Company Announcement no. 4/2015

To: NASDAQ OMX Copenhagen A/S

Hørsholm, Denmark, 3 March 2015

Veloxis Pharmaceuticals publishes Annual Report 2014

Veloxis Pharmaceuticals A/S (OMX: VELO) ('Veloxis') today published the annual report of Veloxis Pharmaceuticals A/S for the financial year 2014. 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 2014 published separately today.

Full Year 2014 Highlights

- Filed an action against the FDA, seeking an order requiring FDA to grant final approval to Envarsus® XR.
- FDA has informed Veloxis of a 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.
- The European Commission (EC) has granted marketing authorization for Envarsus® for the prevention of organ rejection in adult kidney and liver transplant patients in the European Union (EU).
- Once-daily Envarsus® XR (tacrolimus extended-release tablets), demonstrated a lower treatment failure rate in African-Americans compared with twice-daily tacrolimus (Prograf®).
- Two-year results of the pivotal Phase 3 clinical trial, Study 3002, of Envarsus® XR (tacrolimus extended-release tablets) in *de novo* kidney transplant patients continued to demonstrate non-inferiority compared to tacrolimus capsules (Prograf®; Astellas Pharma).
- The FDA has accepted for standard review the company's New Drug Application (NDA) for Envarsus® for the prevention of organ rejection in adult kidney transplant patients.
- 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®.
- During 2014, Veloxis recognized revenue from deferred upfront, milestone payments and commercial sales of DKK 123.4 million compared to DKK 38.2 million in 2013.
- Sales and marketing costs amounted to DKK 41.3 million in 2014. This reflects the hiring and building of the marketing and sales infrastructure.
- Research and development costs decreased by DKK 56.4 million, or by 38.5%, from DKK 146.5 million in 2013 to DKK 90.1 million in 2014. 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 some studies have now been completed.

- Administrative expenses increased from DKK 27.8 million in 2013 to DKK 47.4 million in 2014. The increase in cost is mainly attributable to legal fees in connection with legal actions against the FDA.

- During 2014, Veloxis recognized DKK 36.3 million in net loss compared to DKK 139.3 million in 2013. The net loss is in line with management's expectations for 2014 as reported on 12 November 2014 in connection with the third quarter interim report, which projected a net loss of DKK 20 - 50 million.

- As per 31 December 2014, the balance sheet reflects cash and cash equivalents of DKK 270.4 million compared to DKK 328.7 million as per 31 December 2013. The decrease in cash position reflects the changes in operating activities in 2014. The cash position is in line with management's expectations for 2014, which projected a cash position at the end of 2014 of DKK 255 - 285 million.

Conference Call

On 3 March, 2015, Veloxis' Management will host a conference call, at 4:00 PM CET (Denmark); 3:00 PM GMT (London), 10:00 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 88916362

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	2014	2013	2012	2011	2010
Income Statement					
Revenue	123,395	38,148	6,868	-	1,496
Production costs	(3,247)	-	-	-	-
Gross profit	120,148	38,148	6,868	-	1,496
Sales and marketing costs	(41,278)	-	-	-	-
Research and development costs	(90,111)	(146,512)	(210,739)	(222,053)	(210,426)
Administrative expenses	(47,363)	(27,771)	(36,889)	(47,814)	(52,198)
Operating result before restructuring cost	(58,604)	(136,135)	(240,760)	(269,867)	(261,128)
Restructuring cost	-	-	(21,462)	-	(10,894)
Operating result	(58,604)	(136,135)	(262,222)	(269,867)	(272,022)
Net financial income / (expenses)	20,903	(4,426)	(850)	16,048	(759)
Result before tax	(37,701)	(140,561)	(263,072)	(253,819)	(272,781)
Tax for the period	1,382	1,250	363	1,193	(1,425)
Net result for the period	(36,319)	(139,311)	(262,709)	(252,626)	(274,206)
Statement of Financial Position					
Cash and cash equivalents	270,434	328,652	496,834	297,727	531,519
Total assets	293,723	348,863	509,271	320,927	562,906
Share capital	166,300	166,057	165,932	452,543	452,543
Total equity	253,248	279,042	409,737	255,900	498,238
Investment in property, plant and equipment	1,805	1,055	260	2,981	2,583
Cash Flow Statement					
Cash flow from operating activities	(77,243)	(157,747)	(205,870)	(234,637)	(238,148)
Cash flow from investing activities	(2,547)	(1,055)	169,712	(169,778)	(2,658)
Cash flow from financing activities	989	(3,227)	404,304	(5,948)	440,014
Cash and cash equivalents at period end	270,434	328,652	496,834	297,727	531,519
Financial Ratios					
Basic and diluted EPS (DKK)	(0.02)	(0.08)	(0.43)	(0.56)	(2.84)
Weighted average number of shares	1,662,266,639	1,660,353,248	607,511,489	452,542,480	96,707,708
Average number of employees (FTEs)	26	26	48	52	59
Assets/equity	1.16	1.25	1.24	1.25	1.13
Share price	1.15	0.70	0.34	0.83	1.31

