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

FORM 10-Q

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

For the quarterly period ended September 30, 2018

or

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

Commission file number: 001-36824

PRESBIA PLC

(Exact name of registrant as specified in its charter)

Ireland	**98-1162329**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
Suite 7, Sandyford Office Centre, 17 Corrig Road, Sandyford, Dublin 18 Ireland	
(Address of principal executive offices)	(Zip Code)

+353 (1) 551 1487
(Registrant's telephone number, including area code)

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 every Interactive Data File required to be submitted 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 such files). ☒ Yes ☐ No

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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 November 13, 2018 was 17,157,160 shares, $0.001 par value per share.

PRESBIA PLC

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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 timing, progress and results of our U.S staged pivotal clinical trial and our regulatory submissions;
- our ability to advance our microlens and successfully complete our U.S. staged pivotal clinical trial;
- our ability to obtain pre-market approvals;
- the commercialization of our microlens outside the U.S.;
- our ability to continue as a going concern;
- our anticipated cash needs and our needs for additional financing;
- 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, 2017, filed with the Securities and Exchange Commission (”SEC”) on March 30, 2018 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. CONDENSED CONSOLIDADTED FINANCIAL STATEMENTS

PRESBIA PLC
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share data and par value amount)

	September 30, 2018	December 31, 2017
Assets	(unaudited)	
Current assets		
Cash	$ 1,428	$ 3,236
Accounts receivable	12	8
Inventory, net	68	127
Prepaid expenses and other current assets	277	108
Total current assets	1,785	3,479
Property and equipment, net	388	477
Intangible asset, net	1,378	1,479
Other assets	89	127
Total assets	$ 3,640	$ 5,562
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 738	$ 628
Due to related parties	23	23
Note payable	498	480
Other current liabilities	364	1,151
Total current liabilities	1,623	2,282
Deferred rent	92	107
Due to related parties, net of current portion	—	12
Other liabilities, net of current portion	23	30
Total liabilities	1,738	2,431
Shareholders' equity		
Preferred Shares		
Series A Redeemable Preferred Shares; $0.001 par value, 50,000,000 shares authorized; 100 and 0 shares issued and outstanding at September 30, 2018 and December 31, 2017	—	—
USA Preferred Shares; $0.01 par value, 8,000 shares authorized; 4,900 and 0 shares issued and outstanding at September 30, 2018 and December 31, 2017	—	—
Ordinary Shares		
$0.001 par value, 350,000,000 shares authorized; 17,157,160 and 17,121,857 shares issued and outstanding at September 30, 2018 and December 31, 2017	17	17
Deferred ordinary Shares		
€1.00 (US$1.35) par value, 39,994 shares authorized, issued and outstanding at September 30, 2018 and December 31, 2017	54	54
Additional paid-in capital	96,646	91,362
Accumulated deficit	(94,815)	(88,302)
Total shareholders' equity	1,902	3,131
Total liabilities and shareholders' equity	$ 3,640	$ 5,562

See accompanying notes to these consolidated financial statements.

PRESBIA PLC
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)
(Unaudited)

	Three-Months Ended September 30,		Nine-Months Ended September 30,	
	2018	2017	2018	2017
Revenues	$ 12	$ 8	$ 19	$ 13
Cost of goods sold	2	12	50	40
Gross profit (loss)	10	(4)	(31)	(27)
Operating expenses:				
Research and development	965	2,066	2,647	5,930
Sales and marketing	359	1,017	1,071	2,794
General and administrative	1,140	1,627	2,896	5,030
Total operating expenses	2,464	4,710	6,614	13,754
Operating loss	(2,454)	(4,714)	(6,645)	(13,781)
Other (expense) income	-	—	(10)	—
Interest expense	(11)	(6)	(30)	(24)
Loss before income tax provision	(2,465)	(4,720)	(6,685)	(13,805)
Income tax provision (benefit)	(215)	20	(172)	61
Net loss	$ (2,250)	$ (4,740)	$ (6,513)	$ (13,866)
Net loss per ordinary share-basic and diluted	$ (0.13)	$ (0.28)	$ (0.38)	$ (0.86)
Weighted average shares outstanding - basic and diluted	17,110,677	16,963,468	17,065,382	16,071,419

See accompanying notes to these consolidated financial statements.

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

	Nine-Months Ended September 30,	
	2018	2017
Cash flow from operating activities:		
Net loss	$ (6,513)	$ (13,866)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	186	251
Inventory provisions	45	40
Stock-based compensation	382	1,602
Gain on disposition of fixed assets	10	—
Imputed interest expense	32	62
Changes in operating assets and liabilities:		
Accounts receivable	(4)	(9)
Inventory	14	57
Prepaid expenses and other current assets	(169)	70
Other assets	39	(1)
Accounts payable and other current liabilities	(465)	949
Income taxes payable	(223)	63
Deferred rent	(16)	58
Due to related parties	—	1
Net cash used in operating activities	(6,682)	(10,723)
Cash flow from investing activities:		
Purchases of intangible assets	(2)	(117)
Purchases of property and equipment	—	(18)
Net cash used in investing activities	(2)	(135)
Cash flow from financing activities:		
Proceeds from issuance of ordinary shares from rights offering, net of costs	—	10,534
Proceeds from issuance of preferred shares, net of costs	4,890	—
Net cash provided by financing activities	4,890	10,534
Net decrease in cash	(1,794)	(324)
Effect of exchange rate on cash	(14)	51
Cash balance at beginning of period	3,236	7,333
Cash balance at end of period	$ 1,428	$ 7,060

See accompanying notes to these consolidated financial statements.

