

Mainstay Medical annonce ses résultats financiers semestriels

La dynamique s'accélère vers la commercialisation de ReActiv8®

Dublin, Irlande - 28 Août 2014: Mainstay Medical International plc ("Mainstay" ou "La société") (Euronext Paris: MSTY.PA et *ESM of the Irish Stock Exchange*: MSTY.IE) annonce ses résultats pour la période de six mois close le 30 juin 2014. Mainstay est une société irlandaise de dispositifs médicaux, dont les activités sont basées en Irlande, en Australie et aux Etats-Unis. La société se concentre sur le développement et la commercialisation de ReActiv8, un dispositif de neurostimulation implantable innovant conçu pour traiter les personnes atteintes de lombalgie chronique, en les aidant à rétablir le contrôle des muscles qui stabilisent la colonne lombaire.

Faits marquants

- Une levée de fonds de 20.9 millions de dollars, nette de frais, a été réalisée par appel public à l'épargne. Ces fonds seront employés à faire progresser les essais cliniques avec pour objectif d'obtenir le marquage CE nécessaire à la commercialisation de ReActiv8 en Europe, et pour soutenir les besoins réglementaires aux Etats-Unis dans la préparation des essais cliniques requis en vue d'obtenir l'approbation des autorités américaines.
- Les essais cliniques de ReActiv8-A progressent comme prévu. A la suite du lancement des essais cliniques en Australie, de nouveaux sites ont été ouverts en Belgique et en Angleterre.
- Un dossier d'information de dispense de mise à l'essai d'un appareil expérimental (*pre-IDE : pre-Investigational Device Exemption*) a été soumis aux Etats-Unis à la *Food and Drug Administration* («FDA»). Suite aux commentaires de la FDA, la société prévoit de finaliser le protocole d'essais cliniques américains et de soumettre une demande à la FDA pour débiter un essai clinique sous IDE.
- Les dépenses opérationnelles de 4.8 millions de dollars sont conformes aux prévisions.
- Une position nette de trésorerie de 23.5 millions de dollars au 30 juin 2014.

M. Peter Crosby, Président Directeur-Général de Mainstay, déclare : « *L'appel public à l'épargne et l'introduction en bourse en début d'année sont une étape majeure du développement de Mainstay et nous sommes heureux de l'élan donné pour permettre la commercialisation de ReActiv8. Les essais cliniques se déroulent comme prévu et nous avons soumis notre dossier pré-IDE à la FDA. Lorsqu'il sera disponible, ReActiv8 a le potentiel de changer la vie de millions de personnes qui souffrent de lombalgie chronique.* »

Mainstay a également le plaisir d'annoncer la nomination de Tom Maher aux postes de Directeur Juridique et de Secrétaire Général de la société à compter du 2 septembre 2014. Tom possède une vaste expérience juridique puisqu'il vient d'un grand cabinet d'avocats de Dublin, où il était Associé au sein du département *corporate* et co-responsable de la division Sciences de la vie. Tom a également précédemment occupé les postes de Directeur Juridique et de Secrétaire Général chez Amarin Corporation plc, une entreprise biopharmaceutique cotée au NASDAQ, et de Vice-Président

des Affaires juridiques chez Elan Corporation plc. Hugh Kavanagh, qui occupe actuellement les rôles de Directeur Financier et de Secrétaire Général de la société, poursuit son mandat de Directeur Financier.

Mainstay Medical International plc Interim management report

We are pleased to report on the progress of Mainstay Medical International plc (“Mainstay” or the “Company”) and present the unaudited interim results of the Company and its subsidiaries (the “Group”) for the six month period ended 30 June 2014.

Operations Update

Mainstay is developing innovative neurostimulation therapies for the population of people with debilitating Chronic Low Back Pain. The Group is focused on the development and commercialisation of an active implantable medical device (AIMD) designed to treat Chronic Low Back Pain by helping to restore control to the muscles that stabilise the lumbar spine. The design of the Group’s first product, ReActiv8[®], has been completed and the planned clinical trial, ReActiv8-A, is under way.

