



Dr. Stuart Hendry, Chief Executive Officer and Matthew Hall, Chief Financial Officer will host a presentation for analysts at 11am today at Consilium Strategic Communications, 11th Floor, CityPoint, 1 Ropemaker Street, London EC2Y 9AW. There will also be a live conference call for remote users. A replay will be available after the call. To register your interest for this briefing please contact spheremedical@consilium-comms.com or call +44 (0)207 920 2354

19 September 2013

Sphere Medical Holding plc

Interim Results for the Six Months ended 30 June 2013

Cambridge, UK, 19 September 2013: Sphere Medical Holding plc (AIM: SPHR.L) (“Sphere” or “Sphere Medical” or the “Company”), a leading developer of innovative monitoring and diagnostic devices for the critical care setting, today announces its unaudited interim results for the six months ended 30 June 2013.

Highlights

- Significant progress made towards obtaining CE Mark for the current generation of Proxima and its subsequent launch into the UK market
- Collaboration agreement entered into with Ortho-Clinical Diagnostics, Inc. (“OCD”), part of the Johnson & Johnson family of companies (“J&J”), for the development of Proxima and enhancement of Sphere’s operational and production capabilities
- Announced £9.0 million (before expenses) equity fundraising comprising:
 - £3.3 million equity investment from Johnson & Johnson Development Corporation, the investment arm and a subsidiary of J&J
 - £5.1 million institutional placing including a substantial investment by Life Sciences Partners and £0.6 million open offer
- Total operating expenses £2.9 million (2012: £4.4 million) and Loss before taxation £2.9 million (2012: £4.2 million)
- Cash and cash equivalents and monies on treasury deposit of £2.6 million (2012: £8.3 million) at 30 June 2013

Post-period end highlights

- Balance sheet significantly strengthened since period end with completion of equity fundraising with cash and cash equivalent increasing to £10.7 million at 31 July 2013
- Collaboration with OCD has begun and the Joint Steering Group and the Project Team have been formed
- Commenced the transitioning of Sphere from a research and development group into one centred on serving our customers, manufacturing product and revenue generation



Commenting on these interim results, Dr. Stuart Hendry, Chief Executive Officer of Sphere Medical, said:

“For the first six months of 2013 Sphere Medical has concentrated on progressing Proxima towards European CE Mark and its subsequent launch into the UK. With OCD we believe we have the optimal long-term partner for Proxima and as a consequence, there is a strong commercial future for the Proxima platform and Sphere Medical as a whole.

“During the second half of 2013, we will be working on completing the European CE Mark for the current generation of Proxima and on transitioning Sphere Medical towards a more commercially focused organisation. Our relationship with OCD has begun well and we will continue to work towards achieving the objectives of the collaboration agreement. We thank our shareholders for their continued support and we welcome Johnson & Johnson Development Corporation and Life Sciences Partners as two significant new shareholders. We look forward to updating on the Company’s progress throughout the remainder of 2013.”

For further information, please contact:

Sphere Medical Holding plc

Dr Stuart Hendry, Chief Executive Officer
Matthew Hall, Chief Financial Officer

Tel: +44 (0)1223 875 222

Peel Hunt LLP

James Steel
Dr Vijay Barathan
Jock Maxwell Macdonald

Tel: +44 (0) 20 7418 8900

Consilium Strategic Communication

Mary-Jane Elliott, Amber Bielecka,
Matthew Neal

Tel: +44 (0) 20 7920 2354
spheremedical@consilium-comms.com

Notes for Editors

Sphere Medical (AIM: SPHR.L), is a medical device company developing a range of innovative monitoring and diagnostic devices designed to significantly improve patient care.

Sphere Medical’s products deliver real time analysis of blood gases, electrolytes and drug levels with laboratory accuracy, at the patient’s bedside. Sphere Medical’s products can be used in a wide range of medical applications, enabling faster clinical



decision making and improved patient outcomes, whilst reducing costs for healthcare payers.

Sphere Medical has a number of partnerships with industry leading medical device companies with strategic investments such as Ortho-Clinical Diagnostics, Inc.

