

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

### Highlights

- Record product revenue of tUSD 5,924 achieved in Q3 2017.
- Revenue reached tUSD 22,092 in the first nine months of 2017 representing an increase of 301% compared to the same period last year.
  - U.S. revenue increased 173% to tUSD 10,943
  - EU revenue increased 89% to tUSD 2,839
  - RoW upfront revenues were tUSD 8,250
- 71% of U.S. transplant centers have utilized Envarsus XR since launch.
- Ulf Meier-Kriesche, MD joined the management team as Chief Scientific Officer, bringing substantial clinical transplant experience and senior industry medical affairs experience within transplantation and immunology.
- Veloxis reported a net loss of tUSD 8,421 for the first nine months of 2017 compared to a net loss of tUSD 23,961 for the same period in 2016. The reported operating net loss is in line with expectations.

### In connection with the financial report, Veloxis's CEO Craig Collard said:

"I am very pleased to see the steady momentum with our lead product Envarsus and believe we will continue to see significant growth. The addition of Ulf Meier-Kriesche has expanded our capabilities in development and he should be instrumental in our business development efforts in the future as we search for both commercial and development opportunities that will compliment Envarsus and add shareholder value."

### 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 in the range of USD 10 – 15 million, as noted in the Interim Report for the period 1 January to 30 June 2017.

### Conference Call

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A conference call will be held tomorrow, 15 November, 2017 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:

Confirmation Code: 4943899

UK: +44(0)20 3427 1907

U.S.: +1 646 254 3362

DK: +4532 71 16 59

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

<b>Financial Highlights</b>					
	<b>YTD 2017 USD'000</b>	<b>YTD 2016 USD'000</b>	<b>Q3 2017 USD'000</b>	<b>Q3 2016 USD'000</b>	<b>Year 2016 USD'000</b>
<b>Income Statement</b>					
Revenue	22,092	5,506	5,924	2,239	9,194
Production costs	(3,605)	(1,967)	(1,477)	(413)	(3,019)
Gross profit	18,487	3,539	4,447	1,826	6,175
Selling, general and administrative costs	(24,525)	(26,956)	(8,170)	(8,894)	(34,407)
Research and development costs	(636)	(397)	(450)	(222)	(636)
Other operating income	-	-	-	-	100
Operating result	(6,674)	(23,814)	(4,174)	(7,290)	(28,768)
Net financial income / (expenses)	(1,442)	(147)	(618)	(264)	(45)
Result before tax	(8,116)	(23,961)	(4,792)	(7,554)	(28,813)
Tax for the period	(305)	-	618	-	18,678
Net result for the period	(8,421)	(23,961)	(4,174)	(7,554)	(10,135)
<b>Balance Sheet</b>					
Cash and cash equivalents	8,983	5,295	8,983	5,295	3,359
Total assets	39,841	12,691	39,841	12,691	29,884
Share capital	24,288	24,153	24,288	24,153	24,175
Total equity	5,186	(4,589)	5,186	(4,589)	10,195
Investment in property, plant and equipment	564	125	402	44	176
<b>Cash Flow Statement</b>					
Cash flow from operating activities	(6,386)	(26,595)	(3,567)	(7,057)	(28,057)
Cash flow from investing activities	(564)	(125)	(402)	(44)	(176)
Cash flow from financing activities	12,352	16,090	85	5,147	15,981
Cash and cash equivalents at period end	8,983	5,295	8,983	5,295	3,359
<b>Financial Ratios</b>					
Weighted average number of shares ('000)	1,707,268	1,684,162	1,709,803	1,699,576	1,688,679
Average number of employees (FTEs)	50	50	51	49	38
Assets/equity	7.68	(2.77)	7.68	(2.77)	2.93
Share price DKK	0.97	1.18	0.97	1.18	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

Revenue for the first nine months of 2017, Veloxis reached USD 22,092 compared to USD 5,506 in the same period of 2016. The increase is driven by growth in commercial sales of Envarsus XR in the U.S. from USD 4,003 to USD 10,943, sales to Chiesi Farmaceutici S.p.A (“Chiesi”) in Europe from USD 1,503 to USD 2,839 and rest of world (RoW) upfront revenue of USD 8,250 with no comparable revenue in the prior year.