The purpose of the ReActiv8-A clinical trial is to investigate ReActiv8 as a treatment for adults with debilitating Chronic Low Back Pain for whom surgery is not indicated. Since 31 December 2013, Mainstay has continued to advance its activities for the ReActiv8-A clinical trial in 3 countries:

- In March 2014 the Group secured approval from Ethics Committees in Australia to start the ReActiv8-A clinical trial and recruitment commenced at three sites in Australia. Subsequently a further site has been added in Australia.
- In June 2014 Mainstay received authorisation from the Belgian Federal Agency for Medicines and Health Products and the Central Ethics Committee to expand the ReActiv8-A clinical trial to include two clinical trial sites in Belgium which are currently recruiting subjects. These two sites also participated in the Group’s European Feasibility Study, results of which were presented in mid-2013.
- In July 2014 Mainstay received authorisation from the Medicines and Healthcare Products Regulatory Agency (“MHRA”) and the Central Ethics Committee to expand the ReActiv8-A clinical trial to include clinical trial sites in the United Kingdom.

In July Mainstay submitted a Pre-Investigational Device Exemption information package to the US Food and Drug Administration (“FDA”) for ReActiv8. Under the Pre-IDE Submission Program of the FDA, the Company has requested feedback from the FDA prior to its planned ReActiv8 IDE submission.

The Group is also continuing work to obtain CE Mark, which is required for product commercialisation in Europe.

Corporate developments and financial update

The Company was incorporated and registered in Ireland on 17 February 2014 as a public limited company. Following a reorganisation on 3 April 2014, the Company became the ultimate holding company of the Group. The Company together with its operating subsidiaries Mainstay Medical Limited, MML US, Inc. and Mainstay Medical (Australia) Pty. Limited now form the Mainstay Medical Group. Prior to this reorganisation Mainstay Medical Limited had been the holding company of the Group.

Mainstay is at a pre-revenue stage. Operating expenses related to on-going activities (excluding exceptional items) were \$4.8 million during the six months to 30 June 2014 (June 2013: \$4.4m). Operating expenses related to clinical trial activities, ongoing research and development, and general and administrative expenses.

Net loss attributable to equity holders after exceptional items was \$75.9m (June 2013: \$5.3m). This includes a non-cash exceptional item of \$66.5m associated with requirements under IFRS to “fair value” financial derivative instruments related to preference shares in issue prior to the Company’s listing. All of these preference shares converted on a one for one basis to ordinary shares immediately prior to the listing and accordingly such fair value movements through comprehensive income will not arise in future periods.

On 2 May 2014, the Company listed its ordinary shares on the ESM and Euronext Paris. Total proceeds of \$20.9 million (net of issue costs) were raised by way of a capital increase in conjunction with the listing of the entire issued ordinary share capital of the Company (the “IPO”). The proceeds will be used by Mainstay to fund clinical trial activities to obtain CE Mark, which is required for initial commercialisation of ReActiv8 in Europe.

Outlook and future developments

The Group looks forward to continuing progress with the ReActiv8-A clinical trial as it moves towards obtaining CE Mark and initial commercialisation of ReActiv8.

Principal risks and uncertainties

The principal risks and uncertainties faced by the Group over the remaining six months of 2014 remain substantially unchanged from the disclosures included in the IPO prospectus published by the Company on 9 April 2014 (the “Prospectus”), which is available on the Company’s website (www.mainstay-medical.com). Those risks are referred to on pages 17 to 19 of the Summary part of the Prospectus. These relate to the clinical trial of ReActiv8 necessary to achieve CE Mark approval, and general risks associated with any early-stage pre-revenue medical device company, such as those relating to initial operating losses, on-going funding requirements, intellectual property, liquidity, regulatory and clinical matters, and reliance on a small number of key suppliers.

Auditors review

The condensed interim financial statements have not been reviewed by the Company’s auditors.

On behalf of the board on 27 August 2014,

Oern Stuge
Chairman

Peter Crosby
CEO

Mainstay Medical International plc Directors' responsibility statement

Statement of the Directors in respect of the half-yearly financial report

Each of the directors of the Company (the "Directors"), whose names and functions are listed in Corporate and Shareholder Information, confirm that, to the best of each person's knowledge and belief:

- (a) the condensed interim financial statements comprising the condensed consolidated statement of comprehensive income, the condensed consolidated statement of financial position, the condensed consolidated statement of changes in equity, the condensed consolidated statement of cash flows and related notes 1 to 15 have been prepared in accordance with IAS 34 *Interim Financial Reporting* as adopted by the EU.
- (b) the interim management report includes a fair review of the information required by:
 - i. *Regulation 8(2) of the Transparency (Directive 2004/109/EC) Regulations 2007*, being an indication of important events that have occurred during the first six months of the financial year and their impact on the condensed set of financial statements; and a description of the principal risks and uncertainties for the remaining six months of the year; and
 - ii. *Regulation 8(3) of the Transparency (Directive 2004/109/EC) Regulations 2007*, being related party transactions that have taken place in the first six months of the current financial year and that have materially affected the financial position or performance of the entity during that period; and any changes in the related party transactions described in the last annual report that could do so.

