Mainstay Medical Holdings plc and its subsidiaries

Annual Report

for the year ended 31 December 2020

Mainstay Medical Holdings plc
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Forward looking statements

This annual report includes statements that are, or may be deemed to be, forward looking statements. These forward looking statements can be identified by the use of forward looking terminology, including the terms "anticipates", "believes", "estimates", "expects", "intends", "may", "plans", "projects", "should", "will", or "explore" or, in each case, their negative or other variations or comparable terminology, or by discussions of strategy, plans, objectives, goals, future events or intentions. These forward looking statements include all matters that are not historical facts. They appear throughout this annual report and include, but are not limited to, statements regarding the Company's intentions, beliefs or current expectations concerning, among other things, the Company's plans to commercialize ReActiv8 in the United States, the U.K., Australia and elsewhere; the commercial performance of ReActiv8; and the Company's results of operations, financial position, prospects, financing strategies, expectations for product design and development, regulatory applications and approvals, reimbursement arrangements, costs of sales and market penetration and other commercial performance.

By their nature, forward looking statements involve risk and uncertainty because they relate to future events and circumstances. Forward looking statements are not guarantees of future performance, and actual results may differ materially from those described in, or suggested by, the forward looking statements contained in this annual report. In addition, even if future results and developments are consistent with the forward looking statements contained in this annual report, those results or developments may not be indicative of results or developments in subsequent periods. A number of factors could cause results and developments of the Company to differ materially from those expressed or implied by the forward looking statements, including, without limitation, the successful launch and commercialization of ReActiv8, including securing adequate reimbursement for ReActiv8 implants in the United States and the Company's commercial markets, the availability and cost of capital, general economic and business conditions, global medical device market conditions, industry trends, competition, changes in law or regulation, changes in taxation regimes, the time required to commence and complete clinical trials, the time and process required to obtain regulatory approvals, currency fluctuations, changes in its business strategy, and political and economic uncertainty. The forward-looking statements herein speak only at the date of this annual report.

Mainstay Medical Holdings plc
Corporate and shareholder information

Directors	Oern Stuge MD, Independent Non-Executive Chairman (Resigned 11/02/2021) Jason Hannon, Chief Executive Officer and Executive Director David Brabazon, Independent Non-Executive Director Greg Garfield, Non-Executive Director Antoine Papiernik, Non-Executive Director (Resigned 11/02/2021) James Reinstein, Independent Non-Executive Director (Resigned 11/02/2021) Dan Sachs MD, Non-Executive Director (Resigned 11/02/2021) Charles Chon, Non-Executive Director (Appointed 11/02/2021) Cédric Moreau, Non-Executive Director (Appointed 11/02/2021)
Secretary	Matthew Onaitis
Registered office	77 Sir John Rogerson's Quay Block C, Grand Canal Docklands Dublin 2, Ireland, D02 T804
Registered number	667520
Website	www.mainstay-medical.com
ISIN	IE00BMC4XQ06
Solicitors/ Lawyers	McCann FitzGerald Riverside One Sir John Rogerson's Quay Dublin 2, Ireland Latham & Watkins 885 3rd Avenue, NY 10022, USA
Independent Auditor	KPMG Chartered Accountants 1 Stokes Place St Stephen's Green Dublin 2, Ireland
Principal Bankers	HSBC Bank of Ireland
Registrar	Computershare Investor Services (Ireland) Limited Heron House Corrig Road Sandyford Industrial Estate Dublin 18, Ireland

Mainstay Medical Holdings plc
Directors' report

The Board of Directors are pleased to report on the progress of Mainstay Medical Holdings plc ("Mainstay" or the "Company") and present the Annual Report of the Company and its subsidiaries (the "Group" or "we") for the year ended 31 December 2020.

Principal activities

Mainstay is a medical device company focused on commercializing an innovative implantable restorative neurostimulation system, ReActiv8, for people with disabling mechanical Chronic Low Back Pain.

The Company is headquartered in Dublin, Ireland and has subsidiaries operating in Ireland, the United States, Australia, Germany and the Netherlands. The Company was incorporated in 2020 as a new holding company for the existing group (see below).

As at 31 December 2020, the Company together with its operating subsidiaries Mainstay Medical International Limited, Mainstay Medical Limited, MML US, Inc., Mainstay Medical (Australia) Pty Limited, Mainstay Medical Distribution Limited, Mainstay Medical B.V. and Mainstay Medical GmbH, form the Mainstay Medical Group.

Business review

Reorganisation via Scheme of Arrangement by establishing a new holding company and delisting shares from Euronext Growth and Euronext Paris

On 5 June 2020, Mainstay announced its reorganisation transaction conducted via scheme of arrangement in accordance with the Companies Act 2014, pursuant to which Mainstay Medical Holdings plc was introduced as the new holding company of the Mainstay group, directly above Mainstay Medical International plc. The shares of Mainstay Medical International were delisted from trading on Euronext Paris and the Euronext Growth market of Euronext Dublin on 8 June 2020. In accordance with the terms of the scheme of arrangement, ordinary shareholders of Mainstay Medical International were issued one Mainstay Medical Holdings share for every Mainstay Medical International share held at such time.

Mainstay Medical Holdings carries on the usual activities of a holding company (including the overall stewardship and governance of the Mainstay Group).

This reorganisation was implemented in order to maximise shareholder value. Since the initial public offering of shares of Mainstay Medical International in 2014 there had been limited trading in Mainstay Medical International ordinary shares on Euronext Growth and Euronext Paris. Therefore, Mainstay shareholders were not able to take advantage of the liquidity benefit typically associated with an active trading market for such listings. The lack of liquidity had a disproportionate impact on the share price, with poor demand for shares and thin volumes leading to large volatility in price. In addition, most shares were held by investment funds with a long term investment horizon who had not sought to actively trade their shares, which lead to a lack of supply in the market. The Board believed that the lack of liquidity had been a significant contributing factor to downward pressure on the price of the Company's ordinary shares. Furthermore, the listings required significant expenditure on legal and regulatory advice given the unique listing status of Mainstay and required compliance with applicable stock exchange rules and EU prospectus laws, together with related costs, such as professional fees payable to stock exchange advisers, accountants and public relations advisers.

The Board completed a detailed review of alternatives available to the Group in light of the above facts and concluded that the time and expense involved in maintenance of the listings was not justified. Accordingly, it concluded that cancelling the listings would be in the best interests of the Group and its shareholders as a whole and, after consultation with its advisors, determined that the reorganisation via the scheme of arrangement transaction was the most efficient process to effect such cancellation of the listings.

Commercial Activities

US FDA Approval

On 22 June 2020, the Company announced the U.S. Food and Drug Administration (FDA) had approved the Company's Premarket Approval (PMA) application for ReActiv8.

The FDA approval grants Mainstay the right to market ReActiv8 in the United States as an aid in the management of intractable chronic low back pain associated with multifidus muscle dysfunction, as evidenced by imaging or physiological testing in adults who have failed therapy, including pain medications and physical therapy, and are not candidates for spine surgery.

Based on the FDA approval, Mainstay has developed and begun to implement its commercial launch plans for ReActiv8 in the U.S., including the build out of the commercial team, inventory procurement and related matters.

We look forward to making ReActiv8 available to US patients and physicians beginning in the first half of 2021.

Australia Reimbursement Approval

On 8 June 2020, the Company announced ReActiv8 had been approved for inclusion in the Prostheses List of reimbursed products in Australia, effective as of 1 July 2020. The Prostheses List identifies implantable devices eligible for reimbursement from all private health insurance funds in Australia. This approval followed the December 2019 regulatory approval from the Australian Therapeutic Goods Administration (TGA) for ReActiv8, which confirmed the inclusion of ReActiv8 in the Australian Register of Therapeutic Goods (ARTG), enabling commercialization throughout Australia, which commenced in November 2020.

Covid-19 Impact

The health and safety of our staff continues to be the Group's key priority. The Group is continuing to follow government guidance in each country it operates in and have implemented a number of measures to protect our staff, including remote working where possible, use of appropriate personal protective equipment and increased sanitisation.

Revenue was impacted by Covid-19 during the period arising from elective surgeries being delayed in certain stages of the pandemic across several countries in which we operate. However, despite the limitations, the Company continued to make commercial progress working with key physician partners who are incorporating ReActiv8 into their practises.

US Patents

The total current number of issued US issued patents in the Mainstay portfolio is 32. Mainstay continues to add to its portfolio of issued patents and pending patent applications.

Financial review

Income statement

Revenue during the twelve-month period ending 31 December 2020 was $1.5 million (2019: $1.1 million). Revenue was generated from sales of ReActiv8 systems to customers in Germany, the UK, Australia, Switzerland and Austria.

Operating expenses related to on-going activities were $17.6 million during the year ended 31 December 2020 (2019: $19.2 million). On-going activities during the financial year included research and development, clinical and regulatory activities and selling, general and administrative activities.

Research and development expenses were $3.0 million during the year ended 31 December 2020 (2019: $2.9 million). The increase of $0.1 million in 2020 primarily represents an increase in payroll related costs.

Clinical and regulatory expenses were $2.3 million during the year ended 31 December 2020 and decreased by $1.6 million during the same period in 2019. This is primarily driven by decreased direct trial costs relating to for the ReActiv8-B Clinical Trial.

Our selling, general and administrative expenses were $12.3 million during year ended 31 December 2020, and $12.4 million during the same period in 2019. The variance of $0.1 million represents increases in commercial related payroll costs as we continue to build out our commercial capabilities, offset by a decrease in non-cash related share-based payment expenses.

The loss for the year was $18.9 million (2019: $22.4 million).

Statement of financial position

Total assets of the Group at year end were $10.2 million (2019: $20.6 million). Cash on hand at 31 December 2020 was $6.3 million (2019: $17.4 million). Cash used in operating activities was $14.8 million during the year ended 31 December 2020 (2019: $15.6 million). This operating cash outflow reflects the cost of the research and development of ReActiv8, undertaking our clinical trials, commercialization expenditure and ongoing costs of running the Group.

IPF Debt Facility

In connection with the reorganisation becoming effective, Mainstay and IPF agreed to amend certain terms and conditions of the existing facility and warrant arrangements.

The facility agreement was amended in April 2020 so that the automatic conversion mechanics will engage when FDA approval has been received in respect of ReActiv8 and the Company completes one or more issuances of shares at an average price of €6.00 per share for a total aggregate amount of €20 million.

