Mainstay Medical

Restoring Function. Restoring Life.

Mainstay Medical Holdings plc and its subsidiaries
Annual Report
for the year ended 31 December 2022

Mainstay Medical Holdings plc
Table of contents

Forward looking statements

All statements in this Annual Report other than statements of historical fact are, or may be deemed to be, forward-looking statements. Forward-looking statements may 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, other variations or comparable terminology, and include all matters that are not historical facts. These forward-looking statements may include, without limitation, statements regarding the company's intentions, beliefs or current expectations concerning, among other things, the company's commercial efforts and performance, financial position, financing strategies, product design and development, regulatory applications and approvals, and reimbursement arrangements.

Forward-looking statements involve risk and uncertainty and are not guarantees of future performance. Actual results may differ materially from those described in, or suggested by, the forward-looking statements. 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 to differ materially from those expressed or implied by the forward-looking statements herein, including, without limitation, the Company's ability to successfully commercialize ReActiv8, including (without limitation) 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, the time required to commence and complete clinical trials and their results, the Company's progress in developing new or improved products, the time and process required to obtain regulatory approvals, currency fluctuations, changes in Company's business strategy, and political and economic uncertainty. The forward looking statements herein speak only as of the date of this Annual Report.

Mainstay Medical Holdings plc
Corporate and shareholder information

Directors	Jason Hannon, Chief Executive Officer and Executive Director David Brabazon, Independent Non-Executive Chairman Greg Garfield, Non-Executive Director Charles Chon, Non-Executive Director Cédric Moreau, Non-Executive Director Jeffery Dunn, Non-Executive Director Eric Major, Non-Executive Director
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.mainstaymedical.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 Silicon Valley Bank
Registrar	Computershare Investor Services (Ireland) Limited Heron House Corrig Road Sandyford Industrial Estate Dublin 18, Ireland

Mainstay Medical

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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 2022.

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.

As at 31 December 2022, the Company together with its operating subsidiaries Mainstay Medical International Limited (MMI), Mainstay Medical Limited (MML), MML US, Inc. (MMUS), Mainstay Medical (Australia) Pty Limited (MMA), Mainstay Medical Distribution Limited (MMD), Mainstay Medical B.V. (MMBV), and Mainstay Medical GmbH (MMG), form the Mainstay Medical Group.

Financial review

Income statement

Revenue during the twelve-month period ending 31 December 2022 was $10.1 million (2021: $5.3 million). Revenue was generated from sales of ReActiv8 systems to customers in the United States, Germany, the UK, Australia, Switzerland, Sweden, Austria, and Belgium.

Operating expenses related to on-going activities were $50.0 million during the year ended 31 December 2022 (2021: $35.6 million). On-going activities during the financial year included selling, general and administrative activities, research and development, and clinical and regulatory activities.

Our selling, general and administrative expenses were $38.4 million during year ended 31 December 2022 (2021: $28.2 million). The increase of $10.2 million is primarily due to increases in commercial related payroll costs as we built out our commercial capabilities in addition to an increase in non-cash related share-based payment expenses.

Research and development expenses were $7.6 million during the year ended 31 December 2022 (2021: $4.5 million). The increase of $3.1 million in 2022 is primarily due to added payroll costs caused by an increase in employee headcount and further investments in future product development.

Clinical and regulatory expenses were $4.0 million during the year ended 31 December 2022 (2021: $2.9 million). The $1.1 million increase is primarily driven by increased costs incurred in the continuation of RESTORE clinical trial, offset by decreased direct trial costs relating to the ReActiv8-B clinical trial.

The loss for the year was $49.1 million (2021: $35.7 million).

Statement of financial position

Total assets of the Group at year end were $56.0 million (2021: $87.9 million). Cash on hand at 31 December 2022 was $41.9 million (2021: $76.5 million). Cash used in operating activities was $43.6 million during the year ended 31 December 2022 (2021: $31.6 million). This operating cash outflow reflects the costs of commercialization of ReActiv8, ongoing research and development, undertaking our clinical trials, and ongoing costs of running the Group.

Financing Activities

Debt Financing

In September 2022 the Company entered into a loan and security agreement with Madryn Health Partners under which it can borrow up to $50 million, subject to certain conditions. Concurrently with entering into the agreement with Madryn, the Company borrowed the first tranche of $30 million, plus a separate $5m convertible note, and repaid in full all accrued principal and interest under its existing loan facility with Oxford Finance, the total of which was approximately $22 million. The Madryn debt facility is secured by way of fixed and floating charges over all of the assets and undertakings of the MML and MMUS, including intellectual property.

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 the 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.
- 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 favorable to new investors, or to restrictions significantly limiting our access to additional capital.
- We continue 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.
- Competition in the medical device industry is intense and expected to increase, and new or competing treatments for chronic low back pain may emerge.
- 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 selling or marketing ReActiv8 or other products, and/or reduce our margins.
- 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.
- 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.
- 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 2023 are to continue to accelerate our ReActiv8 commercialization efforts in the US, Europe, and Australia, including securing adequate reimbursement for ReActiv8 implants, as well as continuing to generate clinical and other evidence to support marketing and reimbursement of ReActiv8 and working on future product development.

Directors and Secretary and their interests

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

Jason Hannon, Chief Executive Officer and Executive Director
David Brabazon, Independent Non-Executive Chairman
Greg Garfield, Non-Executive Director
Charles Chon, Non-Executive Director
Cédric Moreau, Non-Executive Director
Jeffery Dunn, Non-Executive Director
Eric Major, Non-Executive Director

Matthew Onaitis served as Company Secretary.