Mainstay Medical International plc
Condensed consolidated statement of comprehensive income
for the half-year ended 30 June 2014

(\$'000)	Notes	Before exceptional items 2014 Unaudited	Exceptional items 2014 Unaudited	6 month period to 30 June 2014 Unaudited	6 month period to 30 June 2013 Unaudited
Revenue		-	-	-	-
Operating expenses	3	(4,780)	-	(4,780)	(4,398)
IPO related expenses	4	-	(4,040)	(4,040)	-
Operating loss		<u>(4,780)</u>	<u>(4,040)</u>	<u>(8,820)</u>	<u>(4,398)</u>
Finance income		20	-	20	-
Fair value (loss)/ gain on derivative financial instruments	4	-	(66,468)	(66,468)	462
Finance expense		<u>(734)</u>	<u>-</u>	<u>(734)</u>	<u>(1,298)</u>
Net finance expense		<u>(714)</u>	<u>(66,468)</u>	<u>(67,182)</u>	<u>(836)</u>
Loss before income taxes		(5,494)	(70,508)	(76,002)	(5,234)
Income taxes	10	<u>(2)</u>	<u>96</u>	<u>94</u>	<u>(29)</u>
Loss for the period and comprehensive loss for the period		<u>(5,496)</u>	<u>(70,412)</u>	<u>(75,908)</u>	<u>(5,263)</u>
Net loss attributable to equity holders		<u>(5,496)</u>	<u>(70,412)</u>	<u>(75,908)</u>	<u>(5,263)</u>
Basic and diluted loss per share (in \$)	9	<u>(3.54)</u>	<u>(45.31)</u>	<u>(48.85)</u>	<u>(64.66)</u>

Mainstay Medical International plc
Condensed consolidated statement of financial position
at 30 June 2014

(\$'000)	Notes	30 June 2014	31 December 2013
		Unaudited	Audited
Non-current assets			
Property, plant and equipment		<u>71</u>	<u>68</u>
Current assets			
Prepayments and other receivables		1,155	385
Cash and cash equivalents		<u>23,478</u>	<u>9,590</u>
Total current assets		24,633	9,975
Total assets		<u>24,704</u>	<u>10,043</u>
Equity			
Share capital	6	61	1
Share premium	6	72,584	250
Share based payment reserve	13	766	534
Other reserves	7	4,700	(9,609)
Retained loss		<u>(55,024)</u>	<u>(13,146)</u>
Surplus/(deficit) on shareholders' equity		<u>23,087</u>	<u>(21,970)</u>
Non-current liabilities			
Preference shares		-	24,965
Derivative financial instruments		-	4,622
Deferred tax	10	<u>-</u>	<u>96</u>
Total non-current liabilities		-	29,683
Current liabilities			
Loans and borrowings	11	-	785
Trade and other payables		<u>1,617</u>	<u>1,545</u>
Total current liabilities		<u>1,617</u>	<u>2,330</u>
Total liabilities		<u>1,617</u>	<u>32,013</u>
Total equity and liabilities		<u>24,704</u>	<u>10,043</u>

Mainstay Medical International plc
Condensed consolidated statement of changes in shareholders' equity
for the half-year ended 30 June 2014

(\$'000)	Share capital	Share premium	Capital conversion reserve	Reorgani- sation reserve	Share based payment reserve	Retained loss	Total equity
Unaudited							
Balance at 1 January 2013	1	250	-	(9,609)	104	(2,828)	(12,082)
Loss for the period	-	-	-	-	-	(5,263)	(5,263)
Share based payments	-	-	-	-	250	-	250
Balance at 30 June 2013	1	250	-	(9,609)	354	(8,091)	(17,095)
Unaudited							
Balance at 1 January 2014	1	250	-	(9,609)	534	(13,146)	(21,970)
Loss for the period	-	-	-	-	-	(75,908)	(75,908)
Share based payments	-	-	-	-	232	-	232
Effect of reorganisation	55	879	-	(34,964)	-	34,030	-
<i>Effect of IPO:</i>							
Issue of shares in Mainstay	1	23,922	-	-	-	-	23,923
Conversion of preference shares	4	47,533	49,273	-	-	-	96,810
Balance at 30 June 2014	61	72,584	49,273	(44,573)	766	(55,024)	23,087

