

## Veloxis Pharmaceuticals Announces Financial Results for the First Three Months of 2017

### Highlights

- It is now estimated that over 6,000 patients in the US and Europe are being treated with Envarsus XR.
- In the US, prescription growth of Envarsus in the first quarter of 2017 grew 19% vs. the fourth quarter of 2016, in contrast to the -2% decline in total tacrolimus market prescriptions over the same period, a decline which is experienced annually due to market seasonality.
- 63% of US transplant centers have utilized Envarsus XR since launch.
- Veloxis entered into an exclusive license, supply and distribution agreement with Taiba Healthcare, a leading healthcare marketing, distributor and retail pharmacies group known regionally for a focus on specialty and rare diseases, to register, commercialize and distribute Envarsus XR in certain countries throughout the Middle East and North Africa region (MENA).
- Veloxis reported a net loss of tUSD 5,891 for the first quarter of 2017 compared to a net loss of tUSD 7,109 for the same period in 2016. The reported operating net loss is in line with expectations and the financial outlook for 2017 is maintained.

### Summary

- First quarter revenue totaled tUSD 4,000, including tUSD 1,000 of an upfront payment from the MENA license, compared with tUSD 1,500 in first quarter 2016, 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.

### Outlook for 2017

Veloxis maintains its 2017 outlook of operating loss before the recognition of income from license agreements and before accounting for stock compensation to be in the range of USD 5 – 15 million.

### Conference Call

A conference call will be held tomorrow, 17 May, 2017 at 4:00 PM CEST (Denmark); 2:00 PM GMT (London), 10:00 AM EST (New York).

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

Confirmation Code: 5325377

UK: +44(0)20 3427 1910

US: +1 212 444 0412

DK: +4532 71 16 59

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

**Financial Highlights**

	<b>Q1 2017 USD'000</b>	<b>Q1 2016 USD'000</b>	<b>Year 2016 USD'000</b>
<b>Income Statement</b>			
Revenue	4,000	1,500	9,194
Production costs	(891)	(764)	(3,019)
Gross profit	3,109	736	6,175
Selling, general and administrative costs	(8,197)	(7,600)	(34,407)
Research and development costs	(135)	(65)	(636)
Other operating income	-	-	100
Operating result	(5,223)	(6,929)	(28,768)
Net financial income / (expenses)	(394)	(180)	(45)
Result before tax	(5,617)	(7,109)	(28,813)
Tax for the period	(274)	-	18,678
Net result for the period	(5,891)	(7,109)	(10,135)
<b>Balance Sheet</b>			
Cash and cash equivalents	7,243	6,650	3,359
Total assets	33,493	12,207	29,884
Share capital	24,227	23,910	24,175
Total equity	5,369	7,998	10,195
Investment in property, plant and equipment	113	-	176
<b>Cash Flow Statement</b>			
Cash flow from operating activities	(4,173)	(10,599)	(28,057)
Cash flow from investing activities	(113)	-	(176)
Cash flow from financing activities	8,138	1,162	15,981
Cash and cash equivalents at period end	7,243	6,650	3,359
<b>Financial Ratios</b>			
Basic and diluted EPS	(0.00)	(0.00)	(0.01)
Weighted average number of shares	1,703,708,460	1,664,261,003	1,688,679,397
Average number of employees (FTEs)	48	30	54
Assets/equity	6.24	1.53	2.93
Share price DKK	1.06	1.46	1.08

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

(in thousands USD, except share and per share data)

### Revenue

For the quarter of 2017 Veloxis recognized revenue of USD 4,000 compared to USD 1,500 in the same period of 2016. Revenue relates to commercial sales of Envarsus XR in the US, sales to Chiesi Farmaceutici S.p.A (Chiesi) in Europe and rest of world upfront payments. See revenue Note 2 for more detail.

### Selling, General and Administrative Costs

For the quarter of 2017, Veloxis' selling, general and administrative costs amounted to USD 8,197 compared to USD 7,600 during the same period in 2016. This reflects the continued build out of the marketing and sales infrastructure in the US in connection with the December 2015 launch of Envarsus XR in the US.

### Research and Development Costs

For the first quarter 2017, Veloxis' research and development costs amounted to USD 135 compared to USD 65 during the same period in 2016.

### Compensation Costs

For the first quarter of 2017, a total of USD 873 was recognized as share-based compensation. The cost is included in selling, general and administrative. The comparable cost for 2016 was USD 309.