(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 wholly-owned subsidiary of Presbia PLC organized in the Cayman Islands, and Presbia Ireland, Limited's subsidiaries, Presbia Deutchland GmbH, Presbia USA, Inc., and OPL, LLC. Presbia Deutchland GmbH is organized in Germany, and 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 ("GAAP"). 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.

Basis of Presentation. The accompanying unaudited consolidated financial statements as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017, respectively, have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") for interim financial reporting, and with the instructions to Form 10-Q and Article 8 of Regulation S-X. The accompanying consolidated balance sheet at December 31, 2017 has been derived from the audited consolidated balance sheet at December 31, 2017, contained in the annual report on Form 10-K for the year ended December 31, 2017. 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, 2017, filed with the Securities and Exchange Commission on March 30, 2018. 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

At September 30, 2018, the Company has an accumulated deficit of $94.8 million and it expects to incur significant additional future operating losses. As it continues to incur losses, the Company's transition to profitability will depend on the successful development, approval and commercialization of its microlens. On October 5, 2018, the Company received notification from the FDA that 36-month data on all subjects enrolled in the Company's staged pivotal clinical trial, including additional safety and efficacy related information, is required before the FDA can complete its review of the Company's PMA. The Company must respond by April 3, 2019, otherwise it must amend the PMA within the 180-day period to request an extension of time to respond. In light of the FDA's typical 180-day review period following the Company's anticipated response date of April 3, 2019, the Company does not anticipate PMA approval prior to the fourth quarter 2019. The foregoing targeted milestones and associated estimated timeframes could be delayed by further interactions with the FDA or by a variety of other factors, including requests for further safety and efficacy related information pertaining to our microlens ophthalmic device. To continue to pursue FDA pre-market approval, the Company will need to raise funds in the fourth quarter of 2018. Based on the Company's current business plan, management believes that its cash and cash equivalents at September 30, 2018 will not be sufficient to meet its anticipated cash requirements during the twelve-month period subsequent to the issuance of the financial statements included in this Quarterly Report on Form 10-Q nor even for the next three months. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year from the date this Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC). The Company's current commercialization strategy is targeted to countries where the Company can establish the market for its technology. This commercialization strategy will undergo continual prioritization and in the future the Company may adjust its commercialization efforts to preserve its existing cash or realize better results than anticipated which could have a positive impact on cash. The Company's U.S. pivotal clinical trial and planned FDA approval is its highest priority. The Company must raise additional capital to fund its operations. It plans to raise additional capital through equity offerings, debt financings, collaborations and/or licensing arrangements. Additional funds may not be available when the Company needs them on terms that are acceptable to the Company, or at all. If adequate funds are not available on acceptable terms, the Company may be required to delay, reduce the scope of,

or curtail, its operations. To the extent that the Company raises additional funds by issuing equity securities, its shareholders will experience dilution, and debt financing, if available, may involve restrictive covenants. The Company may never achieve profitability, and unless and until it does, it will need to continue to raise additional capital.

(2) Summary of Significant Accounting Policies

During the nine months ended September 30, 2018 there have been no changes to the Company's significant accounting policies as described in the Annual Report on Form 10-K for the fiscal year ended December 31, 2017, other than the adoption of the new revenue recognition standard noted below.

Revenue Recognition

Prior to 2018, we recognized revenue when there is persuasive evidence that an arrangement exists with our customers, selling prices are fixed or determinable, title or risk of loss has passed, and collection is reasonably assured. Revenue was recognized upon shipment and payments are either received in advance, or net 30 days for lenses or net 14 days for accessories. Distributor arrangements included certain perfunctory acceptance provisions and a one-year warranty, from the date of shipment, that products are free from defects in material workmanship. Under such provisions customers may reject shipments via written notifications ranging from 14-45 days or exchange defective product under warranty for the same non-defective product. We have not had any significant rejected shipments or warranty claims. We did not grant price concessions to our distributors.

In 2012, we changed our commercialization strategy from exclusively using distributors to also targeting refractive laser centers equipped with femtosecond lasers, except in countries that require the use of distributors or sales representatives. In December 2017, in light our re-ordering of operational priorities, we have focused our commercialization and clinical trial efforts outside of the U.S. in Germany and South Korea, including established ophthalmic clinics in those countries. We recognize revenue from laser centers and ophthalmic clinics based upon an analysis of the terms of each customer arrangement and upon determination that persuasive evidence of an arrangement exists, selling prices are fixed or determinable, title or risk of loss has passed, and collection is reasonably assured. Revenues from laser centers and ophthalmic clinics during the three and nine months ended September 30, 2018 and 2017 were not material.

Effective January 1, 2018, the Company adopted the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers ("ASC 606"), using the modified retrospective transition method. Under this method, the Company recognizes revenue based on an analysis of the goods and services provided to our customers in the ordinary course. We analyze all commercial agreements to identify (i) contracts and arrangements with customers that meet the criteria for revenue recognition under the new standard (ii) identify all performance obligations under the contractual arrangement, such as the delivery of our Microlens to our customers and any other deliverable(s) as defined in a commercial arrangement (iii) the determination of the transaction price and the allocation of such pricing over the defined contractual obligations in the contract with the customer and (iv) the recognition of revenue once the customer has assumed control over the contractual obligations. Control refers to the ability on the part of the customer to obtain substantially all the benefits of possession of the delivered product or service.

