Company Announcement no. 16/2013

To: NASDAQ OMX Copenhagen A/S

Hørsholm, Denmark, 21 August, 2013

Veloxis Pharmaceuticals announces financial results for the first half 2013

Highlights:

- LCP-Tacro™ has 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 study was conducted under a Special Protocol Agreement with the FDA and the results are considered pivotal for the planned U.S. regulatory filing expected to occur in the second half of 2013.

- The European Medicines Agency (EMA) has accepted for review the company's Marketing Authorization Application (MAA) to market LCP-Tacro™ for the prevention of organ rejection in kidney transplant patients in the European Union. Veloxis expects the decision from the European Union in 2014.

- Final STRATO clinical study data have demonstrated the potential for LCP-Tacro™ to improve tacrolimus-induced tremors in stable kidney transplant patients.

- Veloxis reported a net loss of DKK 80.5 million for the first half of 2013 compared to a net loss of DKK 160.6 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 half of 2013, Veloxis' research and development costs amounted to DKK 81.7 million compared to DKK 119.5 million during the same period in 2012.

- On 30 June, 2013, Veloxis had cash and cash equivalents of DKK 399.7 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 30 June 2013, the Company's cash position equaled DKK 399.7 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, 22 August, 2013 at 3:00 PM CET (Denmark); 2:00 PM GMT (London), 9:00 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 30348398

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

Research & development update

LCP-Tacro™ in kidney transplant patients

Veloxis has completed two Phase III studies 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 was a randomized, double-blind, multicenter study that compared once-daily LCP-Tacro™ 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 or BPAR, graft failure, loss to follow up or death) that was evaluated after a 12-month treatment period to demonstrate the non-inferiority of LCP-Tacro™ compared to Prograf®. The treatment failure rate for LCP-Tacro™ was 18.3% compared to 19.6% for Prograf®, well within the 10% pre-specified non-inferiority margin. The primary safety analyses were the differences between LCP-Tacro™ 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. 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 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 LCP-Tacro™ tablets leads to a measurable improvement in tremor. Results from this study demonstrated that patients switched to LCP-Tacro™ 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 LCP-Tacro™.

LCP-Tacro™ 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 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 programme and has been accepted for review by the EMA. 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

	YTD 2013 DKK'000	YTD 2012 DKK'000	Q2 2013 DKK'000	Q2 2012 DKK'000	Year 2012 DKK'000
Income Statement					
Revenue	13,736	-	6,868	-	6,868
Research and development costs	(81,719)	(119,487)	(42,772)	(56,639)	(210,739)
Administrative expenses	(14,611)	(19,693)	(6,834)	(9,462)	(36,889)
Operating loss before restructuring cost	(82,594)	(139,180)	(42,738)	(66,101)	(240,760)
Restructuring cost	-	(21,462)	-	(21,462)	(21,462)
Operating loss	(82,594)	(160,642)	(42,738)	(87,563)	(262,222)
Net financial income / (expenses)	1,654	459	(2,253)	2,051	(850)
Loss before tax	(80,940)	(160,183)	(44,991)	(85,512)	(263,072)
Tax for the period	485	(448)	241	(130)	363
Net loss for the period	(80,455)	(160,631)	(44,750)	(85,642)	(262,709)
Balance Sheet					
Cash and cash equivalents	399,743	152,720	399,743	152,720	496,834
Total assets	409,371	167,799	409,371	167,799	509,271
Share capital	166,057	45,254	166,057	45,254	165,932
Total equity	334,686	98,968	334,686	98,968	409,737
Investment in property, plant and equipment	-	217	-	126	260
Cash Flow Statement					
Cash flow from operating activities	(96,290)	(142,764)	(51,165)	(62,400)	(205,870)
Cash flow from investing activities	-	53,607	-	24,174	169,712
Cash flow from financing activities	(2,506)	(2,395)	(2,555)	(1,085)	404,304
Cash and cash equivalents at period end	399,743	152,720	399,743	152,720	496,834
Financial Ratios					
Basic and diluted EPS	(0.05)	(0.35)	(0.03)	(0.19)	(0.43)
Weighted average number of shares	1,660,130,437	452,542,480	1,660,572,426	452,542,480	607,511,489
Average number of employees (FTEs)	28	55	27	55	48
Assets/equity	1.22	1.70	1.22	1.70	1.24

The interim report is unaudited.

Revenue
For the first half of 2013 Veloxis recognized deferred revenue of DKK 13.7 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 half of 2013, Veloxis' research and development costs amounted to DKK 81.7 million compared to DKK 119.5 million during the same period in 2012. Research and development costs are mainly attributable to the phase III trial in LCP-Tacro™ (*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
For the first half of 2013, Veloxis' administrative cost amounted to DKK 14.6 million compared to DKK 19.7 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 half of 2013, a total of DKK 5.2 million was recognized as share-based compensation. The cost is included in R&D and G&A. The comparable cost for 2012 was DKK 3.5 million.

In the second quarter of 2013, a total of 19,405,513 warrants have been cancelled.

