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ASX Announcement

Visioneering Technologies, Inc., Appendix 4E

Atlanta, Georgia, 19 February 2019 AT: US-based medical device company and producer of the NaturalVue® (etafilcon A) Multifocal 1 Day Contact Lenses Visioneering Technologies, Inc. (ASX: VTI) ('Visioneering' or 'The Company') has today released its Appendix 4E Full Year Final Results for the period ended 31 December 2018.

For more information, please contact:

<i>Company</i>	<i>Investor and media relations</i>
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About VTI:

Visioneering Technologies Inc. (ASX: VTI) is an innovative eye care company committed to redefining vision. Since its founding in 2008, Visioneering has brought together clinical, marketing, engineering, manufacturing and regulatory leaders from top vision care businesses to provide new solutions for presbyopia, myopia and astigmatism.

Headquartered in the US, Visioneering designs, manufactures, sells and distributes contact lenses. Its flagship product is the NaturalVue® Multifocal contact lens, and VTI has expanded its portfolio of technologies to address a range of eye care issues. The company has grown operations across the United States, Australia and Europe and is expanding into Asia with a focus on markets with high rates of myopia.

Foreign ownership restrictions:

VTI's CHES Depositary Interests (**CDIs**) are issued in reliance on the exemption from registration contained in Regulation S of the US Securities Act of 1933 (**Securities Act**) for offers which are made outside the US. Accordingly, the CDIs have not been, and will not be, registered under the Securities Act or the laws of any state or other jurisdiction in the US. As a result of relying on the Regulation S exemption, the CDIs are 'restricted securities' under Rule 144 of the Securities Act. This means that you are unable to sell the CDIs into the US or to a US person for the foreseeable future except in very limited circumstances after the expiration of a restricted period, unless the re-sale of the CDIs is registered under the Securities Act or an exemption is available. To enforce the above transfer restrictions, all CDIs issued bear a 'FOR US' designation on the Australian Securities Exchange (**ASX**). This designation restricts any CDIs from being sold on ASX to US persons. However, you are still able to freely transfer your CDIs on ASX to any person other than a US person. In addition, hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.

APPENDIX 4E (RULE 4.3A)

PRELIMINARY FINAL REPORT FOR THE YEAR ENDED 31 DECEMBER 2018

RESULTS FOR ANNOUNCEMENT TO THE MARKET

	2018 \$USD	2017 \$USD	up/ down	% movement
Revenue from ordinary activities	\$3,294,353	\$1,048,978	up	214%
Loss after tax from ordinary activities attributable to members	(\$16,735,070)	(\$16,981,419)	down	-1.5%
Net loss after tax attributable to members	(\$16,735,070)	(\$16,981,419)	down	-1.5%

Dividend information	Amount per security \$USD	Franked amount per security \$USD
Interim dividend	Nil	Nil
Previous corresponding dividend	Nil	Nil

Net tangible asset backing

	31 Dec 2018 \$USD	31 Dec 2017 \$USD
	\$0.04	\$0.10

- **Annual financial results:** This report is based on the accompanying 2018 consolidated financial statements which have been audited by Grant Thornton, LLP. Our audited financial statements contain an independent audit report which includes a paragraph stating that because we have incurred operating losses and negative cash flows from operations since inception and will be required to obtain additional financing, alternative means of financial support or both in order to continue to fund our operations, there is substantial doubt about our ability to continue as a going concern beyond one year from the date of these financial statements.
- **Changes in control over entities:** There are no entities over which control has been gained or lost during 2018.
- **Details of dividends and dividend reinvestment plans:** No dividends have been declared or proposed.
- **Details of associates or joint ventures:** N/A

- **Set of accounting standards used in compiling the report:** The audited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. (US GAAP) and are denominated in U.S. dollars.
- **Details of audit disputes or audit qualification:** None.

A commentary on the results for the period: The net loss for the year decreased to US\$16,735,070 compared to US\$16,981,419 for the previous corresponding period. Basic and Diluted earnings per share was (US\$0.08) and (US\$0.11) for the years ended 31 December 2018 and 2017, respectively. Net Sales increased to US\$3,294,353 from US\$1,048,978 for the previous period, as a result of the continued expansion in the United States and commercial launch in Australia, New Zealand, Norway, Sweden and Denmark.

Cost of Sales increased to US\$3,373,474 from US\$909,679 for the previous period, as a result of the increase in Net Sales and the recording of an inventory reserve of US\$821,418.

Total Operating Expenses increased to US\$16,835,486 from US\$12,885,299 for the previous period, reflecting increased investment in sales and marketing, clinical and manufacturing, and general administrative expenses as we expanded the commercial launch in the United States and internationally.

Loss on fair value of derivative liability decreased to US\$0 from US\$1,421,054 for the previous period due to the derivative liability being satisfied in the initial public offering (“IPO”) in March 2017.

Loss on share redemption of debt decreased to US\$0 from US\$1,459,653 for the previous period due to write off of the unamortized debt discount when the convertible debt was converted to common stock in connection with the IPO in March 2017 and interest earned on the IPO proceeds. Total Interest income (expense) and other, net increased to US\$179,536 from US (\$1,354,712) due to conversion of debt to common stock in connection with the IPO in March 2017.

The Company had cash and cash equivalents of US\$7,274,702 at 31 December 2018.

The Company operated in one segment only during the period and there were no returns to shareholders or share buy backs.

Please also refer to the separate update on the full year financial results of the Company and the Company’s consolidated financial statements, with accompanying notes, which are attached hereto.

Annual Meeting of Stockholders: The Annual Meeting of Stockholders of the Company will be held at *Johnson Winter & Slattery’s Sydney office* at Level 25, 20 Bond Street Sydney, New South Wales, Australia on Thursday, 18 April 2019 at 10.00am Australian Eastern Standard time.

VISIONEERING TECHNOLOGIES, INC.

FINANCIAL STATEMENTS

For the Years Ended December 31, 2018 and 2017

VISIONEERING TECHNOLOGIES, INC.

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REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

Board of Directors
Vioneering Technologies, Inc.

We have audited the accompanying financial statements of Vioneering Technologies, Inc. (a Delaware corporation), which comprise the balance sheets as of December 31, 2018 and 2017 and the related statements of operations, changes in stockholders' equity (deficit), and cash flows for the years then ended, and the related notes to the financial statements.