Mainstay Medical International plc
Condensed consolidated statement of cash flows
for the half-year ended 30 June 2014

(\$'000)	Notes	6 months period to 30 June 2014	6 months period to 30 June 2013
		Unaudited	Unaudited
Cash flow from operating activities			
Net loss attributable to equity holders		(75,908)	(5,263)
Add/(less) non-cash items			
Depreciation		12	7
Fair value of derivative financial instruments		66,468	(462)
Finance income		(20)	-
Finance expense		734	1,298
Income taxes	10	(94)	29
Share-based compensation		232	250
Add/(less) changes in working capital			
Prepayments and other receivables		(1,153)	13
Trade and other payables		(509)	792
Initial public offering related expenses		4,040	-
Interest paid		(18)	(68)
Net cash used in operations		<u>(6,216)</u>	<u>(3,404)</u>
Cash flow from investing activities			
Acquisition of property and equipment		(15)	(13)
Net cash used in investing activities		<u>(15)</u>	<u>(13)</u>
Cash flow from financing activities			
Net proceeds from issue of shares		20,919	153
Repayment of borrowings	11	(800)	(400)
Net cash from financing activities		<u>20,119</u>	<u>(247)</u>
Net increase/(decrease) in cash and cash equivalents			
Cash and cash equivalents at beginning of period		9,590	17,370
Cash and cash equivalents at end of period		<u>23,478</u>	<u>13,706</u>

Mainstay Medical International plc

Notes to the consolidated interim financial statements

1 General information and reporting entity

Mainstay Medical International plc (“Mainstay” or the “Company”) is a company incorporated and registered in Ireland. Details of the registered office, the officers and advisers to the Company are presented on the Company Information page at the end of this report.

The interim results and the Condensed Consolidated Interim Financial Statements (“the Interim Financial Statements”) in this report for the six month period ended 30 June 2014 comprise the results of the Company and of its subsidiaries (together the “Group”).

The Company was incorporated on 17 February 2014. Following a reorganisation (the “2014 Corporate Reorganisation” detailed in Note 5 below) on 3 April 2014, the Company became the new parent company of the Group. At 30 June 2014, the Group comprises the Company and its operating subsidiaries Mainstay Medical Limited, MML US, Inc. and Mainstay Medical (Australia) Pty. Limited. Prior to 3 April 2014, Mainstay Medical Limited was the ultimate parent company of the Group.

The Group is focused on developing an active implantable medical device (AIMD) designed to treat Chronic Low Back Pain (ReActiv8).

2 Basis of preparation

The Interim Financial Statements have been prepared in accordance with IAS 34 Interim Financial Reporting as adopted by the EU. They do not include all the information necessary for a complete set of IFRS Financial Statements. However, selected explanatory notes are included to explain events and transactions that are significant to an understanding of the changes in the Group’s financial position and performance since the last annual consolidated financial statements as at and for the year ended 31 December 2013.

The Interim Financial Statements have been prepared applying the accounting policies that were applied in the preparation of the Group’s published consolidated financial information for the period ended 31 December 2013 prepared in accordance with IFRS and available from the Company’s website in the prospectus. In addition the Group applied IFRS 10, 11 and 12 for the first time in this interim period, along with the amendment to IAS 32. None of these have had any impact on the Group’s implementation of accounting policies or on its reported results.

There are no significant or material changes to judgements or estimates used in these Interim Financial Statements versus those used in the full Financial Statements for the period ended 31 December 2013.

The comparative information provided in the Interim Financial Statements relating to the period ended 31 December 2013 does not comprise the statutory financial statements of the Group. Those statutory financial statements on which the Group’s auditors gave an unqualified audit opinion, have been delivered to the Registrar of Companies.

Mainstay Medical International plc

Notes to the consolidated interim financial statements (continued)

2 Basis of preparation (continued)

The introduction of Mainstay Medical International plc as the new parent company in the Group by way of the 2014 Corporate Reorganisation has been accounted for as a continuation of Mainstay Medical Limited's business. Consequently the financial information presented represents that of the Group headed by Mainstay Medical Limited for the period to 2 April 2014 and of the Group headed by the Company for the period from 3 April 2014 to 30 June 2014. Further information is provided in note 5 below.