For further information, please visit www.spheremedical.com



BUSINESS REVIEW

INTRODUCTION AND STRATEGY

The Board's principal strategic objective is to transition Sphere Medical from a research & development orientated group into a commercial company centred on serving our customers and generating revenues. Central to our strategy will be ensuring the successful commercialisation of Proxima and the growth of this product platform to serve the specific needs of our customers internationally.

We remain committed to achieving the European CE Mark for the current generation of Proxima, a prerequisite to its launch in the UK and the commencement of our clinical trials for Proxima's US regulatory submission in concert with OCD. We are pleased to report that the work required to deliver this important European regulatory approval is well advanced.

In late June 2013, we announced a transformational collaboration agreement for Proxima with Ortho-Clinical Diagnostics, Inc. ("OCD") which we believe underpins a strong commercial future for the Proxima platform and Sphere Medical as a whole.

PROXIMA

Proxima is Sphere Medical's lead product and is being developed for critical care applications and uses our patented proprietary microanalyser technology. Proxima is a disposable patient-attached arterial blood gas analyser for use in the intensive care unit ("ICU") and operating room ("OR") in hospitals. The device is integrated into existing patient arterial and fluid lines at the bedside to allow the rapid measurement of a panel of blood parameters, including blood gases and electrolytes required for the optimum management of critically ill patients.

During the first six months of 2013 we have brought the Company significantly closer to achieving our vision for Proxima for it to be clearly identified as a product used to provide a global standard of care and improving patient treatment at the same time as reducing healthcare costs.

Proxima CE Mark developments and other regulatory developments

The Company has been concentrating on achieving the important Proxima CE Mark and all aspects of the work required to deliver this European regulatory approval is well advanced.

Activity in the first six months was centred on finalising the microanalyser device performance and reliability and ancillary fluidics, specifically, flush, calibration and quality control. Finalising the software within the dedicated Proxima monitor was also progressed by our in-house software team.



During the period we also undertook a series of clinical trials, interviews and usability studies designed to validate technical and performance aspects of certain components of the Proxima system within a hospital setting. A number of system design improvements were identified which have been incorporated into the final Proxima system being prepared for European CE Mark.

The usability studies and focus group meetings were undertaken with anaesthetists and ICU nurses with a wide range of experience and seniority within a number of UK teaching and district general hospitals. These meetings, which are on-going, have been designed to: validate the use of Proxima within a wider range of clinical settings; refine the use of Proxima within current hospital workflows; and identify those target patient groups to which Proxima would have immediate benefit. This programme will continue throughout the year in order to expand and refine our understanding of the target patient groups as well as the specific purchasing practices within a wide range of UK hospitals.

During the period we have also progressed the US regulatory process for Proxima. A number of UK clinical centres have been identified for performance evaluation studies and these studies are expected to form the basis for the US regulatory submission which we will undertake alongside OCD.

Proxima partnering discussions

In late June we announced a transformational collaboration agreement with OCD for Proxima. This agreement is the culmination of a partnering process which began in January 2012. We believe that OCD is the optimal long-term partner for Proxima.

The collaboration between Sphere Medical and OCD will cover all aspects of Proxima, including market assessment, product development and the enhancement of Sphere's operational and production capabilities.

After the period end, the Sphere Medical and OCD teams have met and the Joint Steering Group and the Project Team have now been formed. The next steps include the finalisation of the Proxima project plan and budget.

Sphere Medical will continue to focus its efforts on meeting the objectives of the collaboration agreement, which in the near term are centred upon the effective commercialisation of Proxima.

PELORUS

We continue to support clinical studies aimed at evaluating the use of Pelorus 1500 propofol analyser to monitor intravenous propofol levels. The work already done at Great Ormond Street Hospital for Children ("GOSH") has highlighted the variability of current dosing models in the concentration of intravenous propofol in patients.



Furthermore the work currently underway at the University Medical Centre Groningen in the Netherlands (“UMCG”) is aimed at investigating the real time adaptation of current dosing models to the individual patient using rapid intravenous propofol measurements provided by the Pelorus 1500 system.

