Company Announcement no. 11/2013

To: NASDAQ OMX Copenhagen A/S Hørsholm, Denmark, 15 May, 2013

Veloxis Pharmaceuticals announces financial results for the first three months of 2013

Highlights:

- On 29 April, 2013 Veloxis submitted the MAA to the European Medicines Agency (EMA) seeking approval to market LCP-Tacro™ for the prevention of organ rejection in kidney transplant patients in the European Union. The MAA submission is based on the favorable results of the LCP-Tacro™ Phase III 3001 study in stable kidney transplant patients and data from an extensive Phase I and II clinical program. Veloxis expects the decision from the European Union in 2014.

- Veloxis reported a net loss of DKK 35.7 million for the first quarter of 2013 compared to a net loss of DKK 75.0 million for the same period in 2012. The reported net loss is in line with expectations and the financial outlook for 2013 is maintained.

- For the first quarter of 2013, Veloxis' research and development costs amounted to DKK 38.9 million compared to DKK 62.8 million during the same period in 2012.

- On 31 March, 2013, Veloxis had cash and cash equivalents of DKK 456.2 million.

Outlook for 2013

Veloxis maintains its 2013 outlook with an operating and net loss of DKK 170-200 million for the financial year 2013.

As at 31 March 2013, the Company's cash position equaled DKK 456.2 million, and as at 31 December 2013, the Company's cash position is expected to be in the range of DKK 270-310 million.

Conference call

A conference call will be held tomorrow, 16 May, 2013 at 2:00 PM CET (Denmark); 1:00 PM GMT (London), 8:00 AM EDT (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 64307755

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

Research & development update

LCP-Tacro™ in kidney transplant patients

Veloxis has completed one Phase III study and has advanced a second Phase III study of LCP-Tacro™ in kidney transplant recipients as the basis for its development programme for LCP-Tacro™ 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 is being undertaken in *de novo* kidney transplant recipients. This study is a randomized, double-blind, multicenter study that compares once-daily LCP-Tacro™ against twice-daily Prograf® in *de novo* adult kidney transplant patients. The primary endpoint of the study, a composite endpoint (biopsy proven acute rejection, graft failure, loss to follow up or death), will be evaluated after a 12-month treatment period to demonstrate the non-inferiority of LCP-Tacro™ compared to Prograf®. Secondary endpoints will include safety, tolerability and renal function assessments. The study completed enrollment in March 2012 of 543 patients at approximately 90 transplant centers, primarily in the U.S. and Europe. Results from this study are expected mid-2013. Patients will participate in a 12-month extension period on treatment for follow-up safety assessments.

In addition to the pivotal Phase III studies, Veloxis is planning a series of Phase IIIb/IV studies to further evaluate potential differences in clinical profile provided by LCP-Tacro's unique PK profile. The first study initiated is the STRATO (Switching kidney TRAnsplant patients with Tremor to LCP-tacrO) study of LCP-Tacro™ in kidney transplant recipients experiencing drug-induced tremors. The STRATO study is 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 LCP-Tacro™ tablets leads to a measurable improvement in tremor. Results from this study are expected to be presented at the American Transplant Congress in Seattle on 19 May, 2013.

LCP-Tacro™ Regulatory Strategy

On 29 April, 2013 a Marketing Authorization Application (MAA) was submitted by Veloxis to the European Medicines Agency seeking approval to market LCP-Tacro™ for the prevention of organ rejection in kidney transplant patients in the European Union. The MAA submission was based on the favorable results of the LCP-Tacro™ Phase III 3001 Study in stable kidney transplant patients and data from an extensive Phase I and II clinical program. Veloxis expects to receive a decision on the application in 2014.

The U.S. submission for LCP-Tacro™, for the prophylaxis of organ rejection, to the FDA (Food and Drug Administration) is planned for the second half of 2013 and will include data from the 3002 *de novo* study in addition to data from Phase I, II and Study 3001.

