**120/121 Baggot Street Lower, Dublin 2 Ireland**  
(Address of principal executive offices)

**98-1162329**

(IRS Employer  
Identification No.)

(Zip Code)

**+353 (1) 659 9446**

(Registrant's telephone number, including area code)

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company) Small reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The number of outstanding shares of the Registrant's ordinary shares as of August 5, 2015 was 13,355,477 shares.

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## Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q, 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 Quarterly Report on Form 10-Q include, among other things, statements about:

- the initiation, timing, progress and results of our clinical trials, our regulatory submissions and our research and development programs;
- our ability to advance our products into, and successfully complete, clinical trials;
- our ability to obtain pre-market approvals;
- the commercialization of our products;
- the implementation of our business model, strategic plans for our business, products and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our products and technology;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- the timing or likelihood of regulatory filings and approvals;
- our financial performance; and
- developments relating to our competitors and our industry.

You should refer to “Part I, Item 1A. Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2014, filed with the Securities and Exchange Commission on March 30, 2015, and “Part II, Item 1A. Risk Factors” of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed with the Securities and Exchange Commission on May 15, 2015, 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 Quarterly Report on Form 10-Q 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.

You should read this Quarterly Report on Form 10-Q and any documents that we reference in this report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

**“PART I. FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

**PRESBIA PLC**  
**CONSOLIDATED BALANCE SHEETS**  
(in thousands, except share data)  
(Unaudited)

	June 30, 2015	December 31, 2014
<b>Assets</b>		
Current assets		
Cash	\$ 29,806	\$ 138
Accounts receivable	32	25
Inventory	401	378
Prepaid expenses and other current assets	469	122
<b>Total current assets</b>	<b>30,708</b>	<b>663</b>
Property and equipment, net	803	747
Intangible asset	40	46
Other assets	49	886
<b>Total assets</b>	<b>\$ 31,600</b>	<b>\$ 2,342</b>
<b>Liabilities and shareholders' equity (deficit)</b>		
Current liabilities		
Accounts payable	\$ 1,624	\$ 1,882
Due to related parties	59	12
Other current liabilities	517	700
<b>Total current liabilities</b>	<b>2,200</b>	<b>2,594</b>
Payable due to the Parent	-	417
Deferred rent	30	37
<b>Total liabilities</b>	<b>2,230</b>	<b>3,048</b>
Commitments and contingencies (note 10)		
<b>Shareholders' equity (deficit)</b>		
Common Ordinary Shares		
\$0.001 par value, 350,000,000 shares authorized; 13,351,874 and -0- shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	13	—
Euro Ordinary Shares		
One Euro (US\$1.35) par value, 40,000 shares authorized, issued and outstanding at June 30, 2015 and December 31, 2014, respectively	54	54
Additional paid-in capital	76,601	36,626
Accumulated deficit	(47,298)	(37,386)
<b>Total shareholders' equity (deficit)</b>	<b>29,370</b>	<b>(706)</b>
<b>Total liabilities and shareholders' equity (deficit)</b>	<b>\$ 31,600</b>	<b>\$ 2,342</b>

The accompanying notes are an integral part of these consolidated financial statements.

**PRESBIA PLC**  
**Consolidated Statements of Operations and Comprehensive Loss**  
(in thousands, except per share data)  
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Revenues	\$ 42	\$ 61	\$ 115	\$ 87
Cost of goods sold	14	33	61	39
Gross profit	28	28	54	48
Operating expenses:				
Research and development	2,502	1,676	4,278	2,407
Sales and marketing	834	394	1,353	643
General and administrative	2,007	4,272	4,326	5,648
Total operating expenses	5,343	6,342	9,957	8,698
Operating loss	(5,315)	(6,314)	(9,903)	(8,650)
Interest expense	—	584	—	1,017
Other income	—	(6)	—	(6)
Loss before income tax provision	(5,315)	(6,892)	(9,903)	(9,661)
Income tax provision	4	3	9	5
Net loss	\$ (5,319)	\$ (6,895)	\$ (9,912)	\$ (9,666)
Total comprehensive loss	\$ (5,319)	\$ (6,895)	\$ (9,912)	\$ (9,666)
Net loss per share-basic and diluted	\$ (0.40)	\$ (0.75)	\$ (0.79)	\$ (1.05)
Shares used to compute basic and diluted net loss per share	13,352	9,167	12,562	9,167

The accompanying notes are an integral part of these consolidated financial statements.

**PRESBIA PLC**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)  
(Unaudited)

	Six Months Ended June 30,	
	2015	2014
<b>Cash flow from operating activities:</b>		
Net loss	\$ (9,912)	\$ (9,666)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	74	65
Amortization	6	2
Inventory provisions	44	32
Write-off of deferred offering costs	—	3,359
Share-based compensation (including allocation from Presbia Holdings)	1,403	194
Non-cash interest expense on funding from the Presbia Holdings	1	1,017
Non-cash operating expenses allocated from the Presbia Holdings	182	183
Changes in operating assets and liabilities:		
Accounts receivable	(7)	(39)
Inventory	(67)	(111)
Prepaid expenses and other current assets	(347)	27
Other assets	(10)	39
Accounts payable and other current liabilities	884	(238)
Income taxes payable	6	5
Deferred rent	(7)	4
Due to related parties	47	(110)
Net cash used in operating activities	<u>(7,703)</u>	<u>(5,237)</u>
<b>Cash flow from investing activities:</b>		
Purchase of property and equipment	(97)	(120)
Net cash used in investing activities	<u>(97)</u>	<u>(120)</u>
<b>Cash flow from financing activities:</b>		
Proceeds from issuance of ordinary shares upon initial public offering, net of underwriting costs	38,750	—
Deferred offering costs	(2,423)	(1,468)
Capitalization of Presbia PLC	—	54
Funding from the Parent	1,141	6,550
Net cash provided by financing activities	<u>37,468</u>	<u>5,136</u>
Net increase in cash	29,668	(221)
Cash balance at beginning of period	138	584
Cash balance at end of period	<u>\$ 29,806</u>	<u>\$ 363</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for income taxes	<u>\$ 3</u>	<u>\$ —</u>
<b>Supplemental disclosures of non-cash investing and financing activities:</b>		
Purchase of property and equipment included in accounts payable	<u>\$ 33</u>	<u>\$ —</u>
Deferred offering costs included in accounts payable and other current liabilities	<u>\$ —</u>	<u>\$ 1,246</u>
Deferred offering costs included in Due to Presbia Holdings	<u>\$ —</u>	<u>\$ 650</u>
Allocated operating expenses funded by the Presbia Holdings	<u>\$ 182</u>	<u>\$ 183</u>
Capitalization of amounts due to Presbia Holdings pursuant to the 2015 Debt Conversion	<u>\$ 1,559</u>	<u>\$ —</u>

The accompanying notes are an integral part of these consolidated financial statements.

