

Company Announcement no. 9/2016

To: NASDAQ OMX Copenhagen A/S

Hørsholm, Denmark, 18 May, 2016

## Veloxis Pharmaceuticals announces financial results for the first three months of 2016

### Highlights:

- First quarter revenue totaled 1,500 tUSD compared with 647 tUSD in first quarter 2015, reflecting the US market launch in December 2015 and the successful adoption of Envarsus® XR. Likewise, Chiesi, under its license for European commercialization, continues to grow European sales and to launch Envarsus® XR in additional European countries.
- Veloxis has entered into a five-year loan and security agreement with Lundbeckfond invest A/S and Novo A/S for up to USD 20 million in financing. The facility may be utilized in tranches and repaid without penalty. It carries a 9.25% interest rate, payable annually in arrears. On 31 March, 2016, Veloxis had cash and cash equivalents of 6,650 tUSD.
- Alastair McEwan has been appointed as Chief Operating Officer. Alastair McEwan has been involved in pharmaceutical development and commercialization for over twenty years and brings substantial operational and financial experience to the Company.
- Veloxis moves all activities to the U.S. where most of the company's current activities are already located. The process is expected to be completed during the second half of 2016.
- Veloxis reported a net loss of 7,109 tUSD for the first quarter of 2016 compared to a net loss of 4,077 tUSD for the same period in 2015. The reported net loss is in line with expectations and the financial outlook for 2016 is maintained.

### Outlook for 2016

Veloxis maintains its 2016 outlook of an operating and net loss of DKK 120 – 160 million, as noted in the 2015 Annual Report. This translates to an operating and net loss of USD 17.6 – 23.4 million for the financial year 2016 based on an assumed average exchange rate of 1 USD = 6.83 DKK.

### Reporting Currency

Effective January 2016 the presentation currency of Veloxis has been changed to USD from DKK. All comparative numbers from previous periods have been converted by using the period average currency rates for profit and loss numbers and the period end currency rate for balance sheet numbers. The rates applied are 1 USD = 6.62 DKK for Q1 2015, and 1 USD = 6.94 DKK as at 31<sup>st</sup> March 2015. 1 USD = 6.73 DKK for total 2015 and 1 USD = 6.83 DKK as at 31<sup>st</sup> December 2015.

### Conference call

A conference call will be held tomorrow, 19 May, 2016 at 3:00 PM CET (Denmark); 2:00 PM GMT (London), 9:00 AM EST (New York).

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

+45 32 71 16 59 (Denmark)

+44 (0) 20 3427 1910 (UK)

+1 646 254 3362 (USA)

Access code 8446996

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

### Business update

Veloxis launched Envarsus<sup>®</sup> XR into the U.S. market in December 2015, promoting the product through the company's own specialized transplant sales force. The commercial infrastructure includes field based sales personnel, supplemented by regional field-based reimbursement and medical affairs personnel, and supported by an in-house marketing, reimbursement and medical affairs team, all with extensive experience with transplant products. Veloxis has also made several senior management changes and additions to enhance the company's focus on commercialization, including key additions in the areas of strategy, operations, supply chain management, corporate development, and legal affairs.

Early adoption of Envarsus<sup>®</sup> XR in the U.S. has been driven by customer recognition of the non-inferiority of Envarsus<sup>®</sup> XR to immediate-release tacrolimus in a once-daily formulation characterized by its smooth pharmacokinetic profile. Our salesforce is meeting reach and frequency objectives in the 198 adult transplant centres in the US, with focus on those accounts identified as most critical to ensuring rapid awareness and adoption of Envarsus XR. Market access and reimbursement results are in line with expectations, and focused efforts towards maintaining access for patients across all payer types are ongoing.

We are pleased to report that account penetration in the U.S. has been strong at this early stage of launch, with prescriptions written by physicians from some 20% of adult transplant centres. Similarly, the number of prescribers from this target market has increased by double-digits in each consecutive month since launch.

In addition to direct commercialization in the U.S., Veloxis has a partnership agreement with Chiesi Farmaceutici S.p.A in respect to the commercialization of Envarsus XR in Europe, Turkey and CIS Countries. Chiesi launched Envarsus XR in 16 EU countries during 2015, with additional countries to be added in 2016. Envarsus XR is performing well in Europe, with an accelerating trend of prescribing. Veloxis continues to seek appropriate partners for additional key geographic territories around the world.

