

Interim Report January - March 2014

XVIVO Perfusion AB (publ)

XVIVO Perfusion is a medical technology company which develops solutions and systems for assessing the usability of organs, allowing for treatment of organs and maintaining organs in good condition outside the body pending transplantation. Currently, the company's product Perfadex® has a market share of more than 90 percent in the traditional preservation of lungs for transplantation.

XVIVO Perfusion employs 10 people at its headquarters in Gothenburg, Sweden, and five at its office for North & South America in Denver, USA. The XVIVO share is listed on NASDAQ OMX First North and has the ticker symbol XVIVO. The Certified Adviser is Redeye, www.redeye.se.



Continued strong sales growth and regulatory successes with XPS™ and STEEN Solution™

FIRST QUARTER 2014 (JAN-MAR)

- Net sales in the quarter amounted to SEK 18.3 (16.3) million, corresponding to an increase of 12 percent in SEK. Sales increased by 10 percent in local currency.
- Operating income before depreciation and amortization (EBITDA) amounted to SEK 3.1 (3.8) million, corresponding to an EBITDA margin of 17 percent.
- Net income amounted to SEK 1.8 (2.4) million, resulting in earnings per share of SEK 0.09 (0.12).
- Cash flow from operating activities was SEK -3.3
 (4.0) million due to changes in trade payables that amounted to SEK -3.6 million and paid taxes that amounted to SEK -2.6 million.
- STEEN Solution™ and related products accounted for 24 (16) percent of total sales.

- The Advisory Panel convened by the FDA voted unanimously, by 10 votes to 0, that the XPS™ System with STEEN Solution™ meets the requirements for HDE (Humanitarian Device Exemption) approval.
- XPS™ (Xvivo Perfusion System) received a CE mark, allowing XPS™ and the accompanying single-use products to be sold in Europe.
- The first lung transplant in Turkey using a lung treated with the STEEN Solution™ method was performed at Sureyyapasa Teaching Hospital.
- Barnes Jewish Hospital in St. Louis, which is a pioneer in lung transplantation, will be the tenth transplant center to participate in the NOVEL trial. Organ Procurement Organization* (OPO) Mid-America Transplant Services in Missouri has bought an XPSTM to strengthen the collaboration between transplant centers and OPOs. The company plans to continue deploying XPSTM with recovery of costs, at transplant centers in the United States during the second quarter.

CONFERENCE CALL

CEO Magnus Nilsson will present the report in a conference call at 2 p.m. CET on Friday, April 23, 2014. Telephone: +46 8 50336434, enter code 1319928

^{*} An OPO or Organ Procurement Organization is responsible for coordination and assessment of donated organs for organ transplantation in a region in the US.

CEO'S COMMENTS



During the quarter XVIVO
Perfusion has passed two
important milestones for a
continued high growth rate:
CE marking of XPS™ (XVIVO
Perfusion System), which allows
XPS™ and the accompanying
single-use products to be
sold in Europe, and that the
Advisory Panel convened by

the FDA voted unanimously that XPS™ using STEEN Solution™ meets the requirements for HDE approval in the US. The Advisory Panel's role is to advise and make recommendations to the FDA on regulatory matters. Such a clear recommendation to the FDA means that the possibilities for a marketing approval within months increased significantly. The company is now in dialog with the FDA to discuss the final stages in the application process. FDA approval would open up the world's largest market for marketing of STEEN Solution™ and XPS™.

The clinical trial in the US involving STEEN Solution™ and XPS™ is continuing to show good clinical results and that many lungs that today are discarded after donation can actually be transplanted to patients who otherwise risk dying waiting for a new organ. Interest in the US for XVIVO's products STEEN Solution™ and XPS™ remains at a high level, and during the quarter the trial was expanded to include a further center. Due to the high interest from transplant centers in the US and Europe as well as regulatory approvals, XVIVO now accelerates the construction and launch of the XPS™. Interest in STEEN Solution™ and the opportunities to use more lungs also

remains high in other parts of the world, and during the quarter another country – Turkey – performed a transplant using a lung treated with the STEEN Solution™ method.

