

**ASX Announcement | 18 February 2021
Visioneering Technologies (ASX:VTI)**

Visioneering Technologies, Inc., Appendix 4E

Atlanta, Georgia, Wednesday, 17 February 2021 (Thursday, 18 February 2021 Sydney time): 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 2020.

Ends.

This release was authorized by the CEO, Stephen Snowdy, PhD

For more information, please contact:

<i>Visioneering Technologies, Inc.</i>	<i>Investor and media relations</i>
Stephen Snowdy CEO, Visioneering Technologies, Inc. Email: ssnowdy@vtivision.com	Julia Maguire The Capital Network Tel: +61 419 815 386 Email: julia@thecapitalnetwork.com.au

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 Depository 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.

Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management. Forward-looking statements involve known and unknown risks, uncertainties, contingencies and other factors, many of which are beyond the Company's control (including but not limited to the COVID-19 pandemic), subject to change without notice and may involve significant elements of subjective judgment and assumptions as to future events which may or may not be correct.

All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements. These include, without limitation, U.S. commercial market acceptance and U.S. sales of our product, as well as our expectations with respect to our ability to develop and commercialize new products.

Any forward-looking statements are provided as a guide only and should not be relied upon as an indication or guarantee of future performance. A number of important factors could cause actual results or performance to differ materially from the forward-looking statements. You should not place undue reliance on forward-looking statements because they speak only as of the date when made, and are subject to change without notice. Given the current uncertainties regarding the on-going impact of the COVID-19 on the trading conditions impacting Visioneering, the financial markets and the health services world-wide, there can be no assurance that future developments will be in accordance with Visioneering's expectations or that the effect of future developments on Visioneering will be those anticipated. Actual results may differ materially from what is expressed in this presentation and investors are cautioned not to place undue reliance on the current trading outlook.

Visioneering does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Visioneering may not actually achieve the plans, projections or expectations disclosed in forward-looking statements.

VTI-IR-ASX-46

APPENDIX 4E (RULE 4.3A)

PRELIMINARY FINAL REPORT FOR THE YEAR ENDED 31 DECEMBER 2020

RESULTS FOR ANNOUNCEMENT TO THE MARKET

(US\$ in 000's, unaudited, except account, per account and per share data)	2020	2019	up/down	% movement
Net Revenue	\$5,105	\$5,722	down	-11%
Shipments to US ECPs (A)	\$5,610	\$5,613	-	-0%
Active US Accounts (B)	2,074	1,997	up	4%
Shipments to US ECPs per Active US Account	\$2,705	\$2,811	down	-4%
Loss after tax from ordinary activities attributable to members	(\$9,239)	(\$12,617)	down	-27%
Net loss after tax attributable to members	(\$9,239)	(\$12,617)	down	-27%
Dividend per security	Nil	Nil		
Franked amount of dividends per security	Nil	Nil		
Net tangible asset backing per CHES Depository Interest / Share of Class A common stock	(\$0.002)	\$0.002		

(A) Shipments to US ECPs, or Eye Care Professionals, represents the gross revenue equivalent of lenses shipped to ECPs located in the US, net of fulfillment fees.

(B) Active US Accounts are ECPs located in the US that purchased VTI products in the most recent fiscal quarter.

- Annual financial results:** This report is based on the accompanying 2020 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 2020.
- 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 (US\$ in 000's except per share data):** The net loss for the year decreased to \$9,239 compared to \$12,617 for the previous corresponding period. Basic and Diluted earnings per share was (\$0.01) and (\$0.04) for the years ended 31 December 2020 and 2019, respectively.
 - Net revenue decreased to \$5,105 from \$5,722 for the previous period, primarily as a result of lower net revenue in the second quarter during which many ECPs were closed or had limited hours of operation due to restrictions associated with the COVID-19 pandemic. In addition, 2019 included an initial stocking order from VTI's private label partner Menicon of \$476. Excluding the Menicon purchase, net revenue decreased 3% between years.

- Shipments to US ECPs were essentially flat with FY19 despite the ongoing COVID-19 pandemic and staffing cuts at the Company.
- Cost of Sales decreased to \$2,881, or 56.4% of net revenue in 2020 from \$3,753, or 65.6% of net revenue, in 2019. The monetary decrease primarily resulted from the decrease in Net revenue. As a percentage of net revenue for the relevant period, Cost of sales decreased due to improvements in gross profit as we gained volume related purchasing efficiencies, increased our selling prices and shifted more sales to our multifocal product that has a higher gross profit than our sphere product.
- Total Operating Expenses decreased to \$9,936 from \$14,626 for the previous period, reflecting lower costs for trial lenses and savings in sales, clinical and manufacturing expenses driven primarily by VTI implementing a reduction of its workforce on 2 April 2020, eliminating 22 of its 42 employees.
- Total Interest income and other, net decreased to \$9 from \$90 due to a decrease in cash on hand.
- Interest expense increased to \$334 from \$164 due to issuance of \$3,000 in Convertible Notes in July 2019 which bear interest at 10%.
- Gain(loss) on fair value of derivative liability decreased to (\$130) from \$123 for the previous period due to the change in fair value of the derivative liability associated with the Convertible Notes.
- Loss on fair value of freestanding options increased to \$1,069 from \$0 for the previous period due to the change in the fair value of the derivative liability associated with the freestanding options issued in June 2020.
- The Company had cash and cash equivalents of \$2,408 at 31 December 2020.
- The Company operated in two reportable segments during the period, including North America and Europe/Asia-Pacific.
- There were no returns to shareholders or share buy backs.