### Financial Highlights

	Q1 2016 USD'000	Q1 2015 USD'000	Year 2015 USD'000
<b>Income Statement</b>			
Revenue	1,500	647	2,103
Production costs	(764)	(626)	(2,250)
Gross profit	736	21	(147)
Sales and marketing costs	(3,806)	(1,484)	(9,840)
Research and development costs	(2,224)	(3,137)	(11,345)
Administrative expenses	(1,627)	(2,421)	(7,968)
Operating result	(6,921)	(7,021)	(29,300)
Net financial income / (expenses)	(188)	2,720	2,168
Result before tax	(7,109)	(4,301)	(27,132)
Tax for the period	-	224	953
Net result for the period	(7,109)	(4,077)	(26,179)
<b>Balance Sheet</b>			
Cash and cash equivalents	6,650	33,642	15,763
Total assets	12,207	37,832	21,809
Share capital	24,692	23,955	24,360
Total equity	7,998	32,943	13,127
Investment in property, plant and equipment	-	-	48
<b>Cash Flow Statement</b>			
Cash flow from operating activities	(10,599)	(8,276)	(25,998)
Cash flow from investing activities	-	-	(48)
Cash flow from financing activities	1,162	5	48
Cash and cash equivalents at period end	6,650	33,642	15,763
<b>Financial Ratios</b>			
Basic and diluted EPS	(0.00)	(0.00)	(0.02)
Weighted average number of shares	1,664,261,003	1,663,002,504	1,663,334,241
Average number of employees (FTEs)	53	30	38
Assets/equity	1.53	1.15	1.66
Share price	1.46 DKK	0.90 DKK	1.75 DKK

The interim report has not been audited or reviewed by the company's independent auditors.

### Revenue

For the first quarter of 2016 Veloxis recognized revenue of 1,500 tUSD compared to 647 tUSD in the same period of 2015. We have changed our method for revenue recognition to ex-factory recognition, which means that approx. 400 tUSD of additional revenue has been recognised in the first quarter 2016.

### Sales and marketing costs

For the first quarter of 2016, Veloxis' sales and marketing costs amounted to 3,806 tUSD compared to 1,484 tUSD during the same period in 2015. This reflects the building of the marketing and sales infrastructure in the US in connection with the December 2015 launch of Envarsus<sup>®</sup> XR in the US.

### Research and development costs

For the first quarter of 2016, Veloxis' research and development costs amounted to 2,224 tUSD compared to 3,137 tUSD during the same period in 2015. The reduction in cost reflects the reduction in study activity as studies have been completed.

### Administrative expenses

For the first quarter of 2016, Veloxis' administrative cost amounted to 1,627 tUSD compared to 2,421 tUSD during the same period in 2015. The reduction in cost reflects mainly a reduction in legal fees.

### Compensation costs

For the first quarter of 2016, a total 309 tUSD was recognized as share-based compensation. The cost is included in S&M, R&D and Admin. The comparable cost for 2015 was 392 tUSD.

In the first quarter of 2016, a total of 5,021,231 warrants have been cancelled, a total of 21,722,966 warrants have been exercised at an exercise price of DKK 0.35 and a total of 1,048,881 warrants have expired.

On 31 March, 2016, there were a total of 91,351,339 warrants outstanding at an average strike price of DKK 0.69. Members of the Board of Directors held 5,107,815 warrants at an average strike price of DKK 0.90. Members of the Executive Management held 20,847,552 warrants at an average strike price of DKK 0.59, while other current and former employees held 65,395,972 warrants at an average strike price of DKK 0.71.

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

### Operating loss

Veloxis' operating loss for the first quarter of 2016 was 6,921 tUSD compared to 7,021 tUSD in the corresponding period of 2015.

### Financial income

During the first quarter of 2016, the Company recognized net financial expenses of 188 tUSD compared to net financial income of 2,720 tUSD in the corresponding period of 2015.

### Net loss

Veloxis' net loss for the first quarter of 2016 was 7,109 tUSD compared to 4,077 tUSD in the corresponding period of 2015.

