SPHERE

Interim Report 2016

Raising the standard of critical care

We have a clear vision for the future of real-time diagnostic care

At a glance

Sphere Medical is a UK-based medical device company developing and commercialising a range of innovative monitoring and diagnostic devices designed to significantly improve patient care.

Sphere Medical's vision is to become a leading solution provider to the critical care market offering innovative, near real-time point of care diagnostic and monitoring products to enable closer control of therapeutic response, improve patient outcomes and reduce the overall cost of care.

Sphere Medical has launched Proxima™ 3 in Europe and commenced marketing in the UK, Germany, The Netherlands and Belgium. Proxima 4, the next generation of the product, is expected to be launched very soon. Sphere Medical is in the process of appointing distributors for Proxima in other key European markets, with Burke and Burke already appointed for Italy.

Online
www.spheremedical.com

Highlights

Operational Highlights

- ☐ Commercial sales of Proxima 3 in Germany and Belgium
- ☐ Increasing Proxima usage, with patient connections up 52% on H2 2015
- ☐ Proxima 4 CE marking well advanced
  - – CE marking completed for three of the four components
- ☐ Proxima 4 commercial launch preparations underway
- ☐ Exclusive distributor appointed for Proxima 4 in Italy
- ☐ University Hospital Southampton time and motion study demonstrates statistically significant workflow benefits of using Proxima
- ☐ Improved connectivity between Proxima and hospital data management systems
- ☐ New production facility opened in Wales and product manufacture commenced

Financial Highlights

- ☐ Continuing tight financial control with operating expenses below budget
  - – Total operating expenses £3.7 million before capitalisation (H1 2015: £3.5 million)
- ☐ Increased confidence in commercial viability of Proxima
  - – Product development costs capitalised £1.1 million (H1 2015: £nil)
- ☐ Loss before taxation £2.6 million (H1 2015: £3.5 million)
- ☐ Research and Development tax credit of £0.6 million received (H1 2015: £nil)
- ☐ Cash and cash equivalents of £6.6 million (2015: £12.8 million) at 30 June 2016

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On track to deliver strategic goals

Sphere Medical's strategy is focused on commercialising the Proxima platform for measuring blood gases, electrolytes and metabolites. The Company is already marketing its Proxima product directly to the critical care market, which includes intensive care units and operating theatres, with a small dedicated field sales force in the UK, Germany, The Netherlands and Belgium. Sphere Medical has also appointed Burke and Burke as its exclusive distributor of Proxima in Italy. The Company also plans to work with other partners to distribute Proxima, firstly, in other key markets in Europe and then worldwide.

Strategic goals:

	Objective	Progress
+ 1.0	Obtain CE mark for Proxima 4 in 2016	*On track. Three of four components CE marked so far*
+ 2.0	Launch Proxima 4 across Europe in 2016	*On track*
+ 3.0	Find commercialisation partners to distribute Proxima in the major markets around the world	*Burke and Burke appointed in Italy*
+ 4.0	Add lactate to the Proxima panel in 2017	*On track*
+ 5.0	Register Proxima in the US	*Investigation of registration route underway*

Poised to launch Proxima 4

Introduction

The commercialisation of our Proxima platform is advancing well. We are now close to completing the CE-marking process, having received CE marks for three of the four components, and are preparing for the commercial launch of Proxima 4. This new generation of the product is a major advancement for the sales potential of the platform and incorporates additional analytes of glucose and sodium, plus it brings a number of important usability improvements, as well as enhanced connectivity.

Proxima 3 was launched primarily to obtain market feedback and there has been a good level of interest expressed in Proxima by clinicians, with more evaluations completed and increasing usage on patients.

Expanding geographic reach is a key part of our strategy for commercialising Proxima. In July 2016 we were very pleased to appoint Burke and Burke as exclusive distributor for Italy, and look forward to appointing more regional distributors in other key markets in Europe over the coming months.

Sales

Sphere Medical has a dedicated sales force in the UK, Germany, The Netherlands and Belgium focusing initially on obtaining direct feedback from the market on Proxima 3. With the launch of Proxima 4 approaching, we are entering a phase of increasing our commercial footprint by adding regional distributors.

Following on from the first commercial sale of Proxima in the UK in 2015, in January 2016 we achieved the first commercial sale in Germany, and in August 2016 this was followed by a first sale in Belgium.

Interest in Proxima continues to grow, with more hospitals evaluating Proxima in the first six months of 2016 than in the same period in 2015, and the number of patients being connected to the product increasing by 52% over the second half of 2015. To date Proxima has been connected to around 150 patients. Our marketing and sales activities have led to a healthy pipeline for Proxima 4, with a large proportion of hospitals that have evaluated Proxima 3 indicating an interest in the enhanced Proxima 4 product.

