Veloxis PHARMACEUTICALS

Company Announcement no. 24/2014

To: NASDAQ OMX Copenhagen A/S

Hørsholm, Denmark, 12 November, 2014

# Veloxis Pharmaceuticals announces financial results for the first nine months of 2014 and improves the full year outlook

## Highlights:

- On 31 October the U.S. Food and Drug Administration has informed Veloxis of the tentative approval of Envarsus® XR. FDA stated that the final approval of Envarsus XR will be delayed until expiration of the exclusivity period for Astellas' Astagraf XL®. Veloxis understands that this expiry is anticipated to occur July 19, 2016. Veloxis is appealing the FDA decision.
- The European Commission has in July 2014 granted marketing authorization for Envarsus® for the prevention of organ rejection in adult kidney and liver transplant patients in the European Union (EU).
- Following the European marketing authorization Veloxis has received a milestone payment of USD 15 million from our European partner Chiesi in the third quarter 2014. The payment is recognized fully as income in the third quarter 2014.
- Veloxis reported a net profit of DKK 12.9 million for the first nine months of 2014 compared to a net loss of DKK 114.6 million for the same period in 2013. The reported net result is in line with expectations and the financial outlook for 2014 is maintained.
- For the first nine months of 2014, Veloxis' research and development costs amounted to DKK 70.4 million compared to DKK 117.0 million during the same period in 2013.
- On 30 September, 2014, Veloxis had cash and cash equivalents of DKK 310.6 million.
- The full year outlook for 2014 is improved. Veloxis now expects an operating loss in the range of DKK 40 70 million, and a net loss in the range of DKK 20 50 million. Veloxis' cash position is expected to be in the range of DKK 255 285 million at year-end 2014.

#### **Outlook for 2014**

The full year outlook for 2014 is improved. Veloxis now expects an operating loss in the range of DKK 40 - 70 million, and a net loss in the range of DKK 20 - 50 million

The improvement is driven by lower clinical study costs and delayed cost in the US sales and marketing infrastructure.



Cash and cash equivalents are expected to be in the range of DKK 255 - 285 million at 31 December 2014. This compares with expectations of DKK 230 – 270 million announced in connection with the annual report for 2013.

#### **Conference call**

A conference call will be held tomorrow, 13 November, 2014 at 3:00 PM CET (Denmark); 2:00 PM GMT (London), 9:00 AM EST (New York).

To access the live conference call, please dial one of the following numbers:

+45 32 72 80 18 (Denmark)

+44 (0) 1452 555 131 (UK)

+1 866 682 8490 (USA)

Access code 28069222

Following the conference call, a recording will be available on the company's website http://www.veloxis.com.



#### Research & development update

Envarsus® in kidney transplant patients

Veloxis has conducted two Phase III studies of Envarsus® in kidney transplant recipients as the basis for its development programme for Envarsus® as a once-daily agent for the prophylaxis of organ rejection in kidney transplantation. The first of these studies, the 3001 Study, was a non-inferiority study performed in 326 stable kidney transplant recipients, and was successfully completed in 2011, meeting its primary efficacy and safety endpoints when compared to Prograf® (tacrolimus, Astellas Pharma Inc.). The second study, Study 3002 was a randomized, double-blind, multicenter study that compared once-daily Envarsus® against twice-daily Prograf® in 543 de novo adult kidney transplant patients and met its primary efficacy and primary safety endpoints. The primary endpoint of the study was a composite endpoint of treatment failure (biopsy-proven acute rejection, graft failure, loss to follow up or death) that was evaluated after a 12month treatment period to demonstrate the non-inferiority of Envarsus® compared to Prograf®. The treatment failure rate for Envarsus® was 18.3% compared to 19.6% for Prograf®, and the difference between the treatments was well within the 10% pre-specified non-inferiority margin. The primary safety analyses were the differences between Envarsus® and Prograf® treatment groups at Month 12 (Day 360) with respect to the incidence of adverse events (AEs) and the incidence of predefined potentially clinically significant laboratory measures including: fasting plasma glucose; platelet count; white blood cell (WBC) count; aminotransaminases; total cholesterol; low density lipoprotein (LDL) cholesterol; triglycerides; and estimated glomerular filtration rate (eGFR). In all instances, there were no statistically significant differences between the two treatments. Specifically, renal function was similar between the two groups at 12 months, as was the incidence of malignancy, infections and new onset diabetes during this period. On June 29, 2014, Veloxis announced the results of the second year of blinded therapy in this study and the results were similar to the oneyear results with Envarsus® continuing to demonstrate non-inferiority to Prograf® on the primary endpoint at the two year time point.