Management's responsibility for the financial statements

Management is responsible for the preparation and fair presentation of these financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditor's responsibility

Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Visioneering Technologies, Inc. as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

Emphasis of matter regarding going concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred recurring losses, negative cash flows from operations, has an accumulated deficit of \$59.0 million as of December 31, 2018, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

Grant Thornton LLP

Atlanta, Georgia
February 18, 2019

VISIONEERING TECHNOLOGIES, INC.

BALANCE SHEETS As of December 31, 2018 and 2017

	December 2018 <u>US\$000</u>	December 2017 <u>US\$000</u>
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 7,275	\$ 16,584
Accounts receivable	495	242
Inventory, net	2,022	2,748
Prepaid expenses and other current assets	<u>276</u>	<u>602</u>
TOTAL CURRENT ASSETS	10,068	20,176
NON-CURRENT ASSETS		
Property and equipment, net	110	162
Intangible assets, net	167	174
Other non-current assets	<u>34</u>	<u>43</u>
TOTAL ASSETS	<u>\$ 10,379</u>	<u>\$ 20,555</u>
LIABILITIES		
CURRENT LIABILITIES		
Accounts payable	\$ 140	\$ 164
Accrued payroll	540	\$ 794
Other accrued liabilities	<u>696</u>	<u>380</u>
TOTAL CURRENT LIABILITIES	1,376	1,338
LONG-TERM LIABILITIES		
Deferred rent	<u>38</u>	<u>31</u>
TOTAL LIABILITIES	<u>1,414</u>	<u>1,369</u>
Commitments and contingencies (Note 12)		
EQUITY		
Common stock, par value \$0.001 per share, 600,000,000 shares authorized and 248,619,294 shares issued and outstanding at December 31, 2018 and 196,989,356 shares issued and outstanding at December 31, 2017	249	197
Additional paid-in capital	67,683	61,221
Accumulated deficit	<u>(58,967)</u>	<u>(42,232)</u>
TOTAL SHAREHOLDERS' EQUITY	<u>8,965</u>	<u>19,186</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 10,379</u>	<u>\$ 20,555</u>

See accompanying notes to financial statements.

VISIONEERING TECHNOLOGIES, INC.

STATEMENTS OF OPERATIONS For the Years Ended December 31, 2018 and 2017

	2018	2017
	In US\$000, except share and per share data	
NET REVENUE	\$ 3,294	\$ 1,049
COST OF SALES		
Product costs	2,552	910
Inventory write-down and reserves	821	-
TOTAL COST OF SALES	3,373	910
GROSS PROFIT	(79)	139
EXPENSES		
Sales and marketing	10,135	7,518
Clinical and manufacturing	2,617	1,509
General and administrative	4,084	3,857
TOTAL EXPENSES	16,836	12,884
OPERATING LOSS	(16,915)	(12,745)
Loss on fair value of derivative liability	-	(1,421)
Loss on share redemption of debt	-	(1,460)
Interest income (expense) and other, net	180	(1,355)
LOSS BEFORE INCOME TAXES	(16,735)	(16,981)
INCOME TAX EXPENSE	-	-
NET LOSS	\$ (16,735)	\$ (16,981)
Net loss per share - Basic and Diluted	\$ (0.08)	\$ (0.11)
Weighted average shares outstanding - Basic and Diluted	215,817,597	155,342,232

See accompanying notes to financial statements.

VISIONEERING TECHNOLOGIES, INC.

STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY (DEFICIT) For the Years Ended December 31, 2018 and 2017

	Common Stock		Preferred Stock		Paid-in Capital US\$000	Accumulated Deficit US\$000	Total US\$000
	Shares Number	Amount US\$000	Shares Number	Amount US\$000			
Balance at December 31, 2016	9,577,298	\$ 96	16,617,758	\$ 166	\$ 7,700	\$ (25,251)	\$ (17,289)
Reduction in par value of common stock	-	(86)	-	-	86	-	-
Issuance of stock through IPO, net of issuance costs	79,365,079	79	-	-	23,316	-	23,395
Conversion of preferred stock	16,617,758	17	(16,617,758)	(166)	149	-	-
Share settlement of convertible debt and derivative	91,429,221	91	-	-	29,476	-	29,567
Stock based compensation	-	-	-	-	494	-	494
Net loss	-	-	-	-	-	(16,981)	(16,981)
Balance at December 31, 2017	196,989,356	197	-	-	61,221	(42,232)	19,186
Issuance of common stock							
Placement and SPP, net of issuance costs (Note 7)	51,113,328	51	-	-	6,193	-	6,244
Stock option exercises	447,320	1	-	-	10	-	11
Stock based compensation	69,290	-	-	-	259	-	259
Net loss	-	-	-	-	-	(16,735)	(16,735)
Balance at December 31, 2018	248,619,294	\$ 249	-	\$ -	\$ 67,683	\$ (58,967)	\$ 8,965

See accompanying notes to financial statements.

VISIONEERING TECHNOLOGIES, INC.

STATEMENTS OF CASH FLOWS For the Years Ended December 31, 2018 and 2017

	2018 US\$000	2017 US\$000
Cash flows from operating activities:		
Net loss	\$ (16,735)	\$ (16,981)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	76	45
Change in fair value of derivative liability	-	1,421
Loss on share redemption of debt	-	1,460
Accrued interest on convertible debt	-	353
Amortization of debt discount	-	446
Unrealized foreign exchange loss	-	688
Inventory write-down and reserves	821	-
Loss on disposal of property and equipment	-	3
Stock based compensation	259	494
Changes in assets and liabilities:		
Accounts receivable	(253)	(212)
Inventory	(95)	(851)
Prepaid expenses and other assets	335	197
Accounts payable	(24)	(207)
Accrued payroll	(254)	713
Other accrued liabilities	323	151
Net cash used in operating activities	(15,547)	(12,280)
Cash flows from investing activities:		
Purchase of property and equipment, net	(10)	(158)
Purchase of intangible assets, net	(7)	(47)
Net cash used in investing activities	(17)	(205)
Cash flows from financing activities:		
Issuance of common stock, net of issuance costs of \$491 in 2018 and \$509 in 2017	6,244	23,395
Proceeds from stock option exercises	11	-
Net cash provided by financing activities	6,255	23,395
Net (decrease) increase in cash and cash equivalents	(9,309)	10,910
Cash and cash equivalents, beginning of period	16,584	5,674
Cash and cash equivalents, end of period	\$ 7,275	\$ 16,584
Supplemental disclosure:		
Cash paid for interest	\$ -	\$ -
Cash paid for taxes	\$ -	\$ -

See non-cash disclosures in Note 6.

See accompanying notes to financial statements.