### **Cash flow**

On 31 March, 2016, the balance sheet reflects cash and cash equivalents of 6,650 tUSD compared to 15,763 tUSD on 31 December, 2015. This represents a decrease of 9,113 tUSD primarily related to the Company's operating activities for the period.

### **Balance sheet**

On 31 March, 2016, total assets were 12,207 tUSD compared to 21,809 tUSD at the end of 2015. Certain prepaid assets are being amortized over a period in excess of 12 months.

Shareholders' equity equalled 7,998 tUSD on 31 March, 2016, compared to 13,127 tUSD at the end of 2015.

Veloxis recognizes that its equity to subscribed capital ratio has fallen below 50% but expects it to recover to normal levels as the commercialization of Envarsus® XR progresses. Management believes that the company's funding arrangements are sufficient to properly maintain its normal business activities during this period and will call an extraordinary general meeting of shareholders in line with section 119 of the Danish Act on Public and Private Limited Companies, to provide them with all requisite information.

### **Significant risks and uncertainties**

Veloxis faces a number of risks and uncertainties related to operations, commercial, research and development and financial activities. For further information about risks and uncertainties, we refer to the Annual Report for 2015. 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 2015.

**For more information, please contact:**

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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 Envarsus® XR**

Envarsus® (tacrolimus prolonged-release tablets) has received marketing authorization in the EU for prophylaxis of organ rejection in kidney and liver transplant recipients and in the U.S., branded as Envarsus® XR (tacrolimus extended-release tablets) for prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate release formulations in combination with other immunosuppressants. Envarsus® XR has received orphan drug designation in the U.S. Veloxis launched 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 offices in North Carolina and New Jersey, U.S.A., 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](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 3 months ended 31 March 2016 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 management's 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, 18 May, 2016

### **Executive Management**

Craig A. Collard  
President & CEO

Alastair McEwan  
Executive Vice President & COO

### **Board of Directors**

Michael Heffernan  
(Chairman)

Mette Kirstine Agger  
(Deputy Chairman)

Thomas Dyrberg

Anders Götzsche

Interim Report  
for the 3 Months Ended 31 March, 2016  
(18 May, 2016)



Financial Highlights					
Quarterly Numbers in USD					
	Q1 2016 USD'000	Q4 2015 USD'000	Q3 2015 USD'000	Q2 2015 USD'000	Q1 2015 USD'000
<b>Income Statement</b>					
Revenue	1,500	170	503	783	647
Production costs	(764)	(1,129)	(250)	(245)	(626)
Gross profit	736	(959)	253	538	21
Sales and marketing costs	(3,806)	(3,742)	(3,189)	(1,425)	(1,484)
Research and development costs	(2,224)	(2,980)	(2,512)	(2,716)	(3,137)
Administrative expenses	(1,627)	(1,930)	(1,909)	(1,708)	(2,421)
Operating result	(6,921)	(9,611)	(7,357)	(5,311)	(7,021)
Net financial income / (expenses)	(188)	181	(42)	(691)	2,720
Result before tax	(7,109)	(9,430)	(7,399)	(6,002)	(4,301)
Tax for the period	-	290	220	219	224
Net result for the period	(7,109)	(9,140)	(7,179)	(5,783)	(4,077)
<b>Balance Sheet</b>					
Cash and cash equivalents	6,650	15,763	23,665	28,656	33,642
Total assets	12,207	21,809	29,072	33,622	37,832
Share capital	24,692	24,360	24,986	24,947	23,955
Total equity	7,998	13,127	22,330	29,025	32,943
Investment in property, plant and equipment	-		7	41	-
<b>Cash Flow Statement</b>					
Cash flow from operating activities	(10,599)	(7,247)	(4,973)	(5,502)	(8,276)
Cash flow from investing activities	-	(1)	(7)	(40)	-
Cash flow from financing activities	1,162	9	21	13	5
Cash and cash equivalents at period end	6,650	15,763	23,665	28,656	33,642
<b>Financial Ratios</b>					
Basic and diluted EPS	(0.00)	(0.01)	(0.00)	(0.00)	(0.00)
Weighted average number of shares	1,664,261,003	1,663,748,856	1,663,408,929	1,663,167,653	1,663,002,504
Average number of employees (FTEs)	53	50	42	31	30
Assets/equity	1.53	1.66	1.30	1.16	1.15



