Company Announcement no. 2/2014

To: NASDAQ OMX Copenhagen A/S

Hørsholm, Denmark, 5 March 2014

Veloxis Pharmaceuticals publishes Annual Report 2013

Veloxis Pharmaceuticals A/S (OMX: VELO) ('Veloxis') today published the annual report of Veloxis Pharmaceuticals A/S for the financial year 2013. The annual report has been prepared in accordance with International Financial Reporting Standards as adopted by the EU and additional Danish disclosure requirements for annual reports of listed companies.

This company announcement should be read in conjunction with Veloxis' annual report 2013 published separately today.

Full Year 2013 Highlights

- Submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for the marketing and sale of Envarsus® for the prevention of organ rejection in kidney transplant recipients.
- Granted Orphan Drug status by the U.S. Food and Drug Administration (FDA) for prophylaxis of organ rejection in patients receiving allogenic kidney transplants. The designation is to encourage the development of drugs that may provide significant benefit to patients suffering from rare diseases.
- Dosing of the first patient in ASERTAA (A Study of Extended Release Tacrolimus in African-Americans) Phase IIIb study of Envarsus® in kidney transplant recipients. The ASERTAA study is designed to compare the pharmacokinetics (PK) of Envarsus®, a once-daily tacrolimus tablet, to generic twice daily tacrolimus capsules in stable African-American renal transplant patients.
- The trade name for LCP-Tacro™ is Envarsus®.
- Envarsus® successfully demonstrated non-inferiority compared to tacrolimus (Prograf®; Astellas Pharma) in its Phase III clinical trial, Study 3002. The Phase III randomized, double-blind and double-dummy study in 543 *de novo* kidney transplant recipients, with Prograf® as the comparator, met its primary efficacy and primary safety endpoints.
- The European Medicines Agency (EMA) accepted for review the company's Marketing Authorization Application (MAA) to market Envarsus® for the prevention of organ rejection in kidney transplant patients in the European Union. Veloxis expects the decision from the European Union in 2014.
- Data from the STRATO study demonstrates the potential for Envarsus® to improve tacrolimus-induced tremors in stable kidney transplant patients.
- Submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) seeking approval to market Envarsus® for the prevention of organ rejection in kidney transplant patients in the European Union.
- During 2013, Veloxis recognized deferred revenue of DKK 38.2 million as revenue compared to DKK 6.9 million in 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 based on planned development periods.

- Research and development costs decreased by DKK 64.2 million, or by 30.5%, from DKK 210.7 million in 2012 to DKK 146.5 million 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 between the two periods is mainly related to effect from the executed restructuring and discontinuation of other pipeline activities in May 2012.

- Administrative expenses decreased by DKK 9.1 million or by 24.7%, from DKK 36.9 million in 2012 to DKK 27.8 million in 2013. The reduction in cost is attributable to the continued focus of reducing overall cost, combined with the effect of the reduction in the number of employees that took place in May 2012.

- During 2013, Veloxis recognized DKK 139.3 million in net loss compared to DKK 262.7 million in 2012. The net loss is better than management's expectations for 2013 as reported on 13 November 2013 in connection with the third quarter interim report, which projected a net loss of DKK 160 - 190 million. The positive deviation is mainly driven by the granted orphan drug status which has reduced regulatory costs.

- As per 31 December 2013, the balance sheet reflects cash and cash equivalents of DKK 328.7 million compared to DKK 496.8 million as per 31 December 2012. The decrease in cash position reflects the changes in operating activities in 2013. The cash position is in line with management's expectations for 2013, which projected a cash position at the end of 2013 of DKK 310 - 340 million.

Conference Call

On 5 March, 2014, Veloxis' Management will host a conference call, at 2:00 PM CET (Denmark); 1:00 PM GMT (London), 8:00 AM ET (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 1728236

Following the conference call, a recording will be available on the company's website www.veloxis.com. A presentation will be available on Veloxis' website (under 'Investors').

Financial Highlights

DKK'000	2013	2012	2011	2010	2009
Income Statement					
Revenue	38,148	6,868	-	1,496	2,476
Research and development costs	(146,512)	(210,739)	(222,053)	(210,426)	(210,140)
Administrative expenses	(27,771)	(36,889)	(47,814)	(52,198)	(62,381)
Operating loss before restructuring cost	(136,135)	(240,760)	(269,867)	(261,128)	(270,045)
Restructuring cost	-	(21,462)	-	(10,894)	(9,489)
Operating loss	(136,135)	(262,222)	(269,867)	(272,022)	(279,534)
Net financial income / (expenses)	(4,426)	(850)	16,048	(759)	8,540
Loss before tax	(140,561)	(263,072)	(253,819)	(272,781)	(270,994)
Tax for the period	1,250	363	1,193	(1,425)	-
Net loss for the period	(139,311)	(262,709)	(252,626)	(274,206)	(270,994)
Balance Sheet					
Cash and cash equivalents	328,652	496,834	297,727	531,519	333,429
Total assets	348,863	509,271	320,927	562,906	379,269
Share capital	166,057	165,932	452,543	452,543	56,568
Total equity	279,042	409,737	255,900	498,238	317,281
Investment in property, plant and equipment	1,055	260	2,981	2,583	11,043
Cash Flow Statement					
Cash flow from operating activities	(157,747)	(205,870)	(234,637)	(238,148)	(251,158)
Cash flow from investing activities	(1,055)	169,712	(169,778)	(2,658)	(11,011)
Cash flow from financing activities	(3,227)	404,304	(5,948)	440,014	729
Cash and cash equivalents at period end	328,652	496,834	297,727	531,519	333,429
Financial Ratios					
Basic and diluted EPS (DKK)	(0.08)	(0.43)	(0.56)	(2.84)	(4.80)
Weighted average number of shares	1,660,353,248	607,511,489	452,542,480	96,707,708	56,443,701
Average number of employees (FTEs)	26	48	52	59	93
Assets/equity	1.25	1.24	1.25	1.13	1.20