VISIONEERING TECHNOLOGIES, INC.

NOTES TO FINANCIAL STATEMENTS

December 31, 2018 and 2017

In US\$

(1) NATURE OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Visioneering Technologies, Inc. (“VTI”, “we”, “us”, “our” or the “Company”) was incorporated as a Delaware corporation on October 23, 2008. Headquartered in Atlanta, Georgia, VTI is a medical device company that designs, manufactures, sells and distributes contact lenses. Our flagship product is the NaturalVue® (etafilcon A) Multifocal 1 Day Contact Lens for adults with Presbyopia (the progressive loss of ability to see near that occurs in middle-age) and children with Myopia (nearsightedness). Within the US, medical devices are regulated by the FDA, under the Federal Food, Drug, and Cosmetic Act of 1938. We obtained FDA clearance for our NaturalVue contact lenses in late 2014 and received the CE Mark, as well as TGA approval in early 2018, enabling us to sell our contact lenses in the US, Europe, Australia and New Zealand. All of our sales were in the United States through September 2018, at which time we began selling internationally as well.

In March 2017, we completed our Initial Public Offering (“IPO”) and associated listing on the Australian Stock Exchange (“ASX”). The ASX uses an electronic system called CHESS for the clearance and settlement of trades on the ASX. The State of Delaware does not recognize the CHESS system of holding securities or electronic transfers of legal title to shares. To enable companies such as VTI to have their securities cleared and settled electronically through CHESS, depository instruments called CDIs are issued. CDIs are units of beneficial ownership in shares and are traded in a manner similar to shares of Australian companies listed on the ASX. The legal title to the shares are held by a depository, CDN, which is a wholly-owned subsidiary of the ASX, and is an approved general participant of ASX Settlement. 79,365,079 CDIs were issued (each representing an interest in one share of newly issued common stock) and \$23.4 million, net of expenses, was received. In conjunction with the IPO, all outstanding convertible debt and preferred stock was converted into common stock.

We currently manage warehousing and distribution of our products through a contract with a Third-Party Logistics provider (the “3PL”). The 3PL stores our inventory and ships it to our customers, which include major contact lens distributors (“Customers”). These Customers generally have non-exclusive rights to market, promote, sell and distribute our products (“Products”) within specified territories, provided that Products shall be sold only to permitted eye care providers (“ECPs”) and shipped only to ECPs or directly to a patient if specifically directed by the ECPs. As of December 31, 2018, VTI had entered into agreements with Customers in the US, Europe, Australia and New Zealand. Prior to August 25, 2017, we outsourced the warehousing and the revenue cycle management function to a contact lens fulfillment company. The related contract expired on August 25, 2017 and was not renewed.

Basis of Presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“US GAAP”). Any reference in these notes to applicable guidance is meant to refer to the authoritative US GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASUs”) of the Financial Accounting Standards Board (“FASB”). Unless otherwise noted, all amounts are presented in US dollars and balances presented within tables are in thousands.

Use of Estimates

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. Examples of estimates which require management's judgment include the collectability of accounts receivable, reserve for excess or obsolete inventory, potential impairment of long-lived assets, valuation allowance for deferred tax assets, and the fair value of share-based awards. Management bases its estimates on historical experience and other factors which it believes to be reasonable under the circumstances. Actual results may differ from these judgments.

Liquidity and Going Concern

Under ASC 205-40, *Presentation of Financial Statements – Going Concern*, the Company shall evaluate whether there are conditions and events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date that the financial statements are issued. This includes a review of the qualitative and quantitative factors, including the effect of potential mitigating effects of management planning, as discussed in ASC 205-40.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustment that might result from the outcome of this uncertainty. To date, the Company has incurred recurring losses, negative cash flows from operations and has accumulated a deficit of \$59.0 million from the Company's inception through December 31, 2018. As of December 31, 2018, the Company's cash and cash equivalents were \$7.3 million. The Company's ability to achieve profitability and positive cash flow is dependent upon its ability to increase revenue and contain its expenses.

In order to meet our working capital needs through the next twelve months, we may need to raise additional debt or equity financing. We historically have been able to raise additional capital through issuance of equity and/or debt financing, and have a plan in place to reduce spending in the absence of further capital being raised to satisfy its obligations due within one year from the date of issuance of these financial statements. Despite these factors, there can be no guarantees regarding our ability to raise additional equity or successfully implement our cost reduction plans. Because no mitigating efforts to raise sufficient capital have been approved prior to the issuance of the 2018 financial statements, there is substantial doubt about the Company's ability to continue as a going concern within one year after these financial statements are issued.

Fair Value of Financial Instruments

We have identified cash, accounts receivable, and accounts payable as financial instruments of the Company. Due to the nature of the cash, accounts receivable, and accounts payable, we believe that the fair value of those accounts approximates their carrying values.

Embedded Conversion, Redemption and Preference Features

We evaluate convertible debt and preferred stock instruments under ASC 480, *Distinguishing Liabilities from Equity*, to determine the appropriate classification of the host instrument. We evaluate embedded conversion, redemption and preference features within those instruments under ASC 815, *Derivatives and Hedging*, to determine whether the feature should be bifurcated from the host contract and accounted for as a derivative at fair value with changes in fair value recorded in earnings. If the conversion feature does not require derivative treatment under ASC 815, we evaluate the instrument under ASC 470-20, *Debt with Conversion and Other Options*, for consideration of any cash conversion equity components and beneficial conversion features.

Cash and Cash Equivalents

Cash and cash equivalents include cash and highly liquid investments that are readily convertible into cash and have a maturity of 90 days or less when purchased. Cash and cash equivalents were \$7.3 million as of December 31, 2018 and \$16.6 million as of December 31, 2017. At times, cash balances may exceed the Federal Deposit Insurance Corporation insurance limit.

Accounts Receivable

The carrying value of accounts receivable is reduced by an allowance for doubtful accounts that reflects management's best estimate of the amounts that will not be collected. In addition to reviewing delinquent accounts receivable, management considers many factors in estimating its general allowance, including historical data, experience, customer types, credit worthiness, and economic trends. We extend credit based on evaluation of a customer's financial condition and do not require collateral. From time to time, management may adjust its assumptions for anticipated changes in any of those or other factors expected to affect collectability. We charge provisions for doubtful accounts to operations at the time we determine these amounts may become uncollectible. Based on our review, we have not recorded an allowance for doubtful accounts as of December 31, 2018 or 2017.