Foreign Currency

The functional currency of subsidiaries outside the United States of America is the U.S. Dollar. Transactions in foreign currencies during the year are re-measured at rates of exchange on the dates of the transactions. Gains and losses related to re-measurement of items arising through operating activities are accounted for in the statement of operations and comprehensive loss and included in general and administrative expense. Aggregate foreign exchange gains and losses are included in the Condensed Consolidated Statement of Operations. Aggregate foreign exchange gain was $12,000 and $19,000 for the three months ended September 30, 2018 and 2017, respectively. Aggregate foreign exchange loss was $12,000 and $60,000 for the nine months ended September 30, 2018 and 2017, respectively.

Comprehensive Loss

Comprehensive income or loss is defined as a change in equity of a company attributable to all transactions excluding those transactions resulting from investment with owners and distributions to owners. There were no differences between net loss and comprehensive loss in the three and nine months ended September 30, 2018 and 2017.

Future Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). The new standard requires lessees to recognize most leases on their balance sheets as lease liabilities with corresponding right-of-use assets and eliminates certain real estate-specific provisions. ASU 2016-02 will be effective for the Company in the first quarter of 2019. ASU 2016-02 will be adopted on a modified retrospective transition basis for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. Although the Company is currently evaluating the full impact of ASU 2016-02 on its consolidated financial statements, upon adoption of ASU 2016-02 the Company anticipates that its operating leases will be recognized on the balance sheet as a lease liability if certain criteria is met, with a corresponding right of use asset.

In February 2018, the FASB issued ASU 2018-02, Income Statement—Reporting Comprehensive Income (Topic 220)—Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income. This update was issued to address the income tax accounting treatment of the stranded tax effects within other comprehensive income due to the prohibition of backward tracing due to an income tax rate change that was initially recorded in other comprehensive income. This issue came about from the enactment of the Tax Cuts and Jobs Act on December 22, 2017, which changed the Company's income tax rate from 35% to 21%. The ASU changed current accounting whereby an entity may elect to reclassify the stranded tax effect from accumulated other comprehensive income to retained earnings. The ASU is effective for periods beginning after December 15, 2018, although early adoption is permitted. The Company does not anticipate that the adoption of this ASU will have a material impact on its consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. The new standard expands the scope of Topic 718 to include all share-based payment transactions for acquiring goods and services from nonemployees. ASU No. 2018-07 specifies that Topic 718 applies to all share-based payment transactions in which the grantor acquires goods and services to be used or consumed in its own operations by issuing share-based payment awards. ASU NO. 2018-07 also clarifies that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under ASC 606. ASU No. 2018-07 will be effective for the Company beginning after December 15, 2019, with early adoption permitted, but no earlier than the Company's adoption of ASC 606. The Company is currently assessing the potential impact of adopting this guidance on its consolidated financial statements.

Recent Accounting Standards

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606). The new standard is based on the principle that revenue should be recognized 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. ASU 2014-09 became effective for the Company in the first quarter of 2018 and allowed for full retrospective or a modified retrospective adoption approach. The Company adopted this new standard in January 2018 and it did not have a material adjustment on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows*, which clarifies the classification of certain cash receipts and payments. The specific cash flow issues addressed by ASU 2016-15, with the objective of reducing the existing diversity in practice, are as follows: (1) Debt prepayment or debt extinguishment costs; (2) Settlement of zero-coupon debt instruments or other debt instruments with insignificant coupon interest rates; (3) Contingent consideration payments made after a business combination; (4) Proceeds from the settlement of insurance claims; (5) Proceeds from the settlement of corporate-owned life insurance policies; (6) Distributions received from equity method investees; (7) Beneficial interest in securitization transactions; and (8) Separately identifiable cash flows and application of the predominance in principle. ASU 2016-15 became effective for fiscal years beginning after December 15, 2017. The Company adopted this new standard in January 2018 and it did not have a material impact on its consolidated financial statements.

In October 2016, the FASB issued ASU. 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other than Inventory.* This update requires entities to recognize the income tax consequences of an intra-entity transfer of an asset

other than inventory when the transfer occurs. This update is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted as of the beginning of a fiscal year. The new standard must be adopted using a modified retrospective transition method, which is a cumulative-effective adjustment to retained earnings as of the beginning of the first effective reporting period. The Company adopted this new standard in January 2018 and it did not have a material impact on its consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting,* which provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. This update is effective for annual reporting periods beginning after December 15, 2017. Early adoption is permitted. The Company adopted this ASU in January 2018 and it did not have a material impact on its consolidated financial statements.

(3) Loss per Share

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, excluding unvested restricted stock awards. 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 for the three and nine months ended September 30, 2018 and 2017 were calculated as follows:

	Three-Months Ended September 30,		Nine-Months Ended September 30,	
	2018	2017	2018	2017
Net Loss	$ (2,250)	$ (4,740)	$ (6,513)	$ (13,866)
Weighted average shares outstanding - basic and diluted	17,110,677	16,963,468	17,065,382	16,071,419
Net loss per ordinary share - basic and diluted	$ (0.13)	$ (0.28)	$ (0.38)	$ (0.86)

Antidilutive securities, which consist of options and unvested restricted shares that are not included in the diluted net loss per share calculation, consisted of an aggregate of 1,456,219 and 1,048,859 weighted average shares for the three months ended September 30, 2018 and 2017, respectively and 1,091,751 and 1,097,068 for the nine months ended September 30, 2018 and 2017, respectively.

(4) Equity Based Awards

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 2,500,000 ordinary shares are authorized for issuance under the Presbia Incentive Plan of which approximately 254,693 were available on September 30, 2018 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 Presbia Incentive 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 based upon all equity awards issued by Presbia PLC included in the Consolidated Statements of Operations for the three and nine months ended September 30, 2018 and 2017. The Company recorded a credit of $23,000 and $547,000 as a result of the reversal of stock-based compensation

for participants whose relationship with the Company terminated in the three and nine months ended September 30, 2018, respectively.