The Interim Financial Statements do not include all of the information required for full annual financial statements and should be read in conjunction with the consolidated financial information of the Group as at and for the period ended 31 December 2013 included in the Prospectus, which is available on the Company's website (www.mainstay-medical.com).

The Interim Financial Statements are presented in US Dollars ("\$"), which is the functional and presentational currency of the Group. Balances in the Interim Financial Statements are rounded to the nearest thousand ("'\$'000") except where otherwise indicated. Transactions in foreign currencies are recorded at the rate ruling 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 the statement of comprehensive income.

Following the Company's IPO in May 2014, which resulted in additional net funds raised of \$20.9m, the Directors are satisfied that the Group has sufficient resources to continue in operation for the foreseeable future, being a period of not less than 12 months from the date of approval of these Interim Financial Statements. Accordingly, these Interim Financial Statements are prepared on a going concern basis.

The Interim Financial Statements were approved by the Board of Directors on 27th August 2014.

3 Operating expenses

(\$'000)	6 months period to 30 June 2014	6 months period to 30 June 2013
	Unaudited	Unaudited
Research and development expenses	1,242	2,436
Clinical and regulatory expenses	1,663	334
General and administration expenses	1,643	1,378
Share-based compensation expenses	232	250
Total operating expenses	4,780	4,398

Mainstay Medical International plc

Notes to the consolidated interim financial statements (continued)

4 Exceptional items

The Directors have presented the following matters as exceptional as they relate to matters arising as a result of the Company's IPO on 2 May 2014.

(\$'000)	6 months period to 30 June 2014	6 months period to 30 June 2013
	Unaudited	Unaudited
Fair value adjustment of derivative financial instruments	66,468	-
IPO related expenses	4,040	-
	70,508	-

On 3 April 2014, pursuant to the 2014 Company Reorganisation (refer note 5) the Company acquired all outstanding ordinary and preference shares in Mainstay Medical Limited. The preference shares having equivalent rights in Mainstay Medical Limited had been classified as non-current liabilities and derivative financial instruments in the statement of financial position of the Group at 31 December 2013. Immediately prior to the reorganisation, a fair value adjustment of \$17,193,978 was recorded in Mainstay Medical Limited's statement of comprehensive income representing the difference between the carrying value at 31 December 2013 and the carrying value at 3 April 2014. There was a corresponding increase in share premium.

Immediately prior to completion of the IPO, all issued Series A, Series B and Series Z preference shares in the Company converted on a one-for-one basis into ordinary shares of €0.001 in the Company. Prior to the conversion of the preference shares in the Company to ordinary shares, a fair value adjustment was recorded in the statement of comprehensive income of \$49,273,644 representing the difference between the carrying value at 3 April 2014 and the fair value as at 28 April 2014. There was a corresponding increase in the capital conversion reserve.

The combined impact of the above events has resulted in a total fair value adjustment of \$66,467,622 recorded in the Group statement of comprehensive income. Following conversion of all preference shares the Company will not incur such fair value movements through the statement of comprehensive income in future periods in relation to these preference shares.

Expenses directly associated with the Company listing its existing shares on the ESM and Euronext Paris of \$4,039,681 have been charged directly to profit or loss in the period.

5 2014 Corporate reorganisation

On 3 April 2014, the Company acquired all outstanding ordinary and preference shares in Mainstay Medical Limited in exchange for issuing 793,425 series A shares, 1,967,177 series B shares, 500,000 series Z shares and 81,400 ordinary shares to former shareholders in Mainstay Medical Limited, in each case on the basis of one share in the Company in place of 20 shares of the same class in Mainstay Medical Limited.

The difference between the carrying amount of preference shares and other equity items, including retained losses previously held by Mainstay Medical Limited, and the fair value of the shares issued by the Company is reflected in the Statement of Changes in Equity where it is recorded in the reorganisation reserve.

The impact of the above on the reorganisation reserve was a transfer of \$34,030,000 from retained losses, representing the accumulated losses of Mainstay Medical Limited at 3 April 2014, and a fair value increase in ordinary shares in issue of \$934,000, resulting in a total transfer to the reorganisation reserve of \$34,964,000.

Both prior to and subsequent to the 2014 Corporate Reorganisation no individual shareholder or party had control of the Group.