Inventory

Inventory is stated at the lower of cost or net realizable value with cost determined under the first in, first out (FIFO) method. We regularly review our inventory quantities on hand and related cost and record a provision for any excess or obsolete inventory based on our estimated forecast of product demand and other factors. We also review our inventory value to determine if it reflects the lower of cost or net realizable value. Based on these reviews, we recorded inventory write-downs of \$821,418 in 2018 and \$0 in 2017. The 2018 write-down was related to launches of new products replacing older products and to excess inventory purchased prior to sufficient demand information being available. All inventory held at December 31, 2018 and 2017 consisted of finished goods.

Intangible Assets

Intangible assets are comprised of patents. We capitalize legal costs and other similar fees to obtain and register patents and expense all other costs to internally develop the patents as incurred. We amortize patents over a 15-year period.

Property and Equipment

We record property and equipment at cost less accumulated depreciation and expense repairs and maintenance costs as incurred. We included depreciation expense in General and administrative expense in the Statements of Operations.

We compute depreciation expense using the straight-line method over the following useful lives:

<u>Asset Classification</u>	<u>Estimate Useful Life</u>
Computer equipment and software	3 years
Office equipment	5 years
Furniture and fixtures	5 years
Leasehold improvements	Lesser of 5 years or life of the lease

Impairment of Long-lived Assets

We test long-lived assets for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that we consider in deciding when to perform an impairment review include, but are not limited to, significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If we perform an impairment review to evaluate a long-lived asset for recoverability, we compare forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. We would recognize an impairment loss when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. We would base the impairment loss on the excess carrying value of the impaired asset over its fair value. No impairment charges were necessary based on our internal assessments in the two years ended December 31, 2018.

Revenue Recognition

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, guidance on recognizing revenue from contracts with customers. The core principle of the revenue model is that an entity recognizes 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. The Company adopted the new revenue standard using a modified retrospective basis on January 1, 2018 to all contracts that were not completed. We did not restate the comparative information and continue to report it under the accounting standards in effect for those periods. The adoption of this guidance had no impact on the amount and timing of revenue recognized, therefore, we did not record any adjustments to our financial statements upon adoption. See Note 2, Revenue Recognition, for additional details on the application of this guidance.

Advertising Costs

We recognize advertising costs as an expense in the period in which we incur them. We incurred advertising expense of \$306,079 in 2018 and \$179,872 in 2017 and included these expenses in Sales and marketing in the Statements of Operations.

Research and Development Costs

We expense research and development costs in the period in which we incur them. Research and development expenses consist of wages, benefits, and other operational costs related to our engineering, regulatory, and quality departments, clinical and nonclinical studies, materials and supplies, and third-party costs for contracted services. We incurred research and development costs of \$20,374 in 2018 and \$7,899 in 2017 and included them in Clinical and manufacturing in the Statements of Operations.

Stock-Based Compensation

We measure the cost of employee services received in exchange for an award of equity instruments, including stock options and restricted stock awards, based on the grant date fair value of the award and recognize such costs as compensation expense on a straight-line basis over the period the employee is required to provide service in exchange for the award, usually the vesting period.

Leases

We classify leases at their inception as either operating or capital leases based on the economic substance of the agreement. We recognize lease payments made under operating leases as an expense on a straight-line basis over the lease term.

Income Taxes

In accordance with the ASC 740, *Income Taxes*, we recognize deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of our assets and liabilities. We record a valuation allowance against our net deferred tax asset to reduce the net carrying value to an amount that is more likely than not to be realized.

We consider income tax positions for uncertainty in accordance with ASC 740-10. We believe that our income tax filing position and deductions will be sustained on audit and do not anticipate any adjustments that will result in a material change to our financial position; therefore, no we have not recorded any ASC 740-10 liabilities for uncertain tax positions. We will recognize accrued interest and penalties related to unrecognized tax benefits, if any, as interest expense and income tax expense, respectively, in the Statements of operations. We do not believe that the amount of unrecognized tax benefits will significantly increase or decrease within 12 months of December 31, 2018. Given the Company's net operating losses, all years since inception are subject to review.

Significant management judgment is involved in determining the provision for income taxes, deferred tax assets and liabilities, and any valuation allowance recorded against net deferred tax assets. Due to uncertainties with respect to realization of deferred tax assets as a result of the Company's history of operating losses, we have established a valuation allowance against the net deferred tax asset balance. We based the valuation allowance on our estimates of taxable income in the jurisdictions in which the Company operates and the period over which deferred tax assets will be recoverable. If actual results differ from these estimates or we adjust these estimates in future periods, a change in the valuation allowance may be needed, which could materially impact our financial position and results of operations.

Earnings Per Share (EPS)

We calculate basic EPS in accordance with ASC 260, *Earnings per Share*, by dividing net income or loss attributable to common stockholders by the weighted average common stock outstanding. We calculate diluted EPS in accordance with ASC 260 by adjusting weighted average common shares outstanding for the dilutive effect of common stock options, warrants, convertible preferred stock, and accrued but unpaid convertible preferred stock dividends. In periods where a net loss is recorded, we give no effect to potentially dilutive securities, since the effect would be anti-dilutive. We did not include the common stock equivalents of the Company's convertible debt and stock options in the computation of dilutive EPS because to do so would have been anti-dilutive.

Reclassifications

Certain amounts in 2017 have been reclassified to conform with current year presentation.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. The ASU requires that organizations that lease assets recognize assets and liabilities on the balance sheet for the rights and obligations created by those leases. The ASU will affect the presentation of lease related expenses on the income statement and statement of cash flows and will increase the required disclosures related to leases. This ASU is effective for the Company beginning January 1, 2019, with early adoption permitted. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*. The amendments provide organizations with an additional (and optional) transition method to adopt the new leases standard by recognizing a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Consequently, an entity's reporting for the comparative periods presented in the financial statements in which it adopts the new leases standard will continue to be in accordance with current GAAP in Topic 840, *Leases*. The Company plans to use the optional transition method to adopt ASC 842 on January 1, 2019, at which time we expect to record the following approximate amounts effective January 1, 2019: a lease liability of \$375,000, a right to use asset of \$337,000 and a reduction of deferred rent of \$38,000.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230)*. The amendments in this update require that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The amendments in this update became effective for the Company beginning January 1, 2018. The adoption of this update did not have a significant impact on the Company's financial statements or the related disclosures.