**PRESBIA PLC**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

**(1) Basis of Presentation**

**Principles of Consolidation.** The accompanying consolidated financial statements have been derived from the historical cost basis of the assets and liabilities, financial condition and cash flows of Presbia PLC and Presbia Ireland, Limited, both organized in Ireland, Presbia Investments, a direct subsidiary of Presbia PLC organized in the Cayman Islands, and Presbia Ireland, Limited's subsidiaries, Presbia USA, Inc., and OPL, LLC. Presbia USA, Inc. and OPL, LLC are both entities organized in the United States, and include Presbia USA, Inc.'s subsidiaries, Visitome, Inc. and PresbiBio, LLC, both organized in the United States, and OPL, LLC's direct and indirect subsidiaries, PIP Holdings, C.V and Presbia Cooperatief U.A., both organized in the Netherlands, and PresbiOptical LLC, organized in the United States (collectively, including Presbia PLC, the "Company"). The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America. The Company's fiscal year ends on December 31. The entities presented in the consolidated financial statements have been under common control during the periods presented. All intercompany accounts have been eliminated in consolidation.

**2013 Restructuring and Formation of Presbia PLC.** Presbia PLC, an Irish public limited company, was formed on February 6, 2014 through the issuance of 40,000 shares for 40,000 Euros (approximately \$54,000) for the purpose of consummating an initial public offering of its ordinary shares. Presbia PLC's ultimate controlling shareholder, Presbia Holdings (the "Parent"), was organized in the Cayman Islands in 2007 as an exempted company with limited liability. On October 21, 2013, the Parent completed a restructuring (the "2013 Restructuring") which involved the formation on September 13, 2013 of an interim holding company, Presbia Ireland, Limited, and the contribution by the Parent of 100% of its direct and indirect ownership interests in its business, assets and subsidiaries to Presbia Ireland, Limited. At the time of the 2013 Restructuring, Presbia Ireland, Limited was wholly-owned by Presbia Holdings and certain intercompany debt was owed to Presbia Holdings by certain of its other subsidiaries. As part of the 2013 Restructuring, approximately \$12.2 million of such outstanding intercompany debt owed to Presbia Holdings was converted to equity of such subsidiaries.

**2014 Debt Conversion.** On November 30, 2014, Presbia Holdings converted all the remaining indebtedness owed to Presbia Holdings by certain subsidiaries of Presbia Ireland, Limited at that time to equity ("2014 Debt Conversion"). In the 2014 Debt Conversion, approximately \$23.5 million of outstanding intercompany debt owed to Presbia Holdings was converted to equity of Presbia Ireland, Limited.

**2015 Debt Conversion.** On January 14, 2015, the Parent converted all the remaining indebtedness owed to the Parent by a subsidiary of Presbia Ireland, Limited at that time to equity (the "2015 Debt Conversion") in the amount of approximately \$1.6 million. See Note 4 for additional discussion.

**2015 Capital Contribution.** On January 14, 2015, the Parent contributed all the share capital in issue in Presbia Ireland, Limited to Presbia PLC (the "2015 Capital Contribution") in exchange for 9,166,667 ordinary shares of Presbia PLC. See Note 4 for additional discussion.

**Initial Public Offering.** On February 3, 2015, Presbia PLC completed its initial public offering ("IPO") of 4,166,667 of its ordinary shares at a price to the public of \$10.00 per ordinary share and commenced trading on The NASDAQ Global Market under the symbol LENS. The Parent acquired 500,000 ordinary shares in the public offering. The net proceeds from the IPO consisted of aggregate gross proceeds of approximately \$41.7 million, less underwriting discounts and commissions of approximately \$2.9 million and other issuance costs of approximately \$2.0 million, resulting in net proceeds of approximately \$36.8 million.

**Liquidation of Presbia Holdings.** On May 13, 2015, the board of directors and the ordinary shareholders of Presbia Holdings approved a voluntary liquidation of Presbia Holdings and the distribution of its assets consisting primarily of 9,666,667 shares of Presbia PLC shares, of which 500,000 shares were acquired during the initial public offering and 9,166,667 were acquired pursuant to the 2015 Capital Contribution, to its ordinary shareholders. On May 13, 2015, the shareholders also approved a plan that would immediately fully vest all outstanding options and restricted share awards and, in the case of the options, accelerate the expiration date of all such options to June 15, 2015. See Notes 6 and 11 for further discussion.

**Basis of Presentation.** The accompanying unaudited consolidated financial statements as of June 30, 2015 and for the three months and six months ended June 30, 2015 and 2014 have been prepared in accordance with the requirements of Form 10-Q and Article 10 of the Securities and Exchange Commission Regulation S-X and therefore do not include all information and notes which would be presented were such consolidated financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). These consolidated financial statements should be read in conjunction with the audited consolidated financial statements presented in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2014. Amounts related to disclosures of December 31, 2014 balances within these interim consolidated financial statements were derived from the aforementioned Form 10-K. In the opinion of management, the accompanying consolidated financial statements reflect all adjustments which are necessary for a fair presentation of the results of operations and cash flows for the periods presented. The results of operations for such interim periods are not necessarily indicative of results of operations to be expected for the full year.

References to amounts in the consolidated financial statement sections are in thousands, except per share data, unless otherwise specified.

### **Liquidity**

The Company has incurred significant operating losses since inception and had relied on funding from the Parent to fund operations prior to its IPO on February 3, 2015. At June 30, 2015, the Company has an accumulated deficit of \$47.3 million. As the Company continues to incur losses, its transition to profitability will depend on the successful development, approval and commercialization of its product and on the achievement of sufficient revenues to support its cost structure. The Company may never achieve profitability, and unless and until it does, it will need to continue to raise additional capital. Management expects that existing cash as of June 30, 2015 will be sufficient to fund the Company's operations for at least twelve months from the balance sheet date.

## **(2) Summary of Significant Accounting Policies**

### **Revenue Recognition**

The Company recognizes revenue when there is persuasive evidence that an arrangement exists with the customer, selling prices are fixed or determinable, title or risk of loss has passed, and collection is reasonably assured. Revenue is recognized upon shipment and payments are either received in advance, or net 30 days. As of June 30, 2015, the Company was not authorized to manufacture or sell any of its products or services within the United States and, as a result, all of the Company's revenues are derived from foreign customers.

### **Clinical Trials**

During 2014, the Company received approval from the United States Food and Drug Administration ("FDA") to commence a staged-enrollment pivotal FDA clinical trial of its microlens involving the implantation of presbyopic patients. The first staged-enrollment commenced during the first quarter of 2014, and during these trials, the Company incurred costs for patient recruiting, acquisition of clinical test equipment to be used in the trials, outside experts to read and interpret the results of the studies and third parties to monitor the investigational sites and perform data collection activities and surgeon costs, as well as patient fees in connection with the surgical procedures and follow-up visits. In February 2015, the Company received approval from the FDA to commence second stage enrollment in this trial. The Company's policy with respect to the recognition of these costs is to record such costs as research and development expense in the consolidated statements of operations and comprehensive loss in the period in which the services are provided. The Company will evaluate the purchases of clinical test equipment, on a case by case basis, to determine if there exists an alternative use for the equipment following the clinical trials. In the event that the Company determines that there is no alternative use for the test equipment, that cost will be expensed as part of research and development expense.

