

Company Announcement no. 7/2012

To: NASDAQ OMX Copenhagen A/S

Hørsholm, Denmark, 15 May, 2012

**Veloxis Pharmaceuticals announces financial results for the first quarter 2012 in line with expectations, Phase III activities for LCP-Tacro™ progressing according to plan**

**Highlights:**

- Enrolment has been completed in the pivotal LCP-Tacro 3002 Phase III study in *de novo* kidney transplant patients. The LCP-Tacro 3002 study is designed to demonstrate non-inferiority versus standard therapy Prograf® and randomized 543 patients at approximately 90 clinical sites around the world.
- Veloxis have initiated the STRATO Study of LCP-Tacro™ in Kidney Transplant Recipients Experiencing Tremors. The 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.
- Veloxis reported a net loss of DKK 75.0 million for the first quarter of 2012 compared to a net loss of DKK 65.8 million for the same period in 2011. The reported net loss is in line with expectations and the financial outlook for 2012 is maintained.
- For the first quarter of 2012, Veloxis' research and development costs amounted to DKK 62.8 million compared to DKK 52.3 million during the same period in 2011.
- On 31 March, 2012, Veloxis had cash and cash equivalents of DKK 213.8 million.

A conference call will be held tomorrow, 16 May, 2012 at 3:00 PM CET (Denmark); 2:00 PM GMT (London), 9:00 AM ET (New York), 6:00 AM PT (San Francisco).

To access the live conference call, please dial one of the following numbers:

+45 32 72 76 25 (Denmark)

+44 (0) 1452 555 566 (UK)

+1 631 510 7498 (USA)

Access code 77202811

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

## Outlook for 2012

Veloxis maintains its 2012 outlook announced in the annual report for 2011, published in March 2012, with an operating loss of DKK 220–250 million and likewise a net loss of DKK 220–250 million. The Company's position of cash and cash equivalents as at 31 December, 2012 is expected to be in the range of DKK 40–80 million.

Management is focused on securing additional funds beyond 2012 by either partner agreements, debt or equity, or a mix thereof.

## Research & development update

### *LCP-Tacro™ in kidney transplant patients*

Veloxis is completing 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 this study 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 subjects at approximately 90 transplant centers, primarily in the U.S and Europe. 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 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.

### *LCP-Tacro™ Regulatory Strategy*

Based upon the favorable results of the 3001 Study, and the totality of an extensive Phase I, II and III clinical safety, efficacy and PK program, the company plans to file an MAA with the EMA mid-2012. The U.S. submission to the FDA will be based on data from Studies 3001 and 3002, as well as on data from Phase I and II studies, and is planned for the second half of 2013.

### Financial Highlights

	Q1 2012 DKK'000	Q1 2011 DKK'000	Year 2011 DKK'000
<b>Income Statement</b>			
Revenue	-	-	-
Research and development costs	(62,848)	(52,261)	(222,053)
Administrative expenses	(10,231)	(11,724)	(47,814)
Operating loss	(73,079)	(63,985)	(269,867)
Net financial income / (expenses)	(1,592)	(1,850)	16,048
Loss before tax	(74,671)	(65,835)	(253,819)
Tax for the period	(318)	-	1,193
Net loss for the period	(74,989)	(65,835)	(252,626)
<b>Balance Sheet</b>			
Cash and cash equivalents	213,786	462,319	297,727
Total assets	235,187	490,578	320,927
Share capital	452,543	452,543	452,543
Total equity	182,545	436,200	255,900
Investment in property, plant and equipment	91	621	2,981
<b>Cash Flow Statement</b>			
Cash flow from operating activities	(80,364)	(65,396)	(234,637)
Cash flow from investing activities	29,433	(299,602)	(169,778)
Cash flow from financing activities	(1,310)	(1,407)	(5,948)
Cash and cash equivalents at period end	213,786	462,319	297,727
<b>Financial Ratios</b>			
Basic and diluted EPS	(0.17)	(0.15)	(0.56)
Weighted average number of shares	452,542,480	452,542,480	452,542,480
Average number of employees (FTEs)	55	54	52
Assets/equity	1.29	1.12	1.25

The interim report is unaudited.