In addition, certain additional rights were granted to IPF following the reorganisation becoming effective. Under these new arrangements IPF are entitled to appoint an observer to the board of directors of the Company. IPF's prior written consent will also be required for the Company to complete an equity raising transaction by means of a share issuance where (i) shares in the Company are to be issued at a price below €6.00 per share and (ii) 49% or more of the aggregate value of the share issuance is to be contributed by institutional shareholders in the Company who are represented on the board of directors of the Company at the time of agreement to enter into such equity raising transaction.

Bridge Financing

On 28 December 2020, the Company completed a bridge financing that involved the issuance by it of convertible promissory notes for an aggregate amount of US$6.44 million to certain current investors of the Company. The notes did not carry interest and were due and payable by the Company on demand to the holders on 31 December 2023. The Company received $4 million in proceeds at 31 December 2020 and the remaining $2.4 million in January 2021.

The outstanding amounts under the notes automatically converted into the same class of preference shares of the Company issued to other investors on completion of the additional financing round in February 2021.

Securing funds

The Group has financed its operations to date principally through the issuance of equity securities and debt funding. The management team continues to develop and strengthen relationships to explore further financing options. These may include debt funding, private placement or public offering of equity or debt securities, and/or strategic partnering.

Effective monitoring of use of funds

Management prepares budgets and rolling forecasts to track and monitor use of funds. Actual expenditure is measured against budget and is reported to and evaluated by the Directors on a monthly basis.

Principal risks and uncertainties

A summary of the principal risks relating to the Group and Company and/or its industry include the following:

- We have incurred significant operating losses and may not be able to achieve or subsequently maintain profitability.
- We have limited history commercializing ReActiv8. Our future financial performance is entirely dependent on the commercial success of ReActiv8, including generating product adoption and market penetration and obtaining adequate reimbursement for ReActiv8.
- There is no guarantee that the commercial performance of ReActiv8 will match the performance of ReActiv8 in clinical trials.
- Active implantable medical devices such as ReActiv8 carry risks associated with the surgical procedure for implant, removal or use of the device, or failure of the device, or associated with the therapy delivered by the device.
- Our business exposes us to an inherent risk of potential product liability claims relating to the manufacturing, clinical trials, marketing and sale, or recall of an active implantable medical device.
- The discovery of serious safety issues with ReActiv8, or a recall of ReActiv8 either voluntarily or at the direction of a regulatory authority, could have a negative impact on us.

- Competition in the medical device industry is intense and expected to increase, and new or competing treatments for chronic low back pain may emerge.
- We expect to require additional funds in the future in order to meet our capital and expenditure needs and further financing may not be available when required or, if available, could be dilutive to current investors, or require us to agree to terms which are specifically favourable to new investors, or to restrictions significantly limiting our access to additional capital.
- Any inability to fully protect and exploit our intellectual property may adversely impact our financial condition, business, prospects and results of operations.
- We could become subject to intellectual property litigation or other disputes that could be costly, result in the diversion of management's time and efforts, require us to pay damages, prevent us from marketing ReActiv8 or other products and/or reduce the margins for ReActiv8.
- We depend on a limited number of third party suppliers for the manufacture of ReActiv8. Disruption of the supply chain or failure to achieve economies of scale could have a material adverse effect.
- We operate in a highly regulated environment. Any non-compliance with regulatory requirements could jeopardize our ability to commercialize ReActiv8, and strict or changing regulatory regimes, government policies and legislation in any of our target markets may delay, prohibit or reduce potential sales.
- We intend to conduct additional clinical trials of ReActiv8 for marketing, reimbursement and other purposes. Clinical trials carry substantial risks and are costly and time consuming, with uncertain results.
- Failure to comply with debt covenants or failure to make repayments on our debt facility could have a material adverse effect.
- Our share ownership is concentrated in the hands of our principal shareholders, who may be able to exercise a direct or indirect controlling influence on us.

Outlook and future developments

Our corporate objectives for 2021 are to advance our global commercial strategy by launching ReActiv8 in the US during 2021 and accelerating our commercialization efforts in Europe and Australia. We will continue to focus on building a number of high-volume ReActiv8 practices that will help us to manage patient outcomes and refine patient selection processes.

Directors and Secretary and their interests

The names of the persons who were Directors during the year are set out as follows:

Oern Stuge MD, Independent Non-Executive Chairman
Jason Hannon, Chief Executive Officer and Executive Director
David Brabazon, Independent Non-Executive Director
Greg Garfield, Non-Executive Director
Antoine Papiernik, Non-Executive Director
James Reinstein, Independent Non-Executive Director
Dan Sachs MD, Non-Executive Director

Matthew Onaitis served as Company Secretary.

The beneficial interest of the Directors and Company Secretary, who held office at 31 December 2020, in the ordinary share capital of the Group at the dates below were as follows:

Ordinary shares

Name		**At 31 December 2020**	**At 31 December 2019**
David Brabazon	Ordinary shares of €0.001 each	212,828	212,828
Dan Sachs MD	Ordinary shares of €0.001 each	515,000	515,000
Jason Hannon	Ordinary shares of €0.001 each	30,000	30,000
Greg Garfield	Ordinary shares of €0.001 each	2,912	2,912

Share options	Deemed date of grant	Exercise price per ordinary share	Expiry date	No. of ordinary shares under option as at 31 December 2020	No. of ordinary shares under option as at 31 December 2019	No. of vested options as at 31 December 2020
Oern Stuge MD	23 Jan 2013	US$1.00	10 years from vesting	55,014	55,014	55,014
Oern Stuge MD	13 Dec 2016	€15.50	10 years from vesting	17,000	17,000	17,000
Jason Hannon	6 Sept 2017	€14.85	10 years from vesting	401,862	401,862	326,511
Jason Hannon	23 March 2018	€16.90	10 years from vesting	118,628	118,628	81,548
Jason Hannon	13 Aug 2019	€3.76	10 years from vesting	464,000	464,000	154,664
Jason Hannon	26 June 2020	US$4.17	10 years from vesting	50,000	-	-
David Brabazon	5 Dec 2013	US$1.00	10 years from vesting	18,427	18,427	18,427
David Brabazon	13 Dec 2016	€15.50	10 years from vesting	5,700	5,700	5,700
James A. Reinstein	2 Sep 2015	€16.87	10 years from vesting	20,000	20,000	20,000
James A. Reinstein	13 Dec 2016	€15.50	10 years from vesting	6,200	6,200	6,200
Matt Onaitis	20 Aug 2018	€15.00	10 years from vesting	100,000	100,000	58,328
Matt Onaitis	13 Aug 2019	€3.76	10 years from vesting	90,000	90,000	2,996
Matt Onaitis	26 June 2020	US$4.17	10 years from vesting	25,000	-	-

RSUs	Deemed date of grant	No. of RSUs	Vesting date
Jason Hannon	1 Feb 2019	138,000	100% will vest 6 months following the completion of a US IPO
Matt Onaitis	1 Feb 2019	46,000	100% will vest 6 months following the completion of a US IPO

Except as disclosed in this report, none of the Directors who held office at 31 December 2020, had a beneficial interest in the share capital of the Company or its subsidiaries and no such interest, the existence of which is known or could with reasonable diligence be ascertained by the relevant Director, is held by any connected person.

Mr. Papiernik held no interest in the issued share capital of the Company other than the interests that he is deemed to hold in the Company by virtue of the interests that he holds in Sofinnova Capital VI FCPR. At 31 December 2020, Sofinnova Capital VI FCPR owned 2,949,146 ordinary shares amounting to approximately 22% of the entire issued ordinary share capital of the Company.

As at 31 December 2020, David Brabazon held 212,828 ordinary shares of the Company. On the 28th December, Drand Limited, a Company of which Mr. Brabazon is a Director, provided the Company with $2 million under a convertible promissory note. This note was subsequently converted into preference shares as part of the equity financing completed in February 2021 and is detailed within Note 24.

Directors' remuneration

The following table shows the amount of remuneration paid and benefits in kind granted to the Directors by the Group for services in all capacities relating to 2020 and 2019:

2020:	Fees	Salary	Annual Incentive	Benefits in Kind	Total
Executive Directors					
Jason Hannon	$41,200	$478,000	$301,552	$96,318	$917,132
Non-Executive Directors					
Oern Stuge MD	$65,897	-	-	-	$65,897
David Brabazon	$41,963	-	-	-	$41,963
Greg Garfield	-	-	-	-	-
Antoine Papiernik	-	-	-	-	-
James A. Reinstein	$41,963	-	-	-	$41,963
Dan Sachs MD	-	-	-	-	-

2019:	Fees	Salary	Annual Incentive	Benefits in Kind	Total
Executive Directors					
Jason Hannon	$40,000	$460,000	$217,500	$105,707	$823,207
Non-Executive Directors					
Oern Stuge MD	$103,906	-	-	-	$103,906
David Brabazon	$58,171	-	-	-	$58,171
Greg Garfield	-	-	-	-	-
Nael Karim Kassar (resigned 20 September 2019)	-	-	-	-	-
Antoine Papiernik	-	-	-	-	-
James A. Reinstein	$58,171	-	-	-	$58,171
Dan Sachs MD	-	-	-	-	-

None of the Directors exercised any share options in either 2020 or 2019.

Issued share capital

At 31 December 2020, the authorized share capital of the Company is €375,000, comprised of 35,000,000 ordinary shares of €0.01 each and 25,000 deferred shares of €1.00 each. A full description of the rights attached to the ordinary and deferred shares of the Company is available in the Articles of Association on the Company's website.

Share Option Plan

The Group operates a share option plan (the "Plan"). As at 31 December 2020, the Plan allows for the Company to grant share options or restricted stock units ("RSUs") to employees of the Group companies, and other eligible persons. Shares are issued when share options are exercised or RSUs are vested in accordance with the Plan.

Memorandum and Articles of Association

The Company's Articles of Association detail the rights attached to the shares; and the rules relating to the Directors, including their appointment, retirement, re-election and powers. Changes to the Articles of Association must be approved by the shareholders in accordance with the legislation in force from time to time.

A copy of the Memorandum and Articles of Association can be obtained from the Group's website.