	Three-Months Ended September 30,		Nine-Months Ended September 30,	
	2018	2017	2018	2017
Research and development	$ 39	$ 135	$ (188)	$ 377
General and administrative	304	446	479	1,087
Sales and marketing	31	(17)	91	138
	$ 374	$ 564	$ 382	$ 1,602

Options

The following table sets forth the Company's option activity for the nine months ended September 30, 2018:

	Number of Presbia PLC Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Balance, January 1, 2018	849,100	$ 9.77	—
Granted	678,943	2.19	—
Exercised	—	—	—
Forfeited/cancelled/expired	(163,250)	$ 8.41	—
Balance, September 30, 2018	1,364,793	$ 6.16	—
Vested, September 30, 2018	667,350	$ 9.80	—
Non Vested, September 30, 2018	697,443	$ 2.68	—
Exercisable, September 30, 2018	667,350	$ 9.80	—

Employee Options

The Company utilizes the Black-Scholes valuation model for estimating the fair value of granted stock options with the following assumptions in addition to the closing price of the Company's ordinary shares on the date of the grant: (i) the Company estimates the expected term of the option utilizing the simplified method because of its limited history of option exercise activity and its options meet the criteria of a "plain-vanilla" option as defined by the Securities Exchange Commission (ii) due to its limited stock price volatility history, the Company uses a peer group average as permitted under Accounting Standards Codification ("ASC") 718 consistent with the expected term of the stock option at the time of the grant and (iii) applies a risk-free interest rate based on the U.S. Treasury securities yield consistent with the expected term of the option at the time of the grant. The simplified method calculates the expected term as the average of the weighted average vesting period and contractual terms of the award.

For those options granted to employees, stock-based compensation expense was 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. The Company adopted ASU 2016-09 on January 01, 2018, electing to account for forfeitures when they occur. The Company issued 314,000 and 679,000 options to employee and directors during the three and nine months ended September 30, 2018. Options granted to employees in 2018 vest 20% annually over a five-year period and expire 6.75 years from the grant date. Options granted to directors in in 2018 have a one-year vesting period and expire 6.75 years from the grant date. The Company did not issue employee options during the three and nine months ended September 30, 2017.

Non-Employee Options

During the three and nine months ended September 30, 2018 and 2017, the Company did not grant options to non-employee consultants and medical advisors. Grants issued prior to 2017 were fully vested as of September 30, 2018. 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, which are disclosed in the following table:

	Three-Months Ended September 30,		Nine-Months Ended September 30,	
	2018	2017	2018	2017
Stock price per share	—	$2.38 -$2.83	$0.85 -$1.95	$1.31 -$2.83
Expected term	—	7.7 - 7.9 Yrs.	6.6 - 7.4 Yrs.	7.7 - 8.3 Yrs.
Volatility	—	69.3% - 78.7%	72.9% - 77.3%	69.3% - 85.8%
Dividends	—	—	—	—
Risk-free rate	—	2.20%	2.6% - 2.8%	2.2% - 2.3%

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 period subject to an adjustment to previously recognized expense in the event forfeitures occur.

Restricted Shares

The following table sets forth the Company's restricted share activity for the nine months ended September 30, 2018:

	Unvested Number of Shares	Weighted Average Fair Value per Share
Balance, December 31, 2017	134,367	$ 3.78
Granted	23,255	2.2
Vested	(115,180)	3.2
Forfeited/cancelled	—	—
Unvested, September 30, 2018	42,442	$ 5.45

During the three and nine-month periods ended September 30, 2018, 0 and 23,255 restricted shares were awarded.

Restricted Share Units

During the three and nine months ended September 30, 2018, the Board of Directors awarded 170,000 restricted share units ("RSU" or "RSU's" or "RSU Plan") to officers and employees in accordance with the guidelines provided by the Presbia Incentive Plan, which includes a performance provision as well as a provision that the recipient must be employed as a condition of vesting.

The following table sets forth the Company's RSU activity for the nine months ended September 30, 2018:

	Unvested Number of Shares	Weighted Average Fair Value per Share
Balance, December 31, 2017	739,000	$ 2.09
Granted	170,000	$ 2.00
Vested	—	—
Forfeited/cancelled	(234,500)	2.75
Unvested, September 30, 2018	674,500	$ 1.27

Unrecognized Share-based Compensation

As of September 30, 2018 and 2017, there were $965,000 and $2,484,000, respectively, of unrecognized compensation expense related to employee and non-employee options of the Company, which collectively is expected to be recognized

by the Company over the weighted average vesting period of 2.0 and 1.6 years, respectively. Unrecognized compensation expense for the same periods related to restricted shares was $203,000 and $453,000, respectively, and is expected to be recognized over the weighted average vesting periods of 1.7 and 1.5 years, respectively. As of September 30, 2018 and 2017, there was approximately $593,000 and 7,265,000 of unrecognized compensation expense with respect to the RSU's over a weighted average remaining derived service period of 1.9 and 2.2 years, respectively.

(5) Concentration of Credit Risk

The Company had cash of $1.4 million and $3.2 million as of September 30, 2018 and December 31, 2017, respectively, which consists of checking account deposits. The Company maintains cash balances at financial institutions located in the United States and secured by the Federal Deposit Insurance Corporation up to $250,000.

As of September 30, 2018, 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' revenues are derived from foreign customers.

With respect to suppliers for the microlens, the Company had a five-year supplier agreement that expired in January 2017 with a lens manufacturer in Israel from which the Company received 100% of its lens supply for use in commercial activities outside the United States. The Company also has its own manufacturing facility in Irvine, California that the Company believes will be sufficient to supply lenses for commercial activities outside the United States once existing inventory is utilized, as well as in the United States, pending FDA approval.