In addition to the pivotal Phase III studies, Veloxis is conducting a series of Phase IIIb/IV studies to further evaluate potential differences in clinical profile provided by Envarsus®' unique PK profile. The first study is the STRATO (Switching kidney TRAnsplant patients with Tremor to LCP-tacrO) study of Envarsus® in kidney transplant recipients experiencing drug-induced tremors. The STRATO study was designed to explore whether a conversion of patients who have symptomatic tremor from treatment with standard immediate release twice-daily tacrolimus capsules to extended release once-daily Envarsus® tablets leads to a measurable improvement in tremor. Results from this study demonstrated that patients switched to Envarsus® demonstrated a statistically significant improvement in hand tremors based on improvement in the FTM Tremor rating scale. Additionally, both the patient- and physician-reported global assessments demonstrated significant overall improvements following the switch to Envarsus®.

Additionally, the ASERTAA (A Study of Extended Release Tacrolimus in African-Americans) Phase IIIb study of Envarsus® in kidney transplant recipients is ongoing. The ASERTAA study is designed to compare the pharmacokinetics of Envarsus® given once-daily to generic twice daily tacrolimus capsules in stable African-American renal transplant patients. Results from this study are anticipated to be available in 2015.

## Envarsus® Regulatory Strategy

On 29 April, 2013 a Marketing Authorization Application (MAA) was submitted by Veloxis to the European Medicines Agency (EMA) seeking approval to market Envarsus® for the prevention of organ rejection in transplant patients in the European Union. On 28 July, 2014, it was announced that the European Commission granted marketing authorization for Envarsus® for the prevention of organ rejection in adult kidney and liver transplant patients in the European Union (EU). The EU marketing authorization is based on review of the favourable results of the Envarsus® Phase III 3001 study in



stable kidney transplant patients and 3002 study in *de novo* kidney transplant recipients as well as data from an extensive Phase I and II clinical program, which included both kidney and liver transplant patients.

Veloxis submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for the marketing and sale of Envarsus® in the US for the prevention of organ rejection in kidney transplant recipients on 30 December, 2013. On 30 October, 2014 the FDA granted Tentative Approval for Envarsus® XR for the prophylaxis of rejection in kidney transplant patients. FDA stated that the final approval of Envarsus XR will be delayed until expiration of the exclusivity period for Astellas' Astagraf XL®. Veloxis understands that this expiry is anticipated to occur 19 July, 2016. FDA's approval notice stated that it is "subject to change on the basis of any new information that may come to FDA's attention." Veloxis disagrees that exclusivity for Astagraf XL, which was not identified as a listed drug or relied upon to support approval of Envarsus XR, should require delay in the formal approval of Envarsus XR. Veloxis plans to appeal this decision within FDA. The tentative approval notification received from FDA included agreement with manufacturing post-marketing commitments as previously proposed by Veloxis during NDA review as well as agreement on final labeling for the product. There were no other conditions attached to the NDA approval.

Previously, the FDA has also granted Envarsus® Orphan Drug status for prophylaxis of organ rejection in patients receiving allogeneic kidney transplants. The designation is to encourage the development of drugs that may provide significant benefit to patients suffering from rare diseases.

### Envarsus® Commercial Strategy

In the US Veloxis is planning to launch and commercialize Envarsus® XR through its own dedicated marketing and sales organization.

In the EU, Chiesi Farmaceutici S.p.A., through an exclusive distribution agreement with Veloxis, will commercialize Envarsus®, with initial country launches anticipated in November 2014.