Substantial shareholders

As at 31 December 2020 before publication of this Directors' Report, in so far as was notified to the Company, the following were holders of 3% or more of the Company's issued ordinary share capital:

Shareholder	No. of ordinary shares	Percentage
Sofinnova Capital VI FCPR	2,949,146	21.9%
Fountain Healthcare Partners Fund 1, L.P.	2,268,553	16.9%
KCK Limited	2,236,418	16.7%
RICA UNIVERSAL S.A	1,064,935	7.9%
Seamus Mulligan (Note 1)	772,039	5.8%
The Ireland Strategic Investment Fund (ISIF)	714,285	5.3%
Dan Sachs MD	515,000	3.8%

Notes:

1. Includes Ordinary Shares held by Barrymore Investments Limited and Nerano Capital Limited

Going concern

The Directors have evaluated whether there are conditions and events, considered in aggregate, that raise doubt about the Group's ability to continue as a going concern. The Directors note the following relevant matters:

- The Group had cash of $6.3 million as at 31 December 2020 ($17.4 million as at 31 December 2019).
- The Group had operating cash out-flows of $14.8 million for the year ended 31 December 2020 (year ended 31 December 2019: $15.6 million).
- Due to the phase of development of the Group, the Group expects to continue to incur losses in the medium term due to the ongoing investment required in research and development, clinical and commercial activities and expects to continue to seek funding from investors or other finance providers as required.

Subsequent to the year end, the Company completed an equity financing in which it raised gross proceeds of US$108 million. Mainstay intends to use the funds to support the company's commercial launch of ReActiv8 in the U.S., continued expansion in Europe and Australia, additional post-market clinical studies and research, and general operations.

The Directors have considered the conditions noted above and other factors and believe that the Group will have sufficient funds to be able to meet its liabilities as they fall due for a period of at least 12 months from the date of the Financial Statements and are satisfied that the Financial Statements should be prepared on a going concern basis.

Dividends

The Directors do not recommend the payment of a dividend.

Related party transactions

Details of related party transactions that have taken place during the reporting period are set forth in Note 23 to the consolidated Financial Statements.

Political and charitable donations

During the year, the Group and Company made no donations requiring disclosure.

Post balance sheet events

Details of important events affecting the Company which have taken place since the end of the year are given in Note 24 to the consolidated Financial Statements.

Subsidiary undertakings

At 31 December 2020, the Company Mainstay Medical Holdings plc had the following subsidiaries:

- Mainstay Medical International Limited ("MMI") is registered in Ireland and its principal activity is the provision of support services to other Group companies.

- Mainstay Medical Limited ("MML") is registered in Ireland and its principal activities include research, development, clinical and regulatory activities and support services to other Group companies.
- MML US, Inc. is registered in the United States of America and its principal activity is the provision of support services to other Group companies.
- Mainstay Medical (Australia) Pty. Limited ("MMA") is registered in Australia and its principal activity is the provision of support services to other Group companies.
- Mainstay Medical Distribution Limited ("MMD") is incorporated in Ireland and its principal activity is the provision of sales and distribution services.
- Mainstay Medical GmbH ("MMG") is registered in Germany and its principal activity is the provision of sales support services.
- Mainstay Medical BV ("MMBV") is registered in the Netherlands and its principal activity is the provision of management and sales support services.

The Company owns 100% of the called-up share capital of each of the above subsidiaries.

Accounting records

The Directors, through the use of appropriate procedures, personnel and systems, have ensured that measures are in place to secure compliance with the Company's and the Group's obligation to keep adequate accounting records under sections 281-285 of the Companies Act 2014. The books of account of the Company and the Group are maintained at its registered office.

Relevant audit information

The Directors believe they have taken all steps necessary to make themselves aware of any relevant audit information and have established that the Group's statutory auditor is aware of that information. In so far as they are aware, there is no relevant audit information of which the Group's statutory auditor is unaware.

Audit Committee

The Audit, Risk and Compliance Committee is chaired by Mr. David Brabazon (the Audit, Risk and Compliance Committee Financial Expert). The Chief Financial Officer and Chief Executive Officer may also be invited to attend meetings of the Committee. It meets at least two times a year and is responsible for ensuring that the financial performance of the Group is properly monitored and reported on. The Committee also meets with and reviews findings of the audit with the external auditor. It meets with the auditors at least once a year without any members of management being present and is also responsible for considering and making recommendations regarding the appointment and remuneration of such auditors.

Directors Compliance Statement:

The Directors, in accordance with Section 225(2) of the Companies Act 2014, acknowledge that they are responsible for securing the Company's compliance with the Relevant Obligations (as defined by the Companies Act 2014), and the Directors confirm that:

(a) a compliance policy statement has been drawn up setting out the Company's policies that are, in their opinion, appropriate with regard to such compliance;

(b) appropriate arrangements or structures are in place that are, in their opinion, designed to provide reasonable assurance of compliance in all material respects with those Relevant Obligations; and

(c) a review has been conducted, during the financial year, of those arrangements or structures.

Auditor

The auditor, KPMG, Chartered Accountants, will continue in office accordance with Section 383(2) of the Companies Act 2014.

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On behalf of the Board on 10 March 2021,

Jason Hannon
CEO

Mainstay Medical Holdings plc
Directors' responsibilities statement

Statement of directors' responsibilities in respect of the directors' report and the financial statements

The directors are responsible for preparing the annual report and the Group and Parent Company financial statements, in accordance with applicable law and regulations.

Company law requires the directors to prepare financial statements for each financial year. Under that law they have elected to prepare the Group and Company financial statements in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU and applicable law as applied in accordance with the Companies Act 2014.

Under company law the directors must not approve the Group and Company financial statements unless they are satisfied that they give a true and fair view of the assets, liabilities and financial position of the Group and Company and of the Group's profit or loss for that year. In preparing the Group and Company financial statements, the directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgements and estimates that are reasonable and prudent;
- state whether applicable Accounting Standards have been followed, subject to any material departures disclosed and explained in the financial statements;
- assess the Group and Parent Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern; and
- use the going concern basis of accounting unless they either intend to liquidate the Group or Parent Company or to cease operations or have no realistic alternative but to do so.

The directors are responsible for keeping adequate accounting records which disclose with reasonable accuracy at any time the assets, liabilities, financial position and profit or loss of the Company and which enable them to ensure that the financial statements of the Group and Company are prepared in accordance with applicable IFRS, as adopted by the EU and comply with the provisions of the Companies Act 2014. They have general responsibility for taking such steps as are reasonably open to them to safeguard the assets of the Group and to prevent and detect fraud and other irregularities. The directors are also responsible for preparing a directors' report that complies with the requirements of the Companies Act 2014.

The directors are responsible for the maintenance and integrity of the corporate and financial information included on the Group's and Parent Company's website http://www.mainstay-medical.com. Legislation in the Republic of Ireland concerning the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

On behalf of the board on 10 March 2021,

Jason Hannon
CEO

Independent auditor’s report to the members of Mainstay Medical Holdings plc

Report on the audit of the financial statements

Opinion

We have audited the financial statements of Mainstay Medical Holdings plc (‘the Company’) and its consolidated undertakings (‘the Group’) for the year ended 31 December 2020 set out on pages 17 to 45, which comprise the Consolidated statement of profit or loss and other comprehensive income, the Consolidated and Parent Company statements of financial position, the Consolidated and Parent Company statements of changes in shareholders’ equity, the Consolidated and Parent Company statements of cash flows and related notes, including the summary of significant accounting policies set out in note 3. The financial reporting framework that has been applied in their preparation is Irish Law and International Financial Reporting Standards (IFRS) as adopted by the European Union.

In our opinion:

- the financial statements give a true and fair view of the assets, liabilities and financial position of the Group and Company as at 31 December 2020 and of the Group’s loss for the year then ended;
- the Group financial statements have been properly prepared in accordance with IFRS as adopted by the European Union;
- the Company financial statements have been properly prepared in accordance with IFRS as adopted by the European Union, as applied in accordance with the provisions of the Companies Act 2014; and
- the financial statements have been properly prepared in accordance with the requirements of the Companies Act 2014.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (Ireland) (ISAs (Ireland)) and applicable law. Our responsibilities under those standards are further described in the Auditor’s responsibilities for the audit of the financial statements section of our report. We are independent of the Group in accordance with ethical requirements that are relevant to our audit of financial statements in Ireland, including the Ethical Standard issued by the Irish Auditing and Accounting Supervisory Authority (IAASA), and we have fulfilled our other ethical responsibilities in accordance with these requirements.

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

Conclusions relating to going concern

In auditing the financial statements, we have concluded that the directors’ use of the going concern basis of accounting in the preparation of the financial statements is appropriate.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the Group's or the Company’s ability to continue as a going concern for a period of at least twelve months from the date when the financial statements are authorised for issue.

Report on the audit of the financial statements (continued)

Other information

The directors are responsible for the other information presented in the Annual Report together with the financial statements. The other information comprises the information included in the directors' report. The financial statements and our auditor's report thereon do not comprise part of the other information. Our opinion on the financial statements does not cover the other information and, accordingly, we do not express an audit opinion or, except as explicitly stated below, any form of assurance conclusion thereon.

Our responsibility is to read the other information and, in doing so, consider whether, based on our financial statements audit work, the information therein is materially misstated or inconsistent with the financial statements or our audit knowledge. Based solely on that work we have not identified material misstatements in the other information.

Based solely on our work on the other information undertaken during the course of the audit , we report that:

- we have not identified material misstatements in the directors' report;
- in our opinion, the information given in the directors' report is consistent with the financial statements;
- in our opinion, the directors' report has been prepared in accordance with the Companies Act 2014.

Opinions on other matters prescribed by the Companies Act 2014

We have obtained all the information and explanations which we consider necessary for the purposes of our audit.

In our opinion the accounting records of the Company were sufficient to permit the financial statements to be readily and properly audited and the financial statements are in agreement with the accounting records.

Matters on which we are required to report by exception

The Companies Act 2014 requires us to report to you if, in our opinion, the disclosures of directors' remuneration and transactions required by Sections 305 to 312 of the Act are not made. We have nothing to report in this regard.

Respective responsibilities and restrictions on use

Responsibilities of directors for the financial statements

As explained more fully in the directors' responsibilities statement set out on page 13, the directors are responsible for: the preparation of the financial statements including being satisfied that they give a true and fair view; such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error; assessing the Group and Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern; and using the going concern basis of accounting unless they either intend to liquidate the Group and Company or to cease operations, or have no realistic alternative but to do so.

Respective responsibilities and restrictions on use (continued)

Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (Ireland) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

A fuller description of our responsibilities is provided on IAASA's website at http://www.iaasa.ie/Publications/Auditing-standards/International-Standards-on-Auditing-for-use-in-Ire/Description-of-the-auditor-s-responsibilities-for.

The purpose of our audit work and to whom we owe our responsibilities

Our report is made solely to the Company's members, as a body, in accordance with Section 391 of the Companies Act 2014. Our audit work has been undertaken so that we might state to the Company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company and the Company's members, as a body, for our audit work, for this report, or for the opinions we have formed.