The beneficial interest of the Directors and Company Secretary, who held office at 31 December 2022, in the ordinary share capital of the Group at the dates below were as follows:

Ordinary shares **Name**		**At 31 December 2022**	**At 31 December 2021**
David Brabazon	Ordinary shares of €0.001 each	212,828	212,828
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 2022**	**No. of ordinary shares under option as at 31 December 2021**	**No. of vested options as at 31 December 2022**
Jason Hannon	28 Apr 2021	US$2.08	10 years from vesting	267,908	267,908	111,628
Jason Hannon	28 Apr 2021	US$2.08	10 years from vesting	79,085	79,085	32,952
Jason Hannon	13 Aug 2019	€3.76	10 years from vesting	464,000	464,000	386,667
Jason Hannon	26 June 2020	US$4.17	10 years from vesting	50,000	50,000	31,250
Jason Hannon	28 April 2021	US$2.08	10 years from vesting	2,238,772	2,238,772	974,448
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
David Brabazon	01 Dec 2021	US$2.08	10 years from vesting	200,000	200,000	50,000
Matt Onaitis	28 Apr 2021	US$2.08	10 years from vesting	66,666	66,666	27,778
Matt Onaitis	13 Aug 2019	€3.76	10 years from vesting	90,000	90,000	75,000
Matt Onaitis	26 June 2020	US$4.17	10 years from vesting	25,000	25,000	15,625
Matt Onaitis	28 April 2021	US$2.08	10 years from vesting	517,142	517,142	215,476

Jeff Dunn	01 Dec 2021	US$2.08	10 years from vesting	200,000	200,000	50,000
Eric Major	01 Dec 2021	US$2.08	10 years from vesting	200,000	200,000	50,000

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 2022 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. Moreau 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 and the Sofinnova Crossover Fund. At 31 December 2022, Sofinnova Capital VI FCPR owned 2,949,146 ordinary shares and 2,702,702 preferred shares, combined representing approximately 5.9% of the issued share capital of the Company, and Sofinnova Crossover owns 5,067,567 preferred shares amounting to approximately 10.1% of the issued share capital of the Company.

As at 31 December 2022, David Brabazon held 212,828 ordinary shares of the Company. Mr Brabazon is deemed to hold additional interest in the Company by virtue of the interests that he holds in AixVio Research Limited. At 31 December 2022, AixVio Research Limited owns 3,413,939 preferred shares. Combined, the ordinary and preferred shares amount to approximately 7.2% of the issued share capital of the Company.

Mr. Chon 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 Ally Bridge. At 31 December 2022, Ally Bridge owned 13,851,351 preference shares amounting to approximately 27.6% of the issued share capital of the Company.

Directors' remuneration

The amount of remuneration paid and benefits in kind granted to all Directors that served during 2022 by the Group for services in all capacities relating to 2022 was $893,152 (2021: $889,740)

None of the Directors exercised any share options in either 2022 or 2021.

Issued share capital

At 31 December 2022, the authorized share capital of the Company is €1,100,000, comprised of 50,000,000 preferred shares of €0.01 each, and 60,000,000 ordinary shares of €0.01 each. A full description of the rights attached to the preferred and ordinary shares of the Company is set out in the constitution of the Company.

Share Option Plan

The Group operates a share option plan (the "Plan"). As at 31 December 2022, 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 preferred shares and the ordinary shares, as well as 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.

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 $41.9 million as at 31 December 2022 ($76.5 million as at 31 December 2021).
- The Group had operating cash out-flows of $43.6 million for the year ended 31 December 2022 (year ended 31 December 2021: $31.6 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, the Group expects to continue to seek funding from investors or other finance providers as required.

After making enquiries and having considered the conditions noted above and the options available to the Group, the Directors have a reasonable expectation that the Group can carefully monitor its cash flows and has the ability to consider various strategies for additional funding and budgets to manage cash to ensure 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 Company did not pay any interim dividends during the year and the Directors do not recommend the payment of a final dividend.

Related party transactions

Details of related party transactions that have taken place during the reporting period are set forth in Note 24 to the consolidated Financial Statements.

Political and charitable contributions

During the year, the Group and Company made no contributions 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 25 to the consolidated Financial Statements.

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.

On behalf of the Board on 23 March 2023,

Jason Hannon
Chief Executive Officer

David Brabazon
Independent Non-Executive Chairman

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 of the Group and the 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 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 Company's website: https://www.mainstaymedical.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 23 March 2023,

Jason Hannon
Chief Executive Officer

David Brabazon
Independent Non-Executive Chairman

KPMG
Audit
1 Stokes Place
St. Stephen's Green
Dublin 2
D02 DE03
Ireland

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 2022 set out on pages 14 to 47, which comprise the Consolidated statement of profit or loss and other comprehensive income, the Consolidated and Company statements of financial position, the Consolidated and Company statements of changes in shareholders' equity, the Consolidated and 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 2022 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 authorized for issue.

Independent auditor's report to the members of Mainstay Medical Holdings plc *(continued)*

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 10, 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.

Independent auditor's report to the members of Mainstay Medical Holdings plc *(continued)*

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 28 March 2023
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 2022

($'000)	Notes	**Year ended 31 December 2022**	**Year ended 31 December 2021** (As Restated)
Revenue	5	10,131	5,327
Cost of sales		(3,117)	(1,773)
Gross profit		7,014	3,554
Operating expenses	6	(49,972)	(35,631)
Other Income - Government grants		-	267
Operating loss		(42,958)	(31,810)
Finance expense	9	(5,573)	(3,294)
Net finance expense		(5,573)	(3,294)
Loss before income taxes		**(48,531)**	**(35,104)**
Income taxes	10	(601)	(587)
Loss for the year		**(49,132)**	**(35,691)**
Net loss attributable to equity holders		**(49,132)**	**(35,691)**
Other Comprehensive Income			
Items that may be reclassified subsequently to the statement of profit or loss:			
Foreign currency translation differences of foreign operations		332	625
Total comprehensive loss for the year		**(48,800)**	**(35,066)**
Total comprehensive loss attributable to equity holders		**(48,800)**	**(35,066)**

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

Mainstay Medical Holdings plc
Consolidated statement of financial position
at 31 December 2022