Financial Highlights

	Q1 2013 DKK'000	Q1 2012 DKK'000	Year 2012 DKK'000
Income Statement			
Revenue	6,868	-	6,868
Research and development costs	(38,947)	(62,848)	(210,739)
Administrative expenses	(7,777)	(10,231)	(36,889)
Operating loss before restructuring cost	(39,856)	(73,079)	(240,760)
Restructuring cost	-	-	(21,462)
Operating loss	(39,856)	(73,079)	(262,222)
Net financial income / (expenses)	3,907	(1,592)	(850)
Loss before tax	(35,949)	(74,671)	(263,072)
Tax for the period	244	(318)	363
Net loss for the period	(35,704)	(74,989)	(262,709)
Balance Sheet			
Cash and cash equivalents	456,216	213,786	496,834
Total assets	465,939	235,187	509,271
Share capital	166,057	452,543	165,932
Total equity	377,276	182,545	409,737
Investment in property, plant and equipment	-	91	260
Cash Flow Statement			
Cash flow from operating activities	(45,125)	(80,364)	(205,870)
Cash flow from investing activities	-	29,433	169,712
Cash flow from financing activities	48	(1,310)	404,304
Cash and cash equivalents at period end	456,216	213,786	496,834
Financial Ratios			
Basic and diluted EPS	(0.02)	(0.17)	(0.43)
Weighted average number of shares	1,659,683,537	452,542,480	607,511,489
Average number of employees (FTEs)	29	55	48
Assets/equity	1.24	1.29	1.24

The interim report is unaudited.

Revenue
For the first quarter of 2013 Veloxis recognized deferred revenue of DKK 6.9 million as revenue compared to no revenue in the same period of 2012. 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 on a straight line basis based on planned development periods.

Research and development costs
For the first quarter of 2013, Veloxis' research and development costs amounted to DKK 38.9 million compared to DKK 62.8 million during the same period in 2012. Research and development costs are mainly attributable to the ongoing phase III trial in LCP-Tacro™ (*de novo* patients, Study 3002). The reduction in cost between the two quarters is mainly related to effect from the executed restructuring and discontinuation of other pipeline activities in May 2012.

Administrative expenses
For the first quarter of 2013, Veloxis' administrative cost amounted to DKK 7.8 million compared to DKK 10.2 million during the same period in 2012. The reduction in cost is attributable to the continued focus of reducing overall cost, combined with the effect of the restructuring and reduction in number of employees that took place in May 2012.

Compensation costs
For the first three months of 2013, a total of DKK 2.9 million was recognized as share-based compensation. The cost is included in R&D and G&A. The comparable cost for 2012 was DKK 1.6 million.

In the first quarter of 2013, a total of 300,000 warrants have been cancelled, a total of 1,250,000 warrants have been exercised at an exercise price of DKK 0.35, and a total of 18,846,300 warrants were granted to Executive Management at a strike price of DKK 0.36, and a total of 1,783,700 warrants at a strike price of DKK 0.36 was granted to Senior Management.

As of 31 March, 2013, there were a total of 104,978,157 warrants outstanding at an average strike price of DKK 0.9. Members of the Board of Directors held 559,011 warrants at an average strike price of DKK 5.1. Members of the Executive Management held 55,300,661 warrants at an average strike price of DKK 0.5, while other current and former employees held 49,118,484 warrants at an average strike price of DKK 1.2.

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

Operating loss
Veloxis' operating loss for the first three months of 2013 was DKK 39.8 million compared to DKK 73.1 million in the corresponding period of 2012.

Financial income
During the first three months of 2013, the Company recognized net financial income of DKK 3.9 million compared to net financial expenses of DKK 1.6 million in the corresponding period of 2012. The income is mainly due to currency gain following the increase in the USD / DKK currency rate during the first quarter of 2013.

Net loss
Veloxis' net loss for the first three months of 2013 was DKK 35.7 million compared to DKK 75.0 million in the corresponding period of 2012.

Cash flow

As per 31 March, 2013, the balance sheet reflects cash and cash equivalents of DKK 456.2 million compared to DKK 496.8 million as per 31 December, 2012. This represents a decrease of DKK 40.6 million primarily related to the Company's operating activities for the period.

Balance sheet

As per 31 March, 2013, total assets were DKK 465.9 million compared to DKK 509.3 million at the end of 2012.

Shareholders' equity equalled DKK 377.3 million as of 31 March, 2013, compared to DKK 409.7 million at the end of 2012.

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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 LCP-Tacro™ and tacrolimus

Tacrolimus is a leading immunosuppression drug used for the prevention of transplant allograft rejection after transplantation. LCP-Tacro™ is an investigational drug that is being developed as a once-daily tablet version of tacrolimus with improved bioavailability, consistent pharmacokinetic performance and reduced peak-to-trough variability when compared to currently approved tacrolimus products. Transplant patients need to maintain a minimum blood level of tacrolimus for the prevention of transplant allograft rejection, but excessive levels may increase the risk of serious side effects such as nephrotoxicity, tremor, diabetes, high blood pressure, and opportunistic infections. Therefore, tacrolimus levels need to be managed carefully, and transplant patients are typically obliged to make frequent visits to the hospital for monitoring and dose adjustments after receiving a new organ.

