28 February 2017

Sphere Medical Holding plc
("Sphere Medical" or "Sphere" or the "Company")

Results for the year ended 31 December 2016

Sphere Medical Holding plc (AIM: SPHR.L), an innovative point-of-care monitoring and diagnostic devices company, announces its results for the year ended 31 December 2016.

Business highlights for 2016 and post year-end

- Successful commercial launch of Proxima 4 in mid-December 2016 in Europe with encouraging early market reaction
  - First sales of Proxima 4 achieved
  - Over 20 hospitals have requested evaluations of Proxima 4
  - 4 hospitals have monitored patients with Proxima 4
  - First paediatric patients monitored
- Key Proxima 4 milestones met:
  - CE mark certification completed
  - Distribution partners appointed in Italy and Spain
- >20% reduction in time to results demonstrated by University Hospital Southampton clinical study
- Improved connectivity between Proxima and hospital data management systems
- New production facilities established and operational in Wales

Financial summary

- Reduced loss after taxation £4.5 million (2015: £5.5 million)
  - Reduced loss per share 3.2 pence (2015: 4.8 pence)
- Operating expenses contained below budget
  - Total operating expenses reduced to £5.1 million (2015: £6.1 million)
  - Product development costs capitalised £2.1 million (2015: £0.9 million)
- Revenue doubled to £30,000 (2015: £15,000)
- R&D tax credit received £0.6 million (2015: £0.6 million)
- Cash and short-term investments at year end of £3.2 million (2015: £10.0 million)
- Additional £3.0 million loan facility secured post year end
  - £1.5 million cash drawn in January 2017
  - £1.5 million conditionally available to draw until March 2018

Commenting on today's announcement, Dr Wolfgang Rencken, Chief Executive Officer of Sphere Medical, said: "We are pleased to have launched Proxima 4 and are very encouraged by the early market reaction to it. As we build a growing customer base, who routinely use Proxima, more patients will be able to benefit from being managed with the system. We continue to advance distributor negotiations to expand Proxima 4's commercial launch with the aim to make it available to a wider patient population across Europe."

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Notes for Editors

About Sphere Medical (AIM: SPHR.L)

Sphere Medical is an innovative point-of-care medical device company. Its Proxima platform measures blood gases, electrolytes and metabolites at the patient's bedside and aims to improve patient care and reduce health system costs. The device is currently sold directly to the critical care market via Sphere Medical's sales force in the UK, Germany, The Netherlands and Belgium and via distributors in Italy and Spain.

For further information, please visit www.spheremedical.com

Strategic Report

INTRODUCTION

A number of significant milestones were achieved with Proxima 4 in 2016. We received CE mark certification in September and, in December, launched Proxima 4 in Europe, enabling us to commence marketing the product directly in the UK, Germany, Belgium and The Netherlands, and in Italy and Spain via our distribution partners. In 2017, we are now focussing our efforts on marketing Proxima 4, generating sales and building a regular customer base. Market reaction to Proxima 4 has been encouraging, building on the interest established with Proxima 3. As well as the key addition of glucose to the analyte panel, other changes such as a quicker set up and expansion of the patient pool to include children, have been very well received. Importantly, these changes increase the addressable market 4x to around £130m in Europe. Four hospitals have monitored patients using Proxima 4 and sales have already been made in the UK and to our newly appointed Italian distributor.

COMMERCIALISATION STRATEGY

Sphere Medical's strategy is focussed on leveraging the Proxima platform. Proxima 3 was the first generation approved for human use and has been in the market for two years. This has enabled us to gain market intelligence, which was successfully incorporated into Proxima 4. Proxima is the only commercially available patient-attached microanalyser device worldwide with the ability to monitor 13 key parameters. This product update incorporates a number of improvements that were based on feedback from clinicians on Proxima 3 and is now applicable to around 40% of critical care patients.