Development

Proxima 4 is Sphere Medical's next generation of patient-attached blood gas analyser. The sensor panel has been expanded to include glucose and sodium. This will significantly expand the list of conditions for which monitoring with Proxima is best suited, expanding the market opportunity for its application. In addition, there are a number of important usability improvements. Connectivity has also been improved, with connectivity now available between Proxima and Conworx and CliniSys data management systems. These systems are used extensively in European hospitals and beyond, and this improvement will enable the seamless transfer of test results from Proxima into patient records and laboratory information systems. We believe Proxima 4 will increase the addressable market fourfold compared to Proxima 3.

Proxima 4 is a major step forward in the product evolution. We have a strong development pipeline focusing on adding further workflow improvements and lactate as the next step. As with glucose and sodium, adding lactate will further expand the range of conditions for which Proxima is best suited.

Distribution Strategy

We recognise that the quickest and most economical way of achieving a rapid roll-out of Proxima into major markets around the world is to establish partnering arrangements. Our strategy is to put in place distributors for the key European markets first while keeping a direct sales presence for continued market feedback, and then expand into other major markets as we complete registration in those territories.

In July 2016, we were pleased to appoint our first European distributor, Burke and Burke, in Italy. Burke and Burke has considerable experience in point of care devices and already markets a number of medical devices, including complex ventilation devices and anaesthesia monitoring devices, to critical care units in hospitals throughout Italy. Under the terms of the distribution agreement, Burke and Burke will commence marketing of Proxima 4 as soon as it is launched and will place an initial order for Proxima 4 monitors and consumables.

Over the coming months, we will aim to put in place distributors for other key European markets. In the longer term, we plan to distribute Proxima in major markets around the world. We have initiated a project to look at the regulatory options for registering in the US.

Time and Motion Study

In conjunction with University Hospital Southampton, we have conducted a time and motion study to investigate the workflow impacts of Proxima in a highly optimised cardiac intensive care unit. Results were presented at the British Association of Critical Care Nurses annual conference earlier this month. The study involved 20 patients and showed a statistically significant reduction in total time taken to deliver results to the bedside by using Proxima, compared with the existing standard process in a highly optimised, well equipped cardiac ICU involving near-patient benchtop blood gas analysers. This confirms the significant workflow benefits from using Proxima on unstable patients requiring frequent blood gas measurements.

Production

Our production facility in St Asaph, North Wales, opened in February 2016 and has already commenced production of Proxima components within a very short space of time. Over the next 12 to 18 months the Company plans to gradually transfer more elements of the production process from its site at Harston, Cambridge to St Asaph. Over the next couple of years, we plan to substantially lower the cost of goods.

Intellectual Property

Work continues to maintain and strengthen the Company's intellectual property portfolio. The Proxima trademark is now registered across the EU and we have over 20 patents granted or in-application.

Financial Review

Operating expenses were £3.7 million (H1 2015: £3.5 million) before capitalisation. Reflecting the commercialisation stage of Proxima, sales and marketing expenses increased from £0.5 million in H1 2015 to £0.7 million in H1 2016 and production overheads increased over the same period by £50,000 to £0.7 million. Administrative expenses remained stable at £1.0 million. Product development costs of £0.1 million (H1 2015: £1.2 million) were expensed in the period and £1.1 million (2015 H1: £nil) of product development costs were capitalised, reflecting increased confidence in the commercial viability of Proxima.

The loss for the period was £2.6 million (H1 2015: £3.5 million). The basic and fully diluted loss per share for the period was 1.4 pence (H1 2015: 4.0 pence).

The net cash outflow from operating and investing activities in the period was £3.3 million, in line with H1 2015. This was after the receipt of a research and development tax credit of £0.6 million (H1 2015: £nil). Net cash and cash equivalents at 30 June 2016 was £6.6 million (30 June 2015: £12.8 million).

The Team at Sphere Medical

Sphere Medical continues to benefit from the hard work and expertise of its employees who, with the Board, are fully committed to making Sphere Medical 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 our shareholders for their ongoing support of Sphere Medical.

Outlook

With the Company now close to completing the CE-marking process and launch of Proxima 4, it is at an exciting stage of its transition into a commercial organisation centred on serving its customers, generating growing revenues and moving towards the goals of substantial cash generation and profitability. We will be focused on growing revenues as quickly as possible once Proxima 4 is launched. The coming months will also bring discussions with more potential distribution partners to increase the geographic reach of Proxima. We look forward to continuing the development of Sphere Medical into a commercially successful company.