Maurice McCann 10 March 2021
for and on behalf of
KPMG
Chartered Accountants, Statutory Audit Firm
1 Stokes Place
St. Stephen's Green
Dublin 2

Mainstay Medical Holdings plc
Consolidated statement of profit or loss and other comprehensive income
for the year ended 31 December 2020

($'000)	Notes	Year ended 31 December 2020	Year ended 31 December 2019
Revenue	4	1,497	1,105
Cost of sales		(761)	(669)
Gross profit		736	436
Operating expenses	5	(17,645)	(19,226)
Operating loss		(16,909)	(18,790)
Finance expense	8	(1,906)	(3,475)
Net finance expense		(1,906)	(3,475)
Loss before income taxes		**(18,815)**	**(22,265)**
Income taxes	9	(64)	(120)
Loss for the year		**(18,879)**	**(22,385)**
Net loss attributable to equity holders		**(18,879)**	**(22,385)**
Other Comprehensive Income			
Items that may be reclassified subsequently to the statement of profit or loss:			
Foreign currency translation differences of foreign operations		(534)	92
Total comprehensive loss for the year		**(19,413)**	**(22,293)**
Total comprehensive loss attributable to equity holders		**(19,413)**	**(22,293)**

The accompanying notes form an integral part of these consolidated Financial Statements.

Mainstay Medical Holdings plc
Consolidated statement of financial position
at 31 December 2020

($'000)	Notes	31 December 2020	31 December 2019
Non-current assets			
Property, plant and equipment	10	142	126
Right of use asset	16	74	290
Total non-current assets		216	416
Current assets			
Trade and other receivables	11	1,604	866
Income tax receivable		189	118
Inventory	12	1,894	1,863
Cash and cash equivalents	13	6,338	17,398
Total current assets		10,025	20,245
Total assets		**10,241**	**20,661**
Equity			
Share capital	17	180	72
Merger reserve	17	29,446	159,429
Share based payment reserve	19	17,057	15,677
Other reserves		134,100	4,718
Retained loss		(198,742)	(179,863)
Total equity		**(17,959)**	**33**
Non-current liabilities			
Loans and borrowings	14	21,866	14,519
Lease liability	16	-	107
Total non-current liabilities		21,866	14,626
Current liabilities			
Loans and borrowings	14	2,175	2,886
Lease liability	16	105	227
Income tax payable		129	141
Deferred revenue		39	49
Trade and other payables	15	3,886	2,699
Total current liabilities		6,334	6,002
Total liabilities		**28,200**	**20,628**
Total equity and liabilities		**10,241**	**20,661**

The accompanying notes form an integral part of these financial statements.

On behalf of the Board on 10 March 2021,

Jason Hannon
CEO

Mainstay Medical Holdings plc
Consolidated statement of changes in shareholders' equity
for the year ended 31 December 2020

($'000)	Share capital	Merger reserve	Capital Reserve	Foreign currency translation reserve	Share based payment reserve	Retained loss	Total equity
Balance as at 1 January 2019	**67**	**143,897**	**4,700**	**(74)**	**11,716**	**(157,073)**	**3,233**
Loss for the year	-	-	-	-	-	*(22,385)*	*(22,385)*
Other comprehensive income	-	-	-	*92*	-	-	*92*
Total comprehensive loss for the year	**-**	**-**	**-**	***92***	**-**	***(22,385)***	***(22,293)***
Transactions with owners of the Company:							
Issue of Shares	*5*	*15,532*	-	-	-	*(405)*	*15,132*
Share based payments	-	-	-	-	*3,961*	-	*3,961*
Balance at 31 December 2019	**72**	**159,429**	**4,700**	**18**	**15,677**	**(179,863)**	**33**
Balance as at 1 January 2020	**72**	**159,429**	**4,700**	**18**	**15,677**	**(179,863)**	**33**
Loss for the year	-	-	-	-	-	*(18,879)*	*(18,879)*
Other comprehensive income	-	-		*(534)*	-	-	*(534)*
Total comprehensive loss for the year	**-**	**-**		**(534)**	**-**	***(18,879)***	**(19,413)**
Issue of shares	-	17	-	-	-	-	17
Impact of change in holding company							
Removal of historic share capital and Merger reserve	(72)	(159,446)	159,518	-	-	-	-
Issue of Shares on change in holding company	180	29,422	(29,602)	**-**	**-**	**-**	-
Issue of Shares post change in holding company	-	24	-	**-**	**-**	**-**	24
Share based payments	**-**	**-**	**-**	**-**	1,380	**-**	*1,380*
Balance at 31 December 2020	**180**	**29,446**	**134,616**	**(516)**	**17,057**	**(198,742)**	**(17,959)**

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

Mainstay Medical Holdings plc
Consolidated statement of cash flows
for the year ended 31 December 2020

($'000)	Notes	Year ended 31 December 2020	Year ended 31 December 2019
Cash flow from operating activities			
Loss for the year		(18,879)	(22,385)
Add/(less) non-cash items			
Depreciation	10,16	261	362
Finance expense	8	1,906	3,475
Share-based compensation	19	1,380	3,961
Income taxes		64	120
Unrealised currency translation gains/(losses)		534	(92)
Add/(less) changes in working capital			
Trade and other receivables		(738)	(96)
Inventory		(31)	642
Trade and other payables		873	(1,201)
Taxes paid		(137)	(114)
Interest paid		-	(245)
Net cash used in operations		**(14,767)**	**(15,573)**
Cash flow from investing activities			
Acquisition of property, plant and equipment	10	(109)	(5)
Net cash used in investing activities		**(109)**	**(5)**
Cash flow used in financing activities			
Gross proceeds from issue of shares		49	15,537
Transaction costs on issue of shares		-	(405)
Proceeds from loans and borrowings	14	4,000	3,341
Repayment of loans and borrowings	14	-	(750)
Payment of lease liabilities	16	(233)	(290)
Net cash from financing activities	28	**3,816**	**17,433**
Net (decrease) / increase in cash and cash equivalents		(11,060)	**1,853**
Cash and cash equivalents at beginning of year		17,398	15,545
Cash and cash equivalents at end of year	13	**6,338**	**17,398**

1 General information and reporting entity

Mainstay Medical Holdings plc (the "Company") is a public limited company incorporated and registered in Ireland. Details of the registered office, the officers and advisers to the Company are presented on the Corporate and Shareholder Information page.

The Consolidated Financial Statements ("the Financial Statements") for the years ended 31 December 2020 and 31 December 2019 comprise the results of the Company and of its subsidiaries (together the "Group").

At 31 December 2020, the Group comprises the Company and its operating subsidiaries Mainstay Medical International Limited, Mainstay Medical Limited, MML US, Inc., Mainstay Medical (Australia) Pty. Limited, Mainstay Medical Distribution Limited, Mainstay Medical BV and Mainstay Medical GmbH.

Mainstay is a medical device company focused on commercializing an innovative implantable restorative neurostimulation system, ReActiv8, for people with disabling mechanical Chronic Low Back Pain.

2 Basis of preparation

Statement of compliance

The Financial Statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB"), as adopted by the European Union ("EU"). The Company Financial Statements have also been prepared in accordance with IFRS as adopted by the EU, as applied in accordance with the Companies Act 2014 (the "2014 Act"), which permits a company that publishes its company and group financial statements together to take advantage of the exemption in Section 304 of the 2014 Act from presenting to its members both its company statement of profit or loss and other comprehensive income and related notes which form part of the approved company financial statements.

The IFRSs adopted by the EU applied by the Group in the preparation of these Financial Statements are those that were effective for accounting periods beginning on or after 1 January 2020 with no early adoption of forthcoming requirements.

The Financial Statements were authorized for issue by the Board of Directors on 10 March 2021.

Going concern

The Directors have evaluated whether there are conditions and events, considered in aggregate, that raise doubt about the Group's ability to continue as a going concern. The Directors note the following relevant matters:

- The Group had cash of $6.3 million as at 31 December 2020 ($17.4 million as at 31 December 2019).
- The Group had operating cash out-flows of $14.8 million for the year ended 31 December 2020 (year ended 31 December 2019: $15.6 million).
- Due to the phase of development of the Group, the Group expects to continue to incur losses. in the medium term due to the ongoing investment required in research and development, clinical and commercial activities and expects to continue to seek funding from investors or other finance providers as required.

Subsequent to the year end, the Company completed an equity financing in which it raised gross proceeds of US$108 million. Mainstay intends to use the funds to support the company's commercial launch of ReActiv8 in the U.S., continued expansion in Europe and Australia, additional post-market clinical studies and research, and general operations.

The Directors have considered the conditions noted above and other factors and believe that the Group will have sufficient funds to be able to meet its liabilities as they fall due for a period of at least 12 months from the date of the Financial Statements and are satisfied that the Financial Statements should be prepared on a going concern basis.

Basis of measurement

The Financial Statements are prepared on the historic cost method, except for share based payments, which are initially measured at grant date fair value, and the conversion option and the warrants associated with the loan, which are carried at fair value.

Currency

The Financial Statements are presented in US Dollars ("$"), which is the functional and presentational currency of the Company. Balances in the Financial Statements are rounded to the nearest thousand ("$'000") except where otherwise indicated.

Use of estimates and judgements

The preparation of the Financial Statements in conformity with IFRS requires management to make judgements, estimates and assumptions. Estimates are reviewed on an ongoing basis. The areas where estimates have the most significant effect on amounts recognized in the Financial Statements are initial fair value measurement of equity-settled share-based payments (Note 19) and the fair value of identifiable instruments relating to the Company's convertible loan (Note 14).

Basis of consolidation

The Financial Statements comprise the consolidated results of Mainstay Medical Holdings plc and its subsidiaries. The insertion of Mainstay Medical Holdings plc as the parent of the Group was a common control transaction and has been accounted for using the merger basis of accounting whereby the results of the Group are presented on a continuing basis as if the Company had existed throughout the presented financial periods. The only change to the consolidated financial statement presentation is to reclassify certain consolidated reserves to "other reserves" in order to present share capital and Merger reserve in accordance with the Companies Act, as detailed in the Statement of Changes in Shareholders Equity.

3 Significant accounting policies

The Financial Statements have been prepared applying the accounting policies as set out below. These have been applied consistently for all years presented. During the current year the Company adopted IFRC 23 Uncertainty over Income Tax Treatments which had no impact on reported results.

a) Revenue recognition

The Group recognizes revenue when it transfers control over a product or service to a customer. This may arise on shipment, on delivery or in accordance with specific terms and conditions agreed with customers and provided there are no material remaining performance obligations required of the Group.