### **Deferred Offering Costs**

During the three and six months ended June 30, 2015, the Company incurred approximately \$1.2 million, respectively, related to its IPO which was completed on February 3, 2015. Upon completion of the IPO, the Company netted approximately \$2.0 million in offering costs, including approximately \$0.8 million recorded as other assets on the balance sheet as of December 31, 2014, against the gross proceeds in shareholders' deficit. During the three and six months ended June 30, 2014, the Company wrote-off approximately \$3.4 million in deferred offering costs due to delays beyond 90 days in the launch of its initial public offering.

### **Fair Value of Financial Instruments**

The carrying values of certain of the Company's financial instruments, such as prepaid expenses, accounts payable and accrued expenses, approximate fair value due to their short maturities. Amounts payable to related parties, which has no fixed maturity or expiration date, do not have readily determinable fair values.

### **Recent Accounting Standards**

In January 2015, the Financial Accounting Standards Board issued Accounting Standards Update ("ASU") 2015-01 which simplifies income statement presentation by eliminating the need to determine whether to classify an item as an extraordinary item. This ASU applies to all entities and is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted, but adoption must occur at the beginning of a fiscal year. An entity can elect to apply the guidance prospectively or retrospectively. The Company is currently evaluating the potential impact that the adoption of this guidance will have on its consolidated financial statements.

In May 2014, FASB issued an Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers: Topic 606* that affects any entity using U.S. GAAP that either enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets unless those contracts are within the scope of other standards (e.g., insurance contracts or lease contracts). This ASU will supersede the revenue recognition requirements in Topic 605, *Revenue Recognition*, and most industry-specific guidance. This ASU also supersedes some cost guidance included in Subtopic 605-35, *Revenue Recognition—Construction-Type and Production-Type Contracts*. In addition, the existing requirements for the recognition of a gain or loss on the transfer of nonfinancial assets that are not in a contract with a customer (e.g., assets within the scope of Topic 360, *Property, Plant, and Equipment*, and intangible assets within the scope of Topic 350, *Intangibles—Goodwill and Other*) are amended to be consistent with the guidance on recognition and measurement (including the constraint on revenue) in this ASU.

The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve that core principle, an entity should: identify the contract(s) with a customer; identify the performance obligations in the contract; determine the transaction price; allocate the transaction price to the performance obligations in the contract; and recognize revenue when (or as) the entity satisfies a performance obligation.

For public companies, the amendments in this ASU are effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early application is not permitted. The Company is evaluating the potential impact of adoption of this ASU on its consolidated financial statements.

### **(3) Composition of Certain Financial Statement Captions**

Inventory is summarized as follows:

	June 30, 2015	December 31, 2014
Lenses	323	\$ 371
Accessories	78	7
Total	<u>\$ 401</u>	<u>\$ 378</u>

During the three and six months ended June 30, 2015, the Company incurred approximately \$70,000 to build inserter inventory, respectively, consisting of approximately \$35,000 of production inventory parts in preparation for internal production of a disposable inserter and approximately \$35,000 for purchases of other inserters.

Property and equipment is summarized as follows:

	June 30, 2015	December 31, 2014
Office equipment and computers	\$ 65	\$ 51
Leasehold improvements	142	132
Production equipment and facilities	714	682
Software	23	7
Construction in process	57	0
Furniture and vehicles	156	155
	<u>1,157</u>	<u>1,027</u>
Less: accumulated depreciation	(354)	(280)
Property & Equipment, net	<u>\$ 803</u>	<u>\$ 747</u>

Other assets are summarized as follows:

	June 30, 2015	December 31, 2014
Prepaid rent and other	\$ 49	\$ 47
Deferred costs related to IPO	—	839
Total	<u>\$ 49</u>	<u>\$ 886</u>

Other current liabilities are summarized as follows:

	June 30, 2015	December 31, 2014
Costs related to the IPO	\$ —	\$ 327
Accrued professional fees	95	20
Accrued payroll & vacation	44	114
Other accrued liabilities	378	239
Total	<u>\$ 517</u>	<u>\$ 700</u>

#### (4) Shareholders' Deficit

##### **Common Ordinary Shares and Deferred Ordinary Shares**

As of June 30, 2015, the share capital of Presbia PLC was \$400,000 and €40,000, divided into: 350,000,000 ordinary shares of \$0.001 each (the "Ordinary Shares"), 13,351,874 of which were outstanding as of June 30, 2015; 50,000,000 preferred shares of \$0.001 (the "Preferred Shares") each, all of which are authorized but unissued; and 40,000 deferred ordinary shares of €1.00 each (the "Deferred Ordinary Shares"), all of which are issued and outstanding as of June 30, 2015. The aggregate 9,166,667 ordinary shares of Presbia PLC have been reflected as issued and outstanding as of the earliest date of the periods presented for purposes of computation of comparable basic and diluted net loss per share.

The rights and restrictions attaching to the Ordinary Shares are as follows: the right to attend and speak at any general meeting of the Company and to exercise one vote per Ordinary Share held at any general meeting of the Company; the right to participate pro rata in all dividends declared by the Company; and the right, in the event of the Company's winding up, to participate pro rata in the total assets of the Company.

The Deferred Ordinary Shares were initially issued as 40,000 ordinary shares of one Euro each on February 6, 2014 in connection with the formation of Presbia PLC. On January 14, 2015, the Company amended its memorandum and articles of association, resulting in the re-designation of such shares as deferred ordinary shares. The rights and restrictions attaching to the Deferred Ordinary Shares are as follows:

*Income:* The holder of a Deferred Ordinary Share shall not be entitled to receive any dividend or distribution declared, made or paid or any return of capital (save as provided below) and a Deferred Ordinary Share shall not entitle its holder to any further or other right of participation in the assets of the Company;

*Capital:* On a winding up of, or other return of capital (other than on a redemption of any class of shares in the capital of the Company) by the Company, the holders of Deferred Ordinary Shares shall be entitled to participate in such return of capital or winding up of the Company, such entitlement to be limited to the repayment of the amount paid up or credited as paid up on such Deferred Ordinary Shares and shall be paid only after the holders of Ordinary Shares shall have received payment in respect of such amount as is paid up or credited as paid up on those Ordinary Shares held by them at that time, plus the payment in cash of \$5,000,000 on each such Ordinary Share.

*Acquisition of Deferred Ordinary Shares:* The Company as agent for the holders of Deferred Ordinary Shares shall have the irrevocable authority to authorize and instruct the Company's secretary (or any other person appointed for the purpose by the Company's board of directors) to acquire, or to accept the surrender of, the Deferred Ordinary Shares for no consideration and to execute on behalf of such holders such documents as are necessary in connection with such acquisition or surrender, and pending such acquisition or surrender to retain the certificates, to the extent issued, for such Deferred Ordinary Shares.

*Voting:* The holders of Deferred Ordinary Shares shall not be entitled to receive notice of, nor attend, speak or vote at, any general meeting.