In February 2017, the FASB issued ASU No. 2017-05, *Other Income: Gains and Losses from the Derecognition of Nonfinancial Assets (Subtopic 610-20)*, to clarify the scope of Subtopic 610-20 and to add guidance for partial sales of nonfinancial assets. Subtopic 610-20 was issued in May 2014 as part of ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which provided guidance for recognizing gains and losses from the transfer of nonfinancial assets in contracts with noncustomers. The amendments in this update became effective for the Company beginning January 1, 2018. The adoption of this update did not have a significant impact on the Company's financial statements or the related disclosures.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting*, that provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The new standard is effective for the Company beginning January 1, 2018. The new guidance must be applied on a prospective basis. The adoption of this standard did not have a significant impact on the Company's financial statements or the related disclosures.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. This ASU addresses narrow issues identified as a result of the complexity associated with applying GAAP for certain financial instruments with characteristics of liabilities and equity. The amendments in Part I of this Update are effective for the Company beginning January 1, 2020. Early adoption is permitted, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The Company is currently evaluating the impact of the adoption of this standard on its financial statements. The amendments in Part II of this Update do not have an accounting effect.

In June 2018, the FASB Issued ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. The amendments expand the scope of ASU 718 to include share-based payments issued to nonemployees for goods or services, thereby substantially aligning the accounting for share-based payments to nonemployees and employees. The amendments are effective starting in the first quarter of 2019. The Company currently does not expect the adoption of these provisions to have a material impact on its consolidated financial statements.

(2) REVENUE RECOGNITION

We sell our products to our Customers, including major contact lens distributors. In addition to distribution agreements with Customers, we enter into arrangements with ECPs that provide for privately-negotiated discounts with respect to their purchase of our products from the Customers. We then reimburse the Customers for discounts they provided on our behalf to the ECPs. Each of our current contracts consist of a master service agreement combined with specific purchase orders and have a single performance obligation, as the promise to transfer the individual goods is not separately identifiable from other promises in the contracts and is, therefore, not distinct.

Currently, we derive all revenue from product sales. We recognize revenues from product sales at a point in time when the Customer obtains control, typically upon shipment to the Customer. We accrue for fulfillment costs when we recognize the related revenue.

We record revenues from product sales at the net sales price (transaction price), which includes estimates of variable consideration related to discounts to distributors and ECPs; product returns; and patient-level rebates relating to sales of our products. We base these reserves on estimates of the amounts earned or to be claimed on the related sales. Our estimates take into consideration historical experience, current contractual requirements, specific known market events and trends, industry data, and Customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration included in the net sales price is limited to the amount that is probable not to result in a significant reversal in the amount of the cumulative revenue recognized in a future period. If actual results vary, we may adjust these estimates, which could impact earnings in the period of adjustment.

We will exchange returned product with replacement inventory, and typically do not provide cash refunds. We receive payments from our Customers based on billing schedules established in each contract and generally range between 30 to 90 days. We record amounts as accounts receivable when our right to consideration is unconditional. We do not assess whether a contract has a significant financing component if we expect that the Customer will pay for the product in one year or less of receiving those products.

(3) INTANGIBLE ASSETS

Intangible assets consist of the following as of December 31, 2018 and 2017:

	2018	2017
	US\$000	US\$000
Patents	\$ 240	\$ 233
Less accumulated amortization	(73)	(59)
Intangible assets, net	<u>\$ 167</u>	<u>\$ 174</u>

Amortization expense was \$13,709 in 2018 and \$8,511 in 2017. The weighted average remaining useful life as of December 31, 2018 was 10.37 years.

We capitalize patent costs and amortize them over their estimated economic lives and perform impairment testing when qualitative factors indicate that the assets may be impaired. We identified no indications of impairment for capitalized patent costs during 2018 and 2017 and did not record impairment charges in those years.

Amortization expense for the next five years is as follow:

	<u>US\$000</u>
2018	\$ 11
2019	11
2020	11
2021	11
2022	11
Thereafter	<u>112</u>
Total	<u>\$ 167</u>

(4) PROPERTY AND EQUIPMENT

Property and equipment consists of the following at December 31, 2018 and 2017:

	2018	2017
	<u>US\$000</u>	<u>US\$000</u>
Computer equipment and software	\$ 113	\$ 103
Office equipment	49	49
Furniture and fixtures	52	52
Leasehold improvements	12	12
Total costs	<u>226</u>	<u>216</u>
Less accumulated depreciation	(116)	(54)
Property and equipment, net	<u>\$ 110</u>	<u>\$ 162</u>

Depreciation expense was \$62,249 in 2018 and \$36,220 in 2017.

(5) CONVERTIBLE DEBT

From March 2012 through September 2014, the Company sold in private placements to qualified buyers and accredited investors notes for total funds received of \$5,371,582 ("Prior Notes"). Interest on the Prior Notes was payable upon maturity and accrued at a rate of 6% per annum. The Prior Notes would mature upon demand. Prior Notes were convertible into Series A-1 preferred stock or equity instruments issued in an equity financing.

From December 2014 to December 2015, the Company sold notes in private placements to qualified buyers and accredited investors for total funds received of \$2,936,397 ("Senior Notes"). Interest on the Senior Notes was due upon maturity and accrued a rate of 10% per annum. The Prior Notes became subordinated to the Senior Notes upon issuance.

In December 2014, upon issuance of the Senior Notes, Prior Note holders were given the option to convert \$2 of Prior Notes, including accrued interest balances, to Senior Notes for every \$1 invested in Senior Notes. As of December 31, 2016, Prior Notes of \$2,451,149 were outstanding. Senior Notes issued upon conversion of Prior Notes totaled \$3,240,523 as of December 31, 2016.

At December 31, 2014 and 2015, the Senior Notes plus accrued interest were convertible into Series C Redeemable Convertible Preferred Stock ("Series C") upon majority vote of the Senior Notes holders at a conversion price of \$0.73 per share. The conversion price was equivalent to the fair value of Series C on the commitment date, as measured by concurrent sales of Series C to external investors. Following conversion of all Series C to Preferred Stock Series A-1 ("Series A-1") and Preferred Stock A-1 NV ("Series A-1NV") in 2016, Senior Notes became convertible into Series A-1 and A-1 NV.

Upon the closing of an equity financing transaction, the Senior Notes plus accrued interest were convertible into the new equity shares at a conversion price equivalent to the price paid by the new equity investors.