Placement and Security Purchase Plan

On 17 February 2021, VTI announced that it had received commitments for an over-subscribed A\$22 million placement (“Placement”). In addition to commitments of new capital from new and existing investors, certain Non-Executive Directors will subscribe for CDIs or shares on the same terms as the Placement to raise approximately an additional A\$120,000. The investors also will receive one option to purchase an additional CDI for each two CDIs purchased in the Placement. The options will have an exercise price of \$0.03 AUD per CDI and will expire in February 2024. VTI also will offer a Security Purchase Plan (“SPP”) of up to A\$1.0 million under the same terms as the Placement.

VTI plans to use the capital for expansion of sales in existing global territories, general working capital, and for clinical trials data that will support approval in China, additional market penetration, and strategic business development. Visioneering expects the new capital to fund the Company through to, or close to, break-even cash flow.

The Placement and SPP are both subject to stockholder approval at a Special Meeting of the Company, which is scheduled for Wednesday, 17 March 2021. If the Placement and related capital raising resolutions are approved at the Special Meeting, settlement of the Placement is expected to occur on or around Monday, 22 March 2021.

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.

VISIONEERING TECHNOLOGIES, INC.

FINANCIAL STATEMENTS

For the Years Ended December 31, 2020 and 2019

VISIONEERING TECHNOLOGIES, INC.

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GRANT THORNTON LLP

1100 Peachtree St. NE, Suite 1200
Atlanta, GA 30309

D +1 404 330 2000

F +1 404 330 2047

REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

Board of Directors
Visioneering Technologies, Inc.

We have audited the accompanying financial statements of Visioneering Technologies, Inc. (a Delaware corporation), which comprise the balance sheets as of December 31, 2020 and 2019, and the related statements of operations, changes in shareholders' 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, 2020 and 2019, 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 \$80.8 million as of December 31, 2020, 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 17, 2021

VISIONEERING TECHNOLOGIES, INC.

BALANCE SHEETS
As of December 31, 2020 and 2019

	December 2020	December 2019
	(in US\$000, except share data)	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 2,408	\$ 1,919
Accounts receivable	944	835
Inventory, net	550	2,211
Prepaid expenses and other current assets	523	195
	4,425	5,160
NON-CURRENT ASSETS		
Property and equipment, net	23	57
Right of use assets, net	183	262
Intangible assets, net	177	153
Other non-current assets	179	198
	4,987	5,830
LIABILITIES		
CURRENT LIABILITIES		
Accounts payable	\$ 330	\$ 279
Accrued payroll	115	839
Derivative liability	1,769	-
Other accrued liabilities	500	659
	2,714	1,777
LONG-TERM LIABILITIES		
Convertible notes payable	2,830	2,863
Paycheck Protection Program note payable	1,035	-
Other non-current liabilities	113	208
	6,692	4,848
Commitments and contingencies (Note 13)		
EQUITY (DEFICIT)		
Class A common stock, par value \$0.001 per share; 2,500,000,000 shares authorized, 993,277,625 shares issued and outstanding at December 31, 2020 and 399,135,152 shares issued and outstanding at December 31, 2019	994	399
Preferred stock, par value \$0.001 per share; 50,000,000 shares authorized, no shares issued and outstanding at December 31, 2020 and December 31, 2019	-	-
Additional paid-in capital	78,124	72,167
Accumulated deficit	(80,823)	(71,584)
	(1,705)	982
TOTAL SHAREHOLDERS' EQUITY (DEFICIT)	(1,705)	982
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)	\$ 4,987	\$ 5,830

See accompanying notes to financial statements

VISIONEERING TECHNOLOGIES, INC.

STATEMENTS OF OPERATIONS
For the Years Ended December 31, 2020 and 2019

	Year Ended December 31,	
	2020	2019
	(in US\$000, except share and per share data)	
Net revenue	\$ 5,105	\$ 5,722
Cost of sales	<u>2,881</u>	<u>3,753</u>
Gross profit	2,224	1,969
Operating Expenses:		
Sales and marketing	5,179	9,147
Clinical and manufacturing	1,438	2,092
General and administrative	<u>3,319</u>	<u>3,387</u>
Total operating expenses	<u>9,936</u>	<u>14,626</u>
Operating loss	(7,712)	(12,657)
Other income and (expenses):		
Interest income and other, net	9	90
Interest expense	(334)	(164)
Gain (loss) on fair value of derivative liability	(130)	123
Loss on fair value of freestanding options	<u>(1,069)</u>	<u>-</u>
Loss before income taxes	(9,236)	(12,608)
Income tax expense	<u>3</u>	<u>9</u>
Net loss	<u>\$ (9,239)</u>	<u>\$ (12,617)</u>
Net loss per share – Basic and Diluted	<u>\$ (0.01)</u>	<u>\$ (0.04)</u>
Weighted average shares outstanding – Basic and Diluted	<u>745,510,730</u>	<u>324,246,597</u>

See accompanying notes to financial statements

VISIONEERING TECHNOLOGIES, INC.

STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY (DEFICIT)
For the Years Ended December 31, 2020 and 2019

	Common Stock		Additional Paid-In Capital US\$000	Accumulated Deficit US\$000	Total US\$000
	Number of Shares	Amount US\$000			
Balance at December 31, 2018	248,619,294	\$ 249	\$ 67,683	\$ (58,967)	\$ 8,965
Issuance of common stock, net of issuance costs	150,515,858	150	4,182	-	4,332
Stock-based compensation	-	-	302	-	302
Net loss	-	-	-	(12,617)	(12,617)
Balance at December 31, 2019	399,135,152	399	72,167	(71,584)	982
Issuance of common stock, net of issuance costs:					
January 2020 placement	66,666,667	67	1,830	-	1,897
June 2020 placement and SPP	441,147,810	441	2,665	-	3,106
Share awards for 2019 compensation	19,676,299	20	216	-	236
Issuance of common stock for convertible debt	10,152,043	10	191	-	201
Exercise of freestanding options	14,257,137	14	269	-	283
Stock-based compensation	42,242,517	43	786	-	829
Net loss	-	-	-	(9,239)	(9,239)
Balance at December 31, 2020	993,277,625	\$ 994	\$ 78,124	\$ (80,823)	\$ (1,705)

See accompanying notes to financial statements

VISIONEERING TECHNOLOGIES, INC.

STATEMENTS OF CASH FLOWS
For the Years Ended December 31, 2020 and 2019

	Year Ended December 31,	
	2020	2019
	(in US\$000)	
Cash flows from operating activities:		
Net loss	\$ (9,239)	\$ (12,617)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	54	68
(Gain) loss on fair value of derivative liability	130	(123)
Interest expense paid with common stock	1	-
Change in fair value of freestanding options	1,069	-
Amortization of right-of-use asset	79	-
Amortization of debt discount	37	22
Stock-based compensation	829	302
Changes in assets and liabilities:		
Accounts receivable	(109)	(340)
Inventory	1,661	(189)
Prepaid expenses and other assets	(328)	(83)
Accounts payable	50	139
Accrued payroll	(488)	299
Other accrued liabilities	(254)	(129)
Net cash used in operating activities	(6,508)	(12,651)
Cash flows from investing activities:		
Purchases of property and equipment, net	(1)	(1)
Purchases of intangible assets	(23)	-
Net cash used in investing activities	(24)	(1)
Cash flows from financing activities:		
Issuance of common stock, net of issuance costs of \$583 in 2020 and \$365 in 2019	5,703	4,332
Proceeds from exercise of freestanding options	283	-
Issuance of convertible debt, net of debt discount of \$36	-	2,964
Issuance of note payable	1,035	-
Net cash provided by financing activities	7,021	7,296
Net increase (decrease) in cash and cash equivalents	489	(5,356)
Cash and cash equivalents, beginning of period	1,919	7,275
Cash and cash equivalents, end of period	\$ 2,408	\$ 1,919
Supplemental disclosure:		
Cash paid for interest	\$ 296	\$ 164
Cash paid for taxes	\$ 3	\$ 9
Share awards for 2019 compensation	\$ 236	\$ -
Issuance of freestanding options	\$ 700	\$ -

See accompanying notes to financial statements

VISIONEERING TECHNOLOGIES, INC.

NOTES TO FINANCIAL STATEMENTS

For the Years Ended December 31, 2020 and 2019

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 United States (“US”), medical devices are regulated by the U.S. Food and Drug Administration (“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 Australian Therapeutic Goods Administration (“TGA”) approval in early 2018, enabling us to sell our contact lenses in the US, Europe, Australia and New Zealand. In 2019, we received approval to sell our contact lenses in Hong Kong and Singapore. In 2020, we received approval to sell our contact lenses in Canada.

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 is held by a depository, CDN, which is a wholly-owned subsidiary of the ASX, and is an approved general participant of ASX Settlement.

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 professionals (“ECPs”) and shipped only to ECPs or directly to a patient if specifically directed by the ECPs. As of December 31, 2020, VTI had entered into agreements with Customers in the US, Europe, Australia, New Zealand, Hong Kong, Singapore and Canada.

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 evaluation 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 \$80.8 million from the Company’s inception through December 31, 2020. As of December 31, 2020, the Company’s cash and cash equivalents were \$2.4 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 and maintain compliance with our debt covenant, we will need to raise additional debt or equity financing. We historically have been able to

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raise additional capital through issuance of equity and/or debt financing and recently announced a potential financing (Note 17). We have a plan in place to reduce spending in the absence of further capital being raised to satisfy our 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 financing or successfully implement our cost reduction plans in order to ensure that we can meet our working capital needs for a full year from the date of issuance of these financial statements. Accordingly, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year after these financial statements are issued.

Effect of the COVID-19 Pandemic

The public health crisis caused by the COVID-19 pandemic and the measures being taken by governments, businesses, and the public to limit the spread of COVID-19 have had, and the Company expects to continue to have, certain negative effects on, and present certain risks to, the Company's business. The Company is currently unable to fully determine the future impact on its business. The COVID-19 pandemic had an adverse impact on the Company's revenues late in the first quarter of 2020 and throughout the second quarter of 2020, when net revenue declined substantially from the first quarter. Net revenue and related metrics improved each month in the second quarter and continued to improve in the third quarter before declining again in the fourth quarter as the virus surged in the US and abroad. The Company is monitoring the pandemic and its effect on the Company's financial position, results of operations and cash flows. Should the pandemic continue for an extended period and revenue metrics decline, the impact on the Company's operations could have an adverse effect on the Company's revenue, financial condition and cash flows.