Revenue is measured at the fair consideration received/receivable for the sale of goods to external customers net of value added tax and discounts. Expected discounts are estimated and provided for as a reduction in revenue based on agreements with customers, agreed promotional arrangements and accumulated experience. Accumulated experience is used to estimate and provide for the discounts, using the expected value method, and revenue is only recognized to the extent that it can be reliably measured and when it is probable that future economic benefits of the transaction will flow to the Group. Service revenues (relating to training and implant support) are recognized when the related services are rendered. When a customer is invoiced, or cash is received but conditions specified within the contract for recognition of the related revenues have not been met, revenue is deferred until all conditions are met. The Group occasionally sells goods and services as a bundled arrangement. Such sales are unbundled based on the relative fair value of the individual goods and services components and each component is recognized separately in accordance with the Group's recognition policy.

b) Subsidiaries

Subsidiaries are entities controlled by the Group. The Group controls an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect these returns through its power over the entity. The financial statements of subsidiaries are included in the Financial Statements from the date that control commences until the date that control ceases. Intra-group balances and transactions, and any unrealized income and expenses arising from intra-group transactions, are eliminated on consolidation.

c) Retirement benefit costs

The Group provides Retirement benefits to its employees in Ireland and Australia under defined contribution schemes. Obligations for contributions to the defined contribution schemes are expensed as the related service is provided.

d) Property, plant and equipment

Property, plant and equipment is stated at cost less accumulated depreciation. Depreciation is calculated to write off the cost of each asset over its estimated future life, as follows:

Computer and office equipment: 3 – 5 years

e) Leases

The Group recognizes a right-of-use asset and a lease liability at the lease commencement date. The right-of-use asset is initially measured at cost, and subsequently at cost less any accumulated depreciation and impairment losses and adjusted for certain remeasurements of the lease liability.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Group's incremental borrowing rate. Generally, the Group uses its incremental borrowing rate as the discount rate.

f) Taxation

Tax expense comprises current and deferred tax. Current and deferred taxes are recognized in the consolidated statement of profit or loss and other comprehensive income except to the extent that they relate to a business combination, or items recognized directly in equity.

Current tax is the expected tax payable or receivable on the taxable result for the year and any adjustments in relation to tax payable or receivable in respect of the previous years.

Deferred tax is recognized in respect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. Deferred tax is not recognized for:

- temporary differences on the initial recognition of assets and liabilities in a transaction that is not a business combination and that affects neither accounting nor taxable profit; or
- temporary differences related to subsidiaries to the extent that it is probable that they will not reverse in the foreseeable future.

Deferred tax is measured at the tax rates at which the temporary differences are expected to reverse, using tax rates enacted or substantively enacted at the reporting date. Deferred tax assets and liabilities are offset where the entity has a legally enforceable right to set off current tax assets against current tax liabilities and the deferred tax assets and liabilities related to the same taxation authority. Deferred tax assets are recognized to the extent that it is probable that there will be taxable profits in the foreseeable future against which they can be utilized. The Group has no recognized deferred tax asset as at 31 December 2020.

The Group recognizes tax credits as a component of income tax in jurisdictions where the tax credit regime is not in substance a government grant.

g) Foreign currency

Transactions in foreign currencies are recorded at the rate prevailing at the date of the transactions. Any resulting monetary assets and liabilities are translated at the exchange rate at the reporting date and all exchange differences thereon are dealt with in consolidated profit or loss.

The income statement and balance sheet of subsidiaries that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities at each reporting date are translated at the closing rate at the reporting date; and
- income and expenses in the income statement and statement of comprehensive income are translated at average exchange rates for the year. Average exchange rates are only permissible if they approximate actual rates.
- All resulting exchange differences are recognized in other comprehensive income and are taken to a separate currency reserve within equity, the foreign currency translation reserve.

h) Financial instruments

Classification and measurement of financial assets and liabilities

On initial recognition a financial asset is classified as measured at Amortized Cost, or Fair Value Through Other Comprehensive Income (FVOCI), or Fair Value Recognized Through Profit and Loss (FVTPL). Financial assets are not reclassified after initial recognition unless the related business model changes. A financial asset is measured at amortized cost if it is held in a business model whose objective is to hold assets to collect contractual cashflows and its contractual terms give rise on specific dates to cash flows that are solely payments of principal or interest.

Trade and other receivables

Trade and other receivables are classified by the Group as amortized cost assets under IFRS 9. These assets are recognized initially at fair value. Subsequent to initial recognition, they are measured at amortized cost using the effective interest method, less any impairment losses.

Cash and cash equivalents

Cash and cash equivalents are classified by the Group as amortized cost assets under IFRS 9. Cash and cash equivalents comprise cash balances and call deposits with maturities of three months or less, which are carried at amortized cost, less any impairment losses.

Trade and other payables

Trade and other payables are classified by the Group as other financial liabilities under IFRS 9. These liabilities are recognized initially at fair value. Subsequent to initial recognition, they are measured at amortized cost using the effective interest method.

Interest-bearing borrowings

Interest-bearing borrowings are classified by the Group as other financial liabilities under IFRS 9 and are recognized initially at fair value including any attributable transaction costs. Subsequent to initial recognition, interest-bearing borrowings are stated at amortized cost using the effective interest method over the contractual term.

Substantial modification of financial liabilities

When the terms of financial liabilities are substantially modified, the Company de-recognizes the existing liability and records any new liabilities at fair value on the date of modification. Any difference between the previous carrying value and the fair value of the new instruments is recorded in the Statement of Profit or Loss and Other Comprehensive Income. Expenses associated with the modification of debt are expensed as incurred.

Derivative financial liabilities

Instruments to be settled in the Company's own shares are recorded as derivative financial liabilities unless they qualify for equity classification due to settlement arising by the exchange of a fixed amount of cash for a fixed number of the Company's own equity.

These instruments are initially recognized at fair value and any subsequent changes in fair value are recorded in the Statement of Profit or Loss and Other Comprehensive Income. The conversion features and warrants issued as part of the Company's debt have variability in the number of shares that may be required to be issued and accordingly are recorded as derivative financial liabilities carried at fair value.

Financial instruments separation

Financial instruments which the Company separates comprise convertible notes issued by the Group that can be converted into ordinary shares by the holder and which are automatically converted in certain circumstances. These instruments were separated into their components based on the fair value of each component at the date of issue. The Company's debt contains the following components:

- Liability component, measured at amortized cost; and
- Derivative component, measured at fair value.

On conversion, any financial liabilities are reclassed to equity.

i) Equity

Ordinary share capital is recognized directly in equity at fair value on issue and is not subsequently remeasured.

j) Impairment

Non-financial assets

All non-financial assets other than deferred taxes are reviewed at the reporting date to determine whether there is evidence of impairment. If such indicators exist, then the asset's recoverable value is determined. An impairment loss is recognized if the carrying value exceeds the recoverable amount. Recoverable amount is the greater of an asset's value in use and its fair value. In assessing value in use, the estimated future cash flows associated with the asset are discounted to their present value using a pre-tax discount rate that reflects current market conditions.

Financial assets

At each reporting date, in accordance with IFRS 9, the Group assesses whether its financial assets, comprising accounts receivable and cash, are impaired. The Group evaluates customer accounts with past-due outstanding balances, and analyses customer credit worthiness, payment patterns and trends. Based upon a review of these accounts and management's analysis and judgement, we estimate the future cash flows expected to be recovered from these receivables. As at 31 December 2020, our trade receivables balances amounted to $0.4 million, and impairment losses are immaterial at this time. Further information on the Group's credit risk is detailed in Note 18. The Company measures loss allowances at an amount equal to lifetime expected credit losses, except for cash which is measured at 12-month expected credit losses. The maximum period considered when estimating expected credit losses is the maximum contractual period of exposure to credit risk.

k) Provisions

A provision is recognized if, as a result of a past event, the Group has a present obligation that it is probable, will result in an outflow of resources and can be estimated reliably.

l) Finance income and expense

Finance income comprises foreign exchange gains on financial items and deposit interest. Interest income is recognized as it accrues. Finance costs comprise interest on borrowings, movement in the fair value of financial instruments and foreign exchange losses.

m) Share based payments

The grant date fair value of equity-settled share-based awards made to employees and non-employees is recognized as an expense, with a corresponding adjustment to equity, over the vesting period of the award. The amount recognized as an expense is adjusted to reflect the number of awards for which the achievement of service and non-market conditions is expected to be met, such that the amount ultimately recognized represents only vested awards.

The grant-date fair value of share options granted to employees is determined using a Black-Scholes model, details of which are provided in Note 19. The grant-date fair value of share options granted to non-employees is determined based on the fair value of services received in return for the option, or where such a value is not available, based on the same model as used for employee options. Options can only be settled by way of share issues. The grant date fair value of Restricted Stock Units (RSUs) granted to employees is estimated based on the closing price of the Company's common stock on the date of grant.

n) Warrants

Warrants issued alongside debt instruments other than those issued as part of the current year's debt modification, which are dealt with above, are initially recognized at fair value with a corresponding reduction in the debt instrument liability whereon this adjustment to the liability is amortized to the income statement on an effective interest rate basis.

o) Research and development expenditure

Expenditure on research is charged to the income statement in the year in which it is incurred.

Expenditure on development is charged to the income statement in the year in which it is incurred, with the exception that development expenditure is capitalized where expenditure is incurred in the development of an asset for sale; is intended to be developed for sale; and for which the likelihood of development and sale is probable. No costs have been capitalized to date.

p) Inventories

Inventories are stated at the lower of cost and net realizable value. The cost of inventories is based on the first in – first out principle and includes expenditure in acquiring the inventories and bringing them to their existing location and condition. Net realizable value is the estimated selling price less the estimated costs of completion and the estimated costs necessary to make the sale. Provision is made, where necessary, for aged, slow moving, obsolete and defective inventories.

4 Revenue

($'000)	**Year ended 31 December 2020**	Year ended 31 December 2019
Revenue arising from the sale of goods	1,497	1,105
Total revenue	**1,497**	**1,105**

5 Operating expenses

($'000)	**Year ended 31 December 2020**	Year ended 31 December 2019
Research and development expenses	3,056	2,896
Clinical and regulatory expenses	2,329	3,893
Selling, general and administration expenses	12,260	12,437
Total operating expenses	**17,645**	**19,226**

6 Employee numbers and benefits

As of 31 December 2020, the Group's employees were based in Ireland, the United Kingdom, Germany, the United States, the Netherlands and Australia.