**Financial Highlights** YTD YTD Q3 Q3 Year 2014 2014 2013 2013 2013 **DKK'000 DKK'000** DKK'000 **DKK'000 DKK'000 Income Statement** Revenue 120,181 25,942 95,769 12,206 38,148 Sales and marketing costs (24,032)(10,378)Research and development costs (116,966)(35,247)(146,512)(70,435)(19,391)Administrative expenses (27,988)(21,314)(10,256)(6,703)(27,771)Operating result (2,274)(112,338)55,744 (29,744)(136, 135)13,332 Net financial income / (expenses) 15,238 (3,001)(4,655)(4,426)Result before tax 12,964 (115,339)69,076 (34,399)(140,561)Tax for the period (106)728 (3,095)242 1,250 Net result for the period 12,858 65,981 (114,611)(34,157)(139,311)**Balance Sheet** Cash and cash equivalents 380,179 310,571 328,652 310,571 380,179 Total assets 330,127 388,982 330,127 388,982 348,863 Share capital 166,300 166,057 166,300 166,057 166,057 Total equity 300,456 302,307 300,456 302,307 279,042 Investment in property, plant and equipment 1,055 657 540 **Cash Flow Statement** Cash flow from operating activities (35,104)(110,330)32,023 (14,040)(157,747)(540)Cash flow from investing activities (657)(1,055)Cash flow from financing activities 989 (2,907)304 (401)(3,227)310,571 310,571 Cash and cash equivalents at period end 380,179 380,179 328,652 **Financial Ratios** Basic and diluted EPS 0.01 (0.07)0.04 (0.02)(80.0)1,662,020,404 1,662,680,554 1,660,279,386 1,660,572,426 1,660,353,248 Weighted average number of shares Average number of employees (FTEs) 25 27 28 26 26

1.10

1.29

1.10

1.29

1.25

The interim report has not been audited or reviewed by the company's independent auditors.

Assets/equity



#### Revenue

For the first nine months of 2014 Veloxis recognized deferred revenue and revenue from milestone payments of DKK 120.2 million as revenue compared to DKK 26.0 million in the same period of 2013. Deferred revenue consist of up-front and milestone payments under Veloxis' distribution agreement with Chiesi Farmaceutici S.p.A. and is recognized in the income statement based on planned development periods.

#### Sales and marketing costs

For the first nine months of 2014, Veloxis' sales and marketing costs amounted to DKK 24.0 million. This reflects the hiring and building of the marketing and sales infrastructure in the US.

#### Research and development costs

For the first nine months of 2014, Veloxis' research and development costs amounted to DKK 70.4 million compared to DKK 117.0 million during the same period in 2013. Research and development costs are mainly attributable to the phase III trial in Envarsus® (*de novo* patients, Study 3002). The reduction in cost is associated with the overall reduction in study activity as the study is approaching finalization.

#### **Administrative expenses**

For the first nine months of 2014, Veloxis' administrative cost amounted to DKK 28.0 million compared to DKK 21.3 million during the same period in 2013. The increase in cost is associated with the building of marketing and sales infrastructure in the US.

#### **Compensation costs**

For the first nine months of 2014, a total of DKK 7.5 million was recognized as share-based compensation. The cost is included in S&M, R&D and G&A. The comparable cost for 2013 was DKK 7.1 million.

In the third quarter of 2014, a total of 44,446 warrants have been cancelled, a total of 470,031 warrants have been exercised (256,639 at an exercise price of DKK 0.35, 54,167 at an exercise price of DKK 0.58, 9,225 at an exercise price of DKK 0.95, 150,000 at an exercise price of DKK 1.16), a total of 196,328 warrants have expired and a total of 250,000 warrants were granted to the Board of Directors at a strike price of DKK 1.86 and a total of 2,005,000 warrants at a strike price of DKK 1.86 was granted to other employees.

As of 30 September, 2014, there were a total of 100,508,566 warrants outstanding at an average strike price of DKK 0.71. Members of the Board of Directors held 635,417 warrants at an average strike price of DKK 1.73. Members of the Executive Management held 61,279,081 warrants at an average strike price of DKK 0.51, while other current and former employees held 38,594,068 warrants at an average strike price of DKK 1.02.

Please refer to Veloxis' latest annual report for additional details on the Company's warrant programs.

## **Operating result**

Veloxis' operating loss for the first nine months of 2014 was DKK 2.3 million compared to DKK 112.3 million in the corresponding period of 2013.



#### Financial income

During the first nine months of 2014, the Company recognized net financial income of DKK 15.2 million compared to net financial expenses of DKK 3.0 million in the corresponding period of 2013. The income is mainly due to unrealized currency gain following an increase in the USD / DKK currency rate during the first nine months of 2014.

#### Net result

Veloxis' net result for the first nine months of 2014 was a profit of DKK 12.9 million compared to a loss of DKK 114.6 million in the corresponding period of 2013.

#### **Cash flow**

As per 30 September, 2014, the balance sheet reflects cash and cash equivalents of DKK 310.6 million compared to DKK 328.7 million as per 31 December, 2013. This represents a decrease of DKK 18.1 million primarily related to the Company's operating activities for the period.

#### **Balance sheet**

As per 30 September, 2014, total assets were DKK 330.1 million compared to DKK 348.9 million at the end of 2013.

