Company Announcement no. 20/2013

To: NASDAQ OMX Copenhagen A/S

Hørsholm, Denmark, 13 November, 2013

Veloxis Pharmaceuticals announces financial results for the first nine months of 2013 and improves the full year Outlook
Envarsus® program progresses according to plan

Highlights:

- Veloxis' Marketing Authorization Application (MAA) to market Envarsus® (formerly LCP-Tacro™) for the prevention of organ rejection in kidney transplant patients in the European Union remains under review with the European Medicines Agency (EMA). The company expects the decision from the European Union in 2014.
- Preparations continue for the submission of a New Drug Application (NDA) for Envarsus® to the US Food and Drug Agency (FDA) in late 2013.
- Veloxis reported a net loss of DKK 114.6 million for the first nine months of 2013 compared to a net loss of DKK 216.2 million for the same period in 2012.
- For the first nine months of 2013, Veloxis' research and development costs amounted to DKK 117.0 million compared to DKK 168.8 million during the same period in 2012.
- On 30 September, 2013, Veloxis had cash and cash equivalents of DKK 380.2 million.
- The full year outlook for 2013 is improved. Veloxis now expects an operating and net loss in the range of DKK 160-190 million. Veloxis' cash position is expected to be in the range of DKK 310-340 million at year-end 2013.

Outlook for 2013

The full year outlook for 2013 is improved. Veloxis now expects an operating and net loss in the range of DKK 160-190 million.

Veloxis' earlier outlook for 2013, which was announced in connection with the annual report for 2012 in March 2013, projected an operating and net loss of DKK 170-200 million.

The improvement is a result of continuous cost optimization. Further, cash position will be positively impacted by timing of accounting costs not yet paid at year-end.

Cash and cash equivalents are expected to be in the range of DKK 310-340 million at 31 December 2013. This compares with expectations of DKK 270–310 million announced in connection with the annual report for 2012.

Conference call

A conference call will be held tomorrow, 14 November, 2013 at 4:00 PM CET (Denmark); 3:00 PM GMT (London), 10:00 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 96780245

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 completed 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 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 Envarsus® compared to Prograf®. The treatment failure rate for Envarsus® 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 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. 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 Envarsus®' unique PK profile. The first study initiated 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®.

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. The MAA submission was based on the favorable results of the Envarsus® 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. The review of the MAA is on-going and Veloxis expects to receive a decision on the application in 2014.

Preparations continue for the submission of the Envarsus® NDA to the US FDA in late 2013 for the prophylaxis of kidney transplant rejection. The submission 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	Q3 2013 DKK'000	Q3 2012 DKK'000	Year 2012 DKK'000
Income Statement					
Revenue	25,942	-	12,206	-	6,868
Research and development costs	(116,966)	(168,849)	(35,247)	(49,362)	(210,739)
Administrative expenses	(21,314)	(26,654)	(6,703)	(6,961)	(36,889)
Operating loss before restructuring cost	(112,338)	(195,503)	(29,744)	(56,323)	(240,760)
Restructuring cost	-	(21,462)	-	-	(21,462)
Operating loss	(112,338)	(216,965)	(29,744)	(56,323)	(262,222)
Net financial income / (expenses)	(3,001)	1,452	(4,655)	993	(850)
Loss before tax	(115,339)	(215,513)	(34,399)	(55,330)	(263,072)
Tax for the period	728	(671)	242	(223)	363
Net loss for the period	(114,611)	(216,184)	(34,157)	(55,553)	(262,709)
Balance Sheet					
Cash and cash equivalents	380,179	86,683	380,179	86,683	496,834
Total assets	388,982	99,590	388,982	99,590	509,271
Share capital	166,057	45,254	166,057	45,254	165,932
Total equity	302,307	42,103	302,307	42,103	409,737
Investment in property, plant and equipment	-	217	-	-	260
Cash Flow Statement					
Cash flow from operating activities	(110,330)	(205,472)	(14,040)	(62,707)	(205,870)
Cash flow from investing activities	-	113,093	-	59,486	169,712
Cash flow from financing activities	(2,907)	(5,844)	(401)	(3,450)	404,304
Cash and cash equivalents at period end	380,179	86,683	380,179	86,683	496,834
Financial Ratios					
Basic and diluted EPS	(0.07)	(0.48)	(0.02)	(0.12)	(0.43)
Weighted average number of shares	1,660,279,386	452,542,480	1,660,572,426	452,542,480	607,511,489
Average number of employees (FTEs)	27	53	26	49	48
Assets/equity	1.29	2.37	1.29	2.37	1.24

The interim report is unaudited.