The rights attaching to the Preferred Shares will be determined by the Company's board of directors. The directors are authorized to issue all or any of the authorized but unissued Preferred Shares from time to time in one or more classes or series, and to fix for each such class or series such voting power, full or limited, or no voting power, and such designations, preferences and relative, participating, optional or other special rights and such qualifications, limitations or restrictions thereof, as shall be stated and expressed in the resolution or resolutions adopted by the Board providing for the issuance of such class or series, including, without limitation, the authority to provide that any such class or series may be: redeemable at the option of the Company, or the holders, or both, with the manner of the redemption to be set by the Company's board of directors, and redeemable at such time or times, including upon a fixed date, and at such price or prices, as shall be determined by the Board; entitled to receive dividends (which may be cumulative or non-cumulative) at such rates, on such conditions and at such times, and payable in preference to, or in such relation to, the dividends payable on any other class or classes of shares or any other series all as shall be determined by the Board; entitled to such rights upon the dissolution of, or upon any distribution of the assets of, the Company, as shall be determined by the Board; or convertible into, or exchangeable for, shares of any other class or classes of shares, or of any other series of the same or any other class or classes of shares, of the Company, at such price or prices or at such rates of exchange and with such adjustments as the Company's board of directors determines.

#### ***Additional Paid-in Capital***

On January 14, 2015, the Parent entered into a Debt Conversion Agreement pursuant to which all outstanding amounts owed to the Parent under the Interest Rate Agreement governing such debt at that time were contributed to paid-in capital of certain of the Parent's subsidiaries.

Additional paid-in capital was \$76.6 million as of June 30, 2015, compared to \$36.6 million as of December 31, 2014. The change consists of a contribution of approximately \$1.6 million pursuant to the Debt Conversion Agreement, share-based compensation of \$1.4 million, payments of \$0.2 million of bonuses paid by Presbia Holdings on behalf of the Company and net proceeds of \$36.8 million from the Company's IPO.

#### **(5) Loss per Share**

Unvested share-based payment awards that contain non-forfeitable rights to dividends are participating securities that should be included in computing loss per share using the two-class method. The Company's nonvested restricted shares qualify as participating securities. Basic net loss per ordinary share is calculated by dividing net loss allocated to ordinary shareholders by the weighted average number of ordinary shares outstanding during the reporting period. Diluted net loss allocated to ordinary shareholders per share is calculated based on the weighted average number of ordinary shares

and dilutive potential ordinary shares outstanding during the period. Dilutive potential ordinary shares consist of the shares issuable upon the exercise of options and upon the vesting of restricted shares under the treasury stock method. In net loss periods, basic and diluted net loss per share are identical since the effect of potential ordinary shares is anti-dilutive and therefore excluded.

Basic and diluted loss per share were calculated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
<b>Basic and diluted net loss per share</b>				
Net loss	\$ (5,319)	\$ (6,895)	\$ (9,912)	\$ (9,666)
Net loss allocated to common shareholders	\$ (5,319)	\$ (6,895)	\$ (9,912)	\$ (9,666)
Weighted average shares outstanding - Basic and diluted	13,352	9,167	12,562	9,167
Basic and diluted net loss per share	<u>\$ (0.40)</u>	<u>\$ (0.75)</u>	<u>\$ (0.79)</u>	<u>\$ (1.05)</u>

The aggregate 9,166,667 ordinary shares of the Company as discussed in Note 4 have been reflected as issued and outstanding as June 30, 2014 for purposes of computation of basic and diluted net loss per share. Antidilutive securities, which consist of options and restricted shares that are not included in the diluted net loss per share calculation, consisted of an aggregate of approximately 1,029,069 and 840,202 weighted average shares for the three and six months ended June 30, 2015, respectively.

## (6) Share Based Awards

### Equity Issued by Parent

Prior to January 14, 2015 and the Company's IPO, the Parent granted options to purchase its ordinary shares and granted awards of restricted ordinary shares, to both employees and non-employees of the Company and share-based compensation related to such awards is recognized as expense in the accompanying consolidated financial statements. Information regarding prior period awards is available in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2014. No new options or restricted shares were granted by the Parent during the six month period ended June 30, 2015.

On May 13, 2015, the shareholders of the Parent approved a plan in which all options and unvested restricted shares outstanding as of that date were to become fully vested and, in the case of the options, the expiration date of the options were accelerated to June 15, 2015. On May 13, 2015, approximately 4.7 million options were outstanding and 1.4 million restricted shares were unvested. During the prescribed exercise period, 3,785,000 options were exercised at an exercise price of \$0.08 and 956,250 options were cancelled or forfeited at an average exercise price of \$0.24 per option. Stock-based compensation expense of approximately \$21,000 was recorded in the three month period ended June 30, 2015 in connection with the acceleration of the vesting periods for 665,000 unvested options.

The following table sets forth the Parent's option activity for the six months ended June 30, 2015:

Parent	Number Of Parent's Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
<b>Balance, December 31, 2014</b>	4,835,000	\$ 0.11	
Granted	—	\$ —	
Exercised	(3,860,000)	\$ 0.08	\$ 656
Forfeited/cancelled	(975,000)	\$ 0.24	
<b>Balance, June 30, 2015</b>	<u>—</u>	<u>\$ —</u>	

### Restricted Shares

No restricted shares were granted by the Parent during the six months ended June 30, 2015. As of May 13, 2015, there were 1,400,000 unvested restricted shares of the Parent with a weighted average grant date fair value of \$0.30 per share. Pursuant to the plan to immediately accelerate the vesting periods of the restricted shares adopted on May 13, 2015, approximately \$104,000, using a fair value of \$0.26 per ordinary share, was recognized as stock-based compensation in the three months ended June 30, 2015 in connection with 400,000 unvested shares. The other 1.0 million unvested restricted shares had been fully expensed at the time of grant in 2013.

### Unrecognized Share-based Compensation

As of June 30, 2015, there was no unrecognized stock-based compensation expense related to the awards issued by the Parent.

### **Equity Issued by Presbia PLC**

#### Presbia Incentive Plan

On January 14, 2015, the Company approved a compensation incentive plan (the "Presbia Incentive Plan"). The Presbia Incentive Plan permits the Company to grant awards of options, restricted shares, share appreciation rights, restricted share units, performance shares, performance share units, dividend equivalent rights in respect of awards and other share-based and cash-based awards, including annual and long-term cash incentive awards. A total of 1,800,000 ordinary shares are authorized for issuance under the Presbia Incentive Plan of which approximately 702,000 were available on June 30, 2015 for future grants and awards. The exercise price of each option award shall be determined by the Board of Directors (or a committee thereof) at the date of grant in accordance with the terms of the 2005 Plan, and under the 2005 Plan awards generally vest 20% annually over a five-year period and expire no later than 10 years from the grant date. The Presbia Incentive Plan terminates on January 14, 2025, unless terminated earlier by the board of directors. Awards under the Presbia Incentive Plan may be granted to employees, directors, consultants and other persons who perform services for the Company or a subsidiary of the Company.