Important to note is that the growth in sales, which was 12 percent during the quarter, is mainly due to the fact that our core product STEEN Solution™ and the accompanying single-use products are used at more centers which account for an increasing share of sales. The company continues its rapid development within all areas: product development, regulatory approvals, market penetration of core products and build-up of top level- and marketing expertise within the organization. This rapid development can be seen alongside a continued good gross margin and a continued positive result

Following a strong start to the year with high focus on regulatory mile stones, we are confidently looking forward to the remainder of 2014 where key focus is shifted to marketing and product launches in Europe and the US. It is also exciting that we see an increasing interest in XVIVO's products in Asia, where we are now intensifying efforts to establish the STEEN Solution TM method. The company's infrastructure is well established and organizational resources are added gradually as the sales and the need is increasing. Our activities are now focused entirely on the global establishment of the STEEN Solution TM method as a standard treatment in lung transplantation – and on continuing to develop its use for other organs.

Magnus Nilsson CEO

FIRST QUARTER 2014 (JANUARY – MARCH)

NET SALES

XVIVO Perfusion's net sales in the quarter amounted to SEK 18.3 (16.3) million, corresponding to an increase of 12 percent in SEK. Sales increased by 10 percent in local currency. STEEN Solution™ and related products accounted for 24 (16) percent of total sales.

INCOME

Operating income before depreciation and amortization (EBITDA) amounted to SEK 3.1 (3.8) million, corresponding to an EBITDA margin of 17 percent.

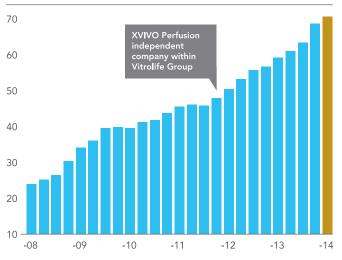
The gross margin during the quarter was 76 (80) percent. Selling expenses in relation to sales were 27 (20) percent. The increase is due to additional resources supporting the continued establishment of STEEN Solution™ and the recruitment of three individuals to strengthen the sales organization. R&D costs were 20 (17) percent of sales. The increase is mainly due to expenses related to CE marking of XPS™ ahead of the European launch and expenses for defending intellectual property rights. The latter refers primarily to ongoing legal expenses for the action against Vivoline and a non-recurring cost of SEK 0.5 million relating to an advance deposit with the Arbitration Institute of the Stockholm Chamber of Commerce, which it has been agreed will decide the corresponding contractual legal case between Igelösa, Stig Steen and XVIVO Perfusion.

Administrative expenses decreased to 14 (20) percent. Net other operating revenues and expenses during the quarter was SEK 0.0 (-0.2) million. During the period, SEK 3.7 million (1.4) of the development costs for STEEN SolutionTM were capitalized as an intangible asset. The increase is mainly coming from the expansion of the NOVEL study and product development of the XPSTM with the goal of decreasing the production cost for the product. Depreciation and amortization for the period amounted to SEK 0.4 million (0.3).

NET SALES (SEK MILLIONS) *



NET SALES ROLLING 12 MONTHS (SEK MILLIONS) *



CASH FLOW

Cash flow from operating activities amounted to SEK -3.3 (4.0) million during the quarter and was mainly affected by changes in trade payables that amounted to SEK -3.6 million and paid taxes that amounted to SEK -2.6 million. Investments amounted to SEK 3.8 (1.6) million, of which SEK 3.7 (1.4) million was invested in the STEEN Solution™ study in the US. The cash flow from financing activities was SEK 5.2 (-8.9) million and consisted of increased use of the overdraft

facility. Cash and cash equivalents at the end of the quarter amounted to SEK 2.1 (1.1) million.