In the first quarter of 2017, a total of 3,041,681 warrants have been cancelled, a total of 600,192 warrants have expired and a total of 3,619,750 warrants have been exercised at an exercise price of DKK 0.37.

On 31 March, 2017, there were a total of 126,217,156 warrants outstanding at an average strike price of DKK 1.24. Members of the Board of Directors held 8,524,080 warrants at an average strike price of DKK 1.08. Members of the Executive Management held 67,420,261 warrants at an average strike price of DKK 1.43, while other current and former employees held 50,272,815 warrants at an average strike price of DKK 1.01.

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 2017 was USD 5,223 compared to USD 6,929 in the corresponding period of 2016.

### Financial Income

During the first quarter of 2017, the Company recognized net financial expense of USD 394 compared to net financial expenses of USD 180 in the corresponding period of 2016.

### Net Loss

Veloxis' net loss for the first quarter of 2017 was USD 5,891 compared to USD 7,109 in the corresponding period of 2016.

### **Cash Flow**

On 31 March, 2017, the balance sheet reflects cash and cash equivalents of USD 7,243 compared to USD 3,359 on 31 December, 2016.

### **Balance Sheet**

On 31 March, 2017, total assets were USD 33,493 compared to USD 29,884 at the end of 2016.

Shareholders' equity equaled USD 5,369 on 31 March, 2017, compared to USD 10,195 at the end of 2016.

### 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 2016. 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 2016.

### For More Information, Please Contact:

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### About Envarsus XR

Envarsus (tacrolimus prolonged-release tablets) have 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

Veloxis Pharmaceuticals A/S is a commercial-stage specialty pharmaceutical company committed to improving the lives of transplant patients. A Danish company, Veloxis Pharmaceuticals A/S operates in the U.S. through Veloxis Pharmaceuticals Inc., a wholly-owned subsidiary headquartered in Cary, North Carolina, USA. Veloxis has successfully developed Envarsus XR (tacrolimus extended-release tablets) based upon the company's unique and patented delivery technology, MeltDose®, which is designed to enhance the absorption and bioavailability of select orally administered drugs. The Company is focused on the direct commercialization of Envarsus XR in the U.S., expansion of partnerships for markets around the world, and acquisition of assets utilized in transplant patients and by adjacent medical specialties. 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 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 2017 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.

Copenhagen, 16 May, 2017

### **Executive Management**

Craig A. Collard  
President & CEO

Alastair McEwan  
Executive Vice President & COO

### **Board of Directors**

Michael Heffernan  
(Chairman)

Mette Kirstine Agger  
(Deputy Chairman)

Lars Kåre Viksmoen

Anders Götzsche

Paul K. Wotton

Robert S. Radie

**Financial Highlights**  
**Quarterly Numbers in USD**

	Q1 2017 USD'000	Q4 2016 USD'000	Q3 2016 USD'000	Q2 2016 USD'000	Q1 2016 USD'000
<b>Income Statement</b>					
Revenue	4,000	3,688	2,239	1,767	1,500
Production costs	(891)	(1,052)	(413)	(790)	(764)
Gross profit	3,109	2,636	1,826	977	736
Selling, general and administrative costs	(8,197)	(7,451)	(8,894)	(10,462)	(7,600)
Research and development costs	(135)	(239)	(222)	(110)	(65)
Other operating income	-	100	-	-	-
Operating result	(5,223)	(4,954)	(7,290)	(9,595)	(6,929)
Net financial income / (expenses)	(394)	102	(264)	297	(180)
Result before tax	(5,617)	(4,852)	(7,554)	(9,298)	(7,109)
Tax for the period	(274)	18,678	-	-	-
Net result for the period	(5,891)	13,826	(7,554)	(9,298)	(7,109)
<b>Balance Sheet</b>					
Cash and cash equivalents	7,243	3,359	5,295	7,206	6,650
Total assets	33,493	29,884	12,691	14,354	12,207
Share capital	24,227	24,175	25,508	25,356	23,910
Total equity	5,369	10,195	(4,589)	843	7,998
Investment in property, plant and equipment	113	51	44	81	-
<b>Cash Flow Statement</b>					
Cash flow from operating activities	(4,173)	(1,462)	(7,057)	(8,939)	(10,599)
Cash flow from investing activities	(113)	(51)	(44)	(81)	-
Cash flow from financing activities	8,138	(109)	5,147	9,781	1,162
Cash and cash equivalents at period end	7,243	3,359	5,295	7,206	6,650
<b>Financial Ratios</b>					
Basic and diluted EPS	(0.00)	0.01	(0.00)	(0.01)	(0.00)
Weighted average number of shares	1,703,708,460	1,702,134,751	1,699,576,055	1,688,478,176	1,664,261,003
Average number of employees (FTEs)	48	47	49	51	30
Assets/equity	6.24	2.93	-2.77	17.03	1.53