(6) Income Taxes

Deferred income tax assets and liabilities are recognized for temporary differences between financial statement and income tax carrying values, using tax rates in effect for the years such differences are expected to reverse. Due to uncertainties surrounding the Company's ability to generate future taxable income and consequently realize such deferred income tax assets, a full valuation allowance has been established. The Company continues to maintain a full valuation allowance against its deferred tax assets as of September 30, 2018.

The impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more likely than not to be sustained upon audit by the relevant tax authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. In December 2017, the Company recorded a liability of $199,000 with respect to unpaid Irish income taxes in accordance with ASC 740-10, Accounting for Uncertainty of Income Taxes, and decreased that liability during the nine months ended September 30, 2018 to $36,000. The Company's policy is to recognize interest expense and penalties related to income tax matters as a component of the income tax provision. As of September 30, 2018 and December 31, 2017, the Company has recognized $7,000 and $39,000, respectively, of tax related accrued interest and penalties on its consolidated balance sheets.

A reconciliation of gross unrecognized tax benefits is as follows:

	September 30, 2018	December 31, 2017
Balance at the beginning of the year	199,000	—
Decreases related to current year tax positions	163,000	199,000
Balance at the end of the year	$ 36,000	$ 199,000

(7) Equity Transaction with Related Party

Private Placements with Related Party

On April 12, 2018, Presbia PLC, its wholly-owned subsidiary, Presbia USA, Inc. and Richard Ressler, a member of Presbia PLC's board of directors and its majority stockholder, entered into a Stock Purchase Agreement pursuant to which Mr. Ressler purchased in a private placement offering 100 preferred shares of the Company, with the rights set forth in the Subscription Letter, dated April 12, 2018, and 4,900 shares of preferred stock of Presbia USA, Inc. for an aggregate purchase price of $5.0 million. Upon closing the offering, Mr. Ressler received a warrant to purchase 1,953,125 ordinary shares of Presbia PLC at an exercise price of $2.56 per share, subject to adjustments as provided under the terms of the warrants. The warrant is exercisable for five years from the issuance date and it contains a cashless exercise provision.

The preferred shares of Presbia PLC and Presbia USA, Inc. carry a one times liquidation preference. The preferred shares are redeemable upon a liquidation event in which all classes of equity holders are entitled to receive the same form of consideration and are redeemable at any time at our sole election, provided that a majority of the independent directors approve such redemption. The preferred shares accrue a dividend at the rate of 10% per annum during the first 18 months, 20% for months 19 through 24 and 30% from month 25 until such preferred shares are redeemed, payable in preferred shares on a quarterly basis. Undeclared PIK dividends for the period from the date of issuance of April 12, 2018 to September 30, 2018 total $237,000 or 237 preferred shares of Presbia USA, Inc. at the original issuance price of $1,000.

As long as the preferred shares remain outstanding, neither the Company nor its subsidiary shall take the following actions, without obtaining the prior consent of the holder of the preferred shares: (a) effect any alteration, repeal, change or amendment of the rights, privileges or preferences of the preferred shares in a manner that adversely affects the rights, privileges or preferences of those shares or any series thereof; (b) amend, modify or repeal any provision of the organizational documents in a manner that adversely affects the powers, preferences or rights of the preferred shares; (c) agree to any debt financing in an amount in excess of $8,000,000 (such amount being the maximum amount payable by the company under the debt instruments); (d) execute a guarantee; (e) effect any restructuring or liquidation; (f) settle any lawsuit or civil investigation requiring the payment of more than $1,000,000; or (g) execute any document or enter into any arrangement that has a potential liability to the Company in excess of $1,000,000.

In addition, Presbia PLC guaranteed Presbia USA's payment of the redemption price and any accrued and unpaid dividends with respect to the preferred shares issued by Presbia USA, Inc.

Shares Issuable Pursuant to Services Agreement with OCV Management, LLC

On December 14, 2017, the Company concluded a services agreement with OCV Management, LLC, a related party co-founded by Richard Ressler and Mark Yung, for the purpose of providing management services for the Company for the period commencing December 14, 2017 until terminated upon thirty (30) days' prior written notice by either of the parties. OCV Management, LLC will receive an annual fee of $250,000, payable annually in arrears. The obligation will be settled in the form of ordinary shares issued by the Company in a private offering. For 2018, the number of shares to be issued was determined to be 72,464 by dividing $250,000 by the closing price on January 2, 2018 and the shares will be issued on January 2, 2019. The Company recorded stock-based compensation of $20,000 and 88,000 for the three and nine-month periods ended September 30, 2018 in relation to services provided in 2018.

(8) Commitments and Contingencies

In May 2012, the Company entered into a five-year non-cancelable lease for office and manufacturing space in Irvine, California that was renewed on June 1, 2016 and provided for an extension of five consecutive years starting from the original lease expiration date of May 31, 2017 through May 31, 2022. The Company maintains a one-year lease (which is now month to month) in Dublin, Ireland that commenced on December 1, 2013. In February 2018, it terminated a 30-month lease in Amsterdam, the Netherlands, that commenced on January 1, 2016. This termination was based on a mutual agreement with the landlord. In December 2017, the Company vacated one of its Irvine, California locations and consolidated its operations into another location in Irvine. At December 31, 2017, a liability of $222,000, representing the fair value of the remaining lease obligation over the remaining 33 months was recorded as part of the short-term portion of deferred rent in the Consolidated Balance Sheet. During the nine-month period ended September 30, 2018, the Company sublet the facility and settled the remaining lease obligation.