The following table shows share-based compensation expense included in the consolidated statements of operations and comprehensive income for the three and six months ended June 30, 2015 and 2014.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Research and development	\$ 81	\$ 52	\$ 107	\$ 135
General and administrative	424	28	1,220	49
Sales and marketing	46	5	76	10
Total	<u>\$ 551</u>	<u>\$ 85</u>	<u>\$ 1,403</u>	<u>\$ 194</u>

### Options

The following table sets forth the Company's option activity for the six months ended June 30, 2015:

<u>Presbia PLC</u>	<u>Number Of Shares</u>	<u>Weighted Average Exercise Price Per Share</u>
<b>Balance, December 31, 2014</b>	—	\$ —
Granted	1,089,000	\$ 9.80
Forfeited/cancelled	(9,750)	\$ 8.63
<b>Balance, June 30, 2015</b>	<u>1,079,250</u>	\$ 9.81
<b>Vested and expected to vest, June 30, 2015</b>	972,000	\$ 9.80
<b>Exercisable, June 30, 2015</b>	92,000	\$ 9.97

### Employee Options

The Company utilizes the Black-Scholes valuation model for estimating the fair value of share-based compensation with the following assumptions. The Company estimated expected life utilizing the simplified method because of its limited history of option exercise activity and its options meet the criteria of the "plain-vanilla" options as defined by the Securities Exchange Commission. The simplified method calculates the expected term as the average of the vesting and contractual terms of the award. The following table presents the grant date assumptions used in the Black-Scholes model for determining the fair value of 1,022,500 employee options issued during the six months ended June 30, 2015:

	<u>Three Months Ended June 30, 2015</u>	<u>Six Months Ended June 30, 2015</u>
Expected life	6.5 years	5.5-6.5 years
Expected volatility	84.5%	76.8% - 84.5%
Expected dividends	0%	0%
Risk-free rate	1.8%	1.3% - 1.8%

The weighted-average grant date fair value of the employee options granted during the six months ended June 30, 2015 was \$6.98 per share. For those options granted to employees, stock-based compensation expense is based upon the fair value of the option as of the grant-date and attributed to future reporting periods on a straight-line basis over the vesting period, or the requisite service period. A 5% forfeiture rate assumption was applied, which reduces the amount of expense recognized each period anticipating that a portion of all options granted will, more likely than not, be cancelled prior to the dates of its vesting periods. The forfeiture rate is subject to review and may be adjusted based upon experience.

### Non-Employee Options

During the six month ended June 30, 2015, 66,500 options were granted to non-employee consultants and medical advisors in which the following assumptions were used in the Black-Scholes valuation model to determine the option fair values:

	<u>Three Months Ended June 30, 2015</u>	<u>Six Months Ended June 30, 2015</u>
Expected life	9.9 years	9.9 years
Expected volatility	78.8%	78.80%
Expected dividends	0%	0%
Risk-free rate	2.4%	1.9% - 2.4%

In contrast to the determination of the fair value of options granted to employees, which are determined based upon the grant-date assumptions and applying the Black-Scholes model, the fair values for non-employee options and the related stock-based compensation expense are remeasured each financial reporting period based upon the assumptions applicable on the dates in which the financial statements are prepared. Because the performance criteria of these grants is based solely upon a requisite service period, but are subject to forfeiture if the service conditions are not met, stock-based compensation expense is determined by a straight-line attribution of the remeasured expense (mark-to-market) over the requisite service subject to a forfeiture rate of 5%.

### Restricted Shares

On March 16, 2015, the Company's board of directors approved grants of 9,270 restricted ordinary shares of the Company each to Robert J. Cresci and to Mark Blumenkranz, both of whom are board members. The aggregate 18,540 shares vest in five equal, annual installments commencing one year after the date of grant. The weighted-average grant date fair value for the restricted shares was estimated using the market price of the ordinary shares on the date of grant (\$8.63 per share on March 16, 2015).

As of June 30, 2015, there were 18,540 restricted shares of the Company outstanding with a weighted average grant date fair value of \$8.63 per share. The Company recorded compensation expense related to restricted shares of approximately \$8,000 and \$9,300 for the three months and six months ended June 30, 2015, respectively. The following table sets forth the Company's restricted share activity for the six months ended June 30, 2015:

<u>Presbia PLC</u>	<u>Number Of Shares</u>	<u>Weighted Average Fair Value Per Share</u>
<b>Balance, December 31, 2014</b>	-	\$ -
Granted	18,540	\$ 8.63
<b>Balance, June 30, 2015</b>	<u>18,540</u>	<u>\$ 8.63</u>
<b>Vested and expected to vest, June 30, 2015</b>	18,540	\$ 8.63
<b>Exercisable, June 30, 2015</b>	-	\$ -

#### Unrecognized Share-based Compensation

As of June 30, 2015, there was \$5.1 million and \$0.4 million of unrecognized compensation expense related to employee and non-employee options of the Company, respectively, which is expected to be recognized by the Company over the weighted average vesting period of 4.0 years. Unrecognized compensation expense related to restricted shares was \$151,000 as of June 30, 2015 and is expected to be recognized over the weighted average vesting period of 4.7 years.

#### **(7) Related Party Transactions**

The following table sets forth the amounts due to related parties reflected in the accompanying consolidated balance sheets:

	<u>June 30, 2015</u>	<u>December 31, 2014</u>
<b>Payable to related parties—current:</b>		
Management services provided by related parties	\$ 59	\$ 12
<b>Total</b>	<u>\$ 59</u>	<u>\$ 12</u>
<b>Payable due to the Parent—noncurrent:</b>		
Principal amounts due to the Parent	\$ —	\$ 417
Accrued interest due to the Parent	—	—
<b>Total</b>	<u>\$ —</u>	<u>\$ 417</u>

#### **(8) Concentration of Credit Risk**

The Company had cash of \$29.8 million and \$138,000 as of June 30, 2015 and December 31, 2014, respectively, which consists of checking account deposits.

#### **(9) Operating Segments and Geographic Information**

The Company has one reportable segment that is evaluated regularly by its chief decision making group in deciding how to allocate resources and in assessing performance.

The following tables set forth the Company's revenues generated from external customers located in foreign countries and long-lived assets by area:

REVENUES	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Ireland	\$ 25	\$ 60	\$ 60	\$ 81
Korea	—	—	36	—
Japan	—	—	—	5
Netherlands	11	—	11	—
Australia	1	—	1	—
Canada	5	1	7	1
Total	<u>\$ 42</u>	<u>\$ 61</u>	<u>\$ 115</u>	<u>\$ 87</u>

LONG-LIVED ASSETS	June 30, 2015	December 31, 2014
U.S.	\$ 771	\$ 716
Foreign	<u>32</u>	<u>31</u>
Total	<u>\$ 803</u>	<u>\$ 747</u>

**(10) Commitments and Contingencies**

From time to time, the Company may be subject to legal proceedings and claims arising in the ordinary course of business. Management does not believe that the outcome of any of these matters will have a material effect on the Company's consolidated financial operations.