### Revenue

For the first quarter of 2012 Veloxis had no revenue as in the same period of 2011.

### Research and development costs

For the first quarter of 2012, Veloxis' research and development costs amounted to DKK 62.8 million compared to DKK 52.3 million during the same period in 2011. Research and development costs are mainly attributable to the phase III trial in LCP-Tacro™ (*de novo* patients, Study 3002).

### Administrative expenses

For the first quarter of 2012, Veloxis' administrative cost amounted to DKK 10.2 million compared to DKK 11.7 million during the same period in 2011.

### Compensation costs

For the first three months of 2012, a total of DKK 1.6 million was recognized as share-based compensation. The cost is included in R&D and G&A. The comparable cost for 2011 was DKK 3.5 million.

In the first quarter of 2012, a total of 109,548 warrants have been cancelled.

As of 31 March, 2012, there were a total of 29,776,146 warrants outstanding at an average strike price of DKK 3.0. Members of the Board of Directors held 828,976 warrants at an average strike price of DKK 7.2. Members of the Executive Management held 9,112,445 warrants at an average strike price of DKK 2.1, while other current and former employees held 19,834,725 warrants at an average strike price of DKK 3.3.

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 2012 was DKK 73.1 million compared to DKK 64.0 million in the corresponding period of 2011.

### Financial income

During the first three months of 2012, the Company recognized net financial expenses of DKK 1.6 million compared to net financial expenses of DKK 1.9 million in the corresponding period of 2011. The loss is mainly due to unrealized currency losses following the decline in the USD / DKK currency rate during the first quarter of 2012.

### Net loss

Veloxis' net loss for the first three months of 2012 was DKK 75.0 million compared to DKK 65.8 million in the corresponding period of 2011.

### Cash flow

As per 31 March, 2012, the balance sheet reflects cash and cash equivalents of DKK 213.8 million compared to DKK 297.7 million as per 31 December, 2011. This represents a decrease of DKK 83.9 million primarily related to the Company's operating activities for the period.

### **Balance sheet**

As per 31 March, 2012, total assets were DKK 235.2 million compared to DKK 320.9 million at the end of 2011.

Shareholders' equity equalled DKK 182.5 million as of 31 March, 2012, compared to DKK 255.9 million at the end of 2011.

As approved at the annual general meeting on 18 April 2012 the company's share capital will be decreased by nominally DKK 407,288,232 from nominally DKK 452,542,480 to nominally DKK 45,254,248 following a four week notice period.

### **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 2011.

### **Financial review**

Veloxis reports its financial statements in Danish Kroner (DKK), which is the functional currency of the Company and the group. Solely for the convenience of the reader, this Interim Report contains a conversion of certain DKK amounts into Euro (EUR) at a specified rate. These converted amounts should not be construed as representations that the DKK amounts actually represent such EUR amounts or could be converted into EUR at the rate indicated or at any other rate. Unless otherwise indicated, conversion herein of financial information into EUR has been made using the Danish Central Bank's spot rate on 31 March, 2012, which was EUR 1.00 = DKK 7.4399.

**For more information, please contact:**

John D. Weinberg  
SVP, Commercial Operations and Investor Relations  
Mobile: +1 732 321 3208  
Email: [jdw@veloxis.com](mailto:jdw@veloxis.com)

Johnny Stilou  
CFO  
Mobile: +45 21 227 227  
Email: [jst@veloxis.com](mailto:jst@veloxis.com)

The forward looking statements and targets contained herein are based on Veloxis Pharmaceuticals A/S' management's current view and assumptions. 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 Veloxis Pharmaceuticals A/S (Veloxis)**

Based in Hørsholm, Denmark, with an office in New Jersey, Veloxis is a specialty pharmaceutical company. Clinical development is the core of Veloxis' efforts to develop a product portfolio which includes the Company's lead product candidate, LCP-Tacro™, for immunosuppression, specifically organ transplantation, and products to combat certain cardiovascular diseases. Veloxis adapts new technologies on a fast commercial timetable. Veloxis' unique, patented delivery technology, MeltDose®, can improve absorption and bioavailability - at low-scale up costs - not only for a broad spectrum of drugs already on the market but also for new chemical entities. Veloxis has a lipid-lowering product, Fenoglide®, currently on the U.S. market and a diversified near and medium-term pipeline with three clinical stage product candidates and a number of projects in preclinical development. 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, 2012