Aggregate company-wide rent expense for the three months ended September 30, 2018 and 2017 was $89,000 and $166,000, respectively, and for the nine months ended for the same period was $297,000 and $502,000, respectively.

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.

(9) Subsequent Event

None

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

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.
- *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 loss, 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 focus on obtaining regulatory approval for our microlens in the United States and to continue to commercialize our microlens in certain strategic countries where we currently have marketing approval. 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 (all European Union member states plus Iceland, Liechtenstein and Norway), or "EEA", and through mutual recognition agreements, in 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, such as South Korea. We obtained a five-year extension of our CE Mark in July, 2018.

We are focused on seeking marketing approval of our microlens in 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 nine-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. In September 2015, we completed the enrollment of the second stage study of 346 subjects at five additional investigational sites. 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.

We pursued a modular PMA submission strategy whereby we submitted to the FDA our first module in the second quarter of 2016, containing information regarding biocompatibility. We submitted the second and third modules in the first quarter of 2017, containing information regarding preclinical testing, engineering and manufacturing. We submitted our fourth PMA module, containing 24-month data on 385 subjects, in the second quarter of 2018. Safety and effectiveness data for subjects with 24-month data was submitted as part of the PMA. On October 5, 2018, we received notification from the

FDA requesting additional information with respect to the PMA submitted in the second quarter of 2018. We must respond by April 3, 2019 to the requests, which must include the complete 36-month data and analyses for all active subjects enrolled in our staged pivotal clinical trial. In light of the FDA's 180-day review period following acceptance of the amended PMA, we do not anticipate PMA approval prior to the fourth quarter 2019. We had previously disclosed in our Quarterly Report on Form 10-Q, dated August 10, 2018, that we were expecting to receive PMA approval during the fourth quarter of 2018, and that we would provide a final report including 36-month data by the end of the first quarter of 2019.

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 September 30, 2018, we had an accumulated deficit of $94.8 million. We expect to continue to incur significant losses for the foreseeable future.

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 GAAP. 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, 2017. 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, 2017. There have been no material changes in our significant accounting policies or critical accounting policies and estimates since the year ended December 31, 2017, except for the adoption of new accounting standards as discussed elsewhere in this report.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2018 and September 30, 2017.

	Three-Months Ended September 30,		Change	
	2018	2017	$000's	%
Revenues	$ 12	$ 8	$ 4	50%
Cost of goods sold	2	12	(10)	-83%
Gross loss	10	(4)	14	-350%
Operating expenses:				
Research and development	965	2,066	(1,101)	-53%
Sales and marketing	359	1,017	(658)	-65%
General and administrative	1,140	1,627	(487)	-30%
Total operating expenses	2,464	4,710	(2,246)	-48%
Operating loss	(2,454)	(4,714)	2,260	-48%
Other expense	—	—	—	0%
Interest (expense) income	(11)	(6)	(5)	83%
Loss before income tax provision	(2,465)	(4,720)	2,255	-48%
Income tax provision (benefit)	(215)	20	(235)	-1175%
Net loss	$ (2,250)	$ (4,740)	$ 2,490	-53%

	Nine-Months Ended September 30,		Change	
	2018	2017	$000's	%
Revenues	$ 19	$ 13	$ 6	46%
Cost of goods sold	50	40	10	25%
Gross loss	(31)	(27)	(4)	15%
Operating expenses:				
Research and development	2,647	5,930	(3,283)	-55%
Sales and marketing	1,071	2,794	(1,723)	-62%
General and administrative	2,896	5,030	(2,134)	-42%
Total operating expenses	6,614	13,754	(7,140)	-52%
Operating loss	(6,645)	(13,781)	7,136	-52%
Other income	(10)	—	(10)	0%
Interest (expense) income	(30)	(24)	(6)	25%
Loss before income tax provision	(6,685)	(13,805)	7,120	-52%
Income tax provision (benefit)	(172)	61	(233)	-382%
Net loss	$ (6,513)	$ (13,866)	$ 7,353	-53%

Revenue

Revenue for the three months ended September 30, 2018 was $12,000 as compared to $8,000 for the corresponding period in 2017. Revenue for the nine months ended September 30, 2018 was $19,000 as compared to $13,000 for the corresponding period in 2017. Revenues were immaterial for both periods presented and are expected to continue to be immaterial in the near-term as we are in the near term undertaking limited commercialization efforts in only a few selected markets. 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 ophthalmic clinics primarily in Germany.

Cost of Goods Sold

Cost of goods sold was $2,000 for the three months ended September 30, 2018 as compared to $12,000 in the three months ended September 30, 2017, or a decrease of $10,000 primarily due to the provisions for inventory obsolescence of $11,000 recorded in the three months ended September 30, 2017. For the nine months ended September 30, 2018 and 2017, cost of goods sold was $50,000 and 40,000, respectively. 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 September 30, 2018 and 2017, we recorded additional provisions for inventory obsolescence and unfavorable adjustments of $0 and $11,000, respectively. For the nine-month period ended September 30, 2018 and 2017, we recorded additional provisions for inventory obsolescence of $45,000 and $40,000, respectively.

Research and Development

Research and development expense declined by $1,101,000 or 53%, for the three months ended September 30, 2018 as compared to the same period in 2017. The decrease in research and development spend is primarily due to (i) a $323,000 cost decrease related to the currently discontinued development of our disposable inserter, (ii) a $203,000 cost decrease related to our U.S. clinical trials, (iii) $215,000 for lower manufacturing costs, and (iv) $361,000 for lower regulatory and quality assurance costs.