Shareholders' equity equalled DKK 300.5 million as of 30 September, 2014, compared to DKK 279.0 million at the end of 2013.

#### Significant risks and uncertainties

Veloxis faces a number of risks and uncertainties related to operations, research and development, commercial and financial activities. For further information about risks and uncertainties, we refer to the Annual Report for 2013. As of the date of this Interim Report, there have been no significant changes to Veloxis' overall risk profile since the publication of the Annual Report for 2013.



#### For more information, please contact:

John D. Weinberg EVP, Chief Operating Officer Mobile: +1 732 321 3208 Email: jdw@veloxis.com Johnny Stilou EVP, Chief Financial Officer Mobile: +45 21 227 227 Email: jst@veloxis.com

The forward looking statements and targets contained herein are based on the current view and assumptions of the Executive Management and the Board of Directors of Veloxis Pharmaceuticals A/S. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. Veloxis Pharmaceuticals A/S expressly disclaim any obligation or undertaking to update or revise any forward looking statements, targets or estimates contained in this interim report to reflect any change in events, conditions, assumptions, or circulations on which any such statements are based unless required by applicable law.

#### About Envarsus®

Tacrolimus is a leading immunosuppression drug used for the prevention of transplant allograft rejection after organ transplantation. Envarsus® (tacrolimus prolonged-release tablets) has received marketing authorization in the EU for prophylaxis of organ rejection in kidney and liver transplant recipients. In the US, Envarsus®, known as Envarsus® XR (tacrolimus extended-release tablets), has received Tentative Approval as a once-daily tablet version of tacrolimus for prophylaxis of organ rejection in kidney transplant patients in combination with other immunosuppressants. Envarsus® XR has received orphan drug designation in the U.S. Veloxis plans to commercialize Envarsus® XR in the US through its own sales force and in the EU through its partnership with Chiesi Farmaceutici SpA.

#### **About Veloxis Pharmaceuticals**

Based in Hørsholm, Denmark, with an office in New Jersey, Veloxis Pharmaceuticals A/S, or Veloxis, is a specialty pharmaceutical company. Veloxis' unique, patented delivery technology, MeltDose®, is designed to enhance the absorption and bioavailability of select orally administered drugs. Veloxis is listed on the NASDAQ OMX Copenhagen under the trading symbol OMX: VELO.

For further information, please visit www.veloxis.com.

Veloxis PHARMACEUTICALS

#### Executive Management's and the Board of Directors' Statement on the Interim Report

The Executive Management and the Board of Directors have considered and adopted the Interim Report for the 9 months ended 30 September 2014 of Veloxis Pharmaceuticals A/S.

The Interim Report is prepared in accordance with International Accounting Standard No. 34 (IAS 34), "Interim Financial Reporting" and additional Danish disclosure requirements for financial reporting of listed companies.

We consider the applied accounting policies to be appropriate and, in our opinion, the Interim Report gives a true and fair view of the assets and liabilities, financial position, results of the operation and cash flow of the group for the period under review. Furthermore, in our opinion the management review includes a fair review of the development and performance of the business and the financial position of the group, together with a description of the material risks and uncertainties the group faces.

Hørsholm, 12 November, 2014

#### **Executive Management**

William J. Polvino Johnny Stilou

President & CEO Executive Vice President & CFO

### **Board of Directors**

Kim Bjørnstrup Thomas Dyrberg (Chairman) (Deputy Chairman)