**(11) Subsequent Event**

On August 3, 2015, Presbia Holdings, as part of the liquidation plan approved on May 13, 2015 by its shareholders, completed the distribution to its shareholders of 9,666,667 ordinary shares of Presbia PLC and 39,994 of deferred ordinary shares, representing all of its holdings in Presbia PLC.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

We refer to the 2013 Restructuring, the formation and initial capitalization of Presbia PLC, the 2014 Debt Conversion, the 2015 Debt Conversion and the 2015 Capital Contribution, each described in Note 1 of the unaudited consolidated financial statements included in this Quarterly Report on Form 10-Q, collectively, as the Reorganization Transactions. Unless we state otherwise, the terms "we," "us," "our," "Presbia" and the "company" refer to Presbia PLC and its consolidated subsidiaries after giving effect to the Reorganization Transactions. Prior to the completion of the Reorganization Transactions, the foregoing terms refer to the entities that became the consolidated subsidiaries of Presbia PLC upon consummation of the Reorganization Transactions.

Our Management's Discussion and Analysis of Financial Condition and Results of Operations is organized as follows:

- *Overview.* This section provides a general description of our Company and background information on certain trends and developments affecting our Company.
- *Critical Accounting Policies and Estimates.* This section discusses those accounting policies that are considered important to the evaluation and reporting of our financial condition and results of operations, and whose application requires us to exercise subjective or complex judgments in making estimates and assumptions. In addition, all of our significant accounting policies, including our critical accounting policies, are summarized in Note 1, "Summary of Significant Accounting Policies," of our notes to consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.
- *Overview of Results of Operations.* This section provides our analysis and outlook for the significant line items on our consolidated statements of operations and comprehensive income, as well as other information that we deem meaningful to understand our results of operations on a consolidated basis.
- *Liquidity and Capital Resources.* This section provides an analysis of our liquidity and cash flows.

### Overview

We are an ophthalmic device company which has developed and is currently marketing a proprietary optical lens implant for treating presbyopia, the age-related loss of the ability to focus on near objects. Our microlens is a miniature lens designed to be surgically implanted in a patient's eye to improve that patient's ability to see objects at close distances. Our current strategy is to continue to commercialize our microlens in certain strategic countries where we currently have marketing approval and to continue to seek to obtain marketing approval in other key markets, including the United States. Our goal is to become a leading provider of corneal inlay presbyopia-correcting treatment worldwide.

Although reading glasses and contact lenses have historically been, and remain, the most common solution for presbyopia, there are significant drawbacks associated with these approaches, as well as with alternative surgical approaches. We believe that our microlens provides an alternative solution to those presbyopic individuals who desire greater freedom from glasses and wish to avoid the daily maintenance and other complications of contact lenses. We believe that our microlens can be both an effective standalone solution for presbyopia and an effective complementary solution that can be used in conjunction with certain other surgical approaches that are used to treat vision disorders other than presbyopia.

Through our European Union CE Mark, we are generally authorized to market our microlens throughout the European Economic Area (27 of the 28 European Union member states plus Iceland, Liechtenstein and Norway), or EEA, and Switzerland. We currently market our microlens in certain strategic EEA countries as well as certain strategic countries outside of the EEA in which we possess marketing approval.

We are presently seeking marketing approval in other strategic countries, including the United States. In December 2013, we received approval to commence a staged pivotal clinical trial as part of the U.S. Food and Drug Administration, or FDA, approval process. Beginning in May 2014, we enrolled a total of 75 subjects at six investigational sites in the United States and each subject underwent insertion of our microlens in the non-dominant eye. Based on six-month data on 52 subjects, in January 2015, we submitted an interim safety report as a supplement to our investigational device exemption, or IDE, to the FDA. In February 2015, we received approval from the FDA to commence second stage enrollment in this trial. We are permitted to enroll up to an additional 337 subjects at up to nine additional investigational sites. Through July 17, 2015, 201 subjects have undergone insertion of our microlens in the second stage of this study. This trial is necessary in order to obtain clinical data to provide the primary support for a safety and effectiveness evaluation to support a pre-market approval, or PMA, for marketing clearance in the United States. Data on a minimum of 300 subjects

with 24-month data will be submitted as part of the PMA, and all subjects will be followed for three years following implantation. We are targeting submission of our final PMA, containing 24-month data on 300 subjects, to the FDA in the third quarter of 2017. We are pursuing a modular PMA submission strategy whereby we intend to submit to the FDA information regarding preclinical testing, engineering, and manufacturing in the fourth quarter of 2015 or the first quarter of 2016 prior to the submission of our final PMA. We are targeting PMA approval of our micro lenses in the first quarter of 2018. We are also targeting submission to the FDA of a final report with 36-month data on these 300 subjects in the third quarter of 2018.

These milestones could be delayed by further interactions with the FDA or by a variety of other factors. 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.

We are a development stage ophthalmic device company with a limited operating history. We are not profitable and have incurred losses in each year since our formation. We have reported recurring net losses and negative cash flow from operating activities since inception and, as of June 30, 2015, we had an accumulated deficit of \$47.3 million. We expect to continue to incur significant losses for the foreseeable future.

On February 3, 2015, we closed the initial public offering of our ordinary shares. We sold a total of 4,166,667 ordinary shares in the offering at a public offering price of \$10.00 per share. The aggregate public offering price was \$41.7 million, and we received net proceeds of approximately \$36.8 million from the offering, after deducting \$4.9 million of underwriting discounts and commissions and issuance costs.

On May 13, 2015, the ordinary shareholders of Presbia Holdings, our controlling shareholder, approved a voluntary liquidation of Presbia Holdings and the distribution of its assets consisting primarily of 9,666,667 shares of Presbia PLC, of which 500,000 shares were acquired during the initial public offering and 9,166,667 were acquired pursuant to the 2015 Capital Contribution described in Note 1 of the unaudited consolidated financial statements. On May 13, 2015, the shareholders approved a plan that would immediately fully vest all outstanding options and restricted share awards and, in the case of the options, accelerate the expiration date of all such options to June 15, 2015. On August 3, 2015, the distribution of the 9,666,667 shares of PLC to the ordinary shareholders of Presbia Holdings was completed.

### **Critical Accounting Policies and Estimates**

The discussion and analysis of our consolidated financial statements and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, costs and expenses and related disclosures. We have based and will base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. In many instances, we could have reasonably used different accounting estimates, and in other instances changes in the accounting estimates are reasonably likely to occur from period to period. Accordingly, actual results could differ significantly from the estimates made by our management. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

We describe our significant accounting policies in Note 2, "Summary of Significant Accounting Policies," of our notes to consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2014. We discuss our critical accounting policies and estimates in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," of our Annual Report on Form 10-K for the year ended December 31, 2014. There have been no material changes in our significant accounting policies or critical accounting policies and estimates since the end of calendar year 2014.