As of 30 June, 2013, there were a total of 85,572,644 warrants outstanding at an average strike price of DKK 0.71. Members of the Board of Directors held 375,941 warrants at an average strike price of DKK 3.35. Members of the Executive Management held 45,631,300 warrants at an average strike price of DKK 0.35, while other current and former employees held 39,565,403 warrants at an average strike price of DKK 1.10.

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

Operating loss
Veloxis' operating loss for the first half of 2013 was DKK 82.6 million compared to DKK 160.6 million in the corresponding period of 2012.

Financial income
During the first half of 2013, the Company recognized net financial income of DKK 1.7 million compared to net financial income of DKK 0.5 million in the corresponding period of 2012. The income is mainly due to currency gain following an increase in the USD / DKK currency rate during the first half of 2013.

Net loss
Veloxis' net loss for the first half of 2013 was DKK 80.5 million compared to DKK 160.6 million in the corresponding period of 2012.

Cash flow

As per 30 June, 2013, the balance sheet reflects cash and cash equivalents of DKK 399.7 million compared to DKK 496.8 million as per 31 December, 2012. This represents a decrease of DKK 97.1 million primarily related to the Company's operating activities for the period.

Balance sheet

As per 30 June, 2013, total assets were DKK 409.4 million compared to DKK 509.3 million at the end of 2012.

Shareholders' equity equalled DKK 334.7 million as of 30 June, 2013, compared to DKK 409.7 million at the end of 2012.

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 2012. 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 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, 21 August, 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

	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	6,868	6,868	6,868	-	-	-
Research and development costs	(42,772)	(38,947)	(41,890)	(49,362)	(56,639)	(62,848)
Administrative expenses	(6,834)	(7,777)	(10,235)	(6,961)	(9,462)	(10,231)
Operating loss before restructuring cost	(42,738)	(39,856)	(45,257)	(56,323)	(66,101)	(73,079)
Restructuring cost	-	-	-	-	(21,462)	-
Operating loss	(42,738)	(39,856)	(45,257)	(56,323)	(87,563)	(73,079)
Net financial income / (expenses)	(2,253)	3,907	(2,302)	993	2,051	(1,592)
Loss before tax	(44,991)	(35,949)	(47,559)	(55,330)	(85,512)	(74,671)
Tax for the period	241	244	1,034	(223)	(130)	(318)
Net loss for the period	(44,750)	(35,704)	(46,525)	(55,553)	(85,642)	(74,989)
Balance Sheet						
Cash and cash equivalents	399,743	456,216	496,834	86,683	152,720	213,786
Total assets	409,371	465,939	509,271	99,590	167,799	235,187
Share capital	166,057	166,057	165,932	45,254	45,254	452,543
Total equity	334,686	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	(51,165)	(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	(2,555)	48	410,149	(3,450)	(1,085)	(1,310)
Cash and cash equivalents at period end	399,743	456,216	496,834	86,683	152,720	213,786
Financial Ratios						
Basic and diluted EPS	(0.03)	(0.02)	(0.08)	(0.12)	(0.19)	(0.17)
Weighted average number of shares	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)	27	29	33	49	55	55
Assets/equity	1.22	1.24	1.24	2.37	1.70	1.29

Income statement and statement of comprehensive income

Income Statement	Consolidated				
(DKK'000)	**YTD 2013**	**YTD 2012**	**Q2 2013**	**Q2 2012**	**Year 2012**
Revenue	13,736	-	6,868	-	6,868
Research and development costs	(81,719)	(119,487)	(42,772)	(56,639)	(210,739)
Administrative expenses	(14,611)	(19,693)	(6,834)	(9,462)	(36,889)
Operating loss before restructuring cost	**(82,594)**	**(139,180)**	**(42,738)**	**(66,101)**	**(240,760)**
Restructuring cost	-	(21,462)	-	(21,462)	(21,462)
Operating loss	**(82,594)**	**(160,642)**	**(42,738)**	**(87,563)**	**(262,222)**
Financial income	9,872	5,226	1,000	3,649	1,481
Financial expenses	(8,218)	(4,767)	(3,253)	(1,598)	(2,331)
Loss before tax	**(80,940)**	**(160,183)**	**(44,991)**	**(85,512)**	**(263,072)**
Tax for the period	485	(448)	241	(130)	363
Net loss for the period	**(80,455)**	**(160,631)**	**(44,750)**	**(85,642)**	**(262,709)**
Basic and diluted EPS	(0.05)	(0.35)	(0.03)	(0.19)	(0.43)
Weighted average number of shares	1,660,130,437	452,542,480	1,660,572,426	452,542,480	607,511,489

Statements of comprehensive income	Consolidated				
(DKK'000)	**YTD 2013**	**YTD 2012**	**Q2 2013**	**Q2 2012**	**Year 2012**
Net loss for the period	**(80,455)**	**(160,631)**	**(44,750)**	**(85,642)**	**(262,709)**
Other comprehensive income:					
Currency translation differences	(277)	248	(149)	173	427
Other comprehensive income for the period	(277)	248	(149)	173	427
Total comprehensive income for the period	**(80,732)**	**(160,383)**	**(44,899)**	**(85,469)**	**(262,282)**