In the third quarter of 2017, revenue grew 165% and reached USD 5,924 compared to USD 2,239 in the comparable period of prior year. U.S. revenue reached USD 4,525, up 182% or USD 2,918 from the third quarter of 2016. Revenue to Chiesi reached USD 1,369, up 117% or USD 737 from the third quarter of 2016.

See Revenue Note 2 for more detail.

### Selling, General and Administrative Costs

For the first nine months of 2017, Veloxis’s selling, general and administrative costs amounted to USD 24,525 compared to USD 26,956 during the same period in 2016. This reflects the continued build out of the marketing and sales infrastructure in the U.S. in connection with the December 2015 launch of Envarsus XR in the U.S. offset by efficiencies gained in consolidating operations to one location.

In the third quarter of 2017, selling, general and administrative costs were USD 8,170 compared to USD 8,894 in the third quarter of 2016. Overall decrease in costs is primarily due to efficiencies gained in consolidating operations to one location.

### Research and Development Costs

For the first nine months of 2017, Veloxis’s research and development costs amounted to USD 636 compared to USD 397 during the same period in 2016.

In the third quarter of 2017, research and development costs were USD 450 compared to USD 222 in the comparable period of 2016.

### Compensation Costs

For the first nine months of 2017, a total of USD 3,006 was recognized as share-based compensation. The cost is included in selling, general and administrative. The comparable cost for 2016 was USD 3,906.

In the third quarter of 2017, a total of 183,318 warrants were cancelled, 59,720 expired and a total of 1,500,000 warrants were exercised (859,000 at an exercise price of DKK 0.35 and 641,000 at an exercise price of DKK 0.36).

On 30 September 2017, there were a total of 153,933,478 warrants outstanding at an average strike price of DKK 1.23. Members of the Board of Directors held 14,131,554 warrants at an average strike price of DKK 1.07. Members of the Executive Management held 81,632,261 warrants at an average strike price of DKK 1.37, while other current and former employees held 58,229,663 warrants at an average strike price of DKK 1.07.

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

### **Operating Loss**

Veloxis's operating loss for the first nine months of 2017 was USD 6,674 compared to USD 23,814 in the corresponding period of 2016.

### **Financial Income**

During the first nine months of 2017, the Company recognized net financial expense of USD1,442 compared to net financial expense of USD 147 in the corresponding period of 2016.

### **Tax for the period**

Net tax expense for the first nine months of 2017 amounts to USD 305. In Q3 the Company revaluated the deferred tax asset which resulted in a tax benefit of USD 755. At 30 September 2017, the deferred tax asset was USD 19,433 compared to USD 18,678 at the end of 2016.

### **Net Loss**

Veloxis's net loss for the first nine months of 2017 was USD 8,421 compared to USD 23,961 in the corresponding period of 2016.

### **Cash Flow**

On 30 September 2017, the balance sheet reflects cash and cash equivalents of USD 8,983 compared to USD 3,359 on 31 December 2016 after drawing an additional USD 12,000 since 31 December 2016 under our current loan facility and receiving funds relating to the RoW agreements.

### **Balance Sheet**

On 30 September 2017, total assets were USD 39,841 compared to USD 29,884 at the end of 2016.

Shareholders' equity equaled USD 5,186 on 30 September, 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's overall risk profile since the publication of the Annual Report for 2016.