## Results of Operations

### Comparison of the Three and Six Months Ended June 30, 2015 and June 30, 2014.

	Three Months Ended June 30,		Change	%
	2015	2014		
Revenues	\$ 42	\$ 61	\$ (19)	-31.1%
Cost of goods sold	14	33	(19)	-57.6%
Operating expenses:				
Research and development	2,502	1,676	826	49.3%
Sales and marketing	834	394	440	111.7%
General and administrative	2,007	4,272	(2,265)	-53.0%
Operating loss	(5,315)	(6,314)	999	-15.8%
Interest expense	—	584	(584)	-100.0%
Other income	—	(6)	6	-100.0%
Loss before income tax provision	(5,315)	(6,892)	1,577	-22.9%
Income tax provision	4	3	1	33.3%
Net loss	\$ (5,319)	\$ (6,895)	\$ 1,576	-22.9%

	Six Months Ended June 30,		Change	%
	2015	2014		
Revenues	\$ 115	\$ 87	\$ 28	32.2%
Cost of goods sold	61	39	22	56.4%
Operating expenses:				
Research and development	4,278	2,407	1,871	77.7%
Sales and marketing	1,353	643	710	110.4%
General and administrative	4,326	5,648	(1,322)	-23.4%
Operating loss	(9,903)	(8,650)	(1,253)	14.5%
Interest expense	—	1,017	(1,017)	-100.0%
Other income	—	(6)	6	-100.0%
Loss before income tax provision	(9,903)	(9,661)	(242)	2.5%
Income tax provision	9	5	4	80.0%
Net loss	\$ (9,912)	\$ (9,666)	\$ (246)	2.5%

#### Revenue

Revenue for the three months ended June 30, 2015 was \$42,000 as compared to \$61,000 for the corresponding period in 2014. The reduction of \$19,000 is primarily attributable to \$35,000 in less revenue in Ireland, offset partially by \$11,000 higher revenue in the Netherlands, a new market for the microlens. For the six month period ended June 30, 2015, revenue was \$28,000 greater than the corresponding period in 2014 due principally to higher revenue in South Korea of \$36,000, a new market for the microlens, \$11,000 higher revenue in the Netherlands, offset partially by a revenue decrease of \$21,000 in Ireland. Unless and until we receive FDA approval to sell and market our microlens within the United States, we are focusing our sales and marketing resources to sell our microlens to refractive laser centers outside the United States.

#### Cost of Goods Sold

Cost of goods sold was \$14,000 for the three months ended June 30, 2015 as compared to \$33,000 in the three months ended June 30, 2014, or a decrease of \$19,000, compared to a \$19,000 decline in revenue for the same period. Cost of sales includes inventory adjustments, such as a provision for inventory obsolescence, which can fluctuate from period to period depending upon the mix, the current shelf life of lens inventory in relation to our regulated policy and the size of our finished goods inventory. During the three months ended June 30, 2015 and 2014, we recorded additional provisions for inventory obsolescence of \$9,000 and \$31,600, respectively. For the six month period ended June 30, 2015 and 2014, cost of goods sold was \$61,000 and \$39,000, respectively, or an increase of \$22,000 compared to a \$28,000 increase in revenue for the same periods. Provisions for inventory reserves was \$44,000 and \$31,600 for the corresponding periods.

### *Research and Development*

Research and development expense increased by \$0.8 million, or 49%, for the three months ended June 30, 2015 as compared to the same period in 2014. The increase is primarily due to (i) a \$0.4 million cost increase related to our U.S. staged pivotal clinical trials attributed to up to 337 subjects in Phase II as compared to a maximum of 75 subjects in Phase I of the pivotal trial, (ii) \$0.3 million in higher surgical training costs related to the Phase II study, and (iii) a \$0.1 million increase in product development costs related to the development of an upgraded inserter. In February 2015, we received approval from the FDA to commence the second phase of the staged clinical trials. For the six months ended June 30, 2015, research and development costs increased by \$1.9 million, or 78%, as compared to the six month period ended June 30, 2014, primarily attributable to (i) a \$1.0 million increase in spending on the Phase II clinical trials with respect to patient recruiting costs, surgeon fees and contract research organization fees required to carry out the trials and test equipment located at investigational sites required to measure the results of the clinical trials, (ii) product development and regulatory cost increases of \$0.3 million, (iii) increase of \$0.1 million in the manufacturing center dedicated to the clinical trials overall and (iv) a \$0.5 million increase in surgical training costs related to the Phase II clinical trials.

### *Sales and Marketing*

Sales and marketing expense increased by \$0.4 million, or 112%, for the three months ended June 30, 2015 as compared to the three months ended June 30, 2014. The increase is a result of higher sales and marketing personnel costs, advertising and promotional costs to attract new clients for our product outside of the United States and travel expenses related to supporting clients outside the United States. Sales and marketing expense increased by \$0.7 million, or 110%, for the six months ended June 30, 2015 as compared to the six months ended June 30, 2014. The increase is a result of higher sales and marketing personnel costs and travel expenses related to opening up new markets in South Korea and the Netherlands and increased corporate marketing spending by \$0.3 million.

### *General and Administrative*

General and administrative expense declined by \$2.3 million, or 53%, for the three months ended June 30, 2015 as compared to the same period in 2014. The change is due primarily to a one-time \$3.4 million write-off of deferred offering costs related to a delay in our initial public offering beyond a 90 day period in the second quarter of 2014. The initial public offering process was restarted in September 2014 and was concluded in February 2015. Excluding the one-time write-off of \$3.4 million, general and administrative expenses increased by \$1.1 million in the second quarter of 2015 as compared to 2014 due primarily to the expected higher costs of being a public registrant and consisting of (i) higher share-based compensation costs of \$0.4 million related to option grants issued at the time of the initial public offering, (ii) higher salaries and wages of \$0.2 million, (iii) increased professional fees, including auditing and legal services of \$0.3 million, (iv) higher directors and officer insurance premiums of \$0.1 million and (v) higher outside services of \$0.1 million related to public company activities such as printing costs and proxy materials and services. For the six month period ended June 30, 2015 as compared to the same period of 2014, and excluding the one-time write-off of \$3.4 million discussed above, general and administrative expenses increased by \$2.1 million, consisting of (i) higher share-based compensation costs of \$1.1 million related to option grants issued at the time of the initial public offering and a portion of these options vesting on the date of the grant, (ii) higher salaries and wages of \$0.3 million, (iii) increased professional fees including auditing and legal services of \$0.3 million, (iv) higher directors and officer insurance premiums of \$0.2 million and (v) higher outside services and other expenses of \$0.2 million related to public company activities such as printing costs and proxy materials and services.

### *Interest Expense*

Interest expense decreased by \$0.6 million and \$1.0 million, or 100%, respectively, for the three and six months ended June 30, 2015, respectively, compared to the same periods in 2014. For the three months and six months ended June 30, 2014, interest expense of \$0.6 million and \$1.0 million, respectively, was based on an average principle due Presbia Holdings of approximately \$16.4 million for the three months ended June 30, 2014 and \$13.7 million for the six month period ended June 30, 2014, at an annual rate of 15% compounded daily. Subsequently, on November 30, 2014 and on January 14, 2015, Presbia Holdings converted all the indebtedness we owed to Presbia Holdings at those times to equity. Also, on November 30, 2014, we entered into an Interest Rate Agreement with Presbia Holdings wherein any future borrowings from Presbia Holdings would accrue interest at a rate equal to the then applicable monthly federal rate of interest for short-term loans, adjusted monthly, compounding daily.

