

Xvivo Perfusion AB (PUBL) Summary January-September 2012<sup>1</sup> Gothenburg, November 1, 2012

# Strong growth – start up and work proceeding according to plan

Xvivo Perfusion can note continued strong sales growth of 22 percent during the third quarter and 23 percent for the period January to September. The setting up of Xvivo Perfusion as an independent company is proceeding according to plan and most of the one-time expenses for this have been carried. The preparations for the launch of STEEN Solution™ are in full swing − amongst other things a wholly owned subsidiary, Xvivo Perfusion Inc, with sales, storage facilities and distribution is operational. An application for marketing approval of STEEN Solution™ has been submitted to the US Food and Drug Administration, FDA. Questions have been received after the end of the period. These have already been discussed with the FDA and processed. The recruitment of patients in the American clinical study is proceeding according to plan with good clinical results. This can also be noted in the long-term follow up of the patients from the earlier clinical study in Canada.

THE FIGURES BELOW ARE FROM VITROLIFE AB'S INTERIM REPORT AND DESCRIBE THE TRANSPLANTATION BUSINESS AS IT WAS NOT YET A SEGMENT OF THIS COMPANY'S BUSINESS.

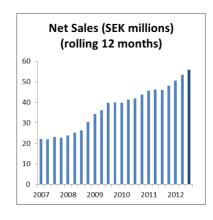
# THIRD QUARTER (JULY-SEP 2012)

- Net sales of SEK 14.4 million, growth of 22 percent compared with the corresponding period in 2011
- Selling expenses of SEK 3.5 million
- Research and development SEK 2.4 million
- Administrative expenses of SEK 7.4 million
- EBITDA SEK -1.5 million
- EBITDA excluding one-time expenses SEK 3.1 million

#### Net Sales (SEK millions) 16.0 13.7 13.8 14.0 14.0 11.3 11.2 11.8 12.0 10.0 8.0 6.0 4.0 2.0 0.0 Q1 Q2 Q3 Q4 Q1 Q2 Q3

# THE PERIOD (JAN-SEP 2012)

- Net sales of SEK 42.2 million, growth of 23 percent compared with the corresponding period in 2011
- Selling expenses of SEK 7.2 million
- Research and development SEK 6.1 million
- Administrative expenses of SEK 12.8 million
- EBITDA SEK 7.7 million
- EBITDA excluding one-time expenses SEK 13.6 million
- EBITDA margin excluding one-time expenses 32%



<sup>&</sup>lt;sup>1)</sup> All figures in this summary are extracts from Vitrolife's reporting. The summary is not an official report for the third quarter of 2012 from Xvivo Perfusion.

# IMPORTANT EVENTS DURING THE THIRD QUARTER

Application for marketing approval of STEEN Solution  $^{\text{TM}}$  in the USA submitted to the US Food and Drug Administration, FDA

# IMPORTANT EVENTS AFTER THE QUARTER

Trade in Xvivo Perfusion AB was begun on NASDAQ OMX First North on October 8. Questions from the FDA have been received and processed.

#### XVIVO IN BRIEF

Xvivo Perfusion AB ("Xvivo") is a medical technology company that develops solutions and systems for selecting usable organs and maintaining them in optimal condition pending transplantation. The company's product Perfadex® today has a market share of over 90 percent in the traditional preservation of lungs for transplantation.

A great problem in transplantation healthcare is the lack of lungs available. Today less than 20 percent of the available donated organs are used in the USA, as it has not been possible to check whether the organ is suitable for transplantation after it has left the donor's body. By using Xvivo's latest product – STEEN Solution<sup>TM</sup> – the organ is cleared of harmful substances from the donor, thus creating a better environment for the organ's cells. The technology thereby allows the organ to "recover" if this is possible and also enables the performing of functional testing outside the body. Furthermore, the time that the organ can be kept outside the body is considerably extended. More donated organs can thereby be used, which is expected to increase the total number of lung transplantations.

Over the years Xvivo has established close relations with most of the world's lung transplantation units and made Perfadex® the completely dominant product in its niche. This is the point of departure for Xvivo's work to make STEEN Solution<sup>TM</sup> available all over the world, in the firm conviction that the number of transplantations will increase as healthcare gains knowledge of and access to STEEN Solution<sup>TM</sup>. The objective of the company is to create value for both patients and shareholders by providing a unique product in a market with great growth potential.

The Xvivo share is listed on NASDAQ OMX First North, with Redeye as its certified adviser.

# **AREAS OF FOCUS**

## Europe/RoW

- Continued launch of STEEN Solution<sup>™</sup> increasing the number of clinics using warm perfusion (the organ is perfused at 37°) using STEEN Solution<sup>™</sup> to increase the number of available lungs
  - The number of clinics that have now ordered STEEN Solution<sup>™</sup> for clinical use has increased to 22 from having been 13 during 2011.

#### South and North America

- Introducing STEEN Solution<sup>™</sup> in North America performing clinical studies to achieve authority approval of STEEN Solution<sup>™</sup> in the USA and Canada
  - o The study is proceeding according to plan and with continued good results: 28 patients have now received transplants using lungs that would not have been used if they had not undergone warm perfusion using STEEN Solution™. The aim of the study is that 42 patients will receive transplants using the STEEN Solution™ method. One further centre has been recently included in the study, the University of Pennsylvania, Philadelphia.
  - Questions from the FDA regarding the application have now been received and answers have been discussed with them. The FDA now has a nominal 75 working days to come back with a new reply regarding the application. It should be emphasized that the time it takes for authorities to process applications varies. The most important thing, however, is that the underlying results from the clinical studies continue to be good.