Looking further ahead, we plan to increase the applicable market for the Proxima platform by adding additional analytes, improving usability and expanding its use to neonatal patients. We also plan to launch Proxima in other major markets, such as the USA and Japan, in the next few years.

SALES PROGRESS

One of the main aims of launching Proxima 3 was to secure feedback on the product and to learn about the sales process and any potential barriers to adoption. Through 2016 hospitals continued to evaluate Proxima 3. Over 80 patient connections were made in the year, more than in the previous year. The feedback received has been very helpful in shaping the development of Proxima 4 so that we can convert more hospitals into regular users of the system.

By adding glucose to the analyte panel in Proxima 4 the addressable market is expanded fourfold from around 10% to around 40% of critical care patients. It is expected that this will increase adoption. In addition there are a number of other improvements to the system, including simpler and faster set-up and improved connectivity with hospital data systems.

In the first few weeks since Proxima 4 launched we have experienced increasing traction. Over 20 hospitals have requested evaluations of Proxima 4, including some paediatric centres which were unable to use Proxima 3 due to restrictions on adult-only use. We believe sales traction will continue to accelerate through 2017.

We have established a direct sales presence in the UK, Germany, The Netherlands and Belgium. Having a direct sales presence has been valuable in enabling us to receive feedback direct from customers.

An important component of building the revenue from Proxima is increasing its geographic presence. The most economical way of doing this beyond our direct markets is through distributors who have access to the appropriate customers. We have appointed Burke and Burke in Italy and Prhoinsa in Spain as regional distributors of Proxima. Both of these distributors are well placed within their markets to sell Proxima. Burke and Burke received their first Proxima 4 shipment in December 2016, as soon as Proxima 4 was launched. Prhoinsa will get underway in the second quarter of 2017. We are in discussions with distributors in other European markets and are targeting a sales presence in 60% of the European Union by the end of 2017.

PRODUCT DEVELOPMENT

As well as the addition of glucose to the panel of analytes, Proxima is now suitable for use with children weighing 15kg and over. Together these changes expand the addressable market fourfold to around £130m in Europe.

Proxima also has improved connectivity to hospital information systems, an important issue for many hospitals. Connectivity is now available between Proxima and Conworx and Clinisys data management systems, which are used extensively in European hospitals and beyond. This enables the seamless transfer of test results from Proxima into patient records and laboratory information systems. We are also working on connectivity to other leading hospital data management systems and expect to introduce this over the coming months.

A number of improvements in the user experience have also been introduced in Proxima 4, with more in development. The system set up process has been simplified and the time required to complete the set up significantly reduced. We are also currently developing a software update that will allow results to be presented graphically as a trend, rather than just at one point in time. This enhancement will bring added value and provide a further point of difference between Proxima and traditional blood gas analysers. Another piece of feedback on Proxima 3 was a request for some scheduling functionality to remind users when the next reading is due to be taken. It is intended to incorporate this in the next software update.

Beyond Proxima 4, the plan is to add lactate and make more improvements in the functionality and usability of the system, including automating the set up process, and in time adapt the system for use with neonates.

TIME AND MOTION STUDY

In conjunction with University Hospital Southampton, we have conducted a time and motion study to examine the workflow impacts of Proxima. Results were presented at the British Association of Critical Care Nurses annual conference in September 2016. The study involved 20 patients and showed a statistically significant reduction of over 20% in total time taken to deliver results to the bedside by comparing Proxima with the existing standard process in a highly optimised, well equipped cardiac ICU involving near-patient benchtop blood gas analysers.

The results of this study confirmed the significant workflow benefits from using Proxima on unstable patients requiring frequent blood gas measurements.

PRODUCTION

In preparation for increased demand for Proxima, we have been expanding our manufacturing capability. In February 2016, we opened our new manufacturing facility in St Asaph, north Wales, which should give us adequate capacity to meet our manufacturing needs for the next few years. Production of Proxima components at St Asaph has commenced on plan and we are in the process of a phased transfer of more elements of the manufacturing process from our site at Harston, Cambridge to St Asaph.