($'000)	Notes	31 December 2022	31 December 2021
Non-current assets			(As Restated)
Property, plant and equipment	11	1,528	656
Right of use asset	17	2,113	2,799
Total non-current assets		**3,641**	**3,455**
Current assets			
Trade and other receivables	12	4,220	2,426
Income tax receivable		190	202
Inventory	13	6,072	5,329
Cash and cash equivalents	14	41,858	76,538
Total current assets		**52,340**	**84,495**
Total assets		**55,981**	**87,950**
Equity			
Share capital		152	152
Share Premium		29,446	29,446
Share based payment reserve		24,482	20,544
Other reserves		135,057	134,725
Retained loss		(283,537)	(234,405)
Total equity		**(94,400)**	**(49,538)**
Non-current liabilities			
Loans and borrowings	15	24,128	19,267
Loan related derivatives	15	10,122	-
Preference shares classified as liabilities	15	106,558	106,519
Lease liability	17	1,739	2,431
Total non-current liabilities		**142,547**	**128,217**
Current liabilities			
Loans and borrowings	15	-	133
Loan related derivatives	15	1,097	1,987
Lease liability	17	691	553
Income tax payable		588	214
Deferred revenue		-	26
Trade and other payables	16	5,458	6,358
Total current liabilities		**7,834**	**9,271**
Total liabilities		**150,381**	**137,488**
Total equity and liabilities		**55,981**	**87,950**

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

On behalf of the Board on 23 March 2023,

Jason Hannon
Chief Executive Officer

David Brabazon
Independent Non-Executive Chairman

Mainstay Medical Holdings plc
Consolidated statement of changes in shareholders' equity
for the year ended 31 December 2022

($'000) As Restated	Share capital	Share Premium	Other Reserves	Share based payment reserve	Retained loss	Total equity
Balance as at 1 January 2021	**180**	**29,446**	**134,100**	**17,057**	**(198,742)**	**(17,959)**
Loss for the year	-	-	-	-	*(35,691)*	*(35,691)*
Other comprehensive income	-	-	*625*	-	-	*625*
Total comprehensive loss for the year	**-**	**-**	**625**	**-**	*(35,691)*	**(34,065)**
Transactions with owners of the Company						
Deferred Shares	*(28)*	-	-	-	*28*	-
Share based payments	**-**	**-**	**-**	3,487	**-**	3,487
Balance at 31 December 2021	**152**	**29,446**	**134,725**	**20,544**	**(234,405)**	**(49,538)**
Balance as at 1 January 2022	**152**	**29,446**	**134,725**	**20,544**	**(234,405)**	**(49,538)**
Loss for the year	**-**	**-**	**-**	**-**	**(49,132)**	**(49,132)**
Other comprehensive income	-	-	332	-	-	332
Total comprehensive loss for the year	**-**	**-**	**332**	**-**	**(49,132)**	**(48,800)**
Transactions with owners of the Company						
Share based payments	-	-	-	3,938	-	3,938
Balance at 31 December 2022	**152**	**29,446**	**135,057**	**24,482**	**(283,537)**	**(94,400)**

The accompanying notes form an integral part of these consolidated financial statements. Please refer to note 4 for impact of restatement following a change in accounting policy.

Mainstay Medical
Restoring Function. Restoring Life.

Mainstay Medical Holdings plc
Consolidated statement of cash flows
for the year ended 31 December 2022

($'000)	Notes	Year ended 31 December 2022	Year ended 31 December 2021
Cash flow from operating activities			
Loss for the year		(49,132)	(35,691)
Add/(less) non-cash items			
Depreciation	10	422	148
Finance expense	8	5,399	3,924
Share-based compensation	20	3,938	3,487
Income taxes	9	601	587
Unrealized currency translation gains/(losses)		174	625
Add/(less) changes in working capital			
Trade and other receivables		(1,783)	(580)
Inventory		(742)	(3,690)
Trade and other payables		(210)	1,795
Taxes paid		(226)	(511)
Interest paid		(2,023)	(1,062)
Net cash used in operations		**(43,582)**	**(31,598)**
Cash flow from investing activities			
Acquisition of property, plant and equipment	10	(1,300)	(662)
Net cash used in investing activities		**(1,300)**	**(662)**
Cash flow used in financing activities			
Gross proceeds from issue of shares		-	108,024
Transaction costs on issue of shares		-	(1,953)
Proceeds from loans and borrowings	14	35,000	20,000
Transaction costs from loans and borrowings		(1,925)	(865)
Repayment of loans and borrowings		(22,100)	(22,344)
Payment of lease liabilities	16	(773)	(402)
Net cash from financing activities		**10,202**	**102,460**
Net increase/ (decrease) in cash and cash equivalents		**(34,680)**	**70,200**
Cash and cash equivalents at beginning of year		76,538	6,338
Cash and cash equivalents at end of year	13	**41,858**	**76,538**

Mainstay Medical Holdings plc
Notes to the consolidated Financial Statements

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 2022 and 31 December 2021 comprise the results of the Company and of its subsidiaries (together the "Group").

At 31 December 2022, 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 ReActiv8®, its implantable Restorative Neurostimulation™ system designed to treat an underlying cause of disabling Chronic Low Back Pain (CLBP).

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 IFRS 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 2022 with no early adoption of forthcoming requirements.

The Financial Statements were authorized for issue by the Board of Directors on 23 March 2023.

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 $41.9 million as at 31 December 2022 ($76.5 million as at 31 December 2021).
- The Group had operating cash out-flows of $43.6 million for the year ended 31 December 2022 (year ended 31 December 2021: $31.6 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, the Group expects to continue to seek funding from investors or other finance providers as required.

After making enquiries and having considered the conditions noted above and the options available to the Group, the Directors have a reasonable expectation that the Group can carefully monitor its cash flows and has the ability to consider various strategies for additional funding and budgets to manage cash to ensure 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. The conversion option and the warrants associated with the loans, in addition to the embedded derivatives contained within the preference shares, 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 and the fair value of identifiable instruments relating to the Company’s convertible loan and preference shares.

Basis of consolidation

The Financial Statements comprise the consolidated results of Mainstay Medical Holdings plc and its subsidiaries.

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.