The table below sets out the number of employees of the Group for each financial year shown, analyzed by category:

($'000)	**Year ended 31 December 2020**	Year ended 31 December 2019
Research and development and quality	4	5
Clinical and regulatory	1	1
Selling, general and administration	35	12
Total employee numbers	**40**	**18**
Parent company employees		
Management and administration	3	3

The aggregate payroll costs of these employees, including Directors, were as follows for each financial year shown:

($'000)	**Year ended 31 December 2020**	Year ended 31 December 2019
Wages and salaries	4,872	4,284
Other remuneration	2,128	732
Social security costs/ payroll taxes	378	304
Share based payments	1,380	3,961
Retirement benefit	46	25
Total	**8,804**	**9,306**

7 Statutory information and Auditor's remuneration

The loss before income tax has been arrived at after charging the following items for each financial year shown:

($'000)	**Year ended 31 December 2020**	Year ended 31 December 2019
Audit services	72	67
Other assurance services	-	78
Taxation advisory services	82	19
Total auditor's remuneration	**154**	**164**
Foreign exchange loss / (gain)	475	(187)
Depreciation of plant and equipment	93	114
Research and development expenditure	3,027	2,896

8 Finance expense

($'000)	**Year ended 31 December 2020**	Year ended 31 December 2019
Finance expense		
Foreign exchange gain/ (loss)	471	(187)
Lease interest	(63)	(38)
Finance expense associated with borrowings:	-	
Interest expense	(2,882)	(1,115)
Impact of substantial modification of borrowings	-	(1,123)
Fair value movement on conversion option	(366)	(105)
Fair value movement on warrants	934	(907)
Total finance expense	**(1,906)**	**(3,475)**

9 Taxes

Current income tax assets and liabilities for the current and prior years are measured at the amount expected to be recovered from or paid to the relevant taxation authorities. The tax rates and tax laws used to compute the amount are those used in Ireland, the United States, Australia, the Netherlands and Germany.

($'000)	**Year ended 31 December 2020**	Year ended 31 December 2019
Irish income tax	-	-
Income tax in other jurisdictions:		
Foreign current tax	147	156
Adjustments in respect of prior years	(82)	(36)
Total income tax charge	**64**	**120**

Certain companies within the Group provide services to other group companies, and consequently generate revenues and profits that are subject to corporation tax in Australia, United States, the Netherlands and Germany.

($'000)	**Year ended 31 December 2019**	Year ended 31 December 2019
Loss before tax	(18,815)	(22,265)
		-
Taxed at tax rate in Ireland of 12.5%	(2,351)	(2,783)
Non-deductible expenses	261	517
Tax credits	62	(115)
Foreign rate differential	(163)	159
Adjustments in respect of prior periods	-	(36)
Unrecognized tax losses	2,255	2,378
Total income tax charge	**64**	**120**

Unrecognized deferred tax assets

The Group has unrecognized potential deferred tax assets. These potential assets are not recognized because future taxable profits against which they can be utilized are not sufficiently certain. The availability of these assets does not expire.

Capital allowances on intellectual property which is recognized as an asset for tax purposes but is not capitalized under IFRS, will be available should the Group generate relevant income in future periods against which the capital allowances are deductible.

The unrecognized deferred tax asset relating to share based payments arises principally in our US subsidiary.

Gross timing differences:	At 1 January 2019	Arising in year	Adjustment in respect of prior years	**At 31 December 2019**	Arising in year	Adjustment in respect of prior years	**At 31 December 2020**
Unrecognized tax losses	107,662	19,031	(140)	126,553	18,610	(4,089)	141,074
Intangible assets	15,000	-	-	15,000	-	-	15,000
Share based payments	916	(424)	-	492	-	(492)	-
Derivative financial instrument – conversion option	-	1,203	-	1,203	366	-	1,569
Derivative financial instrument – warrant	-	2,886	-	2,886	(934)	-	1,952
Total gross temporary differences	**123,578**	**22,696**	**(140)**	**146,134**	**18,042**	**(4,581)**	**159,595**
Unrecognized deferred tax asset			13,457 13,457	2,378 2,378			(17) (17)
Unrecognized tax losses	13,457	2,378	(17)	15,818	2,326	(511)	17,633
Intangible assets	1,875	-	-	1,875	-	-	1,875
Share based payments	201	(93)	-	108	-	(108)	-
Derivative financial instrument – conversion option	-	150	-	150	45		195
Derivative financial instrument – warrant	-	360	-	360	(116)		244
Total unrecognized deferred tax asset	**15,533**	**2,795**	**(17)**	**18,311**	**2,255**	**(619)**	**19,947**

10 Property, plant & equipment

($'000)	**Computer and office equipment Year ended 31 December 2020**	Computer and office equipment Year ended 31 December 2019
Cost		
At beginning of year	630	625
Additions	109	5
At end of year	739	630
Depreciation		
At beginning of year	504	390
Charge for the year	93	114
At end of year	597	504
Carrying value at end of year	**142**	**126**

11 Trade and other receivables

($'000)	**Year ended 31 December 2020**	Year ended 31 December 2019
Trade receivables	468	245
VAT and sales tax receivable	125	170
Prepaid expenses and other current assets	1,011	451
Total trade and other receivables	**1,604**	**866**

Information about the Group's exposure to credit risks and impairment losses for trade receivables is included in Note 18.

12 Inventory

($'000)	**Year ended 31 December 2020**	Year ended 31 December 2019
Raw Materials	158	79
Work in Progress	70	306
Finished Goods	1,666	1,478
Total inventory	**1,894**	**1,863**

There were no provisions netted against inventory as at 31 December 2020. The cost of inventory used in cost of sales during 2020 was $738,000 (2019: 637,000).

13 Cash and cash equivalents

($'000)	**Year ended 31 December 2020**	Year ended 31 December 2019
Cash in bank accounts – USD	6,107	16,965
Cash in bank accounts – EUR	194	272
Cash in bank accounts – AUD	37	161
Total cash and cash equivalents	**6,338**	**17,398**

14 Interest bearing loans and borrowings

IPF Debt Facility – pre Reorganisation

On 24 August 2015, MML entered into the IPF debt facility for up to $15.0 million. The entire initial facility was drawn down in three tranches. In April 2019 a new tranche of €3.0 million (approximately $3.34 million) was made available to Mainstay, which was drawn down in July 2019.

In April 2019, the terms of the existing agreements were amended such that all principal and interest payments were deferred until 2021, the loan term was extended to 2023 and the interest rate on all tranches was changed to 8%. The loan was also made to be convertible in certain circumstances to ordinary shares at a price of €8 per share. In addition, Mainstay issued to IPF a warrant to subscribe for up to 1,500,000 Mainstay Medical International Limited shares at any time up to 18 April 2025 at an exercise price of €6.00 per share.

The minimum cash covenant was amended so that Mainstay is required to hold cash at least equal to its projected cash expenditures for operations and debt repayment for the next three months, and the covenant relating to the achievement of commercial milestones was eliminated.

IPF Debt Facility – post reorganisation

In connection with the reorganisation becoming effective, Mainstay and IPF agreed to amend certain of the existing facility and warrant arrangements.

The facility agreement was amended in April 2020 so that the automatic conversion mechanics will engage when FDA approval has been received in respect of ReActiv8 and the Company completes one or more issuances of shares at an average price of €6.00 per share for a total aggregate amount of €20 million.

In addition, certain additional rights were granted to IPF following the reorganisation becoming effective. Under these new arrangements IPF are entitled to appoint an observer to the board of directors of the Company. IPF's prior written consent will also be required for the Company to complete an equity raising transaction by means of a share issuance where (i) shares in the Company are to be issued at a price below €6.00 per share and (ii) 49% or more of the aggregate value of the share issuance is to be contributed by institutional shareholders in the Company who are represented on the board of directors of the Company at the time of agreement to enter into such equity raising transaction. This restriction shall cease upon satisfaction of certain conditions including full satisfaction of the monies owed under the facility agreement.

Bridge Financing

On 28 December 2020, the Company completed a bridge financing that involved the issuance by it of convertible promissory notes for an aggregate amount of US$6.44 million to certain current investors of the Company. The notes did not carry interest and were due and payable by the Company on demand to the holders on 31 December 2023. The Company received $4 million in proceeds as at 31 December 2020 and the remaining $2.4 million in January 2021.

The outstanding amounts under the notes were automatically converted into the same class of preference shares of the Company issued to other investors on completion of the additional financing in February 2021 which is detailed in note 24.

($'000)	**Year ended 31 December 2020**	Year ended 31 December 2019
Loans and borrowings - current		
Term loan	-	-
Accrued interest	-	-
Derivative financial instrument – warrant	1,952	2,886
Paycheck Protection Program	223	-
Total current loans and borrowings	**2,175**	**2,886**
Loans and borrowings – non-current		
Term loan	16,718	12,620
Accrued interest	3,534	696
Conversion Option	1,569	1,203
Paycheck Protection Program	45	-
Total non-current loans and borrowings	**21,866**	**14,519**
Total loans and borrowings	**24,041**	**17,405**

15 Trade and other payables

($'000)	**Year ended 31 December 2020**	Year ended 31 December 2019
Trade and other payables	2,960	1,534
Payroll tax liability	60	46
Accrued expenses	866	1,119
Total trade and other payables	**3,886**	**2,699**

16 Leases

The Group leases office facilities at two locations.

Information about leases for which the Group is a lessee is presented below.

Right-of-use assets

($'000)	**Year ended 31 December 2020**	Year ended 31 December 2019
Balance at 1 January	290	537
Depreciation charge for the year	(216)	(247)
Additions to right-of-use assets	-	-
Right-of-use assets	**74**	**290**

Amounts recognized in profit or loss

($'000)	**Year ended 31 December 2020**	Year ended 31 December 2019
Interest on lease liabilities	63	38
Total	**63**	**38**

Lease liability

($'000)	**Year ended 31 December 2020**	Year ended 31 December 2019
Balance at 1 January	334	588
Payments made on leased liabilities for the year	(229)	(254)
Additions to right-of-use assets	-	-
Lease liability	**105**	**334**

($'000)	**Year ended 31 December 2020**	Year ended 31 December 2019
Non-current lease liabilities	-	107
Current lease liabilities	105	227
Total	**105**	**334**

17 Called up share capital

The Company's ordinary shares are issued and quoted in Euro and have been translated into US Dollars at the rates prevailing at the date of issue.