INTELLECTUAL PROPERTY

Our intellectual property portfolio is a key asset and we continue to invest in the maintenance and development of our IP estate. We have a variety of patents registered or applied for over the past two decades, with a range of expiry dates up to 2033. We currently have 20 patents either granted or in application, covering chip and sensor design and manufacture, design of analytical systems, methods for chemical assay and methods for sensor calibration. We have an ongoing process of reviewing the patent register in order to focus our financial support on our core patent families and any new intellectual property.

KEY PERFORMANCE INDICATORS

The Group measures its performance according to a wide range of key performance indicators, which during 2016 were as below. A set of similarly challenging measures has been defined for 2017.

Key Performance Indicator	*Comment*
Development milestones	• Proxima 4 received CE mark certification • A number of minor updates to Proxima 3 were developed and rolled out during the year
Revenue indicators and lead indicators	• First Proxima 3 sales achieved in Germany and Belgium • First Proxima 4 sales achieved • A growing number of leads being generated and hospital evaluations being undertaken • Proxima 3 patient connections up to more than 170
Production	• Throughout the period we have maintained a sufficient supply of product
Management of cash resources	• The Group's cash and short-term investments totalled £3.2 million at 31 December 2016, better than budget. • A £3 million loan facility was put in place in January 2017, from which a £1.5 million loan has been drawn.

FINANCIAL REVIEW

Revenue for the year ended 31 December 2016 was £30,000 (2015: £15,000).

Operating expenses before amortisation were £5.1 million (2015: £6.1 million). Selling and marketing expenses increased from £1.0 million to £1.3 million, and production overheads increased from £1.3 million to £1.4 million reflecting the move towards commercialisation of Proxima. Administration costs reduced from £2.2 million to £1.7 million. £0.7 million (2015: £1.7

million) of product development costs were expensed in the period and £2.1 million (2015: £0.9 million) of product development costs were capitalised.

Net finance income was £72,000 (2015: £91,000), primarily representing interest earned on cash deposits.

During the year, £0.6 million was received in respect of research and development tax claims for 2015 (2015: £0.6 million based on 2014 claims). No accrual has been made for any research and development tax claim for the 2016 year.

The post-tax loss for the year was £4.5 million (2015: £5.5 million). The basic and fully diluted loss per share for the year was 3.2 pence (2015: 4.8 pence). The number of ordinary shares in issue was unchanged throught the year at 141.8 million.

Cash and short-term investments as at the end of the year were £3.2 million (2015: £10.0 million). In January 2017 a £3.0 million loan facility was put in place and an initial £1.5 million loan was drawn. A further £1.5 million loan is conditionally available until March 2018. The loans are repayable by 2020. The Company is exploring the best financing options to support its working capital requirements through the on-going commercialisation of Proxima.

THE TEAM AT SPHERE MEDICAL

There were no changes to the Board during 2016 or subsequently.

The Group continues to be supported by a very strong Medical Advisory Board (MAB), which comprises leading critical care clinicians from across Europe. In January 2016 Dr Michael Grocott joined the MAB. Professor Grocott is the Professor of Anaesthesia and Critical Care Medicine at the University of Southampton (UoS) and heads the UoS Centre for Human Integrative Physiology. His research interests include human responses to hypoxia, measuring and improving outcome following surgery, lung injury, and fluid therapy.

Sphere Medical continues to benefit from the hard work and expertise of its employees who, with the Board, are fully committed to the success of Proxima. The Board would like to take this opportunity to thank all our employees for their continued commitment.

OUTLOOK

We are pleased to have launched Proxima 4 as planned and early market reaction is very encouraging. The Board remains committed to pursuing the further development and full commercialisation of the Proxima platform and is exploring its financing options to ensure the Company has sufficent working capital to continue this strategy and to maximise value for shareholders.