Dr Wolfgang Rencken
Chief Executive Officer

Consolidated Statement of Comprehensive Income

for the six months to 30 June 2016

	Notes	**6 months to 30 June 2016 £000 Unaudited**	6 months to 30 June 2015 £000 Unaudited	12 months to 31 December 2015 £000 Audited
Revenue		**6**	10	15
Cost of sales		**(3)**	–	(2)
Gross profit		**3**	10	13
Product development		**(117)**	(1,174)	(1,328)
Quality and regulatory expenses		**(175)**	(177)	(347)
Production overheads		**(670)**	(620)	(1,279)
Selling and marketing expenses		**(681)**	(508)	(978)
Administrative expenses		**(1,003)**	(1,016)	(2,194)
Operating expenses (net)		**(2,646)**	(3,495)	(6,126)
Operating loss		**(2,643)**	(3,485)	(6,113)
Finance income		**45**	19	91
Finance costs		**–**	–	–
Loss before taxation		**(2,598)**	(3,466)	(6,022)
Tax credit		**556**	–	557
Loss and total comprehensive income for the period attributable to the equity holders of the parent		**(2,042)**	(3,466)	(5,465)
Loss per share attributable to the equity holders of the parent				
Basic and diluted	4	**(1.4p)**	(4.0p)	(4.8p)

Total comprehensive income equates to the loss for the period reported above.

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 2016

	Notes	**30 June 2016 £000 Unaudited**	30 June 2015 £000 Unaudited	31 December 2015 £000 Audited
ASSETS				
Non-current assets				
Property, plant and equipment		**214**	101	103
Intangible assets		**2,030**	13	896
		2,244	114	999
Current assets				
Inventories		**433**	275	384
Trade and other receivables		**150**	182	127
Cash and cash equivalents		**6,637**	12,751	10,028
Total assets		**9,464**	13,322	11,538
EQUITY				
Called up share capital	5	**1,418**	1,418	1,418
Share premium account		**58,031**	58,102	58,102
Other reserve		**2,803**	2,835	2,786
Profit and loss account		**(53,611)**	(49,845)	(51,693)
Equity shareholders' funds		**8,641**	12,510	10,613
LIABILITIES				
Current liabilities				
Trade and other payables		**823**	812	925
Total liabilities		**823**	812	925
Total equity and liabilities		**9,464**	13,322	11,538

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

Consolidated Statement of Cash Flow

for the six months to 30 June 2016

	Notes	**6 months to 30 June 2016 £000 Unaudited**	6 months to 30 June 2015 £000 Unaudited	12 months to 31 December 2015 £000 Audited
Operating activities	6	**(2,069)**	(3,253)	(5,117)
Cash flows from investing activities				
Purchase of property, plant and equipment		**(157)**	(57)	(101)
Purchase of intangible assets		**(1,139)**	(7)	(892)
Interest received		**45**	19	91
		(1,251)	(45)	(902)
Cash flows from financing activities				
Issue of share capital		**–**	13,176	13,176
Issue expenses		**(71)**	(830)	(830)
(Discharge) of finance lease liabilities		**–**	–	(2)
		(71)	12,346	12,344
Net change in cash and cash equivalents in the period		**(3,391)**	9,048	6,325
Cash and cash equivalents at beginning of period		**10,028**	3,703	3,703
Cash and cash equivalents at end of period		**6,637**	12,751	10,028

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

Consolidated Statement of Changes in Equity
for the six months to 30 June 2016

	Share capital (Note 5) £000	Share premium £000	Other reserve £000	Retained loss £000	Total equity £000
12 months ended 31 December 2015 – Audited					
Balance as at 31 December 2014	594	46,580	2,933	(46,503)	3,604
Loss for the year ended 31 December 2015	–	–	–	(5,465)	(5,465)
Total comprehensive income for the year ended 31 December 2015	–	–	–	(5,465)	(5,465)
Employee share-based compensation	–	–	128	–	128
Issue expenses	–	(830)	–	–	(830)
Issue of share capital	824	12,352	–	–	13,176
Reclassification following lapse of options	–	–	(275)	275	–
Transactions with owners	824	11,522	(147)	275	12,474
Balance as at 31 December 2015	**1,418**	**58,102**	**2,786**	**(51,693)**	**10,613**
Six months ended 30 June 2016 – Unaudited					
Total comprehensive income for the six months ended 30 June 2016	–	–	–	(2,042)	(2,042)
Issue of share capital	–	–	–	–	–
Issue expenses	–	(71)	–	–	(71)
Employee share-based compensation	–	–	141	–	141
Reclassification following lapse of options	–	–	(124)	124	–
Transactions with owners	–	(71)	17	(1,918)	(1,972)
Balance as at 30 June 2016	**1,418**	**58,031**	**2,803**	**(53,611)**	**8,641**