## Income statement and statement of comprehensive income

Income Statement		Consolidated		
(USD'000)	Q1 2016	Q1 2015	Year 2015	
Revenue - Net	1,500	647	2,103	
Production costs	(764)	(626)	(2,250)	
<b>Gross profit</b>	<b>736</b>	<b>21</b>	<b>(147)</b>	
Sales and marketing costs	(3,806)	(1,484)	(9,840)	
Research and development costs	(2,224)	(3,137)	(11,345)	
Administrative expenses	(1,627)	(2,421)	(7,968)	
<b>Operating result</b>	<b>(6,921)</b>	<b>(7,021)</b>	<b>(29,300)</b>	
Financial income	-	2,723	2,205	
Financial expenses	(188)	(3)	(37)	
<b>Result before tax</b>	<b>(7,109)</b>	<b>(4,301)</b>	<b>(27,132)</b>	
Tax for the period	-	224	953	
<b>Net result for the period</b>	<b>(7,109)</b>	<b>(4,077)</b>	<b>(26,179)</b>	
Basic and diluted EPS	(0.00)	(0.00)	(0.02)	
Weighted average number of shares	1,664,261,003	1,663,002,504	1,663,334,241	

Statements of comprehensive income		Consolidated		
(USD'000)	Q1 2016	Q1 2015	Year 2015	
<b>Net result for the period</b>	<b>(7,109)</b>	<b>(4,077)</b>	<b>(26,179)</b>	
<b>Other comprehensive income:</b>				
<i>Items that may be subsequently reclassified to profit or loss:</i>				
Currency translation differences, net of tax	509	(39)	(12)	
<b>Other comprehensive income for the period</b>	<b>509</b>	<b>(39)</b>	<b>(12)</b>	
<b>Total comprehensive income for the period</b>	<b>(6,600)</b>	<b>(4,117)</b>	<b>(26,191)</b>	

## Balance sheet

<b>Assets</b>	<b>Consolidated</b>		
	<b>(USD'000)</b>	<b>31 Mar. 2016</b>	<b>31 Mar. 2015</b>
Patent rights and software	140	170	146
<b>Intangible assets</b>	<b>140</b>	<b>170</b>	<b>146</b>
Property, plant and equipment	459	571	488
<b>Property, plant and equipment</b>	<b>459</b>	<b>571</b>	<b>488</b>
<b>Non-current assets</b>	<b>599</b>	<b>741</b>	<b>634</b>
<b>Inventories</b>	<b>2,187</b>	<b>1,177</b>	<b>2,487</b>
Trade receivables	935	619	862
Tax receivables	897	1,125	860
Other receivables	304	321	599
Prepayments	635	207	604
<b>Receivables</b>	<b>2,771</b>	<b>2,272</b>	<b>2,925</b>
Cash	6,650	33,642	15,763
<b>Cash and cash equivalents</b>	<b>6,650</b>	<b>33,642</b>	<b>15,763</b>
<b>Current assets</b>	<b>11,608</b>	<b>37,091</b>	<b>21,175</b>
<b>Assets</b>	<b>12,207</b>	<b>37,832</b>	<b>21,809</b>

**Balance sheet**

<b>Equity &amp; Liabilities</b>	<b>Consolidated</b>		
<b>(USD'000)</b>	<b>31 Mar. 2016</b>	<b>31 Mar. 2015</b>	<b>31 Dec. 2015</b>
Share capital	24,692	23,955	24,360
Special reserve	59,632	58,664	59,632
Translation reserves	755	216	246
Retained earnings/loss	(77,081)	(49,892)	(71,111)
<b>Equity</b>	<b>7,998</b>	<b>32,943</b>	<b>13,127</b>
Trade payables	1,504	1,702	2,957
Tax payables	-	89	-
Deferred revenue	-	-	539
Other payables	2,705	3,098	5,186
<b>Current liabilities</b>	<b>4,209</b>	<b>4,889</b>	<b>8,682</b>
<b>Liabilities</b>	<b>4,209</b>	<b>4,889</b>	<b>8,682</b>
<b>Equity and liabilities</b>	<b>12,207</b>	<b>37,832</b>	<b>21,809</b>