### For More Information, Please Contact:

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President & CEO  
Phone: +1 919 591 3090  
Email: cac@veloxis.com

### 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 U.S. 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, U.S.A. Veloxis has successfully developed Envarsus XR (tacrolimus extended-release tablets) based upon the Company's unique and patented delivery technology, MeltDose<sup>®</sup>, 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 9 months ended 30 September 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 Executive 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, 14 November, 2017

### **Executive Management**

Craig A. Collard  
President & CEO

### **Board of Directors**

Michael Heffernan  
(Chairman)

Mette Kirstine Agger  
(Deputy Chairman)

Lars Kåre Viksmoen

Anders Götzsche

Paul K. Wotton

Robert S. Radie

<b>Financial Highlights</b>							
<b>Quarterly Numbers in USD</b>							
	<b>Q3 2017 USD'000</b>	<b>Q2 2017 USD'000</b>	<b>Q1 2017 USD'000</b>	<b>Q4 2016 USD'000</b>	<b>Q3 2016 USD'000</b>	<b>Q2 2016 USD'000</b>	<b>Q1 2016 USD'000</b>
<b>Income Statement</b>							
Revenue	5,924	12,168	4,000	3,688	2,239	1,767	1,500
Production costs	(1,477)	(1,237)	(891)	(1,052)	(413)	(790)	(764)
Gross profit	4,447	10,931	3,109	2,636	1,826	977	736
Selling, general and administrative costs	(8,170)	(8,157)	(8,197)	(7,451)	(8,894)	(10,462)	(7,600)
Research and development costs	(450)	(51)	(135)	(239)	(222)	(110)	(65)
Other operating income	-	-	-	100	-	-	-
Operating result	(4,174)	2,723	(5,223)	(4,954)	(7,290)	(9,595)	(6,929)
Net financial income / (expenses)	(618)	(430)	(394)	102	(264)	297	(180)
Result before tax	(4,792)	2,293	(5,617)	(4,852)	(7,554)	(9,298)	(7,109)
Tax for the period	618	(649)	(274)	18,678	-	-	-
Net result for the period	(4,174)	1,644	(5,891)	13,826	(7,554)	(9,298)	(7,109)
<b>Balance Sheet</b>							
Cash and cash equivalents	8,983	12,806	7,243	3,359	5,295	7,206	6,650
Total assets	39,841	41,464	33,493	29,884	12,691	14,354	12,207
Share capital	24,288	24,264	24,227	24,175	25,508	25,356	23,910
Total equity	5,186	7,989	5,369	10,195	(4,589)	843	7,998
Investment in property, plant and equipment	402	47	113	51	44	81	-
<b>Cash Flow Statement</b>							
Cash flow from operating activities	(3,567)	1,352	(4,172)	(1,462)	(7,057)	(8,939)	(10,599)
Cash flow from investing activities	(402)	(47)	(113)	(51)	(44)	(81)	-
Cash flow from financing activities	85	4,129	8,138	(109)	5,147	9,781	1,162
Cash and cash equivalents at period end	8,983	12,806	7,243	3,359	5,295	7,206	6,650
<b>Financial Ratios</b>							
Basic	(0.00)	0.00	(0.00)	0.01	(0.00)	(0.01)	(0.00)
Diluted EPS (DEPS)	-	0.00	-	0.01	-	-	-
Weighted average number of shares EPS	1,709,803,414	1,708,224,400	1,703,708,460	1,702,134,751	1,699,576,055	1,688,478,176	1,664,261,003
Weighted average number of shares DEPS	1,709,803,414	1,716,197,626	1,703,708,460	1,714,014,614	1,699,576,055	1,688,478,176	1,664,261,003
Average number of employees (FTEs)	51	53	48	47	49	51	30
Assets/equity	7.68	5.19	6.24	2.93	-2.77	17.03	1.53