Anders Götzsche Mette Kirstine Agger



# Financial Highlights Quarterly Numbers in DKK

	Q3 2014	Q2 2014	Q1 2014	Q4 2013	Q3 2013	Q2 2013	Q1 2013
	DKK'000						
Income Statement							
Revenue	95,769	12,206	12,206	12,206	12,206	6,868	6,868
Sales and marketing costs	(10,378)	(13,653)	12,200	12,200	12,200	0,808	0,808
· ·	, , ,		(26,624)	(20 546)	- (2E 247)	(42.772)	(20 047)
Research and development costs	(19,391)	(24,420)		(29,546)	(35,247)	(42,772)	(38,947)
Administrative expenses	(10,256)	(9,983)	(7,749)	(6,457)	(6,703)	(6,834)	(7,777)
Operating result	55,744	(35,850)	(22,167)	(23,797)	(29,744)	(42,738)	(39,856)
Net financial income / (expenses)	13,332	1,228	677	(1,425)	(4,655)	(2,253)	3,907
Result before tax	69,076	(34,622)	(21,490)	(25,222)	(34,399)	(44,991)	(35,949)
Tax for the period	(3,095)	1,495	1,494	522	242	241	244
Net result for the period	65,981	(33,127)	(19,996)	(24,700)	(34,157)	(44,750)	(35,704)
Balance Sheet							
Cash and cash equivalents	310,571	264,240	296,237	328,652	380,179	399,743	456,216
Total assets	330,127	276,493	305,373	348,863	388,982	409,371	465,939
Share capital	166,300	166,252	166,252	166,057	166,057	166,057	166,057
Total equity	300,456	231,649	261,538	279,042	302,307	334,686	377,276
Investment in property, plant and							
equipment	540	(169)	285	1,055	-	-	
Cash Flow Statement							
Cash flow from operating activities	32,023	(33,577)	(33,550)	(47,417)	(14,040)	(51,165)	(45,125)
Cash flow from investing activities	(540)	169	(285)	(1,055)	-	-	-
Cash flow from financing activities	304	-	684	(319)	(401)	(2,555)	48
Cash and cash equivalents at period							
end	310,571	264,240	296,237	328,652	380,179	399,743	456,216
Financial Ratios							
Basic and diluted EPS	0.04	(0.02)	(0.01)	(0.01)	(0.02)	(0.03)	(0.02)
Weighted average number of shares	1,662,680,554	1,662,527,283	1,660,833,074	1,660,572,426	1,660,572,426	1,660,572,426	1,659,683,537
Average number of employees (FTEs)	28	23	22	23	26	27	29
Assets/equity	1.10	1.19	1.17	1.25	1.29	1.22	1.24



## Income statement and statement of comprehensive income

Income Statement			Consolidated		
(DKK'000)	YTD 2014	YTD 2013	Q3 2014	Q3 2013	Year 2013
Revenue	120,181	25,942	95,769	12,206	38,148
Sales and marketing costs	(24,032)	-	(10,378)	-	-
Research and development costs	(70,435)	(116,966)	(19,391)	(35,247)	(146,512)
Administrative expenses	(27,988)	(21,314)	(10,256)	(6,703)	(27,771)
Operating result	(2,274)	(112,338)	55,744	(29,744)	(136,135)
Financial income	15,432	48	13,526	-	1,243
Financial expenses	(194)	(3,049)	(194)	(4,655)	(5,669)
Result before tax	12,964	(115,339)	69,076	(34,399)	(140,561)
Tax for the period	(106)	728	(3,095)	242	1,250
Net result for the period	12,858	(114,611)	65,981	(34,157)	(139,311)
Basic and diluted EPS	0.01	(0.07)	0.04	(0.02)	(80.0)
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Weighted average number of shares	1,662,020,404	1,660,279,386	1,662,680,554	1,660,572,426	1,660,353,248

Statements of comprehensive income			Consolidated			
(DKK'000)	YTD 2014	YTD 2013	Q3 2014	Q3 2013	Year 2013	
Net result for the period Other comprehensive income: Items that may be subsequently reclassified	12,858	(114,611)	65,981	(34,157)	(139,311)	
to profit or loss:  Currency translation differences, net of tax	22	(335)	(52)	(58)	(390)	
Other comprehensive income for the period	22	(335)	(52)	(58)	(390)	
Total comprehensive income for the period	12,880	(114,946)	65,929	(34,215)	(139,701)	



## **Balance sheet**

Assets		Consolidated			
(DKK'000)	30 Sep. 2014	30 Sep. 2013	31 Dec. 2013		
Patent rights and software	415	1,858	494		
Intangible assets	415	1,858	494		
Property, plant and equipment	3,411	2,454	3,333		
Property, plant and equipment	3,411	2,454	3,333		
Non-current assets	3,826	4,312	3,827		
Inventories	7,567	-			
Other receivables Prepayments	7,568 595	3,186 1,305	15,170 1,214		
Receivables	8,163	4,491	16,384		
Cash	310,571	380,179	328,652		
Cash and cash equivalents	310,571	380,179	328,652		
Current assets	326,301	384,670	345,036		
Assets	330,127	388,982	348,863		



## **Balance sheet**

Equity & Liabilities	Consolidated			
(DKK'000)	30 Sep. 2014	30 Sep. 2013	31 Dec. 2013	
Share capital	166,300	166,057	166,057	
Special reserve	407,289	407,289	407,289	
Translation reserves	1,990	2,023	1,968	
Retained earnings/loss	(275,123)	(273,062)	(296,272)	
Equity	300,456	302,307	279,042	
Finance lease	-	320	-	
Trade payables	10,650	13,338	13,026	
Deferred revenue	-	48,823	36,617	
Other payables	19,021	24,194	20,178	
			_	
Current liabilities	29,671	86,675	69,821	
Liabilities	29,671	86,675	69,821	
Equity and liabilities	330,127	388,982	348,863	