Authorized and Issued Share Capital

2020 – Mainstay Medical Holdings plc Authorized	**31 December 2020 €**
35,000,000 ordinary shares of €0.01 each	350,000
25,000 deferred shares of €1.00 each	25,000
	375,000

Issued, called up and fully paid	**2020 $**
13,469,504 ordinary shares of €0.01 each	152,003
25,000 deferred share of €1.00 each	28,212
	180,215
In $'000	**180**

2019 – Mainstay Medical International plc Authorized	**31 December 2019** €
35,000,000 ordinary shares of €0.001 each	35,000
(2019: 40,000 deferred shares of €1.00 each)	40,000
	75,000

Issued, called up and fully paid	**2019 $**
13,421,504 ordinary shares of €0.001 each)	16,421
40,000 deferred shares of €1.00 each	55,268
	71,689
In $'000	**72**

On 8 June 2020, Mainstay Medical Holdings Plc issued 13,439,004 shares to the existing shareholders of Mainstay Medical International Plc in return for the entire share capital of Mainstay Medical International plc.

18 Financial Instruments

The following table shows the carrying amounts and fair values of financial assets and financial liabilities as at 31 December 2020 and 31 December 2019:

2020 ($'000)	Financial assets and liabilities at amortized cost	Other financial liabilities	Financial instruments held at fair value	Fair value
Financial assets				
Cash and cash equivalents	6,338	-	-	N/A
Trade and other receivables	468	-	-	N/A
Financial liabilities				
Trade and other payables	-	(3,886)	-	N/A
Interest bearing loans and borrowings	-	(16,718)	-	(16,665)
Derivative financial instruments – conversion option	-	-	(1,569)	(1,569)
Derivative financial instruments - warrant	-	-	(1,952)	(1,952)
At December 2020	**6,806**	**(20,604)**	**(3,521)**	**N/A**

2019 ($'000)	Financial assets and liabilities at amortized cost	Other financial liabilities	Financial instruments held at fair value	Fair value
Financial assets				
Cash and cash equivalents	17,398	-	-	N/A
Trade and other receivables	245	-	-	N/A
Financial liabilities				
Trade and other payables	-	(2,699)	-	N/A
Interest bearing loans and borrowings	-	(12,620)	-	(12,343)
Derivative financial instruments – conversion option	-	-	(1,203)	(1,203)
Derivative financial instruments - warrant	-	-	(2,886)	(2,886)
At December 2019	**17,643**	**(15,319)**	**(4,089)**	**N/A**

All financial instruments are Level 3.

A. Measurement of fair values

Valuation techniques and significant unobservable inputs

Items held at amortized cost where fair value is disclosed

We disclose the fair value of our financial instruments that are measured at amortized cost using the following fair values hierarchy for valuation inputs. The hierarchy prioritizes the inputs into three levels based on the extent to which inputs used in measuring fair value are observable in the market. Each fair value measurement is reported in one of three levels which are determined by the lowest level input that is significant to the fair value measurement in its entirety. These levels are:

- Level 1: Inputs are based upon quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2: Inputs are based upon other than quoted prices included in Level 1 that are observable for the asset or liability, either directly (i.e. as prices) or indirectly (i.e. derived from prices).
- Level 3: Inputs for the asset or liability that are not based on observable market data (unobservable inputs).

Cash and trade payables are settleable within 30 days and accordingly fair value is deemed to be equal to carrying value.

The fair value of interest-bearing loans and borrowings is calculated based on the present value of future contractual principal plus interest cash flows discounted at appropriate market rates of interest. These are classified as level 3 fair value instruments.

There were no transfers into or out of any classification of financial instruments in any period.

Details of key unobservable inputs and the methodologies used by the Group in determining the fair value disclosures for financial instruments as at 31 December 2020 are detailed in the table below.

Type	Valuation approach	Key unobservable inputs	Interaction between key unobservable inputs and fair value
Loans and borrowings	Income approach	• Marked interest rate (11% to 13%)	• A increase in the interest rate used would decrease the fair value • A decrease in the interest rate would increase the fair value

Items held at fair value

The following table shows the valuation techniques used in measuring the Company's financial instruments which are recorded at fair value on the Company's statement of financial position as well as the significant unobservable inputs:

Type	Valuation Technique	Significant Unobservable Inputs	Relationship Between Inputs and Fair Value
Conversion option	Black Scholes Valuation Model	Term (12 months)	An extension of the term would increase the value of the instrument
		Volatility (151.71%)	A higher volatility would increase the value of the instrument
Warrants	Black Scholes Valuation Model	Term (4.3 years)	An extension of the term would increase the value of the instrument
		Volatility (84.07%)	A higher volatility would increase the value of the instrument

The following table shows a reconciliation between the initial and closing fair values of the above financial instruments:

($'000)	Conversion Option	Warrants
Balance at 1 January 2020	1,203	2,886
Change in fair value recognized in statement of profit and loss	366	(934)
Balance at 31 December 2020	**1,569**	**1,952**

Sensitivity Analysis

The following shows the impact of reasonable possible changes in significant inputs on the value of the above instruments at 31 December 2020:

	Increase in Value / P&L loss	
($'000)	Conversion Option	Warrants
Increase of term by 6 months	737	315
Increase in volatility of 10%	218	332

B. Financial risk management

In terms of financial risks, the Group has exposure to credit risk, liquidity risk and market risk (comprising foreign currency risk and interest rate risk). This note presents information about the Group's exposure to each of these risks together with the Group's objectives, policies and processes for measuring and managing those risks.

I. Risk management framework

Mainstay's Board of Directors has overall responsibility for the establishment and oversight of the Group's risk management framework. The Group's risk management policies are established to identify and analyze the risks faced by the Group, to set appropriate risk limits and controls and to monitor risks and adherence to the limits. Risk management systems and policies will be reviewed regularly as the Group expands its activities and resource base to take account of changing conditions.

The Group has no significant concentrations of financial risk other than concentration of cash with individual banks. The Group is also exposed to credit risk arising on trade receivables, with further information provided under Credit risk below. Other than liquidity risk based on the Company's use of cash during the year, there has been no significant change during the year or since the year end to the types or quantum of financial risks faced by the Group or the Group's approach to the management of those risks.

II. Credit risk

Credit risk is the risk of financial loss to the Group if a customer or counterparty to a financial instrument fails to meet contractual obligations and arises principally from the Group's cash and cash equivalents and trade and other receivables. Credit risk is managed on a Group basis. The maximum exposure to credit risk is represented by the carrying amount of each asset. The carrying value of receivables is a reasonable approximation of fair value.

Trade and other receivables

Trade receivables comprise amounts due from customers, due as at 31 December 2020 and 31 December 2019. The Group's credit risk management policy and process in relation to trade receivables involves carrying out credit checks where appropriate, and by active credit management. The utilization of credit limits is regularly monitored. In addition, it involves periodically assessing the financial reliability of customers, considering their financial position, experience and other factors.

The Company does not have exposure to significantly different categories of customers, and accordingly details of credit risk by customer type or jurisdictions is not provided.

There were no material impairment losses recorded in the period and the provision for expected credit losses recorded at 31 December 2020 is also immaterial. The carrying value of trade receivables of $0.46 million at 31 December 2020 (2019: $0.24 million) represents the maximum exposure to credit risk.

The below table provides an analysis of aging of receivables as at 31 December 2020 and 31 December 2019.

2020				
($'000)	**Current**	**1 - 30 Days**	**31 - 60 Days**	**61 – 90 Days**
Trade and other receivables	165	136	41	126

2019				
($'000)	**Current**	**1 - 30 Days**	**31 - 60 Days**	**61 – 90 Days**
Trade and other receivables	17	94	51	83

Cash and cash equivalents

The Group maintained its cash balances with its principal financial institutions throughout the year, and the Group limits its exposure to any one financial institution by holding cash balances across several financial institutions. The cash and cash equivalents are held with bank and financial institution counterparties, which are rated BBB- to AA-, based on Moody and Standard and Poor's ratings. The credit rating status of the Group's principal financial institutions is reviewed by the Audit Committee or the Board annually.

The cash balance is reported to the Board of Directors on a monthly basis, and a monthly review of all cash balances held at each institution is carried out by the CFO. The Group maintains most of its cash in USD denominated accounts. The Group held cash and cash equivalents of $6.3 million as at 31 December 2020.

Impairment on cash and cash equivalents has been measured on a 12-month expected loss basis and reflects the short maturities of the exposures. The Group considers that its cash and cash equivalents have low credit risk based on the external credit ratings of the counterparties.

Guarantees

The Company has guaranteed the payment of the liabilities and commitments of its subsidiaries in Ireland (as defined in section 357 of the Companies 2014 Act) for the years ended 31 December 2020 and 31 December 2019.

III. Liquidity risk

Liquidity risk is the risk that the Group will encounter difficulty in meeting the obligations associated with its financial liabilities as they fall due.

Since inception the Group has funded its operations primarily through (i) the issuance of equity securities and (ii) debt funding. The Group continually evaluates funding strategies (e.g.: equity, debt, partnering) to support its activities into the future. Adequate additional financing may not be available on acceptable terms, or at all. The Group's inability to raise capital as and when needed would have a negative impact on the Group's financial position and its ability to pursue its business strategy.

The following is an analysis of the maturity of the contractual (undiscounted) outflows associated with the Group's financial liabilities at 31 December 2020 and as at 31 December 2019.

($'000) **31 December 2020:**	**Carrying value**	**Cash flow (total)**	**Less than 1 year**	**Between 1-2 years**	**Between 2-5 years**
Financial Liabilities					
Trade and other payables	3,887	3,887	3,887	-	-
Interest bearing loans and borrowings	20,252	23,546		7,489	16,057
Derivative financial instruments – conversion option	1,569	-	-	-	-
Derivative financial instruments - warrant	1,952	-	-	-	-
Lease liability	105	105	105	-	-
At 31 December 2020	**27,765**	**27,271**	**3,992**	**7,489**	**16,057**

($'000) **31 December 2019:**	**Carrying value**	**Cash flow (total)**	**Less than 1 year**	**Between 1-2 years**	**Between 2-5 years**
Financial Liabilities					
Trade and other payables	2,699	2,699	2,699	-	-
Interest bearing loans and borrowings	13,316	16,544	-	4,296	12,248
Derivative financial instruments – conversion option	1,203	-	-	-	-
Derivative financial instruments - warrant	2,886	-	-	-	-
Lease liability	334	390	265	125	-
At 31 December 2019	**20,438**	**19,633**	**2,964**	**4,421**	**12,248**

The cashflows presented for interest bearing loans and borrowings at 31 December 2020 are the cashflows only in the case of non-conversion of the loans.