Mainstay Medical International plc

Notes to the consolidated interim financial statements (continued)

5 2014 Corporate reorganisation (continued)

As the 2014 Corporate Reorganisation effectively changed the parent company of the Group from a legal perspective only, no business combination in accordance with IFRS 3 was deemed to have occurred. The introduction of Mainstay Medical International plc has been accounted for as a continuation of the business of Mainstay Medical Limited. Consequently, even though the Company was not incorporated until 17 February 2014 and did not become a Group company until 3 April 2014, the disclosures in the interim financial statements include the consolidated financial statements of Mainstay Medical Limited prior to the date of the 2014 Corporate Reorganisation.

6 Share capital

On 2 May 2014, the Company listed its ordinary shares on the ESM and Euronext Paris. As at 2 May 2014, the issued share capital of the Company consisted of 4,294,141 ordinary shares of €0.001 each (which carry voting rights) and 40,000 deferred shares of €1.00 each (which do not carry voting rights, are not entitled to receive any dividend or distribution and have in effect no right to a return of capital on a winding up).

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

Details of movements in shares:

	<i>Number of shares</i>				
	Ordinary shares	Deferred shares	Series A shares	Series B shares	Series Z shares
At 1 January 2014	1,628,000	-	15,868,250	39,343,640	10,000,000
<i>Effect of reorganisation:</i>					
Cancellation of MML shares	(1,628,000)	-	(15,868,520)	(39,343,640)	(10,000,000)
Issue of Mainstay shares	102,400	40,000	793,425	2,008,877	500,000
<i>Effect of IPO</i>					
Issue of new shares	889,439	-	-	-	-
Conversion of pref. shares to ordinary shares	3,302,302	-	(793,425)	(2,008,877)	(500,000)
At 30 June 2014	4,294,141	40,000	-	-	-

Series A, Series B and Series Z shares were classified as non-current liabilities and derivative financial instruments as at 31 December 2013. Immediately prior to the Company's IPO, all Series A, Series B, and Series Z preference shares converted on a one-for-one basis into ordinary shares of €0.001 each in the Company.

Mainstay Medical International plc
Notes to the consolidated interim financial statements (continued)

7 Other reserves

(\$'000)	30 June 2014	31 December 2013
	Unaudited	Audited
Reorganisation reserve	(44,573)	(9,609)
Capital conversion reserve	49,273	-
	<u>4,700</u>	<u>(9,609)</u>

8 Segment reporting

Due to the nature of the Group's current activities, the Company considers there to be one operating segment, active implantable medical devices (AIMDs). The results of the Group are reported on a consolidated basis to the Chief Operating Decision Maker of the Group, the Chief Executive Officer. There are no reconciling items between the Group's reported condensed consolidated statement of comprehensive income and statement of financial position and the results of the AIMDs segment.

The Group has operations in Europe, the U.S. and Australia. The non-current assets in these jurisdictions are detailed below:

(\$'000)	30 June 2014	31 December 2013
	Unaudited	Audited
Europe	24	19
United States	47	49
Australia	-	-
Total non-current assets	<u>71</u>	<u>68</u>

9 Earnings per share

Earnings per share are calculated by dividing net loss attributable to equity holders of the period by the weighted average number of ordinary shares outstanding during the period. As the Group is incurring operating losses, there is no difference between the basic and the diluted earnings per share.

The weighted average number of ordinary shares for the period ended 30 June 2014 (denominator) amounted to 1,553,957 (2013: 81,400). There are no adjustments between reported comprehensive income from continuing operations and earnings used for the purposes of earnings per share.

The loss per share before exceptional items for the period ended 30 June 2014 was \$3.54. The loss per share for the period ended 30 June 2014 after exceptional items was \$48.85 (2013: \$64.66).

Mainstay Medical International plc
Notes to the consolidated interim financial statements (continued)

10 Taxes

Current income tax assets and liabilities for the current and prior period 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 and Australia.

(\$'000)	6 months period to 30 June 2014	6 months period to 30 June 2013
	Unaudited	Unaudited
Irish tax	-	(68)
Income tax in other jurisdictions	2	39
Deferred tax	(96)	58
Total income tax charge/(credit)	(94)	29

11 Repayment of borrowings

The bank loan to Mainstay Medical Limited as at 31 December 2013 of \$800,000 was repaid in full on 7 March 2014.

12 Financial instruments

As at 30 June 2014 the Group's only financial instruments were trade payables and cash. The fair value of these items is equivalent to their carrying value.