For the nine months ended September 30, 2018, research and development expense declined by $3,283,000, or 55%, as compared to the same period in 2017. The decrease in research and development spend is primarily due to (i) a $880,000 cost decrease related to related to the currently discontinued development of our disposable inserter, (ii) a $708,000 cost decrease related to our U.S. clinical trials, (iii) 869,000 for lower allocated manufacturing costs, and (iv) $827,000 for lower regulatory and quality assurance costs.

During 2018, we expect that costs related to our U.S. staged pivotal clinical trial will decline as compared to 2017, primarily due to the main focus of the trial shifting from compliance to submission to the FDA of the remaining PMA modules and clinical data, and management's decision to discontinue development of our disposable inserter.

Sales and Marketing

Sales and marketing expense decreased by $658,000 or 65%, for the three months ended September 30, 2018 as compared to the three months ended September 30, 2017. The decrease is primarily a result of lower advertising and promotional costs of $249,000, (ii) a $281,000 cost decrease related to lower employee compensation due to our reduced headcount, and (iii) other net cost decreases of $129,000 related to travel, compensation and other sales and marketing expenses.

For the nine months ended September 30, 2018, sales and marketing expense declined by $1,723,000, or 62%, as compared to the same period in 2017. The decrease is primarily a result of lower advertising and promotional costs of $526,000, (ii) a $892,000 cost decrease related to lower employee compensation due to our reduced headcount, and (iii) other net cost decreases of $305,000 related to travel, compensation and other sales and marketing expenses.

We evaluated our commercialization strategy as part of the December 2017 re-prioritization of resources, which resulted in limiting our commercialization efforts to Germany, and focusing our resources on completing our U.S. staged pivotal clinical trial.

General and Administrative

General and administrative expense declined by $487,000, or 30%, for the three months ended September 30, 2018 as compared to the same period in 2017. General and administrative expenses declined primarily due to (i) reduced personnel costs of $263,000, due to reduced headcount, (ii) reduced stock based compensation expense of $141,000, and (iii) other net cost decreases of $83,000 related to travel, insurance and other administrative expenses.

For the nine months ended September 30, 2018, general and administrative expense decreased by $2,134,000, or 42%, as compared to the same period in 2017. General and administrative expenses declined primarily due to (i) reduced personnel costs of $926,000, due to reduced headcount, (ii) reduced stock based compensation expense of $608,000, (iii) lower professional fees of $170,000 and (iv) other net cost decreases of $430,000 related to travel, insurance and other administrative expenses.

Interest Expense, net

Interest expense for the three months ended September 30, 2018 was $5,000 higher than the same period in 2017. For the nine months ended September 30, 2018, interest expense was $6,000 higher than the corresponding period in 2017. The change is due primarily to a decrease in interest expense related to the Neoptics asset purchase.

Net Loss

Our net loss of $2.2 million for the three months ended September 30, 2018 was $2.5 million lower, or 53% lower, than the net loss of $4.7 million in the corresponding period in 2017. For the nine months ended September 30, 2018, our net loss was $6.5 million as compared to $13.9 million, or $7.4 million lower for the comparable period in 2017. For the three and nine months ended September 30, 2018, net loss included a tax benefit of $260,000 and $195,000, respectively, with respect to unpaid Irish income taxes. We expect to incur significant additional future losses due to anticipated costs related to our U.S. staged pivotal clinical trial and ongoing costs required to develop the market for our microlens.

Liquidity and Capital Resources

At September 30, 2018, we had cash of $1.4 million, reflecting a $1.8 million decrease from our cash balance at December 31, 2017 of $3.2 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. In April 2018, in a private placement, we sold 5,000 preferred shares to Richard Ressler, a member of the Board of Directors and our principal shareholder, for an aggregate purchase price of $5.0 million. In connection with this transaction, we granted a warrant to Ressler covering 1,953,125 ordinary shares exercisable over a five-year period with an exercise price of $2.56. The preferred shares accrue a dividend at the rate of 10% per annum during the first 18 months, 20% for months 19 through 24 and 30% from month 25 until such preferred shares are redeemed, payable in preferred shares on a quarterly basis. Undeclared PIK dividends for the period from the date of issuance of April 12, 2018 to September 30, 2018 total $237,000 or 237 preferred shares of Presbia USA at the original issuance price of $1,000.

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

- the progress, timing, costs and completion of U.S. staged pivotal clinical trial;
- the outcome, timing and cost of regulatory approvals;
- delays that may be caused by changing regulatory requirements;
- timing and amount of revenue resulting from sales to customers outside the US; and
- timing and amount of investments in our commercialization efforts outside the U.S.

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

	Nine-Months Ended September 30,	
	2018	2017
Net cash used in operating activities	$ (6,682)	$ (10,723)
Net cash used in investing activities	$ (2)	$ (135)
Net cash provided by financing activities	$ 4,890	$ 10,534

At September 30, 2018, we had an accumulated deficit of approximately $94.8 million and we expect to incur additional future operating losses. As we continue to incur losses, our transition to profitability will depend on the successful development, approval and commercialization of our microlens. On October 5, 2018, we received notification from the FDA that 36-month data on all subjects enrolled in our staged pivotal clinical trial, including additional safety and efficacy related information, is required before the FDA can complete its review of our PMA. We must respond by April 3, 2019, otherwise we must amend the PMA within the 180-day period to request an extension of time to respond. In light of the FDA's typical 180-day review period following our anticipated response date of April 3, 2019, we do not anticipate PMA approval prior to the fourth quarter 2019. The foregoing targeted milestones and associated estimated timeframes could be delayed by further interactions with the FDA or by a variety of other factors, including requests for further safety and efficacy related information pertaining to our microlens ophthalmic device. To continue to pursue FDA pre-market approval, we will need to raise funds in the fourth quarter of 2018. Based on our current business plan, we believe that our cash and cash equivalents at September 30, 2018 will not be sufficient to meet our anticipated cash requirements during the twelve-month period subsequent to the issuance of the financial statements included in this Quarterly Report on Form 10-Q nor even for the next three months. We must raise additional capital to fund our operations. We may raise additional capital through equity offerings, debt financings, collaborations and/or licensing arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available on acceptable terms, we may be required to delay, reduce the scope of, or curtail, our operations. To the extent that we raise additional funds by issuing equity securities, our shareholders

will experience dilution, and debt financing, if available, may involve restrictive covenants. We may never achieve profitability, and unless and until we do, we will need to continue to raise additional capital.