This work at GOSH and UMCG is expected to result in the development of the next generation of infusion protocols and control systems which would be a significant opportunity to improve patient care and consequently represents a large commercial opportunity for Sphere Medical.

CARDIOPULMONARY BYPASS MONITOR (“CPB”)

Sphere Medical is developing an in-line blood monitoring system for cardiopulmonary bypass procedures for our partner, Sorin Group Italia S.r.l. (“Sorin”), a global medical devices company and leader in the treatment of cardiovascular diseases.

The development of the CPB microanalyser sensor has moved in parallel with the Proxima sensor and a dedicated CPB monitor has been developed. Sorin has undertaken a number of market studies and Sphere Medical is reviewing and identifying necessary modifications to meet the requirements of Sorin. Further software and technical resource is required to be allocated, however, our development priority remains the Proxima project. The Sphere Medical and Sorin plan is to bring the CPB product to market upon finalisation of the user input.

THE SPHERE MEDICAL TEAM

Sphere Medical continues to benefit from the hard work and expertise of its employees who, with the Board, are fully committed to transforming Sphere Medical into a successful commercial medical device company.

We would like to take this opportunity to thank all our employees and management for their continued commitment and shareholders for their on-going support to Sphere Medical.

FINANCIAL REVIEW

In the six months ended 30 June 2013 revenue was £31,000 (H1 2012: £nil).

Operating expenses were £2.9 million (H1 2012: £4.4 million). Included in operating expenses are research and development and manufacturing costs of £2.0 million (H1 2012: £3.3 million) principally associated with the development of the Proxima



disposable patient-attached arterial blood gas analyser. Administrative expenses were £0.8 million (H1 2012: £0.7 million).

Finance income (net) was £0.1 million (H1 2012: £0.2 million) representing interest earned on term deposits and a change in the fair value of the share warrants.

During the period no research and development tax credit refund was received (H1 2012: £nil) although a tax credit of £410,000 was received after 30 June 2012.

The loss for the period was £2.9 million (H1 2012: £4.2 million). The basic and fully diluted loss per share for the period was 7.8pence (H1 2012: 11.5p).

During the period the Company undertook an equity fundraising to fund the ongoing operations of the Company and to support the future collaboration agreement with OCD. The £9.0 million (before expenses) fundraising comprised: £3.3 million equity investment from Johnson & Johnson Development Corporation, the investment arm and a subsidiary of Johnson & Johnson; £5.1 million institutional placing; and a £0.6 million open offer. These funds were received by the Company after 30 June 2013.

As at 30 June 2013 cash and cash equivalents and monies on treasury deposit was £2.6 million (2012: £8.3 million). The balance sheet was significantly strengthened post period end with the completion of an equity fundraising. Cash and cash equivalents and monies on treasury deposit was £10.7 million at 31 July 2013.

SUMMARY AND OUTLOOK

We remain committed to completing the European CE Marking of Proxima which at the date of this report is well advanced. This regulatory milestone will allow us to proceed with the UK evaluation studies. The collaboration deal for Proxima with OCD was a key objective and we believe this will underpin a strong commercial future for the Proxima platform and Sphere Medical as a whole.

Dr. Stuart Hendry
Chief Executive Officer

Matthew Hall
Chief Financial Officer



Consolidated Statement of Comprehensive Income
For the 6 months ended 30 June 2013

	Notes	6 months to 30 June 2013 Unaudited	6 months to 30 June 2012 Unaudited	12 months to 31 December 2012 Audited
		£000	£000	£000
Revenue		31	-	46
Cost of sales		-	-	(27)
Gross profit		31	-	19
Selling and marketing expenses		(174)	(165)	(391)
Production expenses		(423)	(1,012)	(1,903)
Research and development		(1,569)	(2,276)	(3,877)
Administrative expenses		(759)	(675)	(1,345)
Employee share based compensation		(19)	(260)	(527)
Operating expenses (net)		(2,944)	(4,388)	(8,043)
Operating loss		(2,913)	(4,388)	(8,024)
Finance income		58	155	226
Finance costs		(2)	(2)	39
Loss before taxation		(2,857)	(4,235)	(7,759)
Tax credit		-	-	410
Loss and total comprehensive income for the period attributable to the equity holders of the parent		(2,857)	(4,235)	(7,349)
Loss per share attributable to the equity holders of the parent				
Basic and diluted	4	(7.8p)	(11.5p)	(20.0p)

All amounts derive from continuing operations.