Basis of Presentation

The Company has prepared the accompanying financial statements and notes 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, the fair value of derivatives, 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.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, including cash and cash equivalents and current assets and liabilities approximate their fair value because of their short maturities. The weighted average interest rate of the Company's convertible debt approximates the rate at which the Company could obtain alternative financing; therefore, the carrying amount of the convertible debt approximates fair value. The Company uses a binomial lattice model and assumptions that consider, among other variables, the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the conversion feature of the Convertible Notes (Note 5), and the Black-Scholes option valuation model to determine the fair value of freestanding options (Note 7).

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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 \$2.4 million as of December 31, 2020 and \$1.9 million as of December 31, 2019. 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, 2020 or 2019.

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 did not record any increases to inventory reserves in the years ended December 31, 2020 or 2019. All inventory held at December 31, 2020 and 2019 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 include depreciation expense in General and administrative expense in the Statements of Operations.

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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 assessments in the years ended December 31, 2020 or 2019.

Revenue Recognition

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606, as amended)*, 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. 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 approximately \$696,000 in 2020 and \$309,000 in 2019 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 approximately \$75,000 and \$38,000 in 2020 and 2019, respectively 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.

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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, 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, 2020. 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 shareholders 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, and convertible debt. 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 stock options in the computation of dilutive EPS because to do so would have been anti-dilutive.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") No. 2016-13, *Financial Instruments – Credit Losses (Accounting Standards Codification (ASC 326))*: *Measurement of Credit Losses on Financial Instruments*. This ASU replaces the current incurred loss impairment methodology for financial assets measured at amortized cost with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information, including forecasted information, to develop credit loss estimates. The standard becomes effective for the Company on January 1, 2023. The Company does not anticipate the adoption of this ASU will have a material impact on its financial statements.

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.

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The amendments in Part I of this Update were effective for the Company beginning January 1, 2020. The adoption of this guidance did not have a material impact on the Company's financial statements,

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. This ASU removes certain exceptions to the general principles and simplifies areas such as franchise taxes, step-up in tax basis goodwill, separate entity financial statements and interim recognition of enactment of tax laws or rate changes. The guidance is effective for reporting periods beginning after December 15, 2020, including interim reporting periods within those fiscal years. The Company is evaluating the impact of the adoption of this standard on its financial statements.

In August 2020, the FASB issued ASU 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. This standard simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The standard requires entities to provide expanded disclosures about the terms and features of convertible instruments and amends certain guidance in ASC 260 on the computation of EPS for convertible instruments and contracts on an entity's own equity. The standard becomes effective for the Company on January 1, 2022. The Company is currently assessing the impact of adoption of the ASU.

(2) REVENUE RECOGNITION

We sell our products to our Customers, primarily including major contact lens manufacturers and 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 our Customers. We then reimburse the Customers for discounts they provided on our behalf to the ECPs. Each of our current contracts consists 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 therefore is 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. Taxes collected from Customers relating to product sales and remitted to governmental authorities are excluded from revenues.

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.

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(3) INTANGIBLE ASSETS

Intangible assets consist of the following as of December 31, 2020 and 2019:

	2020 US\$000	2019 US\$000
Patents	\$ 282	\$ 240
Less accumulated amortization	(105)	(87)
Intangible assets, net	\$ 177	\$ 153

Amortization expense was approximately \$18,000 and \$14,000 in 2020 and 2019, respectively. The weighted average remaining useful life of our patents as of December 31, 2019 was 9.4 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 2020 and 2019 and did not record impairment charges in those years.

Amortization expense for the next five years is as follows:

	US\$000
For the year ended December 31,	
2021	\$ 15
2022	15
2023	15
2024	15
2025	15
Thereafter	102
Total	\$ 177

(4) PROPERTY AND EQUIPMENT

Property and equipment consists of the following at December 31, 2020 and 2019:

	2020 US\$000	2019 US\$000
Computer equipment and software	\$ 116	\$ 114
Office equipment	49	49
Furniture and fixtures	52	52
Leasehold improvements	12	12
Total costs	229	227
Less accumulated depreciation	(206)	(170)
Property and equipment, net	\$ 23	\$ 57

Depreciation expense was approximately \$36,000 and \$54,000 in 2020 and 2019, respectively.

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(5) CONVERTIBLE NOTES PAYABLE

The following table presents a reconciliation of the beginning and ending balances for the years ended December 31, 2020 and 2019:

	2020 US\$000	2019 US\$000
Balance at January 1,	\$ 2,863	\$ -
Issuance of debt, net of issuance costs	-	2,964
Conversion of convertible note to CDIs	(200)	-
Amortization of deferred financing costs	37	22
Loss (gain) on derivative liability	130	(123)
Balance at December 31,	\$ 2,830	\$ 2,863

In July 2019, the Company entered into a Note Purchase Agreement (“Convertible Notes”) with Investors raising proceeds of \$3.0 million before issuance costs. The Convertible Notes were issued at face value of \$1 per Note and are convertible at the election of the Note holder at any time before the maturity date to CDIs at a conversion price per CDI of \$0.075AUD. The maturity date at issuance was July 11, 2021. The maturity date was extended to July 11, 2023 in January 2020. The conversion price was adjusted to \$0.028 AUD in connection with the Placement completed in June 2020 (see Note 7).