The Senior Notes were issued in conjunction with embedded, contingently exercisable warrants with a purchase price equivalent to 0.02% of the associated Senior Notes. The number of shares to which the warrant entitles the holder is either (i) one-half the number of shares of stock into which the Senior Notes issued to the holder are converted, or (ii) the number of shares of common stock issuable upon the conversion of one-half of the number of shares of stock into which the Senior Notes issued to the holder are converted. The warrants were exercisable upon a qualified change in control from the period commencing with the date the Senior Notes were converted to equity securities ending with the earliest of December 2021 or the change in control event. The warrants were exercisable into the same equity class into which the Senior Notes are converted. The exercise price of the warrants was equivalent to the conversion price at which the Senior Note converted to equity or the fair market value of common stock.

In March 2016, the Company, entered into a Note and Warrant Purchase Agreement ("Series A-1 Note Purchase Agreement"), pursuant to which the Company issued Series A-1 convertible demand notes ("Series A-1 Notes") and contingently exercisable warrants to purchase shares of the Company's capital stock ("Series A-1 Warrants") and raised proceeds of \$1,418,141. Each lender who purchased a Series A-1 Note received a contingently exercisable Series A-1 Warrant to purchase equity securities of the Company, generally equal to 50% of the number of equity securities into which the Series A-1 Note associated with such Series A-1 Warrant was converted. As part of the Series A-1 Note transaction, the maturity date of each Senior Note was amended to be the date upon which a payment demand for the Series A-1 Notes was made by a majority-in-interest of the Series A-1 Note holders, and each Senior Note was made convertible upon the same terms as the Series A-1 Note and ranking pari passu with each Series A-1 Note in right of payment. In addition, the holders of Prior Notes agreed that the demand for payment of Prior Notes could not be made unless the Senior Notes and Series A-1 had been paid in full.

The Series A-1 Notes were payable upon demand by a majority-in-interest of the Series A-1 Note holders. The Series A-1 Notes were convertible into Series A-1 Stock following the earlier of: (a) the first anniversary of the Series A-1 Note Purchase Agreement, and (b) a liquidation event as defined in the Company's Certificate of Incorporation.

The Series A-1 Notes also were convertible upon the closing of an Equity Financing, which was defined as a subsequent sale by the Company of its equity securities (including the Company's common stock and any preferred stock) following the date of the Series A-1 Note Purchase Agreement. Any conversion was required to be approved by the holders of more than 50% of the aggregate unpaid principal amount of the Series A-1 Notes.

On October 10, 2016, the requisite Series A-1 Note and Senior Note holders entered into amendment agreements pursuant to which each Senior Warrant and Series A-1 Warrant would terminate and upon the conversion of the Series A-1 Notes and Senior Notes in connection with an equity financing, each Series A-1 Note and Senior Note will convert at a 25% discount to the otherwise applicable conversion price. In connection with the amendment of the Series A-1 Notes and Senior Notes, the Company determined that the conversion rights were a contingent share settled redemption feature. As a result of the amendment, the Company recorded derivative liabilities of \$360,898 and \$1,639,904 on the Series A-1 Note and Senior Note, respectively. Because the Series A-1 and Senior notes were due on demand, the Company immediately recorded the debt discounts as an expense at the date of the amendment. The Company recorded the derivative liability at its fair value at the date of the amendment and the fair value was marked to market resulting in a loss on derivative of \$292,233 for the year ended December 31, 2016 and \$597,405 upon conversion at the time of the Company's IPO in March 2017.

In July 2016, the Company entered into a Note Purchase Agreement with investors ("Pre-IPO Note Purchase Agreement"), pursuant to which the Company issued convertible notes, primarily to investors based in Australia ("Pre-IPO Notes"), raising proceeds of A\$13,497,000 (US\$10,109,336). The Pre-IPO Notes were denominated in Australian dollars (A\$) and automatically converted into the Company's equity securities upon an IPO pursuant to a conversion formula specified in the Pre-IPO Note Purchase Agreement. The conversion feature is considered to be a contingent share-settled redemption feature because it allows the holders to redeem the Pre-IPO Notes into common stock at a substantial discount to the fair value of the common stock issued upon conversion. The Company recorded a derivative liability for the fair value of the redemption feature of \$2,396,901. The Company amortized the debt discount resulting from the recognition of the derivative liability over the 18-month term of the Pre-IPO Note until conversion occurred at the time of the Company's IPO on the ASX in March 2017. The Company recorded the change in the fair value of the derivative liability as loss on derivative liability of \$286,051 at December 31, 2016 and \$823,649 upon conversion. At the time of conversion, the Company recorded a loss on share settlement of debt of \$1,459,653 relating to the unamortized debt discount on the Pre-IPO Notes.

All convertible debt was converted to common stock in March 2017 in connection with the Company's IPO.

The convertible debt did not affect diluted earnings per share due to the Company's net loss position.

(6) NON-CASH ACTIVITIES

On March 28, 2017, the convertible debt along with the embedded derivatives were converted to equity in a non-cash transaction totaling \$29,567,000 with an equal offset to Additional paid-in capital.

In 2018, optionees exercised options to purchase 652,250 shares, and redeemed 366,618 stock options to satisfy the exercise price of stock options exercised resulting in a net issuance of 285,632 shares.

(7) SHAREHOLDERS' EQUITY

Common Stock

Each holder of a share of common stock is entitled to one vote per share held. The holders of shares of common stock are entitled to dividends as declared by the Board of Directors ("Board") of the Company.

In March 2017, the Company completed its IPO and associated listing on the ASX. The Company issued 79,365,079 CDIs (each representing an interest in one share of newly issued common stock) and received \$23.4 million, net of expenses. In conjunction with the IPO (See Note 1), all outstanding convertible debt and preferred stock was converted into common stock.

On August 21, 2018, the Company issued 49,200,000 CDIs (representing the same number of shares) to complete a Placement of its shares. On September 12, 2018, the Company completed a Security Purchase Plan ("SPP") under which it issued 1,913,328 CDIs. The Company raised \$6.2 million net of \$0.5 million of issuance costs through the Placement and the SPP.

Preferred Stock Series A-1 and Preferred Stock Series A-1 NV

In 2016, the Company issued Series A-1 Notes and Series A-1 warrants under the Series A-1 Note Purchase Agreement dated March 2, 2016. Holders of the Company's preferred stock (i.e., Series A, Series B and Series C) were entitled to invest up to their pro rata amount in the borrowing. In connection with the transaction, all outstanding Preferred Stock Series A, B and C was converted as follows:

The preferred shares of any holder who did not invest its pro rata amount were automatically converted on April 12, 2016 into the Company's common stock at an exchange rate of one share of common stock for each share of preferred stock which was the conversion rate stated in the original terms of the shareholder agreements for the Series A, B and C.