About Veloxis Pharmaceuticals

Based in Hørsholm, Denmark, with an office in New Jersey, Veloxis is a specialty pharmaceutical company. The company's lead product candidate is LCP-Tacro™ for immunosuppression, specifically organ transplantation. Veloxis' unique, patented delivery technology, MeltDose®, can improve absorption and bioavailability at low scale up costs. Veloxis has a lipid lowering product, Fenoglide®, currently on the U.S. market that is commercialized through partner Santarus, Inc. Veloxis is listed on the NASDAQ OMX Copenhagen under the trading symbol OMX: VELO.

For further information, please visit http://www.veloxis.com.

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 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, 15 May, 2013

Executive Management

Dr. 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

	Q1 2013 DKK'000	Q4 2012 DKK'000	Q3 2012 DKK'000	Q2 2012 DKK'000	Q1 2012 DKK'000
Income Statement					
Revenue	6,868	6,868	-	-	-
Research and development costs	(38,947)	(41,890)	(49,362)	(56,639)	(62,848)
Administrative expenses	(7,777)	(10,235)	(6,961)	(9,462)	(10,231)
Operating loss before restructuring cost	(39,856)	(45,257)	(56,323)	(66,101)	(73,079)
Restructuring cost	-	-	-	(21,462)	-
Operating loss	(39,856)	(45,257)	(56,323)	(87,563)	(73,079)
Net financial income / (expenses)	3,907	(2,302)	993	2,051	(1,592)
Loss before tax	(35,949)	(47,559)	(55,330)	(85,512)	(74,671)
Tax for the period	244	1,034	(223)	(130)	(318)
Net loss for the period	(35,704)	(46,525)	(55,553)	(85,642)	(74,989)
Balance Sheet					
Cash and cash equivalents	456,216	496,834	86,683	152,720	213,786
Total assets	465,939	509,271	99,590	167,799	235,187
Share capital	166,057	165,932	45,254	45,254	452,543
Total equity	377,276	409,737	42,103	98,968	182,545
Investment in property, plant and equipment	-	43	-	126	91
Cash Flow Statement					
Cash flow from operating activities	(45,125)	(399)	(62,707)	(62,400)	(80,364)
Cash flow from investing activities	-	56,619	59,486	24,174	29,433
Cash flow from financing activities	48	410,149	(3,450)	(1,085)	(1,310)
Cash and cash equivalents at period end	456,216	496,834	86,683	152,720	213,786
Financial Ratios					
Basic and diluted EPS	(0.02)	(0.08)	(0.12)	(0.19)	(0.17)
Weighted average number of shares	1,659,683,537	607,511,489	452,542,480	452,542,480	452,542,480
Average number of employees (FTEs)	29	33	49	55	55
Assets/equity	1.24	1.24	2.37	1.70	1.29

Income statement and statement of comprehensive income

Income Statement	Consolidated		
(DKK'000)	**Q1 2013**	**Q1 2012**	**Year 2012**
Revenue	6,868	-	6,868
Research and development costs	(38,947)	(62,848)	(210,739)
Administrative expenses	(7,777)	(10,231)	(36,889)
Operating loss before restructuring cost	**(39,856)**	**(73,079)**	**(240,760)**
Restructuring cost	-	-	(21,462)
Operating loss	**(39,856)**	**(73,079)**	**(262,222)**
Financial income	8,872	1,577	1,481
Financial expenses	(4,965)	(3,169)	(2,331)
Loss before tax	**(35,949)**	**(74,671)**	**(263,072)**
Tax for the period	244	(318)	363
Net loss for the period	**(35,704)**	**(74,989)**	**(262,709)**
Basic and diluted EPS	(0.02)	(0.17)	(0.43)
Weighted average number of shares	1,659,683,537	452,542,480	607,511,489

Statements of comprehensive income	Consolidated		
(DKK'000)	**Q1 2013**	**Q1 2012**	**Year 2012**
Net loss for the period	**(35,704)**	**(74,989)**	**(262,709)**
Other comprehensive income:			
Currency translation differences	(128)	74	427
Other comprehensive income for the period	(128)	74	427
Total comprehensive income for the period	**(35,832)**	**(74,915)**	**(262,282)**