Revenue
For the first nine months of 2013 Veloxis recognized deferred revenue of DKK 26.0 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 based on planned development periods.

Research and development costs
For the first nine months of 2013, Veloxis' research and development costs amounted to DKK 117.0 million compared to DKK 168.8 million during the same period in 2012. 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
For the first nine months of 2013, Veloxis' administrative cost amounted to DKK 21.3 million compared to DKK 26.7 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 nine months of 2013, a total of DKK 7.1 million was recognized as share-based compensation. The cost is included in R&D and G&A. The comparable cost for 2012 was DKK 4.4 million.

In the third quarter of 2013, a total of 250,000 warrants were granted to the Board of Directors at a strike price of DKK 0.58, a total of 89,775 warrants have been cancelled and a total of 499,912 warrants have expired.

As of 30 September, 2013, there were a total of 85,232,958 warrants outstanding at an average strike price of DKK 0.63. Members of the Board of Directors held 589,584 warrants at an average strike price of DKK 1.43. 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 39,012,074 warrants at an average strike price of DKK 0.94.

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

Operating loss
Veloxis' operating loss for the first nine months of 2013 was DKK 112.3 million compared to DKK 217.0 million in the corresponding period of 2012.

Financial income
During the first nine months of 2013, the Company recognized net financial expenses of DKK 3.0 million compared to net financial income of DKK 1.5 million in the corresponding period of 2012. The loss is mainly due to unrealized currency losses following a decrease in the USD / DKK currency rate during the first nine months of 2013.

Net loss
Veloxis' net loss for the first nine months of 2013 was DKK 114.6 million compared to DKK 216.2 million in the corresponding period of 2012.

Cash flow

As per 30 September, 2013, the balance sheet reflects cash and cash equivalents of DKK 380.2 million compared to DKK 496.8 million as per 31 December, 2012. This represents a decrease of DKK 116.6 million primarily related to the Company's operating activities for the period.

Balance sheet

As per 30 September, 2013, total assets were DKK 389.0 million compared to DKK 509.3 million at the end of 2012.

Shareholders' equity equalled DKK 302.3 million as of 30 September, 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.

For more information, please contact:

John D. Weinberg
EVP, Chief Commercial Officer
Mobile: +1 908 304 3389
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® 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 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 for the 9 months ended 30 September 2013 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, 13 November, 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