### Net Loss

Our net loss of \$5.3 million and \$9.9 million for the three and six months ended June 30, 2015, respectively, was \$1.6 million less, or 23% less, and \$0.2 million greater, or 2% greater, respectively, than the net losses in the corresponding periods in 2014. We expect that losses will continue through 2015 and 2016, and possibly further, due to anticipated costs related to our U.S. staged pivotal clinical trial and ongoing costs required to develop the market outside of the United States for our microlens.

### Liquidity and Capital Resources

On February 3, 2015, we completed the initial public offering of our ordinary shares. We sold a total of 4,166,667 ordinary shares at a public offering price of \$10.00 per share. At June 30, 2015, we had cash of \$29.8 million, reflecting a \$29.7 million increase from our cash balance at December 31, 2014 of \$0.1 million. The increase primarily reflects the net proceeds from our initial public offering of approximately \$36.8 million.

Our primary uses of cash are to fund operating expenses, primarily general and administrative expenditures and research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Our future capital requirements are difficult to forecast and will depend on many factors, including:

- the initiation, progress, timing, costs and completion of clinical trials for our products;
- the number and characteristics of products that we market and sell;
- the outcome, timing and cost of regulatory approvals; and
- delays that may be caused by changing regulatory requirements.

The following table summarizes our cash flows for the periods indicated:

	Six Months Ended June 30,	
	2015	2014
Net cash used in operating activities	\$ (7,703)	\$ (5,237)
Net cash used in investing activities	\$ (97)	\$ (120)
Net cash provided by financing activities	\$ 37,468	\$ 5,136

Prior to the consummation of our initial public offering on February 3, 2015, we relied on funding from Presbia Holdings to fund all of our operations including offering costs to complete our initial public offering. At June 30, 2015, we had an accumulated deficit of approximately \$47.3 million and we expect to incur additional operating losses during fiscal years 2015 and 2016, and possibly further. As we continue to incur losses, our transition to profitability will depend on the successful development, approval and commercialization of our microlens in the U.S. and the successful commercialization of our microlens in those jurisdictions outside the United States in which we have or seek marketing approval. We may never achieve profitability, and unless and until we do, we will need to continue to raise additional capital. With existing cash at June 30, 2015, we expect to be able to fund our operations and have sufficient cash reserves for the next 12 months.

### Contractual Obligations

The following table summarizes our contractual obligations as of June 30, 2015 and the effect that such obligations are expected to have on our liquidity and cash in future periods.

Contractual Obligations	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 Years	Total
Operating lease obligations	\$ 197	\$ 110	\$ —	\$ —	\$ 307
Total	\$ 197	\$ 110	\$ —	\$ —	\$ 307

### Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate and foreign exchange sensitivities as follows:

#### *Interest Rate Risk*

We had cash of \$29.8 million and \$138,000 as of June 30, 2015 and December 31, 2014, respectively, which consists of checking account deposits. Historically, we have maintained minimal cash balances. Our levels of interest income on the unused balances will continue to be subject to fluctuations in market interest rates.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. We have not been exposed nor do we anticipate being exposed to material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

From January 1, 2015 to the consummation of our initial public offering on February 3, 2015, we funded our operations through borrowings from Presbia Holdings, at an interest rate equal to the then applicable monthly federal rate of interest for short-term loans, adjusted monthly, compounding daily.

#### *Transaction Risk*

We may be exposed to transaction risk because some of our expenses will be incurred in a different currency than our reporting currency, the U.S. Dollar. To date, we have not attempted to offset our exposure to this risk by investing in derivatives or engaging in other hedging transactions.

### **ITEM 4. CONTROLS AND PROCEDURES**

#### **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and Chief Accounting Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report on Form 10-Q. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on such evaluation, our Chief Executive Officer and Chief Accounting Officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective.

#### **Changes in Internal Control over Financial Reporting**

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended June 30, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

We are not aware of any pending or threatened legal proceeding against us that could have a material adverse effect on our business, operating results or financial condition. However, the medical device industry is characterized by frequent claims and litigation, including claims regarding patent and other intellectual property rights as well as improper hiring practices. As a result, we may be involved in various legal proceedings from time to time.

### **ITEM 1A. RISK FACTORS**

Please refer to "Part I, Item 1A. Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2014, filed with the Securities and Exchange Commission on March 31, 2015, and "Part II, Item 1A. Risk Factors" of our

Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed with the Securities and Exchange Commission on May 15, 2015, for a description of certain significant risks and uncertainties to which our business, operations and financial condition are subject. There have been no material changes to the risk factors disclosed in these Securities and Exchange Commission reports.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

***Use of Proceeds from Initial Public Offering of Ordinary Shares***

On January 28, 2015, our registration statement on Form S-1 (File No 333-194713), as amended, was declared effective by the SEC for our initial public offering. Upon the closing of our initial public offering on February 3, 2015, we sold 4,166,667 ordinary shares, \$0.001 par value per share, at a public offering price of \$10.00 per share, for an aggregate public offering price of \$41.7 million.

There has been no material change in the use or planned use of proceeds from our initial public offering from that described in the final prospectus related to the offering, which we filed with the SEC on January 29, 2015.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not Applicable

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Exhibit Description</b>
31.1+	Certification of Principal Executive Officer Required by Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of Principal Financial Officer Required by Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer and Chief Accounting Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS+	XBRL Instance
101.SCH+	XBRL Taxonomy Extension Schema
101.CAL+	XBRL Taxonomy Extension Calculation
101.DEF+	XBRL Taxonomy Extension Definition
101.LAB+	XBRL Taxonomy Extension Label
101.PRE+	XBRL Taxonomy Extension Presentation

+ Indicates filed herewith.

\* Indicates 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 thereunto duly authorized.

PRESBIA PLC

Date: August 6, 2015

By: /s/ Todd Cooper

Todd Cooper  
President and Chief Executive Officer

Date: August 6, 2015

By: /s/ Richard Fogarty

Richard Fogarty  
Chief Accounting Officer,  
Vice President, Finance and Secretary

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER REQUIRED BY  
RULE 13A-14(A) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Todd Cooper, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Presbia PLC;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 6, 2015

By: /s/ Todd Cooper  
Todd Cooper  
Chief Executive Officer

**CERTIFICATION OF PRINCIPAL ACCOUNTING OFFICER REQUIRED BY  
RULE 13A-14(A) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Richard Fogarty, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Presbia PLC;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 6, 2015

By: /s/ Richard Fogarty  
Richard Fogarty  
Chief Accounting Officer

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF ACCOUNTING OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Presbia PLC (the "Company") for the quarterly period ended June 30, 2015 (the "Report"), the undersigned hereby certify in their capacities as Chief Executive Officer and Chief Accounting Officer of the Company, respectively, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 6, 2015

By: /s/ Todd Cooper

Todd Cooper  
Chief Executive Officer  
(Principle Executive Officer)

Date: August 6, 2015

By: /s/ Richard Fogarty

Richard Fogarty  
Chief Accounting Officer  
(Principle Accounting Officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signatures that appear in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

