

# Interim report January - June 2013

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 four 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](http://www.redeye.se).

**XVIVO**  
**PERFUSION**

# US study has full number of patients and good clinical results presented for patients outside the USA

## SIGNIFICANT EVENTS IN THE SECOND QUARTER

- All the planned 42 + 42 patients have now been included in the clinical study of STEEN Solution™ in the USA and the clinical results are very promising.
- At the ISHLT conference in April, three leading clinics outside the USA (Toronto, Paris and Europe's largest lung transplant clinic in Vienna) presented very good clinical data for 112 patients using XVIVO Perfusion's product STEEN Solution™. The results show that by using STEEN Solution™ the clinics were able to save many lungs that had initially been assessed as unusable. The lungs were transplanted into patients in need, and the results were at least as good as for lungs initially deemed acceptable.
- During the quarter, the company submitted its response to the FDA's supplementary questions regarding the application for marketing approval of STEEN Solution™ on the US market. The FDA is expected to notify its decision in the third quarter.
- At the end of June a total of 47 patients in the USA had been transplanted with lungs made available through the use of STEEN Solution™ and XVIVO's perfusion machine XPS™.

## FIRST HALF (JAN-JUN 2013)

- Sales increased by 21 percent in local currency. Sales amounted to SEK 32.1 (27.8\*) million, corresponding to an increase of 15 percent in SEK.
- Operating income before depreciation and amortization (EBITDA) amounted to SEK 6.1 (9.2\*) million, corresponding to an EBITDA margin of 19 percent.
- Net income amounted to SEK 4.1 million, resulting in earnings per share of SEK 0.21.
- Cash flow from operating activities was SEK 7.9 million

## SECOND QUARTER (APR – JUN 2013)

- Sales increased by 18 percent in local currency. Sales amounted to SEK 15.8 (14.0\*) million, corresponding to an increase of 12 percent in SEK.
- Operating income before depreciation and amortization (EBITDA) amounted to SEK 2.4 (4.2\*) million, corresponding to an EBITDA margin of 15 percent.
- Net income amounted to SEK 1.7 million, resulting in earnings per share of SEK 0.09.
- Cash flow from operating activities was SEK 3.9 million.

## CONFERENCE CALL

CEO Magnus Nilsson will present the report in a conference call at 2 p.m. CET on Thursday, July 11, 2013.  
Telephone: +46 8 50336434, enter code 98290392

\*) See page 4 for an overview of the 2013 income statement and 2012 comparative figures.

## CEO'S COMMENTS



The clinical trial in the USA involving STEEN Solution™ is continuing successfully as planned, and the clinical results are highly promising. All the planned 42 + 42 patients have now been included in the study and will be followed up for a year after their transplants. Recently, three leading clinics outside

the USA – clinics in Toronto and Paris, and also Europe's largest lung transplant clinic in Vienna – presented very good clinical data for 112 patients using XVIVO's product STEEN Solution™. The results show that by using STEEN Solution™ the clinics were able to save many lungs that had initially been assessed as unusable. The lungs were transplanted into patients in need, and the results were at least as good as for lungs initially deemed acceptable. In view of these good treatment results and the shortage of donor organs, the outlook for the commercial development of STEEN Solution™ continues to be very promising.

The FDA is currently processing the company's response to the questions received at the end of March this year, and we expect to receive its decision in the third quarter. Since our marketing application is still being processed, the FDA has consented to the continued use of STEEN Solution™ at our US trial centers. While the FDA is processing the application the clinics can therefore continue to make more lungs available for transplantation, and at the same time the company can continue accumulating and documenting the clinical use of STEEN Solution™ along with XVIVO's perfusion machine 'XPS™'. At the end of the second quarter a

total of 47 patients in the USA had been transplanted with lungs made available through the use of STEEN Solution™ and XPS™. XVIVO has recruited a further two trial centers to the study, each of which has purchased XPS™ from the company. This increases the number of US centers in the study to eight.

The first half of 2013 has seen a strong increase in sales, up 21 percent in local currency, despite the fact that the expected product approval in the USA has been delayed. We are pleased to report that STEEN Solution™ and products related to the use of this solution account for a growing share of the sales volume – 14 percent in the first half of 2013 compared to 9 percent in the same period in 2012. The company's financial position remains strong, with EBITDA at a good level.

The warrants program approved by the general meeting in May has been subscribed for by all employees of XVIVO Perfusion AB. The high take-up is very pleasing and gives all our employees a greater stake in the company as shareholders, increasing their drive to meet our targets still further.