	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	6,868	6,868	6,868	-	-	-
Research and development costs	(35,247)	(42,772)	(38,947)	(41,890)	(49,362)	(56,639)	(62,848)
Administrative expenses	(6,703)	(6,834)	(7,777)	(10,235)	(6,961)	(9,462)	(10,231)
Operating loss before restructuring cost	(29,744)	(42,738)	(39,856)	(45,257)	(56,323)	(66,101)	(73,079)
Restructuring cost	-	-	-	-	-	(21,462)	-
Operating loss	(29,744)	(42,738)	(39,856)	(45,257)	(56,323)	(87,563)	(73,079)
Net financial income / (expenses)	(4,655)	(2,253)	3,907	(2,302)	993	2,051	(1,592)
Loss before tax	(34,399)	(44,991)	(35,949)	(47,559)	(55,330)	(85,512)	(74,671)
Tax for the period	242	241	244	1,034	(223)	(130)	(318)
Net loss for the period	(34,157)	(44,750)	(35,704)	(46,525)	(55,553)	(85,642)	(74,989)
Balance Sheet							
Cash and cash equivalents	380,179	399,743	456,216	496,834	86,683	152,720	213,786
Total assets	388,982	409,371	465,939	509,271	99,590	167,799	235,187
Share capital	166,057	166,057	166,057	165,932	45,254	45,254	452,543
Total equity	302,307	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	(14,040)	(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	(401)	(2,555)	48	410,149	(3,450)	(1,085)	(1,310)
Cash and cash equivalents at period end	380,179	399,743	456,216	496,834	86,683	152,720	213,786
Financial Ratios							
Basic and diluted EPS	(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	1,659,683,537	607,511,489	452,542,480	452,542,480	452,542,480
Average number of employees (FTEs)	26	27	29	33	49	55	55
Assets/equity	1.29	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**	**Q3 2013**	**Q3 2012**	**Year 2012**
Revenue	25,942	-	12,206	-	6,868
Research and development costs	(116,966)	(168,849)	(35,247)	(49,362)	(210,739)
Administrative expenses	(21,314)	(26,654)	(6,703)	(6,961)	(36,889)
Operating loss before restructuring cost	**(112,338)**	**(195,503)**	**(29,744)**	**(56,323)**	**(240,760)**
Restructuring cost	-	(21,462)	-	-	(21,462)
Operating loss	**(112,338)**	**(216,965)**	**(29,744)**	**(56,323)**	**(262,222)**
Financial income	10,917	6,907	1,045	1,681	1,481
Financial expenses	(13,918)	(5,455)	(5,700)	(688)	(2,331)
Loss before tax	**(115,339)**	**(215,513)**	**(34,399)**	**(55,330)**	**(263,072)**
Tax for the period	728	(671)	242	(223)	363
Net loss for the period	**(114,611)**	**(216,184)**	**(34,157)**	**(55,553)**	**(262,709)**
Basic and diluted EPS	(0.07)	(0.48)	(0.02)	(0.12)	(0.43)
Weighted average number of shares	1,660,279,386	452,542,480	1,660,572,426	452,542,480	607,511,489

Statements of comprehensive income	Consolidated				
(DKK'000)	**YTD 2013**	**YTD 2012**	**Q3 2013**	**Q3 2012**	**Year 2012**
Net loss for the period	**(114,611)**	**(216,184)**	**(34,157)**	**(55,553)**	**(262,709)**
Other comprehensive income:					
Currency translation differences	(335)	361	(58)	113	427
Other comprehensive income for the period	(335)	361	(58)	113	427
Total comprehensive income for the period	**(114,946)**	**(215,823)**	**(34,215)**	**(55,440)**	**(262,282)**

Balance sheet

Assets	Consolidated		
(DKK'000)	**30 Sept. 2013**	**30 Sept. 2012**	**31 Dec. 2012**
Patent rights and software	1,858	2,347	2,225
Intangible assets	**1,858**	**2,347**	**2,225**
Property, plant and equipment	2,454	3,958	2,994
Leasehold improvements	-	156	115
Property, plant and equipment	**2,454**	**4,114**	**3,109**
Non-current assets	**4,312**	**6,461**	**5,334**
Other receivables	3,186	5,224	5,181
Prepayments	1,305	1,222	1,922
Receivables	**4,491**	**6,446**	**7,103**
Securities	-	53,487	-
Cash	380,179	33,196	496,834
Cash and cash equivalents	**380,179**	**86,683**	**496,834**
Current assets	**384,670**	**93,129**	**503,937**
Assets	**388,982**	**99,590**	**509,271**

Balance sheet

Equity & Liabilities	Consolidated		
(DKK'000)	**30 Sept. 2013**	**30 Sept. 2012**	**31 Dec. 2012**
Share capital	166,057	45,254	165,932
Special reserve	407,289	407,289	407,289
Translation reserves	2,023	2,292	2,358
Retained earnings/loss	(273,062)	(412,732)	(165,842)
Equity	**302,307**	**42,103**	**409,737**
Finance lease	-	722	-
Non-current liabilities	**-**	**722**	**-**
Finance lease	320	4,109	3,665
Trade payables	13,338	25,078	18,590
Deferred revenue	48,823	-	48,076
Other payables	24,194	27,578	29,203
Current liabilities	**86,675**	**56,765**	**99,534**
Liabilities	**86,675**	**57,487**	**99,534**
Equity and liabilities	**388,982**	**99,590**	**509,271**