## **Cash flow statements**

Cash Flow Statement	Consolidated						
(DKK'000)	YTD 2014	YTD 2013	Q3 2014	Q3 2013	Year 2013		
Operating result	(2,274)	(112,338)	55,744	(29,744)	(136,135)		
Share-based payment	7,545	7,079	2,575	1,835	8,568		
Depreciation and amortization	658	1,022	253	340	1,315		
Write-down Changes in working capital	(36,873)	- (5,982)	- (22,175)	13,606	1,243 (35,294)		
Changes in working capital	(30,873)	(3,362)	(22,173)	13,000	(33,234)		
Cash flow from operating activities before interest	(30,944)	(110,219)	36,397	(13,963)	(160,303)		
Interest received	212	48	(2)	-	1,243		
Interest paid	(194)	51	(194)	(7)	(39)		
Tax received	-	-	-	-	1,352		
Tax paid	(4,178)	(210)	(4,178)	(70)	-		
Cash flow from operating activities	(35,104)	(110,330)	32,023	(14,040)	(157,747)		
Purchase of property, plant and equipment	(657)	-	(540)	-	(1,055)		
Cash flow from investing activities	(657)	-	(540)	-	(1,055)		
Installments on bank borrowings and finance lease	-	(3,345)	-	(401)	(3,665)		
Proceeds from issuance of shares, net	989	438	304	-	438		
Cash flow from financing activities	989	(2,907)	304	(401)	(3,227)		
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Increase/(decrease) in cash	(34,772)	(113,237)	31,787	(14,441)	(162,029)		
Cash at beginning of period	328,652	496,834	264,240	399,743	496,834		
Exchange gains/(losses) on cash	16,691	(3,418)	14,544	(5,123)	(6,153)		
Cash at end of period	310,571	380,179	310,571	380,179	328,652		



## Statement of changes in equity

Consolidated Equity							
	Number of Shares	Share Capital DKK'000	Share Premium DKK'000	Special Reserves DKK'000	Translation Reserves DKK'000	Retained Earnings DKK'000	Total DKK'000
Equity as of 1 Jan. 2013	1,659,322,426	165,932	-	407,289	2,358	(165,842)	409,737
Net result for the year						(114,611)	(114,611
Other comprehensive income for	the year				(335)	(114,011)	(335
Total comprehensive income	yea.				(335)	(114,611)	(114,946
Warrant exercises	1,250,000	125	312				437
Share-based payment	1,230,000	123	312			7,079	7,079
Transfer of retained earnings			(312)			312	
Equity as of 30 Sep. 2013	1,660,572,426	166,057	_	407,289	2,023	(273,062)	302,307
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Net result for the year						(24,700)	(24,700
Other comprehensive income for	the year				(55)		(55
Total comprehensive income					(55)	(24,700)	(24,755
Share-based payment						1,490	1,490
Equity as of 31 Dec. 2013	1,660,572,426	166,057	-	407,289	1,968	(296,272)	279,042
Not recult for the year						12.000	12.000
Net result for the year Other comprehensive income for	the year				22	12,858	12,858 22
Total comprehensive income	the year				22	12,858	12,880
Total comprehensive medine					22	12,030	12,000
Warrant exercises	2,424,888	243	746				989
Share-based payment						7,545	7,545
Transfer of retained earnings			(746)			746	-
Equity as of 30 Sep. 2014	1,662,997,314	166,300	-	407,289	1,990	(275,123)	300,456



#### **Notes**

#### 1. Accounting policies

The interim report is prepared in compliance with International Accounting Standard No. 34 (IAS 34), "Interim Financial Reporting" and in accordance with the NASDAQ OMX Copenhagen's financial reporting requirements for listed companies.

There have been no changes in accounting policies used for the interim report compared to the accounting policies used in the preparation of Veloxis Pharmaceuticals' annual report for 2013. As the company in 2014 holds inventory the below accounting policy has been included.

The balance sheet includes raw materials classified as inventories. Inventories are measured at cost using the first-in, first-out (FIFO) formula. Where net realizable value is lower than cost, inventories are written down to the lower value. Cost of raw materials comprises the acquisition price plus landed costs.