### **Executive Management**

Dr. William J. Polvino  
President and CEO

Peter G. Nielsen  
Executive Vice President

### **Board of Directors**

Kim Björnstrup  
(Chairman)

Thomas Dyrberg  
(Deputy Chairman)

Kurt Anker Nielsen

Anders Götzsche

Mette Kirstine Agger

Ed Penhoet

Interim Report  
for the 3 Months Ended 31 March, 2012  
(15 May, 2012)



**Financial Highlights**  
**Quarterly Numbers in DKK**

	<b>Q1 2012 DKK'000</b>	<b>Q4 2011 DKK'000</b>	<b>Q3 2011 DKK'000</b>	<b>Q2 2011 DKK'000</b>	<b>Q1 2011 DKK'000</b>
<b>Income Statement</b>					
Revenue	-	-	-	-	-
Research and development costs	(62,848)	(61,763)	(43,079)	(64,951)	(52,261)
Administrative expenses	(10,231)	(11,385)	(12,568)	(12,137)	(11,724)
Operating loss	(73,079)	(73,148)	(55,647)	(77,088)	(63,985)
Net financial income / (expenses)	(1,592)	4,528	11,363	2,008	(1,850)
Loss before tax	(74,671)	(68,620)	(44,284)	(75,080)	(65,835)
Tax for the period	(318)	373	1,120	(300)	-
Net loss for the period	(74,989)	(68,247)	(43,164)	(75,380)	(65,835)
<b>Balance Sheet</b>					
Cash and cash equivalents	213,786	297,727	348,252	402,213	462,319
Total assets	235,187	320,927	370,865	426,860	490,578
Share capital	452,543	452,543	452,543	452,543	452,543
Total equity	182,545	255,900	322,516	363,606	436,200
Investment in property, plant and equipment	91	1,123	602	635	621
<b>Cash Flow Statement</b>					
Cash flow from operating activities	(80,364)	(52,139)	(60,481)	(56,621)	(65,396)
Cash flow from investing activities	29,433	26,101	25,878	77,845	(299,602)
Cash flow from financing activities	(1,310)	(1,670)	(1,445)	(1,426)	(1,407)
Cash and cash equivalents at period end	213,786	297,727	348,252	402,213	462,319
<b>Financial Ratios</b>					
Basic and diluted EPS	(0.17)	(0.15)	(0.10)	(0.17)	(0.15)
Weighted average number of shares	452,542,480	452,542,480	452,542,480	452,542,480	452,542,480
Average number of employees (FTEs)	55	51	51	52	54
Assets/equity	1.29	1.25	1.15	1.17	1.12



**Financial Highlights**  
**Quarterly Numbers in EUR**

	Q1 2012 EUR'000	Q4 2011 EUR'000	Q3 2011 EUR'000	Q2 2011 EUR'000	Q1 2011 EUR'000
<b>Income Statement</b>					
Revenue	-	-	-	-	-
Research and development costs	(8,447)	(8,302)	(5,790)	(8,730)	(7,024)
Administrative expenses	(1,375)	(1,530)	(1,689)	(1,631)	(1,576)
Operating loss	(9,822)	(9,832)	(7,479)	(10,361)	(8,600)
Net financial income / (expenses)	(214)	609	1,527	269	(249)
Loss before tax	(10,036)	(9,223)	(5,952)	(10,092)	(8,849)
Tax for the period	(43)	50	150	(40)	-
Net loss for the period	(10,079)	(9,173)	(5,802)	(10,132)	(8,849)
<b>Balance Sheet</b>					
Cash and cash equivalents	28,735	40,018	46,809	54,062	62,140
Total assets	31,612	43,136	49,848	57,374	65,939
Share capital	60,826	60,826	60,826	60,826	60,826
Total equity	24,536	34,396	43,349	48,872	58,630
Investment in property, plant and equipment	12	151	81	85	83
<b>Cash Flow Statement</b>					
Cash flow from operating activities	(10,802)	(7,008)	(8,129)	(7,610)	(8,790)
Cash flow from investing activities	3,956	3,508	3,478	10,463	(40,270)
Cash flow from financing activities	(176)	(224)	(194)	(192)	(189)
Cash and cash equivalents at period end	28,735	40,018	46,809	54,062	62,140
<b>Financial Ratios</b>					
Basic and diluted EPS	(0.02)	(0.02)	(0.01)	(0.02)	(0.02)
Weighted average number of shares	452,542,480	452,542,480	452,542,480	452,542,480	452,542,480
Average number of employees (FTEs)	55	51	51	52	54
Assets/equity	1.29	1.25	1.15	1.17	1.12