Fourth Quarter 2013 Highlights

- Research and development cost were realized at DKK 29.5 million compared to DKK 41.9 million in same period in 2012, and DKK 35.2 million in the previous quarter.
- Administrative expenses were realized at DKK 6.5 million compared to DKK 10.2 million in same period in 2012, and DKK 6.7 million in the previous quarter.
- Operating loss amounted to DKK 23.8 million, while net loss was realized at DKK 24.7 million.

Financial Highlights
Quarterly Numbers in DKK

	Q4 2013 DKK'000	Q3 2013 DKK'000	Q2 2013 DKK'000	Q1 2013 DKK'000	Q4 2012 DKK'000	Q3 2012 DKK'000	Q2 2012 DKK'000	Q1 2012 DKK'000
Income Statement								
Revenue	12,206	12,206	6,868	6,868	6,868	-	-	-
Research and development costs	(29,546)	(35,247)	(42,772)	(38,947)	(41,890)	(49,362)	(56,639)	(62,848)
Administrative expenses	(6,457)	(6,703)	(6,834)	(7,777)	(10,235)	(6,961)	(9,462)	(10,231)
Operating loss before restructuring cost	(23,797)	(29,744)	(42,738)	(39,856)	(45,257)	(56,323)	(66,101)	(73,079)
Restructuring cost	-	-	-	-	-	-	(21,462)	-
Operating loss	(23,797)	(29,744)	(42,738)	(39,856)	(45,257)	(56,323)	(87,563)	(73,079)
Net financial income / (expenses)	(1,425)	(4,655)	(2,253)	3,907	(2,302)	993	2,051	(1,592)
Loss before tax	(25,222)	(34,399)	(44,991)	(35,949)	(47,559)	(55,330)	(85,512)	(74,671)
Tax for the period	522	242	241	244	1,034	(223)	(130)	(318)
Net loss for the period	(24,700)	(34,157)	(44,750)	(35,704)	(46,525)	(55,553)	(85,642)	(74,989)
Balance Sheet								
Cash and cash equivalents	328,652	380,179	399,743	456,216	496,834	86,683	152,720	213,786
Total assets	348,863	388,982	409,371	465,939	509,271	99,590	167,799	235,187
Share capital	166,057	166,057	166,057	166,057	165,932	45,254	45,254	452,543
Total equity	279,042	302,307	334,686	377,276	409,737	42,103	98,968	182,545
Investment in property, plant and equipment	1,055	-	-	-	43	-	126	91
Cash Flow Statement								
Cash flow from operating activities	(47,417)	(14,040)	(51,165)	(45,125)	(399)	(62,707)	(62,400)	(80,364)
Cash flow from investing activities	(1,055)	-	-	-	56,619	59,486	24,174	29,433
Cash flow from financing activities	(319)	(401)	(2,555)	48	410,149	(3,450)	(1,085)	(1,310)
Cash and cash equivalents at period end	328,652	380,179	399,743	456,216	496,834	86,683	152,720	213,786
Financial Ratios								
Basic and diluted EPS	(0.01)	(0.02)	(0.03)	(0.02)	(0.08)	(0.12)	(0.19)	(0.17)
Weighted average number of shares	1,660,572,426	1,660,572,426	1,660,572,426	1,659,683,537	607,511,489	452,542,480	452,542,480	452,542,480
Average number of employees (FTEs)	23	26	27	29	33	49	55	55
Assets/equity	1.25	1.29	1.22	1.24	1.24	2.37	1.70	1.29

Outlook for 2014

Veloxis is expecting an operating loss of DKK 60 - 90 million compared to the realized operating loss of DKK 136 million in 2013. Net loss is expected to be in the range of DKK 55 - 85 million compared to the net loss of DKK 139 million in 2013. As of 31 December 2013, the Company's cash position equaled DKK 329 million and the Company's 31 December 2014 cash position is expected to be in the range of DKK 230 - 270 million.

The above estimates are subject to possible changes primarily due to the timing of regulatory approvals and associated milestone payments along with variation of clinical activities and fluctuating exchange rates.

Important events following the balance sheet date

On 8 January, Veloxis announced that United States Patent and Trademark Office had issued a Notice of Allowance for U.S. Application Serial Number 13/167,420, a patent which covers the diurnal-independent administration of Envarsus®.

For more information, please contact:

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About Envarsus® and tacrolimus

Tacrolimus is a leading immunosuppression drug used for the prevention of transplant allograft rejection after transplantation. Envarsus® 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 Envarsus® 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 www.veloxis.com.