The Convertible Notes bear interest at 10% per annum with interest payable quarterly in arrears. If an event of default occurs, the rate of interest will increase to 12% until such default is cured by the Company or waived by the majority of the Note holders. The Company or Note holder may elect to satisfy the whole or part of an interest payment by issuance of CDIs subject to consent of the other party. The issue price of each CDI under this clause will be the greater of the amount equal to 90% of the average volume weighted average price for the five trading days immediately preceding the date of the election notice or the conversion price. The Convertible Notes contain a prepayment penalty of 2% of the face value of the note if paid prior to the maturity date.

In October 2020, a Note holder converted \$200,000 face value of Convertible Notes and accrued interest and received 10,152,043 CDIs in the conversion.

The conversion feature is considered to be an embedded derivative that is not considered clearly and closely related to the debt host and therefore must be bifurcated and accounted for separately from the debt host. The Company recorded a debt discount and a conversion option liability of approximately \$123,000 for the fair value of the conversion feature at issuance. The Company is amortizing the debt discount over the four-year term of the Convertible Notes. We adjust the conversion option liability to market at each reporting period. We reduced the derivative liability to \$0 as of December 31, 2019 as a result of many factors, including a decrease in the share price. We evaluated the effect of the June 2020 change in the conversion price noted above and determined that the conversion option liability was not impacted by the change in the conversion price. The liability was \$0 at the date of change in the conversion price. We increased the derivative liability to \$130,000 as of December 31, 2020 as a result of many factors, including an increase in the share price.

The Convertible Note includes covenants related to liquidity and net monthly cash flow. The Company has complied with the net monthly cash flow covenant from the issuance of the Convertible Notes through December 31, 2020. The Company was not in compliance with the liquidity covenant in April 2020. The majority holder of the Convertible Notes consented to the Company not meeting the liquidity covenant through the date that the Placement completed in conjunction with the Company agreeing to adjust the conversion rate for the Convertible Notes from \$0.075 AUD to \$0.028 AUD, provided that the majority holder participated in the Placement at a minimum subscription amount. The Placement was completed as planned and the Company returned to compliance with all covenants as of the Placement date and remained in compliance as of December 31, 2020. The convertible debt did not affect diluted earnings per share due to the Company’s net loss position.

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(6) PAYCHECK PROTECTION PROGRAM NOTE PAYABLE

On April 24, 2020, the Company received a loan under the Paycheck Protection Program (“PPP”) administered by the US Small Business Administration (“SBA”) in the amount of \$1,035,115 (“PPP Loan”). The PPP is a disaster relief program in the United States that provides loans to US-based small businesses, for which some or all the loan may be forgiven. The loan proceeds may be used to pay for payroll, rent and utilities.

The PPP Loan originally was a two year note that provided a 6-month deferral period during which no principal or interest was due. Subsequently, the PPP Loan was revised to be a five year note with a one-year deferral of principal and interest. The PPP Loan bears interest at 1% per annum, with equal principal and interest payments due monthly after the deferral period in amounts required to fully amortize the principal amount outstanding by the maturity date.

In January 2021, the Company has applied for forgiveness of approximately \$921,000 of the PPP Loan which, if approved, would leave a remaining balance of approximately \$114,000 (Note 17). The Company is accounting for the PPP Loan as debt and will derecognize the portion of the PPP Loan that is forgiven, if any, when the SBA approves a forgiveness amount and legally releases the Company from liability for that portion of the debt. The remaining balance after forgiveness will be payable monthly through April 2025. The Company expects the SBA to make its forgiveness determination no later than April 26, 2021. The PPP Loan is unsecured.

(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.

Since its initial public offering in March 2017, the Company has raised additional capital through several means. A placement is the sale of newly issued securities to professional and sophisticated investors, or institutional investors. A security purchase plan (“SPP”) is the sale of newly issued securities to retail investors, or non-institutional holders, and is limited by ASX regulations to \$30,000 AUD per investor. A rights offering is the sale of newly issued securities to existing shareholders on a pro rata basis in proportion to their existing holdings.

On January 7, 2020, the Company issued 66,666,667 CDIs (representing the same number of shares) to complete a placement of its shares. The Company raised \$1.9 million net of \$0.2 million of issuance costs through the placement.

On June 3, 2020, the Company issued 364,933,565 CDIs (representing the same number of shares) to complete a placement of its shares. On June 30, 2020, the Company completed an SPP under which it issued 76,214,245 CDIs. The Company raised \$3.8 million net of \$0.4 million of issuance costs through the placement and the SPP. The Company issued each CDI issued under the placement and the SPP at a subscription price of \$0.014 AUD and issued one freestanding option for every two CDIs subscribed for, with each freestanding option having an exercise price of \$0.028 AUD and an expiration date of June 30, 2022. The freestanding options are call options that are not considered clearly and closely related to the Company’s shares and must be accounted for separate from equity. We recorded a liability of \$606,000 as of June 3, 2020 for the fair value of the freestanding options related to the Placement and an additional \$94,000 as of June 30, 2020 for the fair value of the freestanding options related to the SPP. The fair value of all freestanding options as of December 31, 2020 was \$1,769,000. We recorded a loss on fair value of freestanding options of \$1,069,000 in the Statements of Operations for the year ended December 31, 2020.

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In September and October 2020, holders exercised an aggregate of 14,257,137 freestanding options for an exercise price of \$0.3 million.

On June 12, 2019, the Company issued 22,222,222 CDIs (representing the same number of shares) to complete a placement of its shares. The Company raised \$0.7 million net of less than \$0.1 million of issuance costs through the placement.