IV. Foreign currency risk

The Group is exposed to transactional foreign currency risk to the extent that there is a mismatch between the currencies in which sales, purchases, receivables and borrowings are denominated and the respective functional currencies of Group companies. The Group's reporting currency is the US Dollar. The Group's Australian subsidiary has an Australian Dollar functional currency, and three of the Group's subsidiaries located in Ireland, Germany and the Netherlands have a Euro functional currency.

The following table sets forth, for the years indicated, certain information concerning the exchange rate between: (i) the Euro and the US Dollar; and (ii) the Australian Dollar and the US Dollar:

Euro per USD1.00	**End of year**	**Average**
Year ended 31 December 2019	1.123	1.12
Year ended 31 December 2020	1.227	1.147

Australian Dollar per USD1.00	**End of year**	**Average**
Year ended 31 December 2019	0.702	0.696
Year ended 31 December 2020	0.772	0.693

The Group did not have material asset or liability amounts in foreign currencies at year end, other than trade payables and accruals (net of cash) of €78,000 (2019: €160,000) and the debt, conversion options and warrants noted above.

Sensitivity analysis

A strengthening (or weakening) of the US Dollar against the Euro of 5% would have (decreased)/ increased the loss for the year by $4,000 (2019: $10,000). Any reasonable or likely movement between the US Dollar and the Australian Dollar is considered not likely to have a material impact on the Group's statement of profit or loss and other comprehensive income.

V. Interest rate risk

As the Company's debt is now at fixed rates, changes in interest rates would have no impact on finance expense other than immaterial impacts on the fair value of derivative financial instruments.

The Group's cash balances are maintained in short term access accounts and carry a floating rate of interest. A 50 basis points change in the rate of interest applied to the cash balance held by the Group would not have had a material impact on the Group's statement of profit or loss in the year.

19 Share Based Payments

Stock Incentive Plan

The Group operates a share option plan (the "Plan"). As at 31 December 2020, the Plan allows for the Company to grant options over ordinary shares of Mainstay Medical Holdings plc to employees of the Group companies, directors, consultants and other contractors. As at 31 December 2020 3,155,000 (2019: 2,678,000) share options over ordinary shares of the Company that had been granted under the Plan were outstanding.

The Plan also allows for the issue of RSUs, being rights to receive ordinary shares at no cost to the relevant employee, director or consultant. The Company granted 390,000 RSUs during 2019 and 352,000 are outstanding as at 31 December 2020.

The Plan allows for flexibility in the grant conditions of each individual option or RSU including variations on the amounts of options or RSUs granted, the vesting requirements for each option or RSU and the expiration terms of the options or RSUs.

Details of RSU's and share options granted that are outstanding as at 31 December 2020:

	Number of instruments (in thousands)	Contractual life of options
Options granted in 2010	34	10 years from grant
Options granted in 2011	17	10 years from grant
Options granted in 2012	4	10 years from grant
Options granted in 2013	235	10 years from vesting
Options granted in 2014	61	10 years from vesting
Options granted in 2015	261	10 years from vesting
Options granted in 2016	201	10 years from vesting
Options granted in 2017	414	10 years from vesting
Options granted in 2018	353	10 years from vesting
Options granted in 2019	921	10 years from vesting
Options granted in 2020	614	10 years from vesting
Total share options in issue	**3,115**	
RSU's outstanding in 2020	**352**	

The above options all include service vesting conditions related to employee and non-employee service and vest over periods ranging from one to four years.

A breakdown of the outstanding share options as at 31 December 2020 and 31 December 2019 is as follows (in thousands, except prices):

(Number of instruments in thousands)	Year ended 31 December 2020	Weighted average exercise price 2020	Year ended 31 December 2019	Weighted average exercise price 2019
At beginning of year	2,678	€12.29	1,784	€13.23
Options granted during the year	649	€3.3	959	€3.76
Options expired unexercised	-	-	-	-
Options forfeited	(164)	€10.49	(63)	€14.18
Options exercised	(48)	€0.73	(2)	€4.48
Outstanding at end of year	**3,115**	**€8.28**	**2,678**	**€9.88**
Exercisable at end of year	**1,681**	**€10.91**	**1,237**	**€12.29**

Total non-cash expense charged to profit and loss in relation to share options for the year ended 31 December 2020 was $1.4m (2019: $4m) and was based on the fair value of the options granted, measured using a Black-Scholes model with the following inputs:

	Year of Grant	
	2020	**2019**
Weighted average share price (€)	3.3	3.76
Weighted average exercise price (€)	3.3	3.76
Weighted average expected share volatility	63.25%	63.25%
Expected term (years)	7	7
Expected dividends	-	-
Risk free rate (average)	0.03%	0.03%
Fair value of option ($)	10.91	12.29

20 Contingencies

The Directors and management are not aware of any contingencies that may have a significant impact on the financial position of the Group.

Subsidiary guarantee

The Company has guaranteed the payment of the liabilities and commitments of its subsidiaries in Ireland for the purposes of section 357 of the Companies Act 2014 for the years ended 31 December 2020 and 31 December 2019.

21 Retirement benefit schemes

Defined contribution schemes

The Group operates defined contribution retirement benefit schemes for certain employees in Ireland and Australia. The assets of the schemes are held separately from those of the Group in independently administered funds. The advice of a professionally qualified retirement benefit consultant was taken in the setting up and maintenance of the schemes.

Total retirement benefit costs of the defined contribution schemes for the year ended 31 December 2020 amounted to $12,581 (2019: $24,859). There were no accruals or prepayments in respect of the retirement benefit costs at 31 December 2020 (2019: None).

22 Subsidiary undertakings

At 31 December 2020, the Company had the following subsidiaries and owns 100% of the called up ordinary share capital of each such subsidiary:

- Mainstay Medical International Limited is registered in Ireland.
- Mainstay Medical Limited is registered in Ireland.
- MML US, Inc. is registered in the United States of America.
- Mainstay Medical (Australia) Pty. Limited is registered in Australia.
- Mainstay Medical Distribution Limited is registered in Ireland.
- Mainstay Medical GmbH is registered in Germany.
- Mainstay Medical BV is registered in the Netherlands.

23 Related party transactions

As at 31 December 2020, David Brabazon held 212,828 ordinary shares of the Company. On the 28th December, Drand Limited, a Company of which Mr. Brabazon is a Director, provided the Company with $2 million under a convertible promissory note. This note was subsequently converted into preference shares as part of the equity financing completed in February 2021 and is detailed within Note 24. There were no balances due to or from related parties as at 31 December 2019. Details of the shareholding interests and remuneration of the Directors of the Company are included in the Directors' report.

24 Events subsequent to 31 December 2020

On 16 February 2021, Mainstay Medical Holdings plc announced the closing of an equity financing in which it raised gross proceeds of US$108 million. Mainstay intends to use the funds to support the company's commercial launch of ReActiv8 in the U.S., continued expansion in Europe and Australia, additional post-market clinical studies and research, and general operations. The financing consisted of the issuance of 36,600,987 new preference shares to new and existing investors.

In addition, the Company agreed with IPF that warrants to subscribe for ordinary shares held by IPF and provisions of the IPF facility agreement providing for automatic or voluntary conversion of amounts owing thereunder into ordinary shares, were each amended so they relate to preferred shares rather than ordinary shares.

An extraordinary general meeting (EGM) of Mainstay shareholders was held on 9 February 2021 to approve the financing and related matters. At the EGM, all resolutions were duly passed. The results of the voting on each of the resolutions is available on the Company's website.

Parent Company Financial Statements
Mainstay Medical Holdings plc

Company statement of financial position
At 31 December 2020

($'000)	Notes	31 December 2020
Non-current assets		
Investment in subsidiary	(d)	34,219
Current assets		
Prepayments and other receivables	(a)	24
Amounts due from subsidiary undertakings	(c)	4,028
Cash and cash equivalents	(b)	-
Total current assets		4,052
Total assets		**38,271**
Equity		
Share capital		180
Merger reserve		29,446
Share based payment reserve		212
Retained loss		912
Surplus/(deficit) on shareholders' equity		**30,750**
Non-current liabilities		
Loans and Borrowings	(e)	5,569
Total non-current liabilities		5,569
Current liabilities		
Loans and Borrowings	(e)	1,952
Trade and other payables		-
Amounts due to subsidiary undertakings		-
Total current liabilities		1,952
Total liabilities		**7,521**
Total equity and liabilities		**38,271**

On behalf of the Board on 10 March 2021,

Jason Hannon
CEO

Company statement of changes in shareholder's equity
For the year ended 31 December 2020

($'000)	**Share capital**	**Merger reserve**	**Other Reserves**	**Share based payment reserve**	**Retained Earnings**	**Total equity**
Balance at 1 Jan 2020	-	-	-	-	-	-
Impact of change in holding company	180	29,422	-	-		29,602
Comprehensive profit for the year	-	-	-	-	912	912
Transactions with owners of the Company:						
Issue of Shares	-	24	-	-	-	24
Share based payments	-	-	-	212	-	212
Balance at 31 December 2020	**180**	**29,446**	**-**	**212**	**912**	**30,750**

Company statement of cash flows

At 31 December 2020

($'000)	Year ended 31 December 2020
Cash flow from operating activities	
Net gain attributable to equity holders	912
Add/(less) non-cash items	-
Share-based compensation	212
Finance income from derivative financial instruments	(1,124)
Add/(less) changes in working capital	
Prepayments and other receivables	-
Trade and other payables	-
Net cash used in operations	**-**
Cash flow from financing activities	
Net cash from financing activities	**-**
Net increase in cash and cash equivalents	-
	-
Cash and cash equivalents at beginning of year	-
Cash and cash equivalents at end of year	**-**

The following notes are specific to the Company statement of financial position:

(a) Prepayments and other receivables

($'000)	31 December 2020
Prepayments	24
	24

(b) Cash and cash equivalents

($'000)	31 December 2020
Cash in bank accounts – USD	-
	-

(c) Amounts due from subsidiary undertakings

($'000)	31 December 2020
Mainstay Medical International Limited	4,028
	4,028

(d) Investment in subsidiary

($'000)	31 December 2020
Opening balance	-
Investment in subsidiary	34,219
Closing balance	**34,219**

(e) Loans and borrowings

($'000) *Current*	31 December 2020
Derivative financial instrument – warrant	1,952
Total	**1,952**

($'000) *Non-current*	31 December 2020
Term Loan	4,000
Derivative financial instrument – warrant	1,569
Total	**5,569**