The preferred shares of any holder who invested its pro rata amount were deemed to have been exchanged for shares of Series A-1 at an exchange rate of 3.2 shares of Series A-1 for each share of preferred stock. Further, a portion of the Series A-1 was exchanged for shares of Series A-1 NV. Series A-1 NV possesses identical rights to Series A-1, except that its holders have no voting rights. Both the Series A-1 and the Series A-1 NV convert into common stock at their original issue price.

As a result of the Series A-1 financing round in 2016, only common stock, Series A-1 and Series A-1 NV remained issued and outstanding at December 31, 2016. At the time of the Company's IPO in March 2017, the Series A-1 and Series A-1 NV converted into common stock and only common stock has been outstanding since March 2017.

(8) CONCENTRATIONS AND CREDIT RISK

For the year ended December 31, 2018, two Customers accounted for approximately 92.5% of our total sales. Three Customers, including the two noted previously, accounted for 91.9% of our accounts receivable as of December 31, 2018.

For the year ended December 31, 2017, two Customers accounted for approximately 57.7% of our total sales. These two same Customers accounted for 100% of our accounts receivable as of December 31, 2017.

We rely on a single manufacturer for production of our contact lenses.

(9) SEGMENT INFORMATION

The Company's chief operating decision maker is the Chief Executive Officer ("CEO"). While the CEO is apprised of a variety of financial metrics and information, the business is principally managed and organized based upon a single reporting segment.

(10) STOCK COMPENSATION PLANS

Stock-based compensation expense was \$259,268 in 2018 and \$494,291 in 2017.

The Board adopted the 2008 Stock Incentive Plan (“Incentive Plan”), with an effective date of July 1, 2008. The Incentive Plan permits the granting and issuance of Incentive Stock Options, Non-Qualified Stock Options, Restricted Stock Awards, Restricted Stock Units, and Stock Appreciation Rights. Under the Incentive Plan, 12,160,873 shares of common stock have been authorized for share-based awards. The total number of options issued and outstanding as of December 31, 2018 and December 31, 2017 was 8,571,324 and 11,535,574, respectively. The Incentive Plan is the predecessor to the 2017 Plan described below. On January 18, 2017, the Board determined that no additional stock incentives would be awarded under the 2008 Incentive Plan, but stock incentives previously granted would continue to be governed by the terms of the Incentive Plan.

The Board adopted the 2017 Equity Incentive Plan (the “2017 Plan”), with an effective date of January 18, 2017. The 2017 Plan permits the granting and issuance of Incentive Stock Options, Non-Qualified Stock Options, Restricted Stock, Stock Units, Performance Awards and Stock Appreciation Rights. The total number of shares reserved for issuance under the 2017 Plan is 11,000,000. The share reserve may be increased each year in accordance with the 2017 Plan documents. The total number of shares issued and outstanding as of December 31, 2018 and 2017 was 2,758,044 and 978,331, respectively

For both the Incentive Plan and the 2017 Plan (together, the “Plans”), the Board determines vesting terms and exercise price of options and defines them in a stock incentive agreement for each grant. Options generally vest over a one to four-year period from date of grant, with a few grants being vested immediately upon issuance. Stock options issued to employees, directors, and consultants expire 10 years from the date of grant. Vested and unexercised shares are cancelled three months after termination, and unvested awards are canceled on the date of termination of employment and become available for future grants. Upon the exercise of stock options, the Company may issue the required shares out of authorized but unissued common stock.

Additionally, we recognize stock-based compensation expense related to stock options granted to non-employees on a straight-line basis, as the stock options are earned. We issued options to non-employees, which generally vest ratably over the time period we expect to receive services from the non-employee. We believe that the fair value of the stock options is more reliably measurable than the fair value of the services received.

We estimate the grant date fair value of each option award on the date of grant using a Black-Scholes option pricing model that uses certain assumptions. Pre-IPO, we determined the estimated fair value of common stock with the assistance of an independent valuation specialist. Post IPO, we use the ASX stock price to determine fair value of the stock on the date of grant. We base expected volatilities on historical volatility of certain comparable companies over similar expected terms, as determined by the Company. We derive the expected term of options granted using the simplified method, which is the average of the contractual term and the vesting period. We intend to use the simplified method for the foreseeable future until more detailed information about exercise behavior will be more widely available. We base the risk-free rate for periods within the expected term of the option on the U.S. Treasury yield curve in effect at the time of grant. The dividend yield is zero as there are no payments of dividends made or expected. These factors could change in the future, which would affect the stock-based compensation expense for future option grants.

Assumptions for grants in 2018 and 2017 are as follows:

	<u>2018</u>	<u>2017</u>
Risk-free interest rate	1.25%	1.25%
Expected volatility	50%	50%
Expected term (years)	6	6
Dividend Rate	0%	0%

A summary of stock option activity under the Plans is as follows:

	<u>Total Options Outstanding</u>			<u>Nonvested Options</u>	
	Number of Options	Weighted Average Exercise Price US\$	Weighted Average Remaining Contractual Term in Years	Number of Options	Weighted Average Grant-Date Fair Value
<u>Total Stock Options</u>					
Outstanding at December 31, 2017	12,513,905	\$0.09	8.35	7,896,846	\$0.13
Grants	2,758,044	0.14		2,758,044	0.06
Cancellation/forfeitures	(3,495,261)	0.14		(2,594,581)	0.14
Vested	-	-		(1,767,422)	0.13
Exercised	(447,320)	0.07		-	-
Outstanding at December 31, 2018	<u>11,329,368</u>	<u>\$0.09</u>	<u>8.23</u>	<u>6,292,887</u>	<u>\$0.10</u>
Exercisable	<u>5,036,481</u>	<u>\$0.07</u>	<u>7.54</u>		

The weighted average grant date fair value of options granted during the year was \$0.06 in 2018 and \$0.13 in 2017. The intrinsic value of options unexercised as of December 31, 2018 and 2017 was \$360,831 and \$4,242,751, respectively. The intrinsic value of options exercised was \$24,083 in 2018. The total fair value of options vested during the year was \$226,230 in 2018. Options cancelled in 2018 included 366,618 options remitted by optionees to satisfy the exercise price of options exercised.

As of December 31, 2018 and 2017, there was approximately \$566,901 and \$956,328, respectively, of total unrecognized compensation expense related to stock option awards under the combined plans. We expect to recognize that cost over a weighted average period of 2.67 years.