FINANCING

XVIVO Perfusion's total credit facilities consist of an overdraft facility that at the end of the quarter amounted to SEK 15 (15) million, of which SEK 11.8 (0.1) million was utilized. The equity/assets ratio was 75 (84) percent at the end of the quarter.

REGULATORY APPROVAL OF XPS™ IN EUROPE

During the quarter the company obtained a CE mark for XPS™ (Xvivo Perfusion System), its newly developed system for lung perfusion. This allows XPS™ and the accompanying single-use products to be sold in Europe. XPS™ has been used with good clinical results at leading centers in the US within the context of the NOVEL trial. Ex vivo lung perfusion (EVLP) with STEEN Solution™ has been used in more than 300 lung transplants at almost 30 centers, including Vienna, Paris, Toronto and others.

FDA ADVISORY PANEL VOTES UNANIMOUSLY THAT XPS™ WITH STEEN SOLUTION MEETS REQUIREMENTS FOR HDE APPROVAL IN THE US

The Advisory Panel convened by the FDA voted unanimously, by 10 votes to 0, that the $\mathsf{XPS^{TM}}$ system with STEEN Solution™ meets the requirements for HDE (Humanitarian Device Exemption) approval. On March 20, 2014 an Advisory Panel meeting was held in Maryland, USA at which the Advisory Panel gave its opinion on XVIVO Perfusion's HDE application for the XPS™ system with STEEN Solution™. The Advisory Panel's findings were mainly based on the clinical data accumulated in the NOVEL trial. The NOVEL trial is subject to a protocol that includes XPS™ and STEEN Solution™. The Advisory Panel was convened by the FDA and its role is to advise and make recommendations to the FDA on regulatory matters. A decision on the matter of marketing approval will be taken by the FDA. HDE approval allows XVIVO Perfusion to market and sell STEEN Solution™, XPS™ and the accompanying single-use products in the US.

OUTLOOK FOR 2014

Since the number of lungs that can be transplanted using traditional cold perfusion is not expected to increase more than the number of donated lungs, growth is expected to come primarily from warm perfusion using the STEEN SolutionTM method. Therefore, the focus during 2014 will be on establishing the STEEN SolutionTM method as the standard treatment in lung transplantation. In Europe and Australia there is an increased interest in the XPSTM system. The focus during the year will be on launching the XPSTM and establishing the STEEN SolutionTM method at more clinics by using the good clinical results that have been demonstrated to date. At present, Asia, Middle East and

^{*} Q4 2012 and 2013 are XVIVO Perfusion's sales. All previous quarters derive from Vitrolife's Transplantation segment, as reported in Vitrolife's reporting.

Eastern Europe account for around five percent of the total number of lung transplants carried out in the world, but with increased economic opportunities, the number of lung transplants will increase. Establishing the STEEN SolutionTM method early on in these markets will allow this development to take place faster than would otherwise be possible. In the US, the main focus is the HDE approval process for STEEN SolutionTM and the XPSTM until approval and the launch of STEEN SolutionTM and the XPSTM after approval. Before approval, the focus will be to increase the use of STEEN SolutionTM, within the framework of the clinical study, in order to be able to utilize lungs that would not otherwise have been used for transplantation.

When marketing approval has been granted in the USA, resources for sales and marketing will be increased in the USA to establish the use of the STEEN Solution™ technology. Additionally, upon approval, the company will begin to amortize the capitalized expenditure for STEEN Solution™, which will affect operating income. The capitalized assets for STEEN Solution™ amounted to SEK 88 million at the end of the reporting period and it is estimated that straight line amortization will carried out be over a period of ten years.

The availability of organs is the limiting factor when it comes to increasing the number of transplants of organs other than lungs. Therefore, our research and development focus will be on developing the use of the STEEN Solution™ method for other indications.