The accompanying notes form an integral part of this Consolidated Statement of Comprehensive Income.



Consolidated Statement of Financial Position At 30 June 2012

	Notes	30 June 2013 Unaudited	30 June 2012 Unaudited	31 December 2012 Audited
		£000	£000	£000
ASSETS				
Non-current assets				
Property, plant and equipment		276	246	268
Intangible assets		17	18	15
		293	264	283
Current assets				
Inventories		90	28	69
Trade and other receivables		119	214	122
Investment		-	6,000	2,500
Cash and cash equivalents		2,638	2,333	2,879
		3,140	8,839	5,853
EQUITY				
Called up share capital	5	368	368	368
Share premium account		38,258	38,258	38,258
Other reserve		2,889	2,603	2,870
Profit and loss account		(39,515)	(33,544)	(36,658)
		2,000	7,685	4,838
LIABILITIES				
Non-current liabilities				
Obligations under finance leases		10	24	17
		10	24	-
Current liabilities				
Trade and other payables		1,114	1,082	966
Obligations under finance leases		14	12	13
Derivative liabilities – fair value of share warrants		2	36	19
		1,130	1,130	998
		1,140	1,154	1,015
		3,140	8,839	5,853

The accompanying notes form an integral part of this Consolidated Statement of Financial Position.



**Consolidated Statement of Cash Flow
For the 6 months to 30 June 2013**

	Notes	6 months to 30 June 2013 Unaudited £000	6 months to 30 June 2012 Unaudited £000	12 months to 31 December 2012 Audited £000
Operating activities	6	(2,683)	(3,667)	(6,623)
Cash flows from investing activities				
Purchase of property, plant and equipment		(81)	(170)	(254)
Purchase of intangible assets		(10)	(20)	(23)
Inflow from treasury deposits		2,500	-	3,500
Interest received		41	129	226
		<u>2,450</u>	<u>(61)</u>	<u>3,449</u>
Cash flows from financing activities				
Discharge of finance lease liabilities		(8)	(28)	(38)
Interest payable		-	(2)	-
		<u>(8)</u>	<u>(30)</u>	<u>(38)</u>
Net change in cash and cash equivalents in the period		(241)	(3,758)	(3,212)
Cash and cash equivalents at beginning of period		<u>2,879</u>	<u>6,091</u>	<u>6,091</u>
Cash and cash equivalents at end of period		<u>2,638</u>	<u>2,333</u>	<u>2,879</u>

The accompanying notes form an integral part of this Consolidated Statement of Cash Flow.



Consolidated Statement of Changes in Equity For the 6 months to 30 June 2013

	Share Capital £000 (Note 5)	Share premium £000	Other reserve £000	Retained loss £000	Total equity £000
<u>Year ended 31 December 2012 - Audited</u>					
Balance as at 31 December 2011	368	38,258	2,343	(29,309)	11,660
Loss for the year ended 31 December 2012	-	-	-	(7,349)	(7,349)
Total comprehensive income for the year ended 31 December 2012	-	-	-	(7,349)	(7,349)
Employee share-based compensation	-	-	527	-	527
Transactions with owners	-	-	527	-	527
Balance as at 31 December 2012	368	38,258	2,870	(36,658)	4,838
<u>6 months ended 30 June 2013 - Unaudited</u>					
Total comprehensive income for the 6 months ended 30 June 2013	-	-	-	(2,857)	(2,857)
Employee share-based compensation	-	-	19	-	19
Transactions with owners	-	-	19	-	19
Balance as at 30 June 2013	368	38,258	2,889	(39,515)	2,000
<u>6 months ended 30 June 2012 - Unaudited</u>					
Balance as at 31 December 2011	368	38,258	2,343	(29,309)	11,660
Total comprehensive income for the 6 months ended 30 June 2012	-	-	-	(4,235)	(4,235)
Employee share-based compensation	-	-	260	-	260
Transactions with owners	-	-	260	-	260
Balance as at 30 June 2012	368	38,258	2,603	(33,544)	(7,685)

The accompanying notes form an integral part of this Consolidated Statement of Changes in Equity.