The Group's exposure to foreign currency risk arises through expenditure incurred in Euro and Australian Dollars. The Group did not have material asset or liability amounts in foreign currencies at period end other than €520,046 and AU\$28,106 held in cash. A strengthening (or weakening) of the U.S. Dollar against euro of 5 per cent. would have (decreased)/ increased the loss for the period by \$35,000 (2013: \$43,000). Any reasonable or likely movement between the U.S. Dollar and the Australian Dollar are considered not likely to have a material impact on the Group's statement of comprehensive income.

A change in interest rates of 50bps during the interim financial period would have no material impact on comprehensive income for the period.

No fair value or sensitivity analysis information is provided for preference shares or derivative financial instruments in these interim financial statements as these items were extinguished in the period.

13 Share based payments

Stock Incentive Plan

The Group operates a Stock Incentive Plan (the "Plan"). As at 30 June 2014, the Plan allows for the Company to grant various classes of share awards to employees of the Group companies, Directors, consultants and other contractors. As at 30 June 2014, share options over ordinary shares of the Company have been granted under the Plan.

The Plan allows for flexibility in the grant conditions of each individual award, including variations on the amounts of awards granted, the vesting requirements for each award and the expiration terms of the awards. On 3 April 2014, all outstanding share options in Mainstay Medical Limited were surrendered by the holders. In return the Company granted one share option in place of 20 share options on substantially the same terms. All awards are to be settled through the physical delivery of shares in the Company. As this exchange reflected the terms of the 2014 Corporate Reorganisation and was not beneficial to the holders, there was no impact on shareholders' equity or comprehensive income.

Mainstay Medical International plc
Notes to the consolidated interim financial statements (continued)

13 Share based payments (continued)

Share Options

Details of share options granted as at 30 June 2014.

	Number of instruments in thousands	Contractual life of options
Options granted in 2010	41	10 years
Options granted in 2011	17	10 years
Options granted in 2012	3	10 years
Options granted in 2013	255	10 years
Options granted in 2014	81	10 years
Total share options in issue	397	

No share options have expired unexercised or have been exercised during the period ended 30 June 2014. 14,380 share options have been forfeited during the period ended 30 June 2014. The above options all include non-market vesting conditions related to employee and non-employee service and vest over periods ranging from one to four years.

Options granted prior to 2013 have an exercise price of \$0.80. Options granted in 2013 have an exercise price of \$1.00. Options granted in 2014 have an exercise price ranging from €17.08 to €18.51. At 30 June 2014, 140,116 options were exercisable.

The value of services received in return for the share options granted to employees and non-employees was based on the fair value of the options granted, measured using a Black-Scholes model with the following inputs:

	2014	2013	2012	2011
Weighted average share price (\$)	23.26 – 25.05	3.60	0.80	0.80
Weighted average exercise price (\$)	23.26 – 25.05	1.00	0.80	0.80
Weighted average expected share volatility	60%	60%	60%	60%
Expected term (years)	7	7	7	7
Expected dividends	-	-	-	-
Risk free rate	1.21%	1.60%	0.85%	0.85%
Fair value of option (\$)	13.74 – 14.78	3.00	0.40	0.40

14 Related party transactions

During 2014, the Group purchased services of \$36,527 (2013: \$46,582) from Orsco Life Sciences AG, a company controlled by Oern Stuge, a director of Mainstay.

15 Events subsequent to 30 June 2014

There were no material events subsequent to the end of the period to 30 June 2014.

Mainstay Medical International plc
Corporate and shareholder information

Directors	Oern Stuge, Non-Executive Independent Chairman Peter Crosby, Chief Executive Officer Antoine Papiernik, Non-Executive Director Manus Rogan, Non-Executive Director Dan Sachs, Non-Executive Director David Brabazon, Non-Executive Independent Director
Secretary	Hugh Kavanagh
Registered office	Clonmel House Forster Way Swords County Dublin, Ireland
Website	www.mainstay-medical.com
ISIN / Symbol	IE00BJYS1G50 / MSTY.PA (Paris) and MSTY.IE
ESM Adviser and Broker	J&E Davy Davy House 49 Dawson Street Dublin 2, Ireland
Registrar	Computershare Investor Services (Ireland) Limited Heron House Corrig Road Sandyford Industrial Estate Dublin 18, Ireland
Paying Agent (in France)	Société Générale Securities Services 32 rue du Champ de Tir CS 30812 44308 Nantes Cedex 3, France

- Fin -

À propos de Mainstay Medical

Mainstay est une société irlandaise de dispositifs médicaux qui développe un dispositif implantable innovant de neurostimulation, ReActiv8, pour les personnes souffrant de lombalgie chronique invalidante. La lombalgie est l'une des principales causes de limitation de l'activité et d'absence au travail dans les pays développés, faisant peser un poids économique significatif sur les individus, les familles, la société, l'économie et les gouvernements.