Cash flow statements

Cash Flow Statement	Consolidated				
(DKK'000)	**YTD 2013**	**YTD 2012**	**Q3 2013**	**Q3 2012**	**Year 2012**
Operating loss	**(112,338)**	**(216,965)**	**(29,744)**	**(56,323)**	**(262,222)**
Share-based payment	7,079	4,375	1,835	924	7,154
Depreciation and amortization	1,022	9,168	340	440	3,391
Impairment loss	-	-	-	-	6,141
Net gain on sale of fixed assets	-	-	-	-	(2,375)
Changes in working capital	(5,982)	(2,151)	13,606	(7,694)	42,601
Cash flow from operating activities before interest	**(110,219)**	**(205,573)**	**(13,963)**	**(62,653)**	**(205,310)**
Interest received	48	1,234	-	272	1,481
Interest paid	51	(462)	(7)	(103)	(568)
Corporate tax paid	(210)	(671)	(70)	(223)	(1,473)
Cash flow from operating activities	**(110,330)**	**(205,472)**	**(14,040)**	**(62,707)**	**(205,870)**
Purchase of property, plant and equipment	-	(217)	-	-	(260)
Sale of property, plant and equipment	-	-	-	-	3,175
Investments in securities	-	(16,804)	-	(4,869)	(19,909)
Sale of securities	-	130,114	-	64,355	186,706
Cash flow from investing activities	**-**	**113,093**	**-**	**59,486**	**169,712**
Installments on bank borrowings and finance lease	(3,345)	(3,495)	(401)	(1,101)	(4,662)
Proceeds from issuance of shares, net	438	(2,349)	-	(2,349)	408,966
Cash flow from financing activities	**(2,907)**	**(5,844)**	**(401)**	**(3,450)**	**404,304**
Increase/(decrease) in cash	**(113,237)**	**(98,223)**	**(14,441)**	**(6,671)**	**368,146**
Cash at beginning of period	496,834	130,930	399,743	39,747	130,930
Exchange gains/(losses) on cash	(3,418)	489	(5,123)	120	(2,242)
Cash at end of period	**380,179**	**33,196**	**380,179**	**33,196**	**496,834**
Cash and cash equivalents at end of period comprise:					
Securities	-	53,487	-	53,487	-
Deposit on demand and cash	380,179	33,196	380,179	33,196	496,834
	380,179	**86,683**	**380,179**	**86,683**	**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					361	(216,184)	(215,823)
Reduction of share capital		(407,289)		407,289			-
Share-based payment						4,375	4,375
Costs related to capital increases			(2,349)				(2,349)
Transfer of retained earnings			2,349			(2,349)	-
Equity as of 30 September 2012	**452,542,480**	**45,254**	**-**	**407,289**	**2,292**	**(412,732)**	**42,103**
Total comprehensive income					66	(46,525)	(46,459)
Issuance of shares	1,206,779,946	120,678	301,695				422,373
Share-based payment						2,779	2,779
Costs related to capital increases			(11,059)				(11,059)
Transfer of retained earnings			(290,636)			290,636	-
Equity as of 31 December 2012	**1,659,322,426**	**165,932**	**-**	**407,289**	**2,358**	**(165,842)**	**409,737**
Total comprehensive income					(335)	(114,611)	(114,946)
Warrant exercises	1,250,000	125	312				437
Share-based payment						7,079	7,079
Transfer of retained earnings			(312)			312	-
Equity as of 30 September 2013	**1,660,572,426**	**166,057**	**-**	**407,289**	**2,023**	**(273,062)**	**302,307**

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.

2. Transactions with related parties

In the third quarter of 2013 warrants were granted to the members of the Board of Directors. Further details on the grant are provided on page 5.