In July 2019 the Company issued 128,293,636 CDIs (representing the same number of shares) to complete a rights offering of its shares. The Company raised \$3.8 million net of \$0.2 million of issuance costs through the rights offering.

In July 2019, the stockholders also approved an increase in the number of authorized Class A common stock from 500,000,000 to 750,000,000 shares at the special meeting of stockholders. In May 2020, the stockholders approved another increase in the number of authorized Class A common stock from 750,000,000 to 2,500,000,000 shares at the annual meeting of stockholders.

(8) LEASES

We evaluate all contracts to determine whether the contract is or contains a lease at inception. We review contracts for options to extend, terminate or purchase any right of use assets and non-lease components and account for these, as applicable, at inception of the contract. We elected the transition package of three practical expedients permitted within the standard. In accordance with the package of practical expedients, we did not reassess initial direct costs, lease classification, or whether contracts contain or are leases. We made an accounting policy election not to recognize right of use assets and liabilities for leases with a term of 12 months or less, or those that do not meet the Company's capitalization threshold, unless the leases include options to renew or purchase the underlying asset that is reasonably certain to be exercised. We recognize lease costs associated with those leases as incurred. We have chosen the practical expedient that allows entities to combine lease and non-lease components as a single lease component.

We do not recognize lease renewal options as part of the lease liability until we determine it is reasonably certain we will exercise any applicable renewal options. We have determined it is not reasonably certain we will exercise any applicable renewal options. The useful lives of leased assets as well as leasehold improvements, if any, are limited by the expected lease term.

The Company's operating lease activities currently consist of a lease for office space. The lease includes an option to renew for a period of from one to five years. The exercise of the lease renewal option is at the Company's sole discretion. The Company's operating lease agreement includes variable lease costs that are based on common area maintenance and property taxes. We expense these payments as incurred and include them in rent expense. The Company's operating lease agreement does not contain any material residual value guarantees or material restrictive covenants.

Rent expense was approximately \$125,000 in 2020 and \$156,000 in 2019 and is included in General and administrative expenses in the Statements of Operations. These amounts include variable lease costs of \$15,000 in 2020 and \$57,000 in 2019.

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Supplemental balance sheet information as of December 31, 2020 for the Company's operating lease is as follows:

	US\$000
NON-CURRENT ASSETS	
Right of use assets, net	\$ 183
Total lease assets	\$ 183
CURRENT LIABILITIES	
Other accrued liabilities	\$ 95
NON-CURRENT LIABILITIES	
Other non-current liabilities	113
Total lease liabilities	\$ 208

As of December 31, 2020, a schedule of maturity of lease liabilities under all operating leases is as follows:

	US\$000
For the year ended December 31,	
2021	\$ 105
2022	108
2023	9
Total	222
Less amount representing interest	(14)
Present value of minimum lease payments	208
Less current portion	(95)
Non-current portion	\$ 113

Cash paid for operating leases was approximately \$160,000 during 2020.

As of December 31, 2020, the remaining lease term of the Company's operating lease was 2.1 years. The discount rate used to determine the lease liabilities was 6%. When available, the Company uses the rate implicit in the lease or sublease to discount lease payments to present value; however, the Company's lease does not provide a readily determinable implicit rate. Therefore, the Company must estimate its incremental borrowing rate to discount the lease payments based on information available at lease commencement. The incremental borrowing rate is defined as the rate of interest that the Company would have to pay to borrow, on a collateralized basis and over a similar term, an amount equal to the lease payments in a similar economic environment. The discount rate used for the existing lease was established on adoption of the new lease standard at January 1, 2019.

(9) CONCENTRATIONS AND CREDIT RISK

For the year ended December 31, 2020, two Customers accounted for approximately 85.4% of our total sales. The two same Customers accounted for 81.4% of our accounts receivable as of December 31, 2020.

For the year ended December 31, 2019, two Customers accounted for approximately 82.1% of our total sales. The two same Customers accounted for 77.8% of our accounts receivable as of December 31, 2019.

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

(10) 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 geography. We present our operations through two reportable segments:

North America includes our current operations in the US and Canada.

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Europe / Asia-Pacific includes our operations outside of North America.

We record expenses directly attributable to these geographic segments in the segment results and include expenses not specifically attributable to the geographic segments in Corporate Support. These unallocated expenses include the majority of our clinical, manufacturing, general and administrative expenses for which we consider the expenses to benefit the Company as a whole. The Company does not report balance sheet information by segment because it is not reviewed by the Company's chief operating decision maker. We do not have any inter-segment revenue.

	North America	Europe/Asia- Pacific	Corporate Support	Total
2020 (US\$000)				
Net revenue	\$ 4,807	\$ 298	\$ -	\$ 5,105
Cost of sales	2,708	173	-	2,881
Gross profit	2,099	125	-	2,224
Sales and marketing	4,689	490	-	5,179
Clinical and manufacturing	-	13	1,425	1,438
General and administrative	-	7	3,312	3,319
Total expenses	4,689	510	4,737	9,936
Operating loss	<u>\$ (2,590)</u>	<u>\$ (385)</u>	<u>\$ (4,737)</u>	<u>(7,712)</u>
Interest expense and other, net				<u>(1,524)</u>
Loss before income taxes				<u>\$ (9,236)</u>
2019 (US\$000)				
Net revenue	\$ 5,085	\$ 637	\$ -	\$ 5,722
Cost of sales	3,316	437	-	3,753
Gross profit	1,769	200	-	1,969
Sales and marketing	8,181	966	-	9,147
Clinical and manufacturing	-	78	2,014	2,092
General and administrative	-	13	3,374	3,387
Total expenses	8,181	1,057	5,388	14,626
Operating loss	<u>\$ (6,412)</u>	<u>\$ (857)</u>	<u>\$ (5,388)</u>	<u>(12,657)</u>
Interest income and other, net				<u>49</u>
Loss before income taxes				<u>\$ (12,608)</u>

(11) STOCK COMPENSATION PLANS

Stock-based compensation expense was approximately \$829,000 and \$302,000 for the years ended December 31, 2020 and 2019, respectively.