Following a commercially strong first half, which still included a lot of work on building up the organization and completing infrastructure, we are looking forward with confidence to the rest of 2013. No major investments are expected to be necessary and the organization is now focused entirely on establishing the STEEN Solution™ method as the standard treatment in lung transplantation and on developing the use of STEEN Solution™ for additional organs.

Magnus Nilsson, CEO

\*) See page 4 for an overview of the 2013 income statement and 2012 comparative figures.

## INCOME STATEMENT FOR 2013 AND COMPARATIVE FIGURES FOR 2012

On October 1st, 2012, XVIVO Perfusion was distributed to Vitrolife's shareholders and XVIVO Perfusion's share was listed on NASDAQ OMX First North. Trade of the shares began on October 8th, 2012. Comparative figures for 2012 are from Vitrolife's Transplantation segment as it was reported by Vitrolife. Figures for sales are comparable

and are not affected by the fact that XVIVO Perfusion now stands on its own. For expenses that are recorded as comparative figures, it should be taken into consideration that XVIVO Perfusion was part of the Vitrolife Group and did not have an organization (purchasing, production, quality assurance, storage, distribution, finance and administration) of its own. See the table below for the XVIVO Perfusion's 2013 actual income statement and the comparative figures from 2012.

**TABLE 1. OVERVIEW OF XVIVO PERFUSION INCOME STATEMENT 2013 AND COMPARATIVE FIGURES FOR 2012 (SEK THOUSANDS)**

SEK THOUSANDS	January - June 2013	2012	April - June 2013	2012
	XVIVO Perfusion AB (publ)	Vitrolife Segment Transplantation	XVIVO Perfusion AB (publ)	Vitrolife Segment Transplantation
Net sales	32 106	27 845	15 777	14 043
Gross income	25 529	21 840	12 450	10 859
Selling expenses	-7 992	-3 738	-4 719	-2 065
Administrative expenses	-6 286	-5 463	-2 942	-3 106
Research and development costs	-5 684	-3 645	-2 887	-1 631
Other operating revenues and expenses	-102	-175	101	-83
<b>Operating income</b>	<b>5 465</b>	<b>8 819</b>	<b>2 003</b>	<b>3 974</b>
Depreciation and amortization	-682	-366	-349	-201
EBITDA	6 147	9 185	2 352	4 175

## SECOND QUARTER 2013 (APRIL – JUNE)

### NET SALES

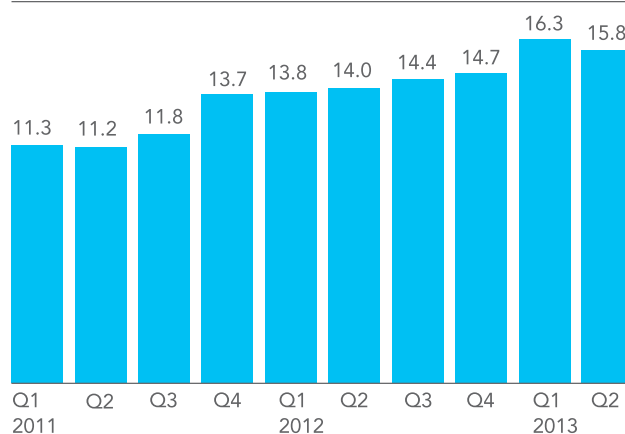
XVIVO Perfusion's net sales increased by 18 percent in local currency. Sales amounted to SEK 15.8 (14.0\*) million, corresponding to an increase of 12 percent in SEK.

### INCOME

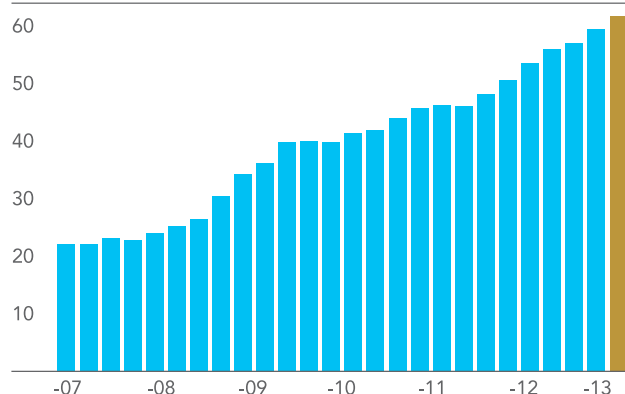
Operating income before depreciation and amortization (EBITDA) amounted to SEK 2.4 (4.2\*) million, corresponding to an EBITDA margin of 15 percent.