Balance sheet

Assets	Consolidated		
(DKK'000)	**31 Mar. 2013**	**31 Mar. 2012**	**31 Dec. 2012**
Patent rights and software	2,103	2,591	2,225
Intangible assets	**2,103**	**2,591**	**2,225**
Property, plant and equipment	2,814	8,334	2,994
Leasehold improvements	79	3,327	115
Property, plant and equipment	**2,893**	**11,661**	**3,109**
Non-current assets	**4,996**	**14,252**	**5,334**
Other receivables	3,267	5,325	5,181
Prepayments	1,460	1,824	1,922
Receivables	**4,727**	**7,149**	**7,103**
Securities	-	137,273	-
Cash	456,216	76,513	496,834
Cash and cash equivalents	**456,216**	**213,786**	**496,834**
Current assets	**460,943**	**220,935**	**503,937**
Assets	**465,939**	**235,187**	**509,271**

Balance sheet

Equity & Liabilities	Consolidated		
(DKK'000)	**31 Mar. 2013**	**31 Mar. 2012**	**31 Dec. 2012**
Share capital	166,057	452,543	165,932
Special reserve	407,289	-	407,289
Translation reserves	2,230	2,005	2,358
Retained earnings/loss	(198,300)	(272,003)	(165,842)
Equity	**377,276**	**182,545**	**409,737**
Finance lease	-	2,698	-
Non-current liabilities	**-**	**2,698**	**-**
Finance lease	3,275	4,318	3,665
Trade payables	20,448	20,346	18,590
Deferred revenue	41,208	-	48,076
Other payables	23,732	25,280	29,203
Current liabilities	**88,663**	**49,944**	**99,534**
Liabilities	**88,663**	**52,642**	**99,534**
Equity and liabilities	**465,939**	**235,187**	**509,271**

Cash flow statements

Cash Flow Statement	Consolidated		
(DKK'000)	**Q1 2013**	**Q1 2012**	**Year 2012**
Operating loss	**(39,856)**	**(73,079)**	**(262,222)**
Share-based payment	2,933	1,560	7,154
Depreciation and amortization	340	1,240	3,391
Impairment loss	-	-	6,141
Net gain on sale of fixed assets	-	-	(2,375)
Changes in working capital	(8,504)	(10,127)	42,601
Cash flow from operating activities before interest	**(45,087)**	**(80,406)**	**(205,310)**
Interest received	48	482	1,481
Interest paid	(18)	(122)	(568)
Corporate tax paid	(68)	(318)	(1,473)
Cash flow from operating activities	**(45,125)**	**(80,364)**	**(205,870)**
Purchase of property, plant and equipment	-	(91)	(260)
Sale of property, plant and equipment	-	-	3,175
Investments in securities	-	(3,761)	(19,909)
Sale of securities	-	33,285	186,706
Cash flow from investing activities	**-**	**29,433**	**169,712**
Installments on bank borrowings and finance lease	(389)	(1,310)	(4,662)
Proceeds from issuance of shares, net	437	-	408,966
Cash flow from financing activities	**48**	**(1,310)**	**404,304**
Increase/(decrease) in cash	**(45,077)**	**(52,241)**	**368,146**
Cash at beginning of period	496,834	130,930	130,930
Exchange gains/(losses) on cash	4,459	(2,176)	(2,242)
Cash at end of period	**456,216**	**76,513**	**496,834**
Cash and cash equivalents at end of period comprise:			
Securities	-	137,273	-
Deposit on demand and cash	456,216	76,513	496,834
	456,216	**213,786**	**496,834**

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 January 2012	**452,542,480**	**452,543**	**-**		**1,931**	**(198,574)**	**255,900**
Total comprehensive income					74	(74,989)	(74,915)
Share-based payment						1,560	1,560
Equity as of 31 March 2012	**452,542,480**	**452,543**	**-**	**-**	**2,005**	**(272,003)**	**182,545**
Total comprehensive income					353	(187,720)	(187,367)
Reduction of share capital		(407,289)		407,289			-
Issuance of shares	1,206,779,946	120,678	301,695				422,373
Share-based payment						5,594	5,594
Costs related to capital increases			(13,408)				(13,408)
Transfer of retained earnings			(288,287)			288,287	-
Equity as of 31 December 2012	**1,659,322,426**	**165,932**	**-**	**407,289**	**2,358**	**(165,842)**	**409,737**
Total comprehensive income					(128)	(35,704)	(35,832)
Warrant exercises	1,250,000	125	313				438
Share-based payment						2,933	2,933
Transfer of retained earnings			(313)			313	-
Equity as of 31 March 2013	**1,660,572,426**	**166,057**	**-**	**407,289**	**2,230**	**(198,300)**	**377,276**

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 2012.