## Income statement and statement of comprehensive income

Income Statement	Consolidated		
(DKK'000)	Q1 2012	Q1 2011	Year 2011
Revenue	-	-	-
Research and development costs	(62,848)	(52,261)	(222,053)
Administrative expenses	(10,231)	(11,724)	(47,814)
<b>Operating loss</b>	<b>(73,079)</b>	<b>(63,985)</b>	<b>(269,867)</b>
Financial income	1,577	1,645	33,238
Financial expenses	(3,169)	(3,495)	(17,190)
<b>Loss before tax</b>	<b>(74,671)</b>	<b>(65,835)</b>	<b>(253,819)</b>
Tax for the period	(318)	-	1,193
<b>Net loss for the period</b>	<b>(74,989)</b>	<b>(65,835)</b>	<b>(252,626)</b>
Basic and diluted EPS	(0.17)	(0.15)	(0.56)
Weighted average number of shares	452,542,480	452,542,480	452,542,480

Statement of comprehensive income	Consolidated		
(DKK'000)	Q1 2012	Q1 2011	Year 2011
<b>Net loss for the period</b>	<b>(74,989)</b>	<b>(65,835)</b>	<b>(252,626)</b>
<b>Other comprehensive income:</b>			
Currency translation differences	74	271	(163)
<b>Other comprehensive income for the period</b>	<b>74</b>	<b>271</b>	<b>(163)</b>
<b>Total comprehensive income for the period</b>	<b>(74,915)</b>	<b>(65,564)</b>	<b>(252,789)</b>

## Balance sheet

Assets		Consolidated		
(DKK'000)	31 Mar. 2012	31 Mar. 2011	31 Dec. 2011	
Patent rights and software	2,591	2,035	2,563	
<b>Intangible assets</b>	<b>2,591</b>	<b>2,035</b>	<b>2,563</b>	
Property, plant and equipment	8,334	11,099	8,967	
Leasehold improvements	3,327	5,317	3,880	
<b>Property, plant and equipment</b>	<b>11,661</b>	<b>16,416</b>	<b>12,847</b>	
<b>Non-current assets</b>	<b>14,252</b>	<b>18,451</b>	<b>15,410</b>	
Other receivables	5,325	6,325	5,480	
Prepayments	1,824	3,483	2,310	
<b>Receivables</b>	<b>7,149</b>	<b>9,808</b>	<b>7,790</b>	
Securities	137,273	299,039	166,797	
Cash	76,513	163,281	130,930	
<b>Cash and cash equivalents</b>	<b>213,786</b>	<b>462,319</b>	<b>297,727</b>	
<b>Current assets</b>	<b>220,935</b>	<b>472,127</b>	<b>305,517</b>	
<b>Assets</b>	<b>235,187</b>	<b>490,578</b>	<b>320,927</b>	

## Balance sheet

<b>Equity &amp; Liabilities</b>		<b>Consolidated</b>	
<b>(DKK'000)</b>	<b>31 Mar. 2012</b>	<b>31 Mar. 2011</b>	<b>31 Dec. 2011</b>
Share capital	452,543	452,543	452,543
Share premium	-	(18,708)	-
Translation reserves	2,005	2,365	1,931
Retained earnings/loss	(272,003)	-	(198,574)
<b>Equity</b>	<b>182,545</b>	<b>436,200</b>	<b>255,900</b>
Finance lease	2,698	7,118	3,715
<b>Non-current liabilities</b>	<b>2,698</b>	<b>7,118</b>	<b>3,715</b>
Finance lease	4,318	5,749	4,612
Trade payables	20,346	12,045	28,263
Other payables	25,280	29,466	28,437
<b>Current liabilities</b>	<b>49,944</b>	<b>47,260</b>	<b>61,312</b>
<b>Liabilities</b>	<b>52,642</b>	<b>54,378</b>	<b>65,027</b>
<b>Equity and liabilities</b>	<b>235,187</b>	<b>490,578</b>	<b>320,927</b>