The gross margin during the quarter was 79 (77\*) percent. Selling expenses in relation to sales were 30 (15\*) percent. The increase is due to additional resources supporting the continued establishment of STEEN Solution™ and the recruitment of two individuals to strengthen the sales organization. R&D costs were 18 (12\*) percent of sales. The increase is due to the costs of research and production development with a goal of enhancing the gross margin. Administrative expenses decreased to 19 (22\*) percent. During the period, SEK 2.0 million of the development costs for STEEN Solution™ were capitalized as an intangible asset. Depreciation and amortization for the period amounted to SEK 0.3 million.

### NET SALES (SEK MILLIONS) \*\*



### NET SALES ROLLING 12 MONTHS (SEK MILLIONS) \*\*



\*) See page 4 for an overview of the 2013 income statement and 2012 comparative figures.

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

## CASH FLOW

Cash flow from operating activities amounted to SEK 3.9 million in the second quarter. Investments amounted to SEK 4.1 million, of which SEK 2.0 million was invested in the STEEN Solution™ study in the US. Cash and cash equivalents at the end of the quarter amounted to SEK 1.2 million.

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## FIRST HALF OF THE YEAR 2013 (JANUARY – JUNE)

### NET SALES

XVIVO Perfusion's net sales increased by 21 percent in local currency. Sales amounted to SEK 32.1 (27.8\*) million, corresponding to an increase of 15 percent in SEK.

### INCOME

Operating income before depreciation and amortization (EBITDA) amounted to SEK 6.1 (9.2\*) million, corresponding to an EBITDA margin of 19 percent.

The gross margin during the period was 80 (78\*) percent. Selling expenses in relation to sales were 25 (13\*) percent. The increase is due to additional resources supporting the continued establishment of STEEN Solution™ and the recruitment of two individuals to strengthen the sales

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## OUTLOOK FOR 2013

The organization and infrastructure are complete and no major investment in these is expected to be necessary for the remainder of the year. The focus for the rest of the year will be on establishing the STEEN Solution™ method as the standard treatment in lung transplantation and on developing the use of STEEN Solution™ for additional organs.

The FDA's decision is expected to be notified in the third quarter. When marketing approval has been granted in the USA, resources for sales and marketing will be increased 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 the operating income for 2013. The capitalized assets for STEEN Solution™ amounted to SEK 76 million at the end of the reporting period and it is estimated that straight line amortization will be carried out over a period of ten years.

## FINANCING

XVIVO Perfusion's total credit facilities consist of an overdraft facility that at the end of the quarter amounted to SEK 15 million, of which SEK 0.1 million was utilized. The equity/assets ratio was 83 percent at the end of the quarter.

organization. R&D costs were 18 (13\*) percent of sales. The increase is due to the costs of research and production development with a goal of enhancing the gross margin. Administrative expenses was 20 (20\*) percent. During the period, SEK 3.4 million of the development costs for STEEN Solution™ were capitalized as an intangible asset. Depreciation and amortization for the period amounted to SEK 0.7 million.

### CASH FLOW

Cash flow from operating activities amounted to SEK 7.9 million for the period. Investments amounted to SEK 5.7 million, of which SEK 3.4 million was invested in the STEEN Solution™ study in the US. The cash flow from financing activities was SEK -9.0 million and consisted of repayments on the overdraft facility. Cash and cash equivalents at the end of the period amounted to SEK 1.2 million.

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## 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, less than 20 percent of the available donated lungs are transplanted as it is considered far too risky to transplant the majority of donated lungs. 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 trials in the USA, it has emerged that, once STEEN Solution™ perfusion has been carried out, many of the organs that were initially

\*) See page 4 for an overview of the 2013 income statement and 2012 comparative figures.

“refused” are assessed as being usable and have been successfully transplanted into patients with end stage lung disease. The use of STEEN Solution™ therefore has the potential to increase the total number of lung transplants.

Over the years, XVIVO has established close relations with most of the world’s lung transplantation units and has made Perfadex® a completely dominant product in its niche. This is the point of departure for XVIVO’s to make STEEN Solution™ 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™. 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 a transplant by providing effective products that increase the availability of organs with good survival potential when transplanted.

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## **OTHER INFORMATION**

### **ORGANIZATION AND PERSONNEL**

At the end of quarter the number of employees was fourteen, of whom six were women and eight men. Of these, ten people were employed in Sweden and four in the USA.