Off-Balance Sheet Arrangements

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

Recent Accounting Pronouncements

Refer to Note 2, "Summary of Significant Accounting Policies," of our notes to consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for a discussion of new accounting standards.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Under Securities and Exchange Commission, or SEC, rules and regulations, as a smaller reporting company we are not required to provide the information otherwise required by this item.

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 September 30, 2018 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, 2017, filed with the Securities and Exchange Commission on March 20, 2018 for a description of certain significant risks and uncertainties to which our business, operations and financial condition are subject. Except as described below there have been no material changes to these risk factors.

Our regulatory pathway has been delayed from previous expectations, and we expect to incur substantial expenses in our pursuit of regulatory approval in the United States and can provide no assurances that we will obtain the necessary approvals from the FDA to market our products in the United States.

The United States is a key market for commercialization of our microlens. Before we can market our products in the United States, we must conduct and successfully complete extensive clinical trials and then receive pre-market approval ("PMA") from the FDA. We had disclosed in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2018 we were targeting PMA approval during the fourth quarter of 2018 (based on 24-month data), and were targeting the submission of a final report containing 36-month data on all enrolled subjects in the first quarter of 2019. On October 5, 2018, we received notification from the FDA that 36-month data on all subjects enrolled in our staged pivotal clinical trial, including additional safety and efficacy related information, is required before the FDA can complete its review of our PMA. We must respond by April 3, 2019, otherwise we must amend the PMA within the 180-day period to request an extension of time to respond. In light of the FDA's typical 180-day review period following the Company's anticipated response date of April 3, 2019, we do not anticipate PMA approval prior to the fourth quarter 2019. The foregoing targeted milestones and associated estimated timeframes could be delayed by further interactions with the FDA or by a variety of other factors, including requests for further safety and efficacy related information pertaining to our microlens ophthalmic device. 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.

Based on our current plan, we will need additional capital in the near term to support our operations.

Based on our current business plan, we believe that our cash and cash equivalents at September 30, 2018 will not be sufficient to meet our anticipated cash requirements to pursue FDA approval in 2019, which is our highest priority. We need to raise additional capital in the fourth quarter of 2018 to be able to fund our operations. We may raise additional capital through equity offerings, debt financings, collaborations and/or licensing arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of, or curtail, our operations. To the extent that we raise additional funds by issuing equity securities, our shareholders will experience dilution, and debt financing or other preferred equity instruments, if available, may involve restrictive covenants.

We are required to meet the NASDAQ Capital Market's continued listing requirements and other NASDAQ rules, or we may risk delisting. Delisting could negatively affect the price of our ordinary shares, which could make it more difficult for us to sell securities in a future financing or for you to sell our ordinary shares.

We are required to meet the continued listing requirements of the NASDAQ Capital Market and other NASDAQ rules, including but not limited to those regarding director independence and independent committee requirements, minimum stockholders' equity on minimum market value of listed securities, minimum share price and certain other corporate governance requirements. In particular, we are required to maintain a minimum stockholders' equity of $2.5 million or a minimum market value of listed securities of $35.0 million. As of September 30, 2018, our stockholders' equity was approximately $1.9 million and the market value of our listed securities was approximately $30.3 million and it has declined since that date. If we do not continue to meet these continued listing requirements, our ordinary shares could be delisted. Delisting from the NASDAQ Capital Market would cause us to pursue eligibility for trading of these securities on other markets or exchanges, or on the "pink sheets." In such case, our stockholders' ability to trade, or obtain quotations of the market value of our ordinary shares may be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices of these securities. There can be no assurance that our securities, if delisted from the NASDAQ Capital Market in the future, would be listed on a national securities exchange, a national quotation service, the over-the-counter markets or the pink sheets. Delisting from the NASDAQ Capital Market, or even the issuance of a notice of potential delisting, would also result in negative publicity, make it more difficult for us to raise additional capital, adversely affect the market price and liquidity of our ordinary shares, decrease securities analysts' coverage of us or diminish investor, supplier and employee confidence.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description
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: November 13, 2018

By: /s/ Mark Yung
Mark Yung
President and Chief Executive Officer

Date: November 13, 2018

By: /s/ Richard Fogarty
Richard Fogarty
Chief Accounting Officer,
Vice President, Finance and Secretary

Exhibit 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

I, Mark Yung, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) 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

   (d) 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: November 13, 2018

By: /s/ Mark Yung

Mark Yung

Chief Executive Officer

Exhibit 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

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) 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

   (d) 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: November 13, 2018

By: /s/ Richard Fogarty

Richard Fogarty

Chief Accounting Officer

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL 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 September 30, 2018 (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: November 13, 2018

By: /s/ Mark Yung
Mark Yung
Chief Executive Officer
(Principle Executive Officer)

Date: November 13, 2018

By: /s/ Richard Fogarty
Richard Fogarty
Chief Accounting Officer
(Principle Financial 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.