Adoption of newly effective accounting standards and amendments

The Group applied the following standards in the current year:

- Annual Improvements to IFRS Standards 2018-2020
- Property, Plant and Equipment: Proceeds before Intended Use (Amendments to IAS 16)
- Reference to the Conceptual Framework (Amendments to IFRS 3)
- COVID-19-Related Rent Concessions beyond 30 June 2021 (Amendment to IFRS 16)
- Onerous Contracts – Cost of Fulfilling a Contract (Amendments to IAS 37)

The adoption of these new or amended standards did not have a material impact on the Group’s financial statements.

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. 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) Government grants

Grants that compensate the Group for expenses incurred are recognized in profit or loss as other income on a systematic basis in the periods in which the expenses are recognized. The Group recognized a conditional government grant related to the Paycheck Protection Program in profit or loss as other income when the grant became fully receivable.

c) 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.

d) 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.

e) 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
Leasehold Improvements:	5 years

f) 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.

g) 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 2022.

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.

h) 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.

i) 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 arrangement have variability in the number of shares that may be required to be issued and accordingly were 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 could be converted into shares by the holder and which could be 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 would be reclassed to equity.

j) Equity

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

Preference shares, the purchase price of which may be repayable on the occurrence of contingent settlement events, are classified as liabilities. 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.

k) 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 analyzes 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 2022, our trade receivables balances amounted to $4.2 million, net of a write off of $0.15 million relating to unpaid invoices which the Group does not expect to collect. Further information on the Group's credit risk is detailed in Note 19. 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.

l) 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.

m) 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.

n) 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 20. 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.

o) Warrants

Warrants issued alongside the Company's debt instruments were initially recognized at fair value with a corresponding reduction in the debt instrument liability, whereon this adjustment to the liability was amortized to the income statement on an effective interest rate basis.

p) 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.

q) 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 Prior period adjustment – change in accounting policy

The IAASB issued revised guidance subsequent to the approval of the 2021 financial statements with respect to the classification of financial instruments that contain settlement features that are within the control of a company's shareholders. The Company's preference shares contain features whereby the purchase price may be repayable on the occurrence of contingent settlement events that are within the control of the Company's shareholders. These instruments were classified as equity as at 31 December 2021. As a result of the revised guidance, the Company has revised its accounting policies with respect to the classification of financial instruments as liabilities or equity and the Company now classifies these instruments as liabilities held at amortised cost under the revised policy.

In accordance with the Company's existing accounting policies with respect to liabilities, the reclassification of preference shares as liabilities held at amortized cost resulted in an additional requirement to separate certain anti-dilution features from the preference shares and record these as derivative financial instruments held at fair value and also to reclassify warrants related to the preference shares as liabilities held at fair value.

The below tables detail the impact of the change in accounting policy on the opening Statement of Profit or Loss and Statement of Financial Position:

Consolidated Statement of Profit or Loss

($'000)	As previously stated 31 December 2021	Change in accounting policy 2021	As restated 2021
Finance expense	2,784	510	3,294
Total comprehensive loss	**34,556**	**510**	**35,066**

Consolidated Statement of Financial Position

($'000)	As previously stated 31 December 2021	Change in accounting policy 2021	As restated 2021
Non-current loans and borrowings	19,267	-	19,267
Current loans and borrowings	133	-	133
Loan related derivatives	-	1,987	1,987
Preference shares classified as liabilities	-	106,519	106,519
Total liabilities	**19,400**	**108,506**	**127,906**
Share Capital	582	(430)	152
Share Premium	137,040	(107,594)	29,446
Total Equity	**137,622**	**108,024**	**29,598**

5 Revenue

($'000)	**Year ended 31 December 2022**	Year ended 31 December 2021
Revenue arising from the sale of goods	10,131	5,327
Total revenue	**10,131**	**5,327**

6 Operating expenses

($'000)	**Year ended 31 December 2022**	Year ended 31 December 2021
Research and development expenses	7,625	4,491
Clinical and regulatory expenses	3,978	2,969
Selling, general and administration expenses	38,369	28,171
Total operating expenses	**49,972**	**35,631**

7 Wages, Salaries and other remuneration

As of 31 December 2022, the Group's employees were based in Ireland, the United Kingdom, Germany, the United States, and Australia.

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

	Year ended 31 December 2022	Year ended 31 December 2021
Research and development, quality and operations	18	13
Clinical and regulatory	1	4
Selling, general and administration	86	62
Total employee numbers	**105**	**79**
Parent company employees		
Management and administration	1	4

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

($'000)	**Year ended 31 December 2022**	Year ended 31 December 2021
Wages and salaries	15,428	9,918
Other remuneration	6,486	4,564
Social security costs/ payroll taxes	1,184	733
Share based payments	3,938	3,487
Retirement benefit	256	165
Total	**27,292**	**18,867**

8 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 2022**	Year ended 31 December 2021
Fees paid to Statutory auditor:		
Audit services	88	72
Audit Project Fees	63	-
Taxation advisory services	18	12
Total auditor's remuneration	**169**	**84**
Foreign exchange loss	506	1,216
Depreciation of plant and equipment	422	148
Right of use Asset Depreciation	686	441
Research and development expenditure	7,625	4,491
Directors Remuneration (Includes Share Based Payments)	2,028	2,310

9 Finance expense

($'000)	**Year ended 31 December 2022**	Year ended 31 December 2021
Finance expense		
Foreign exchange (gain) / loss	506	1,216
Lease interest	219	115
Finance expense associated with borrowings:		
Interest expense	5,747	3,454
Fair value gain on financial instruments	(899)	(1,493)
Total finance expense	**5,573**	**3,698**

10 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 2022**	Year ended 31 December 2021
Irish income tax	-	-
Income tax in other jurisdictions:		
Foreign current tax	443	370
Adjustments in respect of prior years	158	217
Total income tax charge	**601**	**587**

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 2022**	Year ended 31 December 2021
Loss before tax	48,531	(34,594)
Taxed at tax rate in Ireland of 12.5%	(6,066)	(4,324)
Non-deductible expenses	695	497
Tax credits	190	145
Foreign rate differential	(101)	(174)
Adjustments in respect of prior periods	158	217
Unrecognized tax losses	5,725	4,226
Total income tax charge	**601**	**587**

Unrecognized deferred tax assets

The Group has unrecognized potential deferred tax assets as disclosed below. 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 provided the group continues generating losses or taxable profits in the same trade.