THE COMPANY IN BRIEF

OPERATIONS

XVIVO Perfusion AB is a medical technology company which develops solutions and systems for selecting usable organs and maintaining them in optimal condition pending transplantation. Today, the company's product Perfadex® has a market share of more than 90 percent in the traditional preservation of lungs for transplantation.

A great problem in transplantation healthcare is the lack of available lungs. Currently in the USA, only around 20 percent of the available donated lungs are transplanted as it is considered far too risky to transplant the remaining majority. By using XVIVO's product STEEN Solution™, 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" when possible. It also allows for functional testing to be performed outside the body. In clinical use in Europe, Australia and Canada, and in a clinical trial in the USA, it has emerged that once STEEN Solution™ perfusion has been carried out, many of the organs that were initially "refused" are assessed as being usable and have been successfully transplanted into patients with end stage lung disease. Therefore the use of

STEEN SolutionTM has the potential to increase the total number of lung transplants.

Over the years, XVIVO has established close relationships with most of the world's lung transplant centers and has made Perfadex® a completely dominant product in its niche. XVIVO intends to make STEEN Solution™ available all over the world with the firm conviction that the number of transplants will increase as healthcare systems gain knowledge of and access to STEEN Solution™. 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.

BUSINESS CONCEPT

XVIVO Perfusion's business concept is to increase the survival rate of patients in need of an organ transplant by providing effective products that increase the availability and survival potential of organs once transplanted.

VISION

The company's vision is that no one should have to die waiting for a new organ.

STRATEGY

XVIVO Perfusion's strategy focuses on getting lung evaluation outside the body using the STEEN Solution™ method accepted as a standard procedure. A basic precondition of the strategy is to obtain regulatory approval for STEEN Solution™ in all important markets. XVIVO Perfusion has demonstrated through published preclinical and clinical studies that warm perfusion of organs using the STEEN Solution™ method results in more available organs, thereby giving more patients the potential to have a life-saving treatment, better quality of life, socioeconomic gains, and lower morbidity and mortality. Furthermore, the company will strive to increase awareness of the STEEN Solution™ method in important groups of stakeholders and will work with key opinion leaders in the area.

OTHER INFORMATION

ORGANIZATION AND PERSONNEL

At the end of quarter the number of employees was fifteen, of whom six were women and nine were men. Of these, ten people were employed in Sweden and five in the USA. In addition, the company uses five consultants.

INFORMATION ON TRANSACTIONS WITH RELATED PARTIES

No transactions that have substantially affected the company's results and financial position have been carried out with related parties during the quarter.

RISK MANAGEMENT

XVIVO Perfusion is constantly working to identify, evaluate, and manage risks in different systems and processes. Risk analyses are performed continually with regard to the company's normal business activities and also in connection with activities that are outside XVIVO Perfusion's regular quality system. The most important strategic and operative risks affecting the company are described in the 2013 annual report.

SEASONAL EFFECTS

XVIVO Perfusion's sales are marginally affected by seasonal effects. There is slightly less activity during the summer months.

EVENTS AFTER THE END OF THE REPORTING PERIOD

No events have occurred after the end of the reporting period that significantly affect the assessment of the financial information in this report.

ANNUAL GENERAL MEETING AND ANNUAL REPORT

The Annual General Meeting will be held on Tuesday April 29, 2014, at 5 pm at XVIVO Perfusion's premaises in Gothenburg, visitors' address Mässans gata 10.

April 23, 2014 Gothenburg

The Board

THIS REPORT HAS NOT BEEN REVIEWED BY THE COMPANY'S AUDITORS.

FINANCIAL REPORTS

XVIVO Perfusion's interim reports are published on the company's website, www.xvivoperfusion.com.