**Income Statement and Statement of Comprehensive Income**

<b>(USD'000)</b>	<b>Q1 2017</b>	<b>Q1 2016</b>	<b>Year 2016</b>
Revenue - Net	4,000	1,500	9,194
Production costs	(891)	(764)	(3,019)
<b>Gross profit</b>	<b>3,109</b>	<b>736</b>	<b>6,175</b>
Selling, general and administrative costs	(8,197)	(7,600)	(34,407)
Research and development costs	(135)	(65)	(636)
Other operating income	-	-	100
<b>Operating result</b>	<b>(5,223)</b>	<b>(6,929)</b>	<b>(28,768)</b>
Financial income	19	-	643
Financial expenses	(413)	(180)	(688)
<b>Result before tax</b>	<b>(5,617)</b>	<b>(7,109)</b>	<b>(28,813)</b>
Tax for the period	(274)	-	18,678
<b>Net result for the period</b>	<b>(5,891)</b>	<b>(7,109)</b>	<b>(10,135)</b>
Basic and diluted EPS	(0.00)	(0.00)	(0.01)
Weighted average number of shares	1,703,708,460	1,664,261,003	1,688,679,397

**Statements of comprehensive income**

<b>(USD'000)</b>	<b>Q1 2017</b>	<b>Q1 2016</b>	<b>Year 2016</b>
<b>Net result for the period</b>	<b>(5,891)</b>	<b>(7,109)</b>	<b>(10,135)</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	(392)
<b>Other comprehensive income for the period</b>	<b>-</b>	<b>509</b>	<b>(392)</b>
<b>Total comprehensive income for the period</b>	<b>(5,891)</b>	<b>(6,600)</b>	<b>(10,527)</b>

**Balance Sheet**

<b>Assets</b>	<b>Consolidated</b>		
	<b>(USD'000)</b>	<b>31 Mar. 2017</b>	<b>31 Mar. 2016</b>
Patent rights and software	106	140	114
<b>Intangible assets</b>	<b>106</b>	<b>140</b>	<b>114</b>
Property, plant and equipment	551	459	482
<b>Tangible fixed assets</b>	<b>551</b>	<b>459</b>	<b>482</b>
Deferred tax asset	18,425	-	18,678
<b>Financial assets</b>	<b>18,425</b>	<b>-</b>	<b>18,678</b>
<b>Non-current assets</b>	<b>19,082</b>	<b>599</b>	<b>19,274</b>
<b>Inventories</b>	<b>5,041</b>	<b>2,187</b>	<b>4,141</b>
Trade receivables	1,434	935	2,212
Tax receivables	-	897	-
Other receivables	62	304	96
Prepayments	631	635	802
<b>Receivables</b>	<b>2,127</b>	<b>2,771</b>	<b>3,110</b>
Cash	7,243	6,650	3,359
<b>Cash and cash equivalents</b>	<b>7,243</b>	<b>6,650</b>	<b>3,359</b>
<b>Current assets</b>	<b>14,411</b>	<b>11,608</b>	<b>10,610</b>
<b>Assets</b>	<b>33,493</b>	<b>12,207</b>	<b>29,884</b>

**Balance Sheet Cont.**

<b>Equity &amp; Liabilities</b>	<b>Consolidated</b>		
<b>(USD'000)</b>	<b>31 Mar. 2017</b>	<b>31 Mar. 2016</b>	<b>31 Dec. 2016</b>
Share capital	24,227	23,910	24,175
Special reserve	57,804	57,804	57,804
Translation reserves	(4,052)	(3,151)	(4,052)
Retained earnings/loss	(72,610)	(70,565)	(67,732)
<b>Equity</b>	<b>5,369</b>	<b>7,998</b>	<b>10,195</b>
Loan	21,776	-	13,816
<b>Non-current liabilities</b>	<b>21,776</b>	<b>-</b>	<b>13,816</b>
Trade payables	1,987	1,504	957
Tax payables	22	-	-
Other payables	4,339	2,705	4,916
<b>Current liabilities</b>	<b>6,348</b>	<b>4,209</b>	<b>5,873</b>
<b>Liabilities</b>	<b>28,124</b>	<b>4,209</b>	<b>19,689</b>
<b>Equity and liabilities</b>	<b>33,493</b>	<b>12,207</b>	<b>29,884</b>