Gross timing differences:	At 1 January 2021	Arising in year	Adjustment in respect of prior years	**At 31 December 2021**	Arising in year	Adjustment in respect of prior years	**At 31 December 2022**
Unrecognized tax losses	141,074	33,810	(3,879)	171,005	44,815	(1,413)	214,407
Intangible assets	15,000	-	-	15,000	-	-	15,000
Derivative financial instruments	3,521	410	-	3,931	8,950	-	12,880
Total gross temporary differences	**159,595**	**34,220**	**(3,879)**	**189,936**	**53,764**	**(1,413)**	**242,287**
Unrecognized deferred tax asset							
Unrecognized tax losses	17,635	4,227	(485)	21,377	5,602	(177)	26,802
Intangible assets	1,875	-	-	1,875	-	-	1,875
Derivative financial instruments	441	51	-	492	1,118	-	1,610
Total unrecognized deferred tax asset	**19,951**	**4,278**	**(485)**	**23,742**	**6,721**	**(177)**	**30,287**

11 Property, plant & equipment

($'000)	**Computer and office equipment Year ended 31 December 2022**	Computer and office equipment Year ended 31 December 2021
Cost		
At beginning of year	1,401	739
Additions	1,294	662
At end of year	2,695	1,401
Depreciation		
At beginning of year	745	597
Charge for the year	422	148
At end of year	1,167	745
Carrying value at end of year	**1,528**	**656**

12 Trade and other receivables

($'000)	**Year ended 31 December 2022**	Year ended 31 December 2021
Trade receivables	3,277	1,229
Prepaid expenses and other current assets	944	1,196
Total trade and other receivables	**4,220**	**2,425**

Information about the Group's exposure to credit risks and impairment losses for trade receivables is included in Note 19.

13 Inventory

($'000)	**Year ended 31 December 2022**	Year ended 31 December 2021
Raw Materials	-	-
Work in Progress	638	377
Finished Goods	5,433	4,952
Total inventory	**6,071**	**5,329**

There were no provisions netted against inventory as at 31 December 2022. The cost of inventory used in cost of sales during 2022 was $3.1m (2021: $1.8m).

14 Cash and cash equivalents

($'000)	**Year ended 31 December 2022**	Year ended 31 December 2021
Cash in bank accounts – USD	40,379	73,753
Cash in bank accounts – EUR	1,045	1,079
Cash in bank accounts – AUD	434	1,706
Total cash and cash equivalents	**41,858**	**76,538**

15 Interest bearing loans and borrowings and other financing-related liabilities

Madryn Debt Financing

In September 2022 the Company entered into a loan and security agreement with Madryn Health Partners under which it can borrow up to $50 million, subject to certain conditions. Concurrently with entering into the agreement with Madryn, the Company borrowed the first tranche of $30 million, plus a separate $5m convertible note, and repaid in full all accrued principal and interest under its existing loan facility with Oxford Finance, the total of which was approximately $22 million. The Madryn debt facility is secured by way of fixed and floating charges over all of the assets and undertakings of the MML and MMUS, including intellectual property.

The agreements contain features, the convertible feature of the convertible note and conditional warrants, which require separation as derivative financial instruments, as their economic characteristics and associated risks are not deemed to be closely related to the host instrument. 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.

IPF Warrants

Following repayment of the Company's debt held by IPF Partners (IPF) in 2021, IPF continues to hold its warrant to purchase 1.5 million preferred shares at a per share price of €6 which has been classified as a financial liability. The warrant was 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.

Series A Preferred Shares

The preferred shares are convertible into ordinary shares at the discretion of the holders on a one-to-one basis, with the conversion ratio subject to a weighted average adjustment in the event of certain dilutive share issuances.

Because the preference shares are repayable on the occurrence of contingent settlement events, the Company has determined that they should be classified as liabilities. In addition, the antidilution feature of the preference shares requires separation as a derivative financial instrument. 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.

Loans and borrowings

($'000)	**Year ended 31 December 2022**	Year ended 31 December 2021
Loans and borrowings - current		
Term loan	-	-
Accrued interest	-	133
Deferred finance costs	-	-
Total current loans and borrowings	**-**	**133**
Loans and borrowings – non-current		
Term loan	25,455	20,000
Accrued interest	505	-
Deferred finance costs	(1,832)	(733)
Total non-current loans and borrowings	**24,128**	**19,267**
Total loans and borrowings	**24,128**	**21,520**

Loan related derivatives ($'000)	**Year ended 31 December 2022**	Year ended 31 December 2021
Derivatives– current		
Derivative financial instrument – IPF warrant	1,097	1,987
Total current derivatives	**1,097**	**1,987**
Derivatives – non-current		
Derivative financial instrument – Madryn convertible note	6,658	-
Derivative financial instrument – Madryn warrant	3,464	-
Total non-current derivatives	**10,122**	**-**
Total loan related derivatives	**11,219**	**1,987**

Preference shares classified as liabilities ($'000)	**Year ended 31 December 2022**	Year ended 31 December 2021
Preference shares classified as liabilities – non-current		
Preference shares	106,161	106,161
Derivative financial instrument – preference share antidilution feature	1,557	1,904
Deferred finance costs	(1,160)	(1,546)
Total preference shares classified as liabilities	**106,558**	**106,519**

See note 19 for detail on the valuation of financial instruments.

16 Trade and other payables

($'000)	**Year ended 31 December 2022**	Year ended 31 December 2021
Trade and other payables	1,243	1,660
Payroll tax liability	12	43
Accrued expenses	4,203	4,655
Total trade and other payables	**5,458**	**6,358**

17 Leases

The Group leases office facilities at two locations. The Group measures the lease liability at the present value of the lease payments unpaid at that date, discounted using the Group's incremental borrowing rate at the lease inception of 7.8%.