Consolidated statement of comprehensive income
for the year ended 31 December 2016

	Notes	2016 £000	2015 £000
Revenue		**30**	15
Cost of sales		**(20)**	(2)
Gross profit		**10**	13
Selling and marketing expenses		**(1,327)**	(978)
Production overheads		**(1,392)**	(1,279)
Product development		**(727)**	(1,675)
Administrative expenses		**(1,705)**	(2,194)
Operating expenses (net)		**(5,151)**	(6,126)
Operating loss		**(5,141)**	(6,113)
Finance income		**72**	91
Loss before taxation		**(5,069)**	(6,022)
Tax credit		**556**	557
Loss and total comprehensive income for the period attributable to the equity holders of the parent		**(4,513)**	(5,465)
Loss per share attributable to the equity holders of the parent			
Basic and diluted	2	**(3.2p)**	(4.8p)

Consolidated statement of financial position
at 31 December 2016

	Notes	2016 £000	2015 £000
ASSETS			
Non-current assets			
Property, plant and equipment	3	**189**	103
Intangible assets	4	**2,928**	896
		3,117	999
Current assets			
Inventories		**427**	384
Trade and other receivables		**181**	127
Cash and cash equivalents		**3,241**	10,028
Total assets		**6,966**	11,538
EQUITY			
Called up share capital	5	**1,418**	1,418
Share premium account		**58,031**	58,102
Other reserve		**2,705**	2,786
Profit and loss account		**(55,945)**	(51,693)
Equity shareholders' funds		**6,209**	10,613
LIABILITIES			
Current liabilities			
Trade and other payables		**757**	925
Total liabilities		**757**	925
Total equity and liabilities		**6,966**	11,538

Consolidated statement of cash flow
for the year ended 31 December 2016

	Notes	2016 £000	2015 £000
Operating activities	6	**(4,521)**	(5,117)
Cash flows from investing activities			
Purchase of property, plant and equipment		**(183)**	(101)
Purchase of intangible assets		**(2,089)**	(892)
Sale of property, plant and equipment		**5**	-
Interest received		**72**	91
		(2,195)	(902)
Cash flows from financing activities			
Issue of share capital		**-**	13,176
Issue expenses		**(71)**	(830)
Discharge of finance lease liabilities		**-**	(2)
		(71)	12,344
Net change in cash and cash equivalents in the year		**(6,787)**	6,325
Cash and cash equivalents at beginning of year		**10,028**	3,703
Cash and cash equivalents at end of year		**3,241**	10,028

Consolidated statement of changes in equity
For the year ended 31 December 2016

	Share capital £000	Share premium £000	Other reserve £000	Retained loss £000	Total equity £000
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 period	**-**	**-**	**-**	**(5,465)**	**(5,465)**
Issue of share capital	**824**	**12,352**	**-**	**-**	**13,176**
Issue expenses	**-**	**(830)**	**-**	**-**	**(830)**
Employee share-based compensation	**-**	**-**	**128**	**-**	**128**
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**
Loss for the year ended 31 December 2016	**-**	**-**	**-**	**(4,513)**	**(4,513)**
Total comprehensive income for the period	**-**	**-**	**-**	**(4,513)**	**(4,513)**
Issue expenses	**-**	**(71)**	**-**	**-**	**(71)**
Employee share-based compensation	**-**	**-**	**180**	**-**	**180**
Reclassification following lapse of options	**-**	**-**	**(261)**	**261**	**-**
Transactions with owners	**-**	**(71)**	**(81)**	**261**	**109**
Balance as at 31 December 2016	**1,418**	**58,031**	**2,705**	**(55,945)**	**6,209**

Notes

1. Basis of preparation

The financial information set out in the announcement does not constitute the Group's statutory accounts for the year ended 31 December 2016 or 31 December 2015. The auditor has confirmed that the auditor's report that is required to be contained in the Annual Report and Accounts 2016 includes an unmodified opinion together with an emphasis of matter paragraph on going concern relating to the potential need to raise additional finance, as described in the Going Concern paragraph below. The statutory accounts for the year ended 31 December 2016 have not yet been delivered to the Registrar of Companies. The statutory accounts for the year ended 31 December 2015 were delivered to the Registrar of Companies as published on the Group's website on 23 March 2016.