Interim report April-June: Wednesday August 13 Interim report July-September: Friday October 24

FOR FURTHER INFORMATION, PLEASE CONTACT

Magnus Nilsson, CEO, tel: +46 31 788 21 50, e-mail: magnus.nilsson@xvivoperfusion.com

Christoffer Rosenblad, CFO, tel: +46 31 788 21 59, e-mail: christoffer.rosenblad@xvivoperfusion.com

The Certified Adviser is Redeye, www.redeye.se Certified Adviser är Redeye, www.redeye.se

XVIVO Perfusion is required to publish the information in this report in accordance with the Swedish Securities Market Act and/or the Financial Instruments Trading Act. The information was submitted for publication on April 23, 2014 at 8.30 am.

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

CONSOLIDATED INCOME STATEMENTS

		nuary – March
<u>SEK THOUSANDS</u>	2014	2013
Net sales	18 258	16 329
Cost of goods sold	-4 382	-3 250
Gross income	13 876	13 079
Selling expenses	-4 976	-3 273
Administrative expenses	-2 550	-3 344
Research and development costs	-3 573	-2 797
Other operating revenues and expenses	-39	-203
Operating income	2 738	3 462
Financial income and expenses	-93	-164
Income after financial items	2 645	3 298
Taxes	-824	-898
Net income	1 821	2 400
Attributable to		
Parent Company's shareholders	1 821	2 400
Earnings per share, SEK	0,09	0,12
Earnings per share, SEK*	0,09	0,12
Average number of outstanding shares	19 562 769	19 562 769
Average number of outstanding shares*	19 757 769	19 562 769
Number of shares at closing day	19 562 769	19 562 769
Number of shares at closing day*	19 757 769	19 562 769

CONSOLIDATED BALANCE SHEETS

SEKTHOUSANDS	Mar 31, 2014	Mar 31, 2013	Dec 31, 2013
ASSETS			
Goodwill	2 808	3 610	3 008
Other intangible fixed assets	89 820	76 451	86 214
Tangible fixed assets	847	809	917
Financial fixed assets	6 832	3 178	4 405
Inventories	16 407	11 655	17 990
Accounts receivable	7 249	10 643	7 518
Other current receivables	5 325	1 423	3 382
Liquid funds	2 127	1 124	4 131
Total assets	131 415	108 893	127 565
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity, attributable to the Parent Company's shareholders	98 334	91 187	96 635
Provisions	5 394	2 412	5 272
Accounts payable	5 614	4 545	8 419
Overdraft	11 811	106	6 659
Current tax liabilities	3 452	3 110	3 212
Other short-term liabilities	549	466	458
Accrued expenses and prepaid income	6 261	7 067	6 910
Total shareholders' equity and liabilities	131 415	108 893	127 565
Pledged assets for own liabilities	15 250	15 250	15 250
Contingent liabilities	-	-	-

Depreciation, amortization and write downs has reduced income for the period by SEK 368 (333) thousand.

* After dilution. XVIVO Perfusion has one outstanding share warrant program, comprising 195 000 warrants. The net present values of the issue price in the program is lower than the share price at closing day and higher than the average share price for the last 3 months.

CONSOLIDATED KEY RATIOS

		January – March	
SEKTHOUSANDS	2014	2013	
Gross margin, %	76	80	
Operating margin before R&D costs, %	35	38	
EBITDA, %	17	23	
Operating margin, %	15	21	
Net margin, %	10	15	
Equity/assets ratio, %	75	84	
Return on equity, %	2	3	
Income per share, SEK	0,09	0,12	
Shareholders' equity per share, SEK	5,03	4,66	
Share price on closing day, SEK	39,00	20,10	

CONSOLIDATED CASH FLOW STATEMENTS

		January – March	
SEKTHOUSANDS	2014	2013	
Income after financial items	2 645	3 298	
Adjustment for items not affecting cash flow	367	359	
Paid taxes	-2 610	-203	
Change in inventories	1 584	1 720	
Change in trade receivables	-1 755	-948	
Change in trade payables	-3 580	-268	
Cash flow from operating activities	-3 349	3 958	
Cash flow from investing activities	-3 808	-1 568	
Cash flow from financing activities	5 152	-8 983	
Cash flow for the period	-2 005	-6 593	
Liquid funds at beginning of period	4 131	7 776	
Exchange rate difference in liquid funds	1	-59	
Liquid funds at end of period	2 127	1 124	

CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

	Attributable to Parent Company's shareholders			
SEKTHOUSANDS	Share capital	Restricted reserves	Non- restricted reserves and result for the year	Sum share- holders' equity
Opening balance January 1, 2013	500	4 925	83 340	88 765
Total net income			8 054	8 054
Shift between restricted and non-restricted reserves		1 521	-1 521	0
Share warrant program			127	127
Change in currency diff. subsidiary			-311	-311
Closing balance December 31, 2013	500	6 446	89 689	96 635
Opening balance January 1, 2014	500	6 446	89 689	96 635
Total net income			1 821	1 821
Change in currency diff. subsidiary			-122	-122
Closing balance March 31, 2014	500	6 446	91 388	98 334

INCOME STATEMENTS FOR THE PARENT COMPANY

		January – March	
SEK THOUSANDS	2014	2013	
Net sales	27 020	17 474	
Cost of goods sold	-3 752	-4 169	
Gross income	23 268	13 305	
Selling expenses	-3 556	-2 454	
Administrative expenses	-1 980	-2 954	
Research and development costs	-3 373	-2 438	
Other operating revenues and expenses	-39	-203	
Operating income	14 320	5 256	
Financial income and expenses	-204	-164	
Income after financial items	14 116	5 092	
Year end dispositions	-	-	
Taxes	-2 841	-1 120	
Net income	11 275	3 972	

Depreciation, amortization and write downs has reduced income for the period by SEK 139 thousand (115).

BALANCE SHEETS FOR THE PARENT COMPANY

SEKTHOUSANDS	Mar 31, 2014	Mar 31, 2013	Dec 31, 2013
ASSETS			
Balanced expenditures for development	88 538	75 145	84 904
Patents and licencies	1 248	1 252	1 270
Trademarks	29	34	30
Tangible fixed assets	374	238	419
Participation in affiliated companies	14 475	14 475	14 475
Other financial fixed assets	2 882	828	2 784
Inventories	3 260	2 815	5 315
Accounts receivable	3 281	4 688	3 641
Receivables from affiliated companies	19 700	10 693	6 883
Other current receivables	5 202	1 364	3 162
Liquid funds	882	65	2 568
Total assets	139 871	111 597	125 451
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity	102 902	90 860	91 627
Untaxed reserves	8 238	6 288	8 238
Provisions	3 581	1 029	3 459
Overdraft	11 811	106	6 659
Accounts payable	4 062	3 821	6 899
Liabilities to affiliated companies	-	-	-
Current tax liabilities	3 306	2 673	2 490
Other short-term liabilities	5 971	6 820	6 079
Total shareholders' equity and liabilities	139 871	111 597	125 451
Pledged assets for own liabilities Contingent liabilities	15 250 -	15 250	15 250

NOTE 1. ACCOUNTING PRINCIPLES

This interim report was prepared pursuant to the Swedish Annual Accounts Act. Effective January 1, the company applies framework BFNAR 2012-1 from the Swedish Accounting Standards Board (K3). The transition to K3 has had no impact on the financial statements.

NOTE 2. WARRANT PROGRAM

The annual shareholder meeting in XVIVO Perfusion AB on May 7, 2013 approved the warrant program of a maximum of 195,000 warrants (equivalent to 195,000 shares) to be offered to all employees in XVIVO Perfusion AB. The warrant program was fully subscribed and a total of 195,000 warrants with the right to subscribe for new shares were issued. Upon full exercise of the warrants, the share capital increase is SEK 5,070 corresponding to a dilution of about 1 percent of the total number of shares and votes. Each warrant has in June 2015 the right to subscribe for one new share at a price of SEK 32.40.