Notes to the interim financial statements

1. Nature of financial information

These half year financial statements, which were approved by the Board on 18 September 2013, are unaudited and do not constitute statutory accounts as defined in section 434 of the Companies Act 2006.

The financial statements have been prepared under the historical cost convention and in accordance with the recognition and measurement principles of International Financial Reporting Standards (“IFRS”) as adopted by the European Union. These interim financial statements do not contain all the information required for full annual financial statements and should be read in conjunction with the consolidated financial statements of the Group for the year ended 31 December 2012.

Statutory accounts for the Group and the Company for the year ended 31 December 2012, which contain an unqualified audit report from Grant Thornton UK LLP, have been delivered to the Registrar of Companies and did not contain statements under section 498(2) or section 498(3) of the Companies Act 2006. The comparative financial information for that period has been extracted without adjustment from such accounts.

The comparative information for the six months ended 30 June 2012 is unaudited.

2. Significant accounting estimates and judgements

Share options and warrants

Share options are granted over a discretionary period and vest in tranches over a three-year period. The fair value of options is determined using the Black-Scholes valuation model, which requires a number of estimates and assumptions. The significant inputs into the model are the share price at the date of grant, the exercise price, the expected option life, the expected volatility and the risk-free interest rate.

Deferred tax asset

The Board uses its judgement in the assessment of the extent, if any, to which to recognise the deferred tax asset, based on the forecast trading performance and the expected use of trading losses.



Research and development expenditure

The Board uses its judgement in the assessment of the extent, if any, to which expenditure is identified as development expenditure rather than research expenditure. Development expenditure has not been capitalised as regulatory and other uncertainties relating to the current stage of the Group's development projects mean that all the criteria for capitalisation of development expenditure as required by International Financial Reporting Standards have not been met.

3. Principal accounting policies

The accounting policies for the six months ended 30 June 2013 are unchanged from those set out in the financial statements for the year ended 31 December 2012.

The financial statements consolidate the financial statements of Sphere Medical Holding plc and its subsidiary undertaking Sphere Medical Limited.

4. Loss per share

Fully diluted loss per share is calculated after showing the effect of outstanding options in issue. As the effect of the options would be to reduce the loss per share, the diluted loss per share is the same as the undiluted loss per share.

Calculation of loss per share is based on the following loss and numbers of shares:

	6 months to 30 June 2013 Unaudited £000	6 months to 30 June 2012 Unaudited £000	12 months to 31 December 2012 Audited £000
Loss attributable to equity holders in the Company	(2,857)	(4,235)	(7,349)
Weighted average number of equity shares in issue:	Number (‘000)	Number (‘000)	Number (‘000)
For basic loss per share	36,806	36,806	36,806



5. Share capital

	30 June 2013 Unaudited	30 June 2012 Unaudited	31 December 2012 Audited
	Number	Number	Number
Issued and fully paid			
Ordinary shares of £0.01	<u>36,805,644</u>	<u>36,805,644</u>	<u>36,805,644</u>
	£	£	£
Nominal value			
Ordinary shares of £0.01	<u>368,057</u>	<u>368,057</u>	<u>368,057</u>

Share issue

No issues of shares were made during the period of 6 months to 30 June 2013.

Share options

Share options are awarded to all Directors and permanent employees who have completed their probationary period at the time of the Remuneration Committee's review which is held at least annually. The options generally vest in three tranches based on time since grant.