Balance sheet

Assets	Consolidated		
(DKK'000)	**30 June 2013**	**30 June 2012**	**31 Dec. 2012**
Patent rights and software	1,981	2,469	2,225
Intangible assets	**1,981**	**2,469**	**2,225**
Property, plant and equipment	2,634	4,236	2,994
Leasehold improvements	39	200	115
Property, plant and equipment	**2,673**	**4,436**	**3,109**
Non-current assets	**4,654**	**6,905**	**5,334**
Other receivables	3,964	5,057	5,181
Prepayments	1,010	3,117	1,922
Receivables	**4,974**	**8,174**	**7,103**
Securities	-	112,973	-
Cash	399,743	39,747	496,834
Cash and cash equivalents	**399,743**	**152,720**	**496,834**
Current assets	**404,717**	**160,894**	**503,937**
Assets	**409,371**	**167,799**	**509,271**

Balance sheet

Equity & Liabilities	Consolidated		
(DKK'000)	**30 June 2013**	**30 June 2012**	**31 Dec. 2012**
Share capital	166,057	45,254	165,932
Special reserve	407,289	407,289	407,289
Translation reserves	2,081	2,179	2,358
Retained earnings/loss	(240,741)	(355,754)	(165,842)
Equity	**334,686**	**98,968**	**409,737**
Finance lease	-	1,718	-
Non-current liabilities	**-**	**1,718**	**-**
Finance lease	721	4,214	3,665
Trade payables	20,179	19,614	18,590
Deferred revenue	34,340	-	48,076
Other payables	19,445	43,285	29,203
Current liabilities	**74,685**	**67,113**	**99,534**
Liabilities	**74,685**	**68,831**	**99,534**
Equity and liabilities	**409,371**	**167,799**	**509,271**

Cash flow statements

Cash Flow Statement	Consolidated				
(DKK'000)	**YTD 2013**	**YTD 2012**	**Q2 2013**	**Q2 2012**	**Year 2012**
Operating loss	**(82,594)**	**(160,642)**	**(42,738)**	**(87,563)**	**(262,222)**
Share-based payment	5,243	3,451	2,310	1,891	7,154
Depreciation and amortization	681	8,728	341	7,488	3,391
Impairment loss	-	-	-	-	6,141
Net gain on sale of fixed assets	-	-	-	-	(2,375)
Changes in working capital	(19,587)	5,544	(11,083)	15,670	42,601
Cash flow from operating activities before interest	**(96,257)**	**(142,919)**	**(51,170)**	**(62,514)**	**(205,310)**
Interest received	48	962	-	480	1,481
Interest paid	58	(359)	76	(237)	(568)
Corporate tax paid	(139)	(448)	(71)	(129)	(1,473)
Cash flow from operating activities	**(96,290)**	**(142,764)**	**(51,165)**	**(62,400)**	**(205,870)**
Purchase of property, plant and equipment	-	(217)	-	(126)	(260)
Sale of property, plant and equipment	-	-	-	-	3,175
Investments in securities	-	(11,935)	-	(8,174)	(19,909)
Sale of securities	-	65,759	-	32,474	186,706
Cash flow from investing activities	**-**	**53,607**	**-**	**24,174**	**169,712**
Installments on bank borrowings and finance lease	(2,944)	(2,395)	(2,555)	(1,085)	(4,662)
Proceeds from issuance of shares, net	438	-	-	-	408,966
Cash flow from financing activities	**(2,506)**	**(2,395)**	**(2,555)**	**(1,085)**	**404,304**
Increase/(decrease) in cash	**(98,796)**	**(91,552)**	**(53,720)**	**(39,311)**	**368,146**
Cash at beginning of period	496,834	130,930	456,216	76,513	130,930
Exchange gains/(losses) on cash	1,705	369	(2,753)	2,545	(2,242)
Cash at end of period	**399,743**	**39,747**	**399,743**	**39,747**	**496,834**
Cash and cash equivalents at end of period comprise:					
Securities	-	112,973	-	112,973	-
Deposit on demand and cash	399,743	39,747	399,743	39,747	496,834
	399,743	**152,720**	**399,743**	**152,720**	**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					248	(160,631)	(160,383)
Reduction of share capital		(407,289)		407,289			-
Share-based payment						3,451	3,451
Equity as of 30 June 2012	**452,542,480**	**45,254**	**-**	**407,289**	**2,179**	**(355,754)**	**98,968**
Total comprehensive income					179	(102,078)	(101,899)
Issuance of shares	1,206,779,946	120,678	301,695				422,373
Share-based payment						3,703	3,703
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					(277)	(80,455)	(80,732)
Warrant exercises	1,250,000	125	313				438
Share-based payment						5,243	5,243
Transfer of retained earnings			(313)			313	-
Equity as of 30 June 2013	**1,660,572,426**	**166,057**	**-**	**407,289**	**2,081**	**(240,741)**	**334,686**

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.