La société est basée à Dublin, en Irlande, elle dispose d'activités basées aux États-Unis et en Australie, et est cotée sur Euronext Paris et sur l'ESM de l'Irish Stock Exchange.

A propos de la lombalgie chronique

Une des causes reconnues de la lombalgie chronique est un affaiblissement du contrôle par le système nerveux central des muscles qui stabilisent la colonne vertébrale du bas du dos, et l'instabilité de la colonne vertébrale peut provoquer des maux de dos. ReActiv8 est conçu pour stimuler électriquement les nerfs responsables de la contraction de ces muscles et ainsi de contribuer à restaurer le contrôle musculaire et d'améliorer la stabilité de la colonne vertébrale, ce qui permet au corps de récupérer de la lombalgie chronique.

Les personnes atteintes de lombalgie chronique invalidante ont généralement une qualité de vie réduite et un niveau très élevé de la douleur, du handicap, de la dépression, de l'anxiété et des troubles du sommeil. Leur douleur et leur handicap peuvent persister malgré les meilleurs traitements médicaux disponibles, et seulement un faible pourcentage de cas résulte d'un état pathologique identifié, ou d'un défaut anatomique qui peut être corrigée par la chirurgie rachidienne. Leur capacité à travailler ou à être productif est sérieusement affectée par ce mal, et les journées de travail perdues, les prestations d'invalidité et le recours aux prestations de santé pèsent sur l'économie.

Des informations complémentaires sont disponibles sur le site www.mainstay-medical.com

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Déclarations prospectives

Le présent communiqué contient des déclarations qui sont ou pourraient être comprises comme étant prospectives. Ces déclarations peuvent souvent être identifiées par les mots tels que « anticiper », « croire », « estimer », « s'attendre à », « ambitionner », « avoir l'intention de », « planifier », à travers l'utilisation le cas échéant du conditionnel ou dans chaque cas, la forme négative de ces mêmes termes, ou toute autre variante ou terminologie similaire, ou par une discussion de la stratégie, des objectifs, événements futurs ou intentions. Ces déclarations prospectives intègrent tous les éléments qui ne constituent pas un fait historique. Ces déclarations sont mentionnées dans différents paragraphes du présent communiqué et contiennent, mais ne sont pas limitées à, des déclarations relatives aux intentions, aux estimations et aux attentes de la Société concernant, notamment, ses résultats d'exploitation, sa situation financière, ses perspectives, ses objectifs, sa stratégie de financement, ses attentes en termes de recherche et de développement produit, les approbations par les autorités compétentes, le système de remboursement pour le produit, les coûts de vente et le taux de pénétration de ses produits.

Par leur nature, ces déclarations prospectives sont soumises à de nombreux risques et incertitudes dans la mesure où elles concernent les événements et circonstances futurs. Les déclarations prospectives ne constituent pas une garantie de résultats futurs et les résultats actuels de la Société (ainsi que le développement du marché et de l'industrie au sein desquels la Société évolue) pourraient différer significativement de ceux qui sont exprimés, induits ou prévus dans les informations et déclarations prospectives mentionnées dans le présent communiqué. Même si les résultats opérationnels, la situation financière et la croissance future de la Société ainsi que le développement des marchés et de l'industrie où la Société opère sont en ligne avec ces déclarations prospectives, ces résultats et développements ne seront pas nécessairement un indicateur de résultats ou développements futurs. Les facteurs importants susceptibles d'entraîner des différences entre les objectifs énoncés et les réalisations effectives comprennent notamment l'évolution globale de l'activité économique et industrielle, les conditions du marché pour les équipements médicaux, l'évolution de l'industrie, la concurrence, les changements réglementaires et législatifs, les modifications de dispositifs fiscaux, la disponibilité et le coût de financement, les fluctuations des taux de change, les changements dans la stratégie de la Société, et les incertitudes politiques ou économiques. Les déclarations prospectives mentionnées dans le présent communiqué sont données uniquement à la date de ce communiqué.

La Société décline toute obligation ou tout engagement de mettre à jour ou de réviser les énoncés prospectifs contenus dans le présent document pour tenir compte de tout changement dans les attentes, toute évolution des événements, conditions ou circonstances sur lesquels ces déclarations sont basées sauf si requis par la loi ou les réglementations applicables.