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

Right-of-use assets

($'000)	**Year ended 31 December 2022**	Year ended 31 December 2021
Balance at 1 January	2,799	74
Depreciation charge for the year	(686)	(441)
Additions to right-of-use assets	-	2,161
Modification to right-of-use assets	-	1,005
Right-of-use assets	**2,113**	**2,799**

Amounts recognized in profit or loss

($'000)	**Year ended 31 December 2022**	Year ended 31 December 2021
Interest on lease liabilities	219	115
Total	**219**	**115**

Lease liability

($'000)	**Year ended 31 December 2022**	Year ended 31 December 2021
Balance at 1 January	2,984	105
Payments made on leased liabilities for the year	(773)	(402)
Additions to liabilities	-	2,276
Interest on lease liabilities	219	115
Modifications to liabilities	-	890
Lease liability	**2,430**	**2,984**

($'000)	**Year ended 31 December 2022**	Year ended 31 December 2021
Non-current lease liabilities	1,739	2,431
Current lease liabilities	691	553
Total	**2,430**	**2,984**

18 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.

Series A preferred shares

The terms of the Series A preferred shares are as follows:

The preferred shares are convertible into ordinary shares at the discretion of the holders on a one-to-one basis, with the conversion ratio subject to a weighted average adjustment in the event of certain dilutive share issuances. The preferred shares will automatically convert to ordinary shares upon an initial public offering of the Company's ordinary shares that meets certain thresholds, or otherwise upon the consent of the holders of at least 55% of the then-issued preferred shares.

In the event of any liquidation, dissolution or winding up of the Company (including certain change of control transactions), the holders of preferred shares are entitled to receive, prior and in preference to any distribution of any of the assets or surplus funds of the Company to the holders of ordinary shares, an amount equal to the purchase price paid for the preferred shares, plus all dividends accrued or declared but unpaid on the preferred shares. The remaining proceeds will be distributed on a pro rata basis among the holders of preferred shares and ordinary shares, treating all preferred shares as if they had been converted to ordinary shares immediately prior to such distribution.

The holders of preferred shares are entitled to that number of votes on all matters presented to shareholders equal to the number of ordinary shares then arising upon conversion of such preferred shares and shall vote together with the ordinary shares on an as-converted basis. The holders of preferred shares are separately entitled to elect two members of the Board of Directors and have the ability to vote separately to consent to certain material actions of the Company.

The Company and certain holders of preferred shares entered into agreements providing such holders with customary registration rights, information rights, pre-emptive rights, veto and/or approval rights, rights of first refusal, co-sale rights and drag-along rights.

Authorized and Issued Share Capital

2022 – Mainstay Medical Holdings plc Authorized	**31 December 2022 €**
50,000,000 preferred shares of €0.01 each	50,000
60,000,000 ordinary shares of €0.01 each	60,000
	1,100,000

Issued, called up and fully paid	**2022 $**
13,618,536 ordinary shares of €0.01 each	153,048
36,600,987 preferred shares of €0.01 each	429,147
	582,195
In $'000	**582**

2021 – Mainstay Medical Holdings plc	31 December
Authorized	**2021** **€**
50,000,000 ordinary shares of €0.01 each	50,000
60,000,000 preferred shares of €0.01 each	60,000
	1,100,000

Issued, called up and fully paid	**2021** **$**
13,594,734 ordinary shares of €0.01 each	153,047
36,600,987 preferred share of €0.01 each	429,147
	582,194
In $'000	**582**

Share Premium

The share premium on the shares above have been classified as follows:

($'000)	**Year ended 31 December 2022**	Year ended 31 December 2021
Within equity	29,446	29,446
Within financial liabilities (includes embedded derivatives and deferred financing costs)	106,558	106,519
Balance at 31 Dec	**136,004**	**135,965**

19 Financial Instruments

The following table shows the carrying amounts and fair values of financial assets and financial liabilities as at 31 December 2022 and 31 December 2021:

2022 ($'000)	**Financial assets and liabilities at amortized cost**	**Other financial liabilities**	**Financial instruments held at fair value**	**Fair value**
<u>Financial assets</u>				
Cash and cash equivalents	41,858	-	-	N/A
Trade and other receivables	4,220	-	-	N/A
<u>Financial liabilities</u>	-	-	-	N/A
Trade and other payables	-	(5,458)	-	N/A
Interest bearing loans and borrowings	-	(24,128)	-	(24,128)
Loan related derivatives	-	-	(11,219)	(11,219)
Preference shares classified as liabilities (includes embedded derivatives and deferred financing costs)	-	-	(106,558)	(106,558)
At 31 December 2022	**46,078**	**(29,586)**	**(117,777)**	**(141,905)**

2021 ($'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	76,538	-	-	N/A
Trade and other receivables	2,425	-	-	N/A
Financial liabilities	-	-	-	N/A
Trade and other payables	-	-	-	N/A
Interest bearing loans and borrowings	-	(21,520)	-	(21,520)
Loan related derivatives	-	-	(1,987)	(1,987)
Preference shares classified as liabilities (includes embedded derivatives and deferred financing costs)	-	-	(106,519)	(106,519)
At December 2021	**78,963**	**(21,520)**	**(108,506)**	**(130,026)**

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 is 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. The fair value of derivative financial instruments is calculated based on accepted derivative valuation models, including the Black Scholes valuation model & Monte Carlo simulation. All of 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 2022 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	• Market interest rate (12-14%)	• An 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**
Derivatives	Black Scholes Valuation Model & Monte Carlo	Term (used multiple scenarios detailing various potential financing events)	An extension of the term would increase the value of the instrument
		Volatility (75%)	A higher volatility would increase the value of the instrument
Warrants	Black Scholes Valuation Model & Monte Carlo	Term (used multiple scenarios detailing various potential financing events)	An extension of the term would increase the value of the instrument

On issuance of the instruments related to the Madryn debt on 9 September 2022, the following were the significant unobservable inputs:

	Conversion Option	Warrants
Term	Used multiple scenarios detailing various potential financing events	Used multiple scenarios detailing various potential financing events
Volatility	75%	70%

The following table shows a reconciliation between the initial and closing fair values of the financial instruments relating to the Madryn debt:

($'000)	**Conversion Option**	**Warrants**
Balance at 1 January 2022	-	-
Amount recognized on issue	6,275	3,509
Change in fair value recognized in statement of profit and loss	383	(45)
Balance at 31 December 2022	6,658	3,464