Going concern

At 31 December 2016 the cash balance available to the Group was £3.2m while for the year the cash outflow from operating activities was £4.5m. In January 2017 the Group agreed a £3.0m loan facility with Silicon Valley Bank and drew an initial £1.5m loan.

The Board's confidence that the commercialisation of the Group's principal product, Proxima, will prove to be successful has been reinforced by the launch of Proxima 4 into the European market, and by the positive reception it has received, including the first sales and the appointment of distributors in Italy and Spain. However, the Group's revenues from sales of products are expected not to be sufficient for the Group to become cash generative from commercial operations over the next 12 months.

The Group is intending to raise additional finance and has a good track record of being able to do so 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.

Nonetheless, with £3.2m of cash as at 31 December 2016, the £1.5m additional cash funding in January 2017, a clear 2017 budget approved by the Board of Directors, a strong business plan for the next several years and the Group's track record of raising additional finance, the Board of Directors have reasonable expectation that the business will be able to continue in operation for at least 12 months from the date of approval of these financial statements. For these reasons, the Board of Directors continue to adopt the going concern basis of accounting in preparing these financial statements.

2. 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:

	2016 £000	2015 £000
Loss attributable to equity holders in the Company	**(4,513)**	(5,465)
	Number ('000)	Number ('000)
Weighted average number of equity shares in issue for basic loss per share	**141,758**	114,457
	Loss per share (pence)	Loss per share (pence)
Basic and diluted loss per share	**(3.2)**	(4.8)

Notes

3. Property, plant and equipment

Plant and equipment	2016 £000	2015 £000
Cost:		
At start of year	**1,674**	1,754
Additions	**183**	101
Disposals	**(5)**	(181)
At end of year	**1,852**	1,674
Depreciation:		
At start of year	**1,571**	1,646
Disposals	**(3)**	(181)
Provided in the year	**95**	106
At end of year	**1,663**	1,571
Net book value:		
At end of year	**189**	103
At end of previous year	**103**	108

Notes

4. Intangible assets

	Software £000	Capitalised Development £000	2016 Total £000	2015 Total £000
Cost:				
At start of year	**135**	**888**	**1,023**	131
Additions	**5**	**2,084**	**2,089**	892
At end of year	**140**	**2,972**	**3,112**	1,023
Amortisation:				
At start of year	**127**	**-**	**127**	119
Provided in the year	**10**	**47**	**57**	8
At end of year	**137**	**47**	**184**	127
Net book value:				
At end of year	**3**	**2,925**	**2,928**	896
At end of previous year	**8**	**888**	**896**	12

5. Share capital

	2016		2015	
	Start of period	**End of period**	Start of period	End of period
Issued and fully paid				
Ordinary Shares (number) of £0.01	**141,757,872**	**141,757,872**	59,208,660	141,757,872
Ordinary Shares (nominal) of £0.01	**£1,417,579**	**£1,417,579**	£592,087	£1,417,579

Share issue

No shares were issued during the period (2015: 82,352,582)

Notes

6. Reconciliation of operating loss to operating cash flows

	2016 £000	2015 £000
Operating activities – loss for the period before interest and tax	**(5,141)**	(6,113)
Depreciation	**92**	106
Amortisation	**57**	8
Share-based payments	**180**	128
Increase in inventory	**(43)**	(169)
(Increase)/decrease in trade and other receivables	**(54)**	77
(Decrease)/increase in trade and other payables	**(168)**	289
Taxes received	**556**	557
	(4,521)	(5,117)