## Cash flow statements

Cash Flow Statement	Consolidated		
(USD'000)	Q1 2016	Q1 2015	Year 2015
<b>Operating result</b>	<b>(6,921)</b>	<b>(7,021)</b>	<b>(29,300)</b>
Share-based payment	309	392	1,797
Depreciation and amortization	56	53	219
Changes in working capital	(4,036)	(1,697)	372
<b>Cash flow from operating activities before interest</b>	<b>(10,592)</b>	<b>(8,273)</b>	<b>(26,912)</b>
Interest received	0	-	21
Interest paid	(7)	(3)	(37)
Corporate tax received	-	-	930
<b>Cash flow from operating activities</b>	<b>(10,599)</b>	<b>(8,276)</b>	<b>(25,998)</b>
Purchase of property, plant and equipment	-	-	(48)
<b>Cash flow from investing activities</b>	<b>-</b>	<b>-</b>	<b>(48)</b>
Proceeds from issuance of shares, net	1,162	5	48
<b>Cash flow from financing activities</b>	<b>1,162</b>	<b>5</b>	<b>48</b>
<b>Increase/(decrease) in cash</b>	<b>(9,437)</b>	<b>(8,271)</b>	<b>(25,998)</b>
Cash at beginning of period	15,763	38,952	39,595
Exchange gains/(losses) on cash	324	2,961	2,166
<b>Cash at end of period</b>	<b>6,650</b>	<b>33,642</b>	<b>15,763</b>

## Statement of changes in equity

Consolidated Equity						
	Number of Shares	Share Capital USD'000	Special Reserves USD'000	Translation Reserves USD'000	Retained Earnings USD'000	Total USD'000
<b>Equity as of 1 Jan. 2015</b>	<b>1,662,997,314</b>	<b>24,349</b>	<b>59,632</b>	<b>258</b>	<b>(47,160)</b>	<b>37,079</b>
Net result for the year					(4,077)	(4,077)
Other comprehensive income for the year				(39)		(39)
<b>Total comprehensive income</b>				<b>(39)</b>	<b>(4,077)</b>	<b>(4,117)</b>
Warrant exercises	93,416	1			3	5
Share-based payment					392	392
Currency adjustment		(395)	(968)	(2)	950	(416)
<b>Other transactions</b>	<b>93,416</b>	<b>(394)</b>	<b>(968)</b>	<b>(2)</b>	<b>1,345</b>	<b>(19)</b>
<b>Equity as of 31 Mar. 2015</b>	<b>1,663,090,730</b>	<b>23,955</b>	<b>58,664</b>	<b>216</b>	<b>(49,892)</b>	<b>32,943</b>
Net result for the year					(22,102)	(22,102)
Other comprehensive income for the year				27		27
<b>Total comprehensive income</b>				<b>27</b>	<b>(22,102)</b>	<b>(22,075)</b>
Warrant exercises	692,845	10			32	42
Share-based payment					1,405	1,405
Currency adjustment		395	968	3	(554)	812
<b>Other transactions</b>	<b>692,845</b>	<b>405</b>	<b>968</b>	<b>3</b>	<b>883</b>	<b>2,259</b>
<b>Equity as of 31 Dec. 2015</b>	<b>1,663,783,575</b>	<b>24,360</b>	<b>59,632</b>	<b>246</b>	<b>(71,111)</b>	<b>13,127</b>
Net result for the year					(7,109)	(7,109)
Other comprehensive income for the year				509		509
<b>Total comprehensive income</b>				<b>509</b>	<b>(7,109)</b>	<b>(6,600)</b>
Warrant exercises	21,722,966	332			830	1,162
Share-based payment					309	309
<b>Other transactions</b>	<b>21,722,966</b>	<b>332</b>	<b>-</b>	<b>-</b>	<b>1,139</b>	<b>1,471</b>
<b>Equity as of 31 Mar. 2016</b>	<b>1,685,506,541</b>	<b>24,692</b>	<b>59,632</b>	<b>755</b>	<b>(77,081)</b>	<b>7,998</b>

## 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 2015.

From 2016 the presentation currency of Veloxis is changed to USD from DKK. All comparative numbers from previous periods have been converted by using the average currency rates for profit and loss numbers and the period end currency rate for balance numbers.

### 2. Revenue recognition

We have changed our method for revenue recognition to ex-factory recognition.