	Share capital (Note 5) £000	Share premium £000	Other reserve £000	Retained loss £000	Total equity £000
Six months ended 30 June 2015 – Unaudited					
Balance as at 31 December 2014	594	46,580	2,933	(46,503)	3,604
Total comprehensive income for the six months ended 30 June 2015	–	–	–	(3,466)	(3,466)
Issue of share capital	824	12,352	–	–	13,176
Issue expenses		(830)			(830)
Employee share-based compensation	–	–	26	–	26
Reclassification following lapse of options	–	–	(124)	124	–
Transactions with owners	824	11,522	(98)	124	12,372
Balance as at 30 June 2015	**1,418**	**58,102**	**2,835**	**(49,845)**	**12,510**

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

1. Nature of financial information

These half-year financial statements, which were approved by the Board on 21 September 2016, 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 (IFRSs) 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 as at the year ended 31 December 2015.

Statutory accounts for the Group and the Company for the year ended 31 December 2015, 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 from such accounts.

The comparative information for the six months ended 30 June 2015 has been extracted from the unaudited management accounts and is correspondingly shown as unaudited.

Going concern

At 30 June 2016 the cash balance available to the Group was £6.6 million and the net cash outflow from operating activities and investing activities in the six months ended 30 June 2016 was £3.3 million.

The Group's revenues from sales of products are not expected to be sufficient for the Group to become cash generative from commercial operations over the next 12 months. The Board's confidence that the development and commercialisation of the Group's principal product, Proxima, will prove to be successful has been increased by the positive feedback Proxima has received in the market, including its first sales, and by the good progress that has been made towards launching Proxima 4 in Europe.

The Group may need to raise additional finance before it becomes cash generative. The Group has a good track record of being able to raise additional finance when it has needed to do so. The Board of Directors has concluded that the combination of these circumstances represents a material uncertainty which may cast significant doubt about the Group's ability to continue as a going concern and, therefore, that it may be unable to realise its assets and discharge its liabilities in the normal course of business.

Nevertheless, based on the £6.6 million of cash and cash equivalents as at 30 June 2016, the 2016 budget approved by the Board of Directors, the business plan for the next several years and the Company's track record in raising additional finance, the Board of Directors continues to believe it is appropriate to adopt the going concern basis of accounting in preparing these financial statements.

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. Key to this judgement is assessing whether or not the asset will generate probable future economic benefits and determining that the Group has adequate technical, financial and other resources to complete the development. Having launched Proxima 3 and achieved the first commercial sale the Directors reassessed the technical and commercial feasibility of the Proxima system and decided that the conditions for capitalising development costs had been met.

3. Principal accounting policies

The accounting policies for the six months ended 30 June 2016 are unchanged from those set out in the financial statements for the year ended 31 December 2015.

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 2016 £000 Unaudited	6 months to 30 June 2015 £000 Unaudited	12 months to 31 December 2015 £000 Audited
Loss attributable to equity holders in the Company	**(2,042)**	(3,466)	(5,465)
	Number (000)	Number (000)	Number (000)
Weighted average number of equity shares in issue: For basic loss per share	**141,758**	86,704	114,457

5. Share capital

Number of shares	6 months to 30 June 2016 Unaudited Start of period	6 months to 30 June 2016 Unaudited End of period	6 months to 30 June 2015 Unaudited Start of period	6 months to 30 June 2015 Unaudited End of period	12 months to 31 December 2015 Audited Start of period	12 months to 31 December 2015 Audited End of period
Issued and fully paid						
Ordinary Shares of £0.01	**141,757,872**	**141,757,872**	59,405,290	141,757,872	59,405,290	141,757,872
Nominal value						
Ordinary Shares of £0.01	**1,417,579**	**1,417,579**	594,052	1,417,579	594,052	1,417,579

6. Reconciliation of operating loss to operating cash flows

	6 months to 30 June 2016 £000 Unaudited	6 months to 30 June 2015 £000 Unaudited	12 months to 31 December 2015 £000 Audited
Operating activities – loss for the period before interest and tax	**(2,643)**	(3,485)	(6,113)
Depreciation included in expenses	**45**	64	106
Amortisation included in expenses	**6**	6	8
Share-based payments	**141**	26	128
Change in inventory	**(49)**	(60)	(169)
Change in trade and other receivables	**(23)**	22	77
Change in trade and other payables	**(102)**	174	289
Taxes received	**556**	–	557
	(2,069)	(3,253)	(5,117)

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