**Cash Flow Statements**

<b>Cash Flow Statement</b>			
<b>(USD'000)</b>	<b>Q1 2017</b>	<b>Q1 2016</b>	<b>Year 2016</b>
<b>Operating result</b>	<b>(5,223)</b>	<b>(6,921)</b>	<b>(28,768)</b>
Share-based payment	873	309	5,430
Depreciation and amortization	52	56	208
Changes in working capital	126	(4,043)	(5,787)
<b>Cash flow from operating activities before interest</b>	<b>(4,172)</b>	<b>(10,599)</b>	<b>(28,917)</b>
Interest paid	-	-	-
Corporate tax received	-	-	860
<b>Cash flow from operating activities</b>	<b>(4,172)</b>	<b>(10,599)</b>	<b>(28,057)</b>
Purchase of property, plant and equipment	(113)	-	(176)
<b>Cash flow from investing activities</b>	<b>(113)</b>	<b>-</b>	<b>(176)</b>
Proceeds from borrowings	8,000	-	14,000
Cost of borrowings	(54)	-	(184)
Proceeds from issuance of shares	192	1,162	2,165
<b>Cash flow from financing activities</b>	<b>8,138</b>	<b>1,162</b>	<b>15,981</b>
<b>Increase/(decrease) in cash</b>	<b>3,853</b>	<b>(9,437)</b>	<b>(12,252)</b>
Cash at beginning of period	3,359	15,763	15,763
Exchange gains/(losses) on cash	31	324	(152)
<b>Cash at end of period</b>	<b>7,243</b>	<b>6,650</b>	<b>3,359</b>

## Statement of Changes in Equity

<b>Consolidated Equity</b>						
	<b>Number of Shares</b>	<b>Share Capital USD'000</b>	<b>Special Reserves USD'000</b>	<b>Translation Reserves USD'000</b>	<b>Retained Earnings USD'000</b>	<b>Total USD'000</b>
<b>Equity as of 1 Jan. 2016</b>	<b>1,663,783,575</b>	<b>23,578</b>	<b>57,804</b>	<b>(3,660)</b>	<b>(64,595)</b>	<b>13,127</b>
Net result for the year					(7,109)	(7,109)
Currency adjustment				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
Other transactions	21,722,966	332	-	-	1,139	1,471
<b>Equity as of 31 Mar. 2016</b>	<b>1,685,506,541</b>	<b>23,910</b>	<b>57,804</b>	<b>(3,151)</b>	<b>(70,565)</b>	<b>7,998</b>
Net result for the year					(3,026)	(3,026)
Currency adjustment				(901)		(901)
<b>Total comprehensive income</b>				<b>(901)</b>	<b>(3,026)</b>	<b>(3,927)</b>
Warrant exercises	17,867,340	265			738	1,003
Share-based payment					5,121	5,121
Other transactions	17,867,340	265	-	-	5,859	6,124
<b>Equity as of 31 Dec. 2016</b>	<b>1,703,373,881</b>	<b>24,175</b>	<b>57,804</b>	<b>(4,052)</b>	<b>(67,732)</b>	<b>10,195</b>
Net result for the year					(5,891)	(5,891)
Currency adjustment				-		-
<b>Total comprehensive income</b>				<b>-</b>	<b>(5,891)</b>	<b>(5,891)</b>
Warrant exercises	3,619,750	52			140	192
Share-based payment					873	873
Other transactions	3,619,750	52	-	-	1,013	1,065
<b>Equity as of 31 Mar. 2017</b>	<b>1,706,993,631</b>	<b>24,227</b>	<b>57,804</b>	<b>(4,052)</b>	<b>(72,610)</b>	<b>5,369</b>

Comparative figures between equity accounts have changed. The only impact is within the equity accounts.

## 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 2016.

### 2. Revenue

Revenue was comprised of the following:

	YTD March	
	2017	2016
(USD'000)		
Europe	428	313
United States	2,572	1,187
Upfront payments	1,000	-
<b>Total</b>	<b>4,000</b>	<b>1,500</b>