On issuance of the instruments related to the preference shares equity financing on February 2021 the following were the significant unobservable inputs:

	Preference share antidilution feature
Term	Used multiple scenarios detailing various potential financing events
Volatility	70%

The following tables show a reconciliation between the initial and closing fair values of the preference share financial instruments:

($'000)	**Preference Share – antidilution feature**
Balance at 1 January 2021	-
Amount recognized on issue	1,863
Change in fair value recognized in statement of profit and loss	41
Balance at 31 December 2021	1,904

($'000)	**Preference Share – antidilution feature**
Balance at 1 January 2022	1,904
Change in fair value recognized in statement of profit and loss	(347)
Balance at 31 December 2022	1,557

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

($'000)	Warrants
Balance at 1 January 2021	1,952
Change in fair value recognized in statement of profit and loss	35
Balance at 31 December 2021	**1,987**

($'000)	Warrants
Balance at 1 January 2022	1,987
Change in fair value recognized in statement of profit and loss	(890)
Balance at 31 December 2022	**1,097**

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 A3, 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 at least 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 $41.9 million as at 31 December 2022.

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 2022 and 31 December 2021.

Risks

I. 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 the issuance of equity securities and 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 2022 and 31 December 2021.

($'000)	Carrying value	Cash flow (total)	Less than 1 year	Between 1-2 years	Between 2-5 years
31 December 2022:					
Financial Liabilities					
Trade and other payables	5,458	5,458	5,458	-	-
Interest bearing loans and borrowings	-	54,308	2,223	4,905	47,180
At 31 December 2022	**5,458**	**59,766**	**7,681**	**4,905**	**47,180**

($'000)	Carrying value	Cash flow (total)	Less than 1 year	Between 1-2 years	Between 2-5 years
31 December 2021:					
Financial Liabilities					
Trade and other payables	6,358	6,358	6,358		
Interest bearing loans and borrowings	19,400	28,707	1,582	3,163	24,487
At 31 December 2021	**25,758**	**35,065**	**7,940**	**3,163**	**24,487**

The cashflows presented for interest bearing loans and borrowings at 31 December 2022 are the cashflows only in the case of the term loan A repayment features.

II. 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 rates 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 2021	1.133	1.183
Year ended 31 December 2022	1.067	1.050

Australian Dollar per USD1.00	**End of year**	**Average**
Year ended 31 December 2021	0.725	0.751
Year ended 31 December 2022	0.680	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 €383,000 (2021: €244,000).

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 $65,000 (2021: $20,000). A strengthening (or weakening) of the US Dollar against the Australian Dollar of 5% would have (decreased)/ increased the loss for the year by $68,000 (2021: $55,000)

III. Interest rate risk

The Company's debt is at a floating rate of interest. Changes in interest rates would not be expected to have a material impact on the Group's 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.

20 Share Based Payments

Stock Incentive Plan

The Group operates a share option plan (the "Plan"). As of 31 December 2022, 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 of 31 December 2022, 9,536,000 (2021: 8,970,000) 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 no RSUs during 2022 and 369,000 are outstanding as of 31 December 2022.

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 of 31 December 2022:

	Number of instruments (in thousands)	**Contractual life of options**
Options granted in 2010	-	10 years from grant
Options granted in 2011	-	10 years from grant
Options granted in 2012	1	10 years from grant
Options granted in 2013	209	10 years from vesting
Options granted in 2014	49	10 years from vesting
Options granted in 2015	178	10 years from vesting
Options granted in 2016	137	10 years from vesting
Options granted in 2017	-	10 years from vesting
Options granted in 2018	91	10 years from vesting
Options granted in 2019	1,231	10 years from vesting
Options granted in 2020	580	10 years from vesting
Options granted in 2021	6,212	10 years from vesting
Options granted in 2022	848	10 years from vesting
Total share options in issue	**9,536**	
RSU's outstanding in 2022	**369**	

All of the above options 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 of 31 December 2022 and 31 December 2021 is as follows (in thousands, except prices):

(Number of instruments in thousands)	Year ended 31 December 2022	Weighted average exercise price 2022	Year ended 31 December 2021	Weighted average exercise price 2021
At beginning of year	8,970	$4.93	3,115	$8.04
Options granted during the year	848	$2.08	6,076	$2.12
Options forfeited	(257)	$2.19	(151)	$2.48
Options exercised	(22)	$4.03	(70)	$0.80
Outstanding at end of year	**9,539**	**$4.56**	**8,970**	**$4.93**
Exercisable at end of year	**5,600**	**$4.75**	**1,670**	**$7.21**

Total non-cash expense charged to profit and loss in relation to share options for the year ended 31 December 2022 was $3.9m (2021: $3.5m) and was based on the fair value of the options granted, measured using a Black-Scholes model with the following inputs:

	Year of Grant	
	2022	**2021**
Weighted average share price ($)	1.98	1.8
Weighted average exercise price ($)	1.98	1.8
Weighted average expected share volatility	70%	63.04%
Expected term (years)	7	7
Expected dividends	-	-
Risk free rate (average)	1.98%	0.56%
Fair value of option ($)	1.39	1.23

21 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 2022 and 31 December 2021.

22 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 establishment and maintenance of the schemes.

Total retirement benefit costs of the defined contribution schemes for the year ended 31 December 2022 amounted to $177,398 (2021: $102,404). There were no accruals or prepayments in respect of the retirement benefit costs at 31 December 2022 (2021: None).

23 Subsidiary undertakings

At 31 December 2022, 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.

24 Related party transactions

The Group defines key management as its non-executive directors, executive directors and senior management. Details of remuneration for key management personnel for the year end are provided below:

($'000)	**31 Dec 2022**	**31 Dec 2021**
Salaries	875	936
Annual incentive	381	391
Non-executive directors' fees	111	82
Other remuneration	65	176
Payroll taxes	27	35
Share based payments	1,413	1,901
Total remuneration	**2,872**	**3,521**

There were no other related party transactions in the year. Please refer to page 8 within the Directors Report detailing their beneficial interest as of 31 December 2022.