Fourth Quarter 2014 Highlights

- Sales and marketing cost were realized at DKK 17.2 million compared to DKK 0 million in same period in 2013, and DKK 10.4 million in the previous quarter.
- Research and development cost were realized at DKK 19.7 million compared to DKK 29.5 million in same period in 2013, and DKK 19.4 million in the previous quarter.
- Administrative expenses were realized at DKK 19.4 million compared to DKK 6.5 million in same period in 2013, and DKK 10.3 million in the previous quarter.
- Operating result amounted to a loss of DKK 56.3 million, while net result was realized at a loss of DKK 49.2 million.

Financial Highlights
Quarterly Numbers in DKK

	Q4 2014 DKK'000	Q3 2014 DKK'000	Q2 2014 DKK'000	Q1 2014 DKK'000	Q4 2013 DKK'000	Q3 2013 DKK'000	Q2 2013 DKK'000	Q1 2013 DKK'000
Income Statement								
Revenue	3,214	95,769	12,206	12,206	12,206	12,206	6,868	6,868
Production costs	(3,247)	-	-	-	-	-	-	-
Gross profit	(33)	95,769	12,206	12,206	12,206	12,206	6,868	6,868
Sales and marketing costs	(17,246)	(10,378)	(13,653)	-	-	-	-	-
Research and development costs	(19,677)	(19,391)	(24,420)	(26,624)	(29,546)	(35,247)	(42,772)	(38,947)
Administrative expenses	(19,375)	(10,256)	(9,983)	(7,749)	(6,457)	(6,703)	(6,834)	(7,777)
Operating result	(56,331)	55,744	(35,850)	(22,167)	(23,797)	(29,744)	(42,738)	(39,856)
Net financial income / (expenses)	5,666	13,332	1,228	677	(1,425)	(4,655)	(2,253)	3,907
Result before tax	(50,665)	69,076	(34,622)	(21,490)	(25,222)	(34,399)	(44,991)	(35,949)
Tax for the period	1,488	(3,095)	1,495	1,494	522	242	241	244
Net result for the period	(49,177)	65,981	(33,127)	(19,996)	(24,700)	(34,157)	(44,750)	(35,704)
Statement of financial position								
Cash and cash equivalents	270,434	310,571	264,240	296,237	328,652	380,179	399,743	456,216
Total assets	293,723	330,127	276,493	305,373	348,863	388,982	409,371	465,939
Share capital	166,300	166,300	166,252	166,252	166,057	166,057	166,057	166,057
Total equity	253,248	300,456	231,649	261,538	279,042	302,307	334,686	377,276
Investment in property, plant and equipment	1,149	540	(169)	285	1,055	-	-	-
Cash Flow Statement								
Cash flow from operating activities	(42,139)	32,023	(33,577)	(33,550)	(47,417)	(14,040)	(51,165)	(45,125)
Cash flow from investing activities	(1,891)	(540)	169	(285)	(1,055)	-	-	-
Cash flow from financing activities	-	304	-	684	(319)	(401)	(2,555)	48
Cash and cash equivalents at period end	270,434	310,571	264,240	296,237	328,652	380,179	399,743	456,216
Financial Ratios								
Basic and diluted EPS	(0.03)	0.04	(0.02)	(0.01)	(0.01)	(0.02)	(0.03)	(0.02)
Weighted average number of shares	1,662,997,314	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)	31	28	23	22	23	26	27	29
Assets/equity	1.16	1.10	1.19	1.17	1.25	1.29	1.22	1.24

Outlook for 2015

Veloxis is expecting an operating loss of DKK 200 - 240 million compared to the realized operating loss of DKK 59 million in 2014. Net loss is expected to be in the range of DKK 195 - 235 million compared to the net loss of DKK 36 million in 2014. As of 31 December 2014, the Company's cash position equaled DKK 270 million and the Company's 31 December 2015 cash position is expected to be in the range of DKK 55 - 95 million.

The above estimates are assuming launch of Envarsus® XR in the US in the second half of 2015. The outlook is therefore subject to possible changes primarily related to the timing and outcome of the ongoing lawsuit regarding approval of Envarsus® XR.

Management is focused on securing additional funds beyond 2015 by either partner agreements, debt or equity, or a mix thereof.

Important events following the balance sheet date

13 January, Veloxis announced that it has received notice from the FDA stating that FDA continues to take the position that the exclusivity for Astagraf XL should require delay in the formal approval of Envarsus® XR.

For more information, please contact:

Veloxis Pharmaceuticals A/S

Bill Polvino
President & CEO
Phone: +1 732 321 3202
Email: wjp@veloxis.com

Johnny Stilou
EVP, Chief Financial Officer
Phone: +45 3053 3364
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.