## Cash flow statements

Cash Flow Statement	Consolidated		
(DKK'000)	Q1 2012	Q1 2011	Year 2011
<b>Operating loss</b>	<b>(73,079)</b>	<b>(63,985)</b>	<b>(269,867)</b>
Share-based payment	1,560	3,526	10,451
Depreciation and amortization	1,240	1,899	7,320
Changes in working capital	(10,127)	(6,649)	13,094
<b>Cash flow from operating activities before interest</b>	<b>(80,406)</b>	<b>(65,209)</b>	<b>(239,002)</b>
Interest received	482	1,047	5,418
Interest paid	(122)	(1,234)	(2,246)
Corporate tax paid	(318)	-	1,193
<b>Cash flow from operating activities</b>	<b>(80,364)</b>	<b>(65,396)</b>	<b>(234,637)</b>
Purchase of property, plant and equipment	(91)	(621)	(2,981)
Investments in bonds	(3,761)	(376,031)	(406,128)
Sale of bonds	33,285	76,992	239,331
Cash transfer to restricted security deposit	-	58	-
<b>Cash flow from investing activities</b>	<b>29,433</b>	<b>(299,602)</b>	<b>(169,778)</b>
Installments on bank borrowings and finance lease	(1,310)	(1,407)	(5,948)
<b>Cash flow from financing activities</b>	<b>(1,310)</b>	<b>(1,407)</b>	<b>(5,948)</b>
<b>Increase/(decrease) in cash</b>	<b>(52,241)</b>	<b>(366,405)</b>	<b>(410,363)</b>
Cash at beginning of period	130,930	530,081	531,519
Exchange gains/(losses) on cash	(2,176)	(1,775)	9,774
<b>Cash at end of period</b>	<b>76,513</b>	<b>161,901</b>	<b>130,930</b>
<b>Cash and cash equivalents at end of period comprise:</b>			
Restricted bank deposit	-	1,379	-
Securities	137,273	299,039	166,797
Deposit on demand and cash	76,513	161,901	130,930
	<b>213,786</b>	<b>462,319</b>	<b>297,727</b>

## Statement of changes in equity

<b>Consolidated Equity</b>						
	<b>Number of Shares</b>	<b>Share Capital DKK'000</b>	<b>Share Premium DKK'000</b>	<b>Translation Reserves DKK'000</b>	<b>Retained Earnings DKK'000</b>	<b>Total DKK'000</b>
<b>Equity as of 1 January 2011</b>	<b>452,542,480</b>	<b>452,543</b>	<b>43,601</b>	<b>2,094</b>	<b>-</b>	<b>498,238</b>
Total comprehensive income				271	(65,835)	(65,564)
Share-based payment					3,526	3,526
Transfer of retained earnings			(62,309)		62,309	-
<b>Equity as of 31 March 2011</b>	<b>452,542,480</b>	<b>452,543</b>	<b>(18,708)</b>	<b>2,365</b>	<b>-</b>	<b>436,200</b>
Total comprehensive income				(434)	(186,791)	(187,225)
Share-based payment					6,925	6,925
Transfer of retained earnings			18,708		(18,708)	-
<b>Equity as of 31 December 2011</b>	<b>452,542,480</b>	<b>452,543</b>	<b>-</b>	<b>1,931</b>	<b>(198,574)</b>	<b>255,900</b>
Total comprehensive income				74	(74,989)	(74,915)
Share-based payment					1,560	1,560
<b>Equity as of 31 March 2012</b>	<b>452,542,480</b>	<b>452,543</b>	<b>-</b>	<b>2,005</b>	<b>(272,003)</b>	<b>182,545</b>

The share capital is not available for distribution, while other reserves are distributable for dividend purposes subject to the provision of the Danish Public Company Act.