At 30 June 2013 the Company had outstanding options over ordinary shares as follows:

Date granted	Exercise price per ordinary share	Number of shares at 31 December 2012	Granted during the 6 months to 30 June 2013	Exercised during the 6 months to 30 June 2013	Lapsed during the 6 months to 30 June 2013	Number of shares at 30 June 2013	Scheme	Life of option and vesting period	Estimated fair value per share (see below)
22 July 2004	£0.1325	311,330	-	-	-	311,330	EMI	(1)	£0.060
20 Dec 2005	£1.25	40,000	-	-	-	40,000	EMI	(2)	£0.563
20 Dec 2005	£1.25	100,470	-	-	-	100,470	Unapproved	(3)	£0.563
1 Feb 2006	£1.25	86,110	-	-	-	86,110	EMI	(4)	£0.563
13 Nov 2006	£1.55	304,830	-	-	(10,000)	294,830	EMI & unapproved	(5)	£0.698
15 May 2007	£1.55	10,000	-	-	-	10,000	EMI	(6)	£0.730
11 Dec 2007	£1.55	10,000	-	-	(10,000)	-	EMI	(7)	£0.730
9 Dec 2008	£1.70	11,250	-	-	(5,000)	6,250	EMI & unapproved	(8)	£0.702
13 Jan 2009	£1.70	158,257	-	-	-	158,257	EMI & unapproved	(9)	£0.699
26 Oct 2011	£0.925	18,245	-	-	-	18,245	EMI & unapproved	(10)	£0.382
31 Oct 2011	£0.925	1,619,448	-	-	-	1,619,448	EMI & unapproved	(10)	£0.382
18 May 2012	£0.925	70,000	-	-	-	70,000	Unapproved	(10)	£0.334
18 May 2012	£1.25	350,000	-	-	(350,000)	-	Unapproved	(11)	£0.2734
1 Jun 2012	£0.925	697,410	-	-	(51,250)	646,160	EMI	(10)	£0.334
Total		3,787,350	-	-	(426,250)	3,361,100			

- (1) Fully vested. Expiry 21 July 2014.
- (2) Fully vested. Expiry 19 December 2015.
- (3) Fully vested. Expiry 5 May 2015.
- (4) Fully vested. Expiry 31 January 2016.
- (5) Fully vested. Expiry 12 November 2016.
- (6) Fully vested. Expiry 14 May 2017.
- (7) Fully vested. Expiry 10 December 2017.
- (8) Fully vested. Expiry 8 December 2018.
- (9) Fully vested. Expiry 12 January 2019.
- (10) Vesting 50% after one year, 25% after two years and the remaining 25% after three years of grant.
- (11) Vesting 100% were conditional upon the Company signing a commercial agreement relating to Proxima. The percentage of share options which vested reduced over time until 31 March 2013 at which point they lapsed.

The expense arising from share options in the period was £19,000 (full year to 31 Dec 2012 - £527,000).



6. Reconciliation of operating loss to operating cash flows

	6 months to 30 June 2013	6 months to 30 June 2012	12 months to 31 December 2012
	£000 Unaudited	£000 Unaudited	£000 Audited
Operating activities – loss for the period before interest and tax	(2,913)	(4,388)	(8,024)
Depreciation	74	56	117
Amortisation	7	3	10
Share-based payments	19	260	527
(Increase)/decrease in inventory	(21)	(13)	(54)
(Decrease)/(increase) in trade and other receivables	3	18	110
Increase in trade and other payables	148	397	281
Taxes received	-	-	410
	<u>(2,683)</u>	<u>(3,667)</u>	<u>(6,623)</u>

Tax credit received in the period £nil (2012 - £410k). This is due to timing of the receipt of the research and development tax credit refund.

Further Copies

Copies of this announcement and, on finalisation, the interim report will be available, free of charge, for a period of one month from the Company's Nominated Adviser and Broker, Peel Hunt LLP, Moor House, 120 London Wall, London EC2Y 5ET, Tel: 020 7418 8900 or from Sphere Medical Holding plc, Harston Mill, Harston Cambridgeshire CB22 7GG, Tel: 01223 875222. Copies of the interim report will be made available to shareholders in due course.