25 Events subsequent to 31 December 2022

There were no events subsequent to the year ended 31 December 2022 that would have a material impact on the Financial Statements.

Parent Company Financial Statements
Mainstay Medical Holdings plc
Company statement of financial position
At 31 December 2022

($'000)	Notes	31 December 2022	31 December 2021
Non-current assets			
Investment in subsidiary	(d)	46,240	31,945
Amounts due from subsidiary undertakings	(c)	-	-
Total non-current assets		**46,240**	**31,945**
Current assets			
Prepayments and other receivables	(a)	155	-
Amounts due from subsidiary undertakings	(c)	110,938	112,573
Cash and cash equivalents	(b)	330	-
Total current assets		**111,423**	**112,573**
Total assets		**157,663**	**144,518**
Equity			
Share capital		582	582
Share premium		29,446	29,446
Share based payment reserve		7,635	3,699
Retained loss		65	226
Surplus/(deficit) on shareholders' equity		**37,728**	**33,952**
Non-current liabilities			
Derivatives	(e)	10,122	-
Preference shares classified as liabilities	(e)	106,558	106,519
Total non-current liabilities		**116,680**	**106,519**
Current liabilities			
Derivatives	(e)	1,098	1,988
Trade and other payables	(f)	204	107
Amounts due to subsidiary undertakings	(g)	1,953	1,953
Total current liabilities		**3,255**	**4,048**
Total liabilities		**119,935**	**110,566**
Total equity and liabilities		**157,663**	**144,518**

On behalf of the Board on 23 March 2023,

Jason Hannon
Chief Executive Officer

David Brabazon
Independent Non-Executive Chairman

Company statement of changes in shareholder's equity
For the year ended 31 December 2022

($'000)	Share capital	Share Premium	Other Reserves	Share based payment reserve	Retained Earnings	Total equity
Balance at 1 Jan 2021	180	29,446	-	212	912	30,750
Comprehensive profit for the year	-	-	-	-	1,239	1,239
Transactions with owners of the Company:						
Issue of Shares	430	-	-	-	(1,953)	(1,523)
Deferred shares	(28)	-			28	-
Share based payments	-	-	-	3,487	-	3,487
Conversion of warrant liability to equity	-	-	-	-	-	-
Balance at 31 December 2021	**582**	**29,446**	**-**	**3,699**	**226**	**33,953**
Balance at 1 Jan 2022	**582**	**29,446**	**-**	**3,699**	**226**	**33,953**
Comprehensive profit for the year	-	-	-	-	(161)	(161)
Transactions with owners of the Company:						
Issue of Shares	-	-	-	-	-	-
Deferred shares	-	-	-	-	-	-
Share based payments	-	-	-	3,936	-	3,936
Conversion of warrant liability to equity	-	-	-	-	-	-
Balance at 31 December 2022	**582**	**29,446**	**-**	**7,635**	**65**	**37,728**

Company statement of cash flows

At 31 December 2022

($'000)	Year ended 31 December 2022	Year ended 31 December 2021
Cash flow from operating activities		
Net (loss)/ gain attributable to equity holders	(161)	(1,239)
Add/(less) non-cash items		
Share-based compensation	3,937	3,487
Add/(less) changes in working capital		
Prepayments and other receivables	(156)	23
Amounts due from subsidiary undertakings	(3,302)	(4,857)
Trade and other payables	97	107
Net cash used in operations	**415**	**-**
Cash flow from financing activities		
Capitalized Deferred Financing Costs	(85)	-
Net cash from financing activities	**(85)**	**-**
Net increase in cash and cash equivalents	330	-
Cash and cash equivalents at beginning of year	-	-
Cash and cash equivalents at end of year	**330**	**-**

Notes to the Company Financial Statements

Notes 1, 2, 3, 20 and 25 to the Consolidated Financial Statements (as provided earlier herein) also directly apply to the Company Financial Statements. The accounting policies of the Company are the same as the accounting policies of the Group as set out in Note 3 to the consolidated Financial Statements.

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

(a) Prepayments and other receivables

($'000)	**31 December 2022**	**31 December 2021**
Prepayments	155	-
	156	**-**

(b) Cash and cash equivalents

($'000)	**31 December 2022**	**31 December 2021**
Cash in bank accounts – USD	330	-
	330	-

(c) Amounts due from subsidiary undertakings

($'000)	**31 December 2022**	**31 December 2021**
Mainstay Medical International Limited	110,938	112,573
	110,938	**112,573**

(d) Investment in subsidiary

($'000)	**31 December 2022**	**31 December 2021**
Opening balance	33,062	34,219
Investment in subsidiary movement	13,179	(2,273)
Closing balance	**46,241**	**31,946**

(e) Loans and borrowings

Derivatives ($'000)	**Year ended 31 December 2022**	Year ended 31 December 2021
Loans and borrowings – current		
Derivative financial instrument – IPF warrant	1,097	1,987
Total current derivatives	**1,097**	**1,987**
Derivatives – non-current		
Derivative financial instrument – Madryn convertible note	6,658	-
Derivative financial instrument – Madryn warrant	3,464	-
Total non-current derivatives	**10,122**	**-**
Total derivatives	**11,219**	**1,987**

Preference shares classified as liabilities ($'000)	**Year ended 31 December 2022**	Year ended 31 December 2021
Preference shares classified as liabilities – non-current		
Preference shares	106,161	106,161
Derivative financial instrument – preference share antidilution feature	1,557	1,904
Deferred finance costs	(1,160)	(1,546)
Total preference shares classified as liabilities	**106,558**	**106,519**

(f) Trade and other payables

($'000)	**31 December 2022**	**31 December 2021**
Payroll tax liability	1	24
Payroll Liabilities	25	-
Accounts Payable	42	-
Vat Liability	(26)	-
Accrued expenses	162	83
Closing balance	**204**	**107**

(g) Amounts due to subsidiary undertakings

($'000)	**31 December 2022**	**31 December 2021**
Mainstay Medical International Limited	1,953	1,953
	1,953	**1,953**