### **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

### **VISION**

The company’s vision is to establish warm perfusion of organs with STEEN Solution™ as the standard treatment in the transplantation of lungs and other organs.

### **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 and thereby gives more patients life-saving treatment and thus 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.

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 2012 annual report.

### **SEASONAL EFFECTS**

XVIVO Perfusion’s sales are marginally affected by seasonal effects.

### **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.

July 11, 2013  
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](http://www.xvivoperfusion.com).

**It is planned that the following reports will be submitted during 2013: Interim report January-September: Thursday November 7**

### **FOR FURTHER INFORMATION, PLEASE CONTACT**

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

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

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**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 July 11, 2013 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

SEK THOUSANDS	January - June 2013	April - June 2013
Net sales	32 106	15 777
Cost of goods sold	-6 577	-3 327
<b>Gross income</b>	<b>25 529</b>	<b>12 450</b>
Selling expenses	-7 992	-4 719
Administrative expenses	-6 286	-2 942
Research and development costs	-5 684	-2 887
Other operating revenues and expenses	-102	101
<b>Operating income</b>	<b>5 465</b>	<b>2 003</b>
Financial income and expenses	111	275
<b>Income after financial items</b>	<b>5 576</b>	<b>2 278</b>
Taxes	-1 463	-565
<b>Net income</b>	<b>4 113</b>	<b>1 713</b>
<b>Attributable to</b>		
Parent Company's shareholders	4 113	1 713
Earnings per share, SEK	0,21	0,09
Earnings per share, SEK*	0,21	0,09
Average number of outstanding shares	19 562 769	19 562 769
Average number of outstanding shares*	19 562 769	19 562 769
Number of shares at closing day	19 562 769	19 562 769
Number of shares at closing day*	19 562 769	19 562 769

Depreciation and amortization has reduced income for the period by SEK 682 thousand, of which SEK 349 thousand for the quarter.

\* 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 higher than both the share price at closing day and the average share price for the last 9 months.

## CONSOLIDATED BALANCE SHEETS

SEK THOUSANDS	Jun 30, 2013	Dec 31, 2012
<b>ASSETS</b>		
Goodwill	3 410	3 811
Other intangible fixed assets	78 412	75 174
Tangible fixed assets	854	748
Financial fixed assets	5 728	2 497
Inventories	13 631	13 375
Accounts receivable	8 782	8 297
Other current receivables	1 061	2 840
Liquid funds	1 156	7 776
<b>Total assets</b>	<b>113 034</b>	<b>114 518</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>		
Shareholders' equity, attributable to the Parent Company's shareholders	93 466	88 765
Provisions	4 599	2 032
Accounts payable	4 202	6 700
Overdraft	79	9 089
Current tax liabilities	4 346	1 885
Other short-term liabilities	537	317
Accrued expenses and prepaid income	5 805	5 730
<b>Total shareholders' equity and liabilities</b>	<b>113 034</b>	<b>114 518</b>
Pledged assets for own liabilities	15 250	15 250
Contingent liabilities	-	-

## CONSOLIDATED KEY RATIOS

SEK THOUSANDS	January - June 2013	April - June 2013
Gross margin, %	80	79
Operating margin before R&D costs, %	35	31
EBITDA, %	19	15
Operating margin, %	17	13
Net margin, %	13	11
Equity/assets ratio, %	83	83
Return on equity, %	5	2
Income per share, SEK	0,21	0,09
Shareholders' equity per share, SEK	4,78	4,78
Share price on closing day, SEK	23,80	23,80

## CONSOLIDATED CASH FLOW STATEMENTS

SEK THOUSANDS	January - June 2013	April - June 2013
Income after financial items	5 576	2 278
Adjustment for items not affecting cash flow	435	76
Paid taxes	-453	-250
Change in inventories	293	-1 427
Change in trade receivables	1 401	2 349
Change in trade payables	628	896
<b>Cash flow from operating activities</b>	<b>7 880</b>	<b>3 922</b>
Cash flow from investing activities	-5 691	-4 123
Cash flow from financing activities	-9 010	-27
<b>Cash flow for the period</b>	<b>-6 821</b>	<b>-228</b>
Liquid funds at beginning of period	7 776	1 124
Exchange rate difference in liquid funds	201	260
<b>Liquid funds at end of period</b>	<b>1 156</b>	<b>1 156</b>

## CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK THOUSANDS	Attributable to Parent Company's shareholders			Sum share- holders' equity
	Share capital	Restricted reserves	Non restricted reserves and result for the year	
<b>Shareholders' equity when the group company was created October 1, 2012</b>	<b>500</b>	<b>3 160</b>	<b>85 906</b>	<b>89 566</b>
Total comprehensive income			-769	-769
Shift between restricted and non-restricted reserves		1 765	-1 765	0
Change in currency diff. subsidiary			-32	-32
<b>Closing balance December 31, 2012</b>	<b>500</b>	<b>4 925</b>	<b>83 340</b>	<b>88 765</b>
<b>Opening balance January 1, 2013</b>	<b>500</b>	<b>4 925</b>	<b>83 340</b>	<b>88 765</b>
Total comprehensive income			4 113	4 113
Share warrant program			127	127
Change in currency diff. subsidiary			461	461
<b>Closing balance June 30, 2013</b>	<b>500</b>	<b>4 925</b>	<b>88 041</b>	<b>93 466</b>



## INCOME STATEMENTS FOR THE PARENT COMPANY

SEK THOUSANDS	January - June 2013	2012	April - June 2013	2012
Net sales	34 762	29 048	17 288	16 255
Cost of goods sold	-7 012	-5 725	-2 843	-2 874
<b>Gross income</b>	<b>27 750</b>	<b>23 323</b>	<b>14 445</b>	<b>13 381</b>
Selling expenses	-6 171	-2 478	-3 717	-1 229
Administrative expenses	-5 432	-4 296	-2 478	-2 332
Research and development costs	-5 222	-3 726	-2 784	-1 688
Other operating revenues and expenses	-102	-182	101	-126
<b>Operating income</b>	<b>10 823</b>	<b>12 641</b>	<b>5 567</b>	<b>8 006</b>
Financial income and expenses	111	-690	275	766
<b>Income after financial items</b>	<b>10 934</b>	<b>11 951</b>	<b>5 842</b>	<b>8 772</b>
Year end dispositions	-	-	-	-
Taxes	-2 305	-	-1 185	-
<b>Net income</b>	<b>8 629</b>	<b>11 951</b>	<b>4 657</b>	<b>8 772</b>

Depreciation and amortization has reduced income for the period by SEK 236 thousand (175), of which SEK 121 thousand (106) for the quarter.

## BALANCE SHEETS FOR THE PARENT COMPANY

SEK THOUSANDS	130630	120630	121231
<b>ASSETS</b>			
Balanced expenditures for development	77 096	65 163	73 821
Patents and licences	1 266	1 365	1 294
Trademarks	32	37	35
Tangible fixed assets	290	120	184
Participation in affiliated companies	14 475	-	14 475
Other financial fixed assets	2 587	304	522
Inventories	3 998	4 353	3 956
Accounts receivable	3 862	4 380	4 366
Receivables from affiliated companies	13 071	-	8 710
Other current receivables	1 003	1 468	2 782
Liquid funds	439	2 798	4 574
<b>Total assets</b>	<b>118 119</b>	<b>79 988</b>	<b>114 719</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
Shareholders' equity	95 644	23 859	86 888
Untaxed reserves	6 288	4 025	6 288
Provisions	3 215	378	649
Overdraft	79	-	9 089
Accounts payable	3 757	1 658	5 250
Liabilities to affiliated companies	-	46 315	-
Current tax liabilities	3 693	-	1 733
Other short-term liabilities	5 443	3 753	4 822
<b>Total shareholders' equity and liabilities</b>	<b>118 119</b>	<b>79 988</b>	<b>114 719</b>
Pledged assets for own liabilities	15 250	-	15 250
Contingent liabilities	-	-	-

### NOTE 1. ACCOUNTING PRINCIPLES

This interim report was prepared pursuant to the Swedish Annual Accounts Act and the general advice and pronouncements of the Swedish Accounting Standards Board with the exception of BFNAR2012:1 – The Annual Accounts and Consolidated Accounts (K3) unless otherwise stated. The consolidated accounts were prepared in accordance with RR1:00. The accounting principles applied are identical, unless otherwise stated below, to the accounting principles used in the preparation of XVIVO Perfusion AB's latest Annual Report.

### 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.



[WWW.XVIVOPERFUSION.COM](http://WWW.XVIVOPERFUSION.COM)

XVIVO Perfusion AB, Box 53015, SE-400 14 Göteborg, Sweden, Tel +46-31-788 21 50, Fax +46-31-788 21 69, [info@xvivoperfusion.com](mailto:info@xvivoperfusion.com)  
XVIVO Perfusion Inc., 3666 South Inca St, Englewood, CO 80110, USA, Tel: +1 303 395 9171, Fax: +1 800 694 5897