(11) EMPLOYEE BENEFIT PLAN

The Company has a 401(k) retirement plan ("401(k) Plan") for the benefit of eligible employees, as defined. Each participant may elect to contribute to the 401(k) Plan each year up to the maximum amount allowed by law, subject to certain Internal Revenue Service limitations. The Company makes matching contributions up to 100% of the participant's election not to exceed 4% of the participant's compensation. The Company contributed \$212,724 in 2018 and \$135,350 in 2017.

(12) COMMITMENTS AND CONTINGENCIES

The Company's headquarters and principal operations are located in metropolitan Atlanta, Georgia. We record operating leases with escalating rents as expense on a straight-line basis over the life of the lease. In addition to minimum rental payments, we expense additional payments based on real estate taxes, common

area maintenance and insurance when incurred. Net rental expense under this and previous agreements were \$157,459 in 2018 and \$109,000 in 2017.

As of December 31, 2018, future rental commitments are as follows:

	US\$000
2019	\$ 99
2020	101
2021	105
2022	108
2023	9
	<u>\$ 422</u>

The Company may be subject to legal proceedings and claims, which may arise, in the ordinary course of its business. No such matters presently exist, and management is not aware of any such matters which may arise in the future.

In addition, the Company warrants to customers that its products operate substantially in accordance with the product's specifications. Historically, we have not incurred any significant costs related to product warranties and expect none in the future, and as such have not recorded any accruals for product warranty costs as of December 31, 2018.

(13) RELATED PARTIES

We incurred \$560,232 in fees and expenses in 2018 for clinical and regulatory consulting services provided by a company owned by one of our former officers. We included the unpaid portion of this amount of \$50,875 in Other accrued liabilities as of December 31, 2018.

(14) FAIR VALUE

The Company applies ASC 820, *Fair Value Measurements*, in determining the fair value of certain assets and liabilities. Under this standard, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

In determining fair value, we use various valuation approaches. The hierarchy of those valuation approaches is broken down into three levels based on the reliability of inputs as follows:

Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. An active market for the asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis. The valuation under this approach does not entail a significant degree of judgment.

Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs include quoted prices for similar assets or liabilities in active markets, inputs other than quoted prices that are observable for the asset or liability, and contractual prices for the underlying financial instrument, as well as other relevant economic measures.

Level 3 inputs are unobservable inputs for the asset or liability. Unobservable inputs shall be used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at the measurement date.

There have been no changes in the methodologies used as of December 31, 2018 and 2017.

The Company's assets and liabilities measured at fair value on a recurring basis include cash equivalents of \$7.0 million and \$16.3 million as of December 31, 2018 and 2017, respectively.

(15) INCOME TAXES

The Company is a C-Corporation for U.S. federal income tax purposes.

On December 22, 2017, the President signed into law the Tax Cuts and Jobs Act ("the Act"), which took effect on January 1, 2018. Some notable provisions of the Act include a reduction of the corporate income tax rate from 35 percent to 21 percent, adjustments to deductible compensation, and 100 percent bonus depreciation on capital expenditures. Under the accounting rules, companies are required to recognize the effects of changes in tax laws and tax rates on deferred tax assets and liabilities in the period in which the new legislation is enacted. As a result, as of December 31, 2017, the Company revalued its deferred tax assets and liabilities, which resulted in no impact to the statement of operations due to the Company being in a fully reserved deferred tax asset position. We believe that the adjustments resulting from these components of the Act are complete as of December 31, 2017.

The provision for income taxes consists of the following components:

	2018 US\$000	2017 US\$000
Current expense		
Federal	\$ -	\$ -
State	-	-
Total current income tax expense	<u>\$ -</u>	<u>\$ -</u>
Deferred expense (benefit)		
Federal	\$ (3,302)	\$ 1,643
State	<u>(1,107)</u>	<u>(176)</u>
Total deferred income tax expense (benefit)	(4,409)	1,467
Valuation allowance	<u>4,409</u>	<u>(1,467)</u>
Deferred income tax expense (benefit)	-	-
Total income tax expense	<u>\$ -</u>	<u>\$ -</u>

The following summarizes the Company's valuation allowance:

	2018 US\$000	2017 US\$000
Beginning of year	\$ (8,567)	\$ (10,034)
Income tax provision	(4,409)	(2,529)
Deferred rate change	-	3,996
End of year	<u>\$ (12,976)</u>	<u>\$ (8,567)</u>

Net deferred tax assets and liabilities are as follows:

	2018 US\$000	2017 US\$000
Deferred tax assets		
NOL carryforwards	\$ 11,882	\$ 7,508
R&D tax credits	915	867
Inventory	223	-
Other deferred tax assets	39	192
Valuation allowance	(12,976)	(8,567)
Total deferred tax assets	<u>\$ 83</u>	<u>\$ -</u>
Deferred tax liabilities		
Amortization	\$ (83)	\$ -
Total deferred tax liabilities	<u>(83)</u>	<u>-</u>
Net deferred income tax assets	<u>\$ -</u>	<u>\$ -</u>

A reconciliation from the federal statutory rate to the total provision for income taxes is as follows:

	2018		2017	
	US\$000	Percent	US\$000	Percent
Federal tax benefit at statutory rate	\$ (3,514)	21%	\$ (5,774)	34%
State tax expense, net of federal benefit	(1,107)	7%	(116)	1%
Permanent items and other	212	-1%	40	0%
Conversion of debt to equity	-	0%	3,321	-20%
Impact of Tax Cuts and Jobs Act	-	0%	3,996	-24%
Change in valuation allowance	4,409	-26%	(1,467)	9%
Total tax expense	<u>\$ -</u>	<u>0%</u>	<u>\$ -</u>	<u>0%</u>

As of December 31, 2018, the Company had federal NOL carryforwards of approximately \$46.8 million and state NOL carryforwards of \$2.1 million (tax effected), that are available to reduce future income unless otherwise taxable. As of December 31, 2018, the Company has federal and state research and development ("R&D") credits of approximately \$0.9 million, that are available to reduce future federal and state income tax. We have not performed a study of our NOLs for limitations Internal Revenue Code Section 382. Due to the ownership change as a result of the IPO, our NOLs could be subject to significant annual limitations. If not utilized, the federal and state NOL carryforwards will expire at various dates between 2024 and 2037, except that \$15.6 million of NOLs originating in 2018 do not expire. The federal and state R&D credits will expire at various dates between 2021 and 2037.

(16) SUBSEQUENT EVENTS

The Company evaluated the accounting and disclosures requirements for subsequent events through February 18, 2019, the issuance date of the financial statements.