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, 2020 and 2019 was 561,000 and 8,571,324, 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

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Options, Restricted Stock, Stock Units, Performance Awards and Stock Appreciation Rights. The total number of shares reserved for issuance under the 2017 Plan was increased from 11,000,000 to 201,000,000 at the Company's Annual Meeting of Stockholders in May 2020. The share reserve may be increased each year in accordance with the 2017 Plan documents. The total number of options issued and outstanding as of December 31, 2020 and December 31, 2019 was 93,025,345 and 10,981,704, respectively. In addition, 61,918,816 share awards were granted and vested as of December 31, 2020. As of December 31, 2020, there were 46.6 million awards available for grant under the 2017 Plan.

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 some 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. 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 the years ended December 31, 2020 and 2019 are as follows:

	2020	2019
Risk-free interest rate	0.31-0.43%	1.82-2.49%
Expected volatility	50-89.0%	50.0%
Expected term (years)	5-6.25	5-6.26
Dividend rate	0.0%	0.0%

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

	Total Options Outstanding			Nonvested Options	
	Number of Options	Weighted Average Exercise Price US\$	Weighted Average Remaining Contractual Term in Years	Number of Options	Weighted Average Grant-Date Fair Value
Outstanding at December 31, 2019	19,553,028	\$0.07	8.16	12,059,563	\$0.05
Grants	91,788,277	0.01		91,788,277	0.01
Cancellation / forfeitures	(18,315,960)	0.07		(7,942,354)	0.04
Vested	-	-		(12,496,616)	0.02
Exercised	-	-		-	-
Outstanding at December 31, 2020	93,025,345	\$0.01	9.39	83,408,870	\$0.01
Exercisable at December 31, 2020	9,616,475	\$0.02	9.41		

The weighted average grant date fair value of options granted during the year was \$0.01 in 2020 and \$0.05 in 2019. The intrinsic value of options unexercised as of December 31, 2020 and 2019 was approximately \$602,000 and \$0, respectively. The total fair value of options vested during the year ending December 31, 2020 was approximately \$124,000. In 2020 five senior executives of the Company agreed to cancel a total of 16,226,269 options with exercise prices ranging from US\$0.0438 to US\$0.3230 for no consideration.

As of December 31, 2020 and 2019, there was approximately \$581,000 and \$482,000, 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 2.16 years.

A summary of stock grant activity under the 2017 Plan is as follows:

	Total Stock Grants Outstanding	
	Number of Shares	Weighted Average Grant Date Fair Value US\$
Nonvested at December 31, 2019	-	\$ -
Grants	60,413,371	0.012
Cancellation / forfeitures	(447,934)	0.012
Vested	(59,965,437)	0.012
Nonvested at December 31, 2020	-	-

In the year ended December 31, 2020, the Company granted of 19,676,299 shares in lieu of earned but unpaid short-term cash incentive for 2019 that were fully vested on the date of grant. Of these grants, 17,722,920 were issued to current employees under the 2017 Plan and 1,953,379 were issued to a former employee and were outside the 2017 Plan. The grant date fair value of the shares issued was \$236,000 and was recorded as an offset to accrued payroll. In addition, the Company granted 42,690,451 restricted shares to employees in lieu of a portion of the employees' fixed cash remuneration for the period from April to December 2020. The restricted shares vested in equal fortnightly tranches over the period from April to December 2020. As of December 31, 2020, 42,242,517 of the restricted shares had vested and were no longer restricted. The remaining 447,934 restricted shares were forfeited in 2020. The grant date fair value of the restricted shares was \$512,000 and was included in operating expenses in the December 31, 2020 Statement of Operations.

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(12) 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. In October 2020 the Company made an additional discretionary contribution to all eligible employees. The Company contributed approximately \$244,000 and \$228,000 in the years ending December 31, 2020 and 2019, respectively.

(13) COMMITMENTS AND CONTINGENCIES

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, 2020.

(14) RELATED PARTIES

We incurred approximately \$9,000 and \$99,000 in fees and expenses for the years ending December 31, 2020 and 2019, respectively, for clinical and regulatory consulting services provided by a company owned by one of our former officers.

(15) 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, 2020 and 2019.

The Company's assets and liabilities measured at fair value on a recurring basis include cash equivalents of \$2.2 million as of December 31, 2020 and \$1.7 million as of December 31, 2019, the fair value of the conversion

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feature of the Convertible Notes of \$130,000 at December 31, 2020 and \$0 at December 31, 2019, and the fair value of freestanding options of \$1,769,000 as of December 31, 2020. We consider the factors used in determining the fair value of our cash equivalents to be Level 1 inputs and the fair value of the conversion feature and freestanding options to be Level 3 inputs.