## **CEO'S COMMENTS**

The third quarter of 2012 – and subsequently – have been characterized by rapid development of our organization and business as well as continued sales growth, with an increase in net sales of 22 percent compared with the same period in 2011. We have now in a short period of time set up a sales office and store in Denver, USA, from where we now deliver products directly to customers in North America while distribution under the company's own management is estimated to start in Europe during December 2012. We have a strong position in the lung transplantation market with our product Perfadex® which is used in nearly all lung transplantations worldwide, at the same time as much of the future growth will be based on the next generation of technology − STEEN Solution™. Today approximately 200 lung transplantations have already been performed in Europe and North America using STEEN Solution™ and the interest in the method is increasing rapidly among leading clinics, which can be seen both in the number of new scientific publications and in the number of new customers. Xvivo will continue to focus on lung transplantations in order to establish a strong market position for the new STEEN Solution™ technology as well. However, in the future the company aims to try to expand the area of use to liver transplants for example, where there is a great lack of organs.

As Xvivo's growth continues, the company's international presence is increasing. Since the spin-off from Vitrolife, Xvivo has set up offices of its own in Gothenburg and Denver, USA, where the company is building up resources for marketing, administration, storage and distribution so as to be able to serve the key markets in Europe and North America, but also to be able to reach new markets such as Australia and Asia.

The single most important market for the company's products is the USA. We are therefore focusing our efforts on the activities that will lead to market approval and which are prelaunching STEEN Solution™ on the US market. The most important activity for this is the clinical study that is ongoing there. We are pleased to see that the study results continue to be good and that the recruitment of patients is proceeding according to plan. At present, 28 out of 42 patients have received transplants, and it is estimated that all the patients in the study will have been treated during 2013. In July we applied to the FDA for initial market approval, so-called Humanitarian Device Exemption (HDE), and aim to apply for full market approval, PreMarket Approval (PMA), when the whole study has been completed. The FDA has come back to us with questions and we have discussed the answers to these with them. We must now await their reaction to this for up to 75 days. It is notoriously difficult to estimate authorities' processing times, but the most important thing is that our underlying clinical data continue to be built up and that the clinical treatment results continue to be good.

Getting Xvivo to stand on its own feet and at the time preparing for a launch in the USA claim resources of course, as can be seen in the one-time expenses that were charged to income for the third quarter. It is assessed that in total the building up of the organization, the infrastructure and distribution as well as the listing on the Stock Exchange involve one-time expenses of approximately SEK 8 million. Of these approximately SEK 6 million have already been carried as an expense, of which SEK 1.5 million during the second quarter and SEK 4.5 million during the third quarter. It is estimated that a further SEK 2 million approximately will be charged to net income for the whole of 2012. Our preparations for the launch in commercially the most important market, the USA, will require time, resources and investments in the time ahead. These investments will be charged to income above all during 2013.

The aim of the spin-off of Xvivo was, in the intensive phase that the business was in, to increase resources for management and administration so as to more rapidly achieve critical objectives and to highlight the company's competitive product range and great growth potential. The challenge ahead is to provide proof of this – and it is our assessment that the company has very good chances of succeeding in this.

Magnus Nilsson, CEO, Xvivo Perfusion

# IMPORTANT EVENTS DURING THE THIRD QUARTER

# Application for marketing approval of STEEN Solution™ in the USA submitted to the US Food and Drug Administration, FDA

Vitrolife submitted an application for marketing approval to the US Food and Drug Administration, FDA, with regard to STEEN Solution™, which is used to evaluate and preserve lungs outside the body pending transplantation.

# IMPORTANT EVENTS AFTER THE QUARTER

# Trade in Xvivo Perfusion AB was begun on NASDAQ OMX First North on October 8.

On October 1, Xvivo Perfusion AB was spun off from Vitrolife AB, whereby the shareholders of Vitrolife received one share in Xvivo Perfusion for every share they owned in Vitrolife. Trade in Xvivo Perfusion AB shares was begun on NASDAQ OMX First North on October 8.

Questions from the FDA have been received and processed.

# **FUTURE REPORTS**

Year-end report for the financial year 2012\_\_\_\_\_\_\_February 15, 2013

Xvivo Perfusion AB will present long-term goals in connection with the year-end report

# FOR FURTHER INFORMATION, PLEASE CONTACT

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For further information on Xvivo Perfusion's business, please refer to the company's website, www.xvivoperfusion.com

Xvivo Perfusion AB is a medical technology company which develops solutions and systems for assessing and preserving organs outside the body and for selecting usable organs and maintaining them in optimal condition pending transplantation.

The company is headquartered in Gothenburg, Sweden, and has one office in the USA. The Xvivo share is listed on NASDAQ OMX First North and has the ticker symbol XVIVO. More information can be found on the website www.xvivoperfusion.com. The Certified Adviser is Redeye, www.redeye.se.

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This is a translation of the Swedish version of the press release. When in doubt, the Swedish wording prevails.