For Level 3 instruments carried at fair value measured on a recurring basis using significant unobservable inputs, the following table presents a reconciliation of the beginning and ending balances for the years ended December 31, 2020 and 2019:

	2020 US\$000	2019 US\$000
Convertible notes conversion feature		
Balance at January 1,	\$ -	\$ -
Conversion feature issued with convertible debt, at fair value		123
Total (gains) losses – realized/unrealized	130	(123)
Balance at December 31,	<u>\$ 130</u>	<u>\$ -</u>
Freestanding options		
Balance at January 1,	\$ -	\$ -
Call options issued with Placement and SPP, at fair value	700	-
Total (gains) losses – realized/unrealized	1,069	-
Balance at December 31,	<u>\$ 1,769</u>	<u>\$ -</u>

The unrealized gains and losses for assets within the Level 3 category presented in the tables above include changes in fair value that are attributable to both observable and unobservable inputs. Assumptions for valuations in the year ended December 31, 2020 are as follows:

	Freestanding Options	Conversion Feature
Risk-free interest rate	0.255-0.285%	0.18%
Expected volatility	89.0%	45.0%
Expected term (years)	2.0-2.7	3.0-3.1
Dividend rate	0.0%	0.0%
Coupon rate	N/A	10.0%
Conversion price	N/A	A\$0.028-A\$0.075
Foreign exchange rates	N/A	0.686-0.691

(16) INCOME TAXES

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

The Company's income tax expense and resulting effective tax rate are based upon the respective estimated annual effective tax rates applicable for the respective periods adjusted for the effects of items required to be treated as discrete to the period, including changes in tax laws, changes in estimated exposures for uncertain tax positions and other items. Income tax positions are considered for uncertainty in accordance with ASC 740-10. Tax years remain subject to examination at the U.S. federal level between 2010 and 2018, and subject to examinations at various state levels between 2008 and 2018.

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The provision for income taxes consists of the following components:

	2020 US\$000	2019 US\$000
Current expense		
Federal	\$ -	\$ -
State	3	9
Total current income tax expense	3	9
Deferred expense (benefit)		
Federal	(1,660)	(2,616)
State	(467)	(718)
Total deferred income tax benefit	(2,127)	(3,334)
Valuation allowance	2,127	3,334
Deferred income tax expense (benefit)	-	-
Total income tax expense	\$ 3	\$ 9

The following summarizes the Company's valuation allowance:

	2020 US\$000	2019 US\$000
Beginning of year	\$ (16,310)	\$ (12,976)
Income tax provision	(2,127)	(3,334)
End of year	\$ (18,437)	\$ (16,310)

Net deferred tax assets and liabilities are as follows:

	2020 US\$000	2019 US\$000
Deferred tax assets		
NOL carryforwards	\$ 17,424	\$ 15,192
R&D tax credits	1,029	1,029
Inventory	20	37
Other deferred tax assets	73	139
Valuation allowance	(18,437)	(16,310)
Total deferred tax assets	\$ 109	\$ 87
Deferred tax liabilities		
Amortization	\$ (109)	\$ (87)
Total deferred tax liabilities	(109)	(87)
Net deferred income tax assets	\$ -	\$ -

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

	2020		2019	
	US\$000	Percent	US\$000	Percent
Federal tax benefit at statutory rate	\$ (1,940)	21.0%	\$ (2,650)	21.0%
State tax expense, net of federal benefit	(467)	5.0%	(718)	5.7%
Permanent items and other	280	-3.4%	34	-0.3%
Change in valuation allowance	2,127	-22.6%	3,334	-26.4%
Total tax expense	\$ -	0.0%	\$ -	0.0%

As of December 31, 2020, the Company had federal NOL carryforwards of approximately \$67.8 million and state NOL carryforwards of \$3.2 million (tax effected), that are available to reduce future income unless otherwise taxable. As of December 31, 2020, the Company has federal and state research and development ("R&D") credits of approximately \$1.0 million, that are available to reduce future federal and state income

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tax. We have not performed a study of our NOLs for limitations required by the 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 \$36.6 million of NOLs originating since 2018 do not expire. The federal and state R&D credits will expire at various dates between 2021 and 2037.³

(17) SUBSEQUENT EVENTS

On January 26, 2021, the Company submitted a Loan Forgiveness Application to the SBA requesting forgiveness of approximately \$921,000 of the PPP Loan. The Company is accounting for the PPP Loan as debt and will derecognize the portion of the PPP Loan that is forgiven, if any, when the SBA approves a forgiveness amount and legally releases the Company from liability for that portion of the debt. The Company expects the SBA to make its forgiveness determination no later than April 26, 2021. The Company has recorded the full amount of the PPP Loan in its Balance Sheet as of December 31, 2020.

On February 16, 2021, the Company announced that it had received commitments for a placement to sophisticated and professional investors and certain Non-Executive Directors in the amount of approximately \$22.1 million AUD to result in the issuance of approximately 1.3 billion CDIs at \$0.017 AUD per CDI. The Company expects to receive the cash from the placement in late March 2021. The investors also will receive one option to purchase an additional CDI for each two CDIs purchased in the placement. The options will have an exercise price of \$0.03 AUD per CDI and will expire in February 2024. The Company also plans to offer an SPP of up to \$1.0 million AUD to investors in Australia and New Zealand under the same terms as the placement.

The Company evaluated the accounting and disclosures requirements for subsequent events through February 17, 2021, the issuance date of the financial statements.