## Income Statement and Statement of Comprehensive Income

Income Statement		Consolidated				
(USD'000)	YTD 2017	YTD 2016	Q3 2017	Q3 2016	Year 2016	
Revenue - Net	22,092	5,506	5,924	2,239	9,194	
Production costs	(3,605)	(1,967)	(1,477)	(413)	(3,019)	
<b>Gross profit</b>	<b>18,487</b>	<b>3,539</b>	<b>4,447</b>	<b>1,826</b>	<b>6,175</b>	
Selling, general and administrative costs	(24,525)	(26,956)	(8,171)	(8,894)	(34,407)	
Research and development costs	(636)	(397)	(450)	(222)	(636)	
Other operating income	-	-	-	-	100	
<b>Operating result</b>	<b>(6,674)</b>	<b>(23,814)</b>	<b>(4,174)</b>	<b>(7,290)</b>	<b>(28,768)</b>	
Financial income	191	178	39	(19)	643	
Financial expenses	(1,633)	(325)	(657)	(245)	(688)	
<b>Result before tax</b>	<b>(8,116)</b>	<b>(23,961)</b>	<b>(4,792)</b>	<b>(7,554)</b>	<b>(28,813)</b>	
Tax for the period	(305)	-	618	-	18,678	
<b>Net result for the period</b>	<b>(8,421)</b>	<b>(23,961)</b>	<b>(4,174)</b>	<b>(7,554)</b>	<b>(10,135)</b>	
Basic EPS	(0.00)	(0.01)	(0.00)	(0.00)	(0.01)	
Diluted EPS	(0.00)	(0.01)	(0.00)	(0.00)	(0.01)	
Weighted average number of shares EPS	1,707,267,750	1,684,161,541	1,709,803,414	1,699,576,055	1,688,679,397	
Weighted average number of shares DEPS	1,707,267,750	1,684,161,541	1,709,803,414	1,699,576,055	1,688,679,397	

Statements of comprehensive income		Consolidated				
(USD'000)	YTD 2017	YTD 2016	Q3 2017	Q3 2016	Year 2016	
<b>Net result for the period</b>	<b>(8,421)</b>	<b>(23,961)</b>	<b>(4,174)</b>	<b>(7,554)</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	-	(41)	-	151	(392)	
<b>Other comprehensive income for the period</b>	<b>-</b>	<b>(41)</b>	<b>-</b>	<b>151</b>	<b>(392)</b>	
<b>Total comprehensive income for the period</b>	<b>(8,421)</b>	<b>(24,002)</b>	<b>(4,174)</b>	<b>(7,403)</b>	<b>(10,527)</b>	

**Balance Sheet**

<b>Assets</b>	<b>Consolidated</b>		
	<b>(USD'000)</b>	<b>30 Sep. 2017</b>	<b>30 Sep. 2016</b>
Patent rights and software	89	124	114
<b>Intangible assets</b>	<b>89</b>	<b>124</b>	<b>114</b>
Property, plant and equipment	916	490	482
<b>Tangible fixed assets</b>	<b>916</b>	<b>490</b>	<b>482</b>
Deferred tax asset	19,433	-	18,678
<b>Financial assets</b>	<b>19,433</b>	<b>-</b>	<b>18,678</b>
<b>Non-current assets</b>	<b>20,437</b>	<b>614</b>	<b>19,274</b>
<b>Inventories</b>	<b>6,135</b>	<b>3,067</b>	<b>4,141</b>
Trade receivables	3,355	1,641	2,212
Tax receivables	-	881	-
Other receivables	70	123	96
Prepayments	861	1,070	802
<b>Receivables</b>	<b>4,286</b>	<b>3,715</b>	<b>3,110</b>
Cash	8,983	5,295	3,359
<b>Cash and cash equivalents</b>	<b>8,983</b>	<b>5,295</b>	<b>3,359</b>
<b>Current assets</b>	<b>19,405</b>	<b>12,077</b>	<b>10,610</b>
<b>Assets</b>	<b>39,841</b>	<b>12,691</b>	<b>29,884</b>

**Balance Sheet Cont.**

<b>Equity &amp; Liabilities</b>	<b>Consolidated</b>		
<b>(USD'000)</b>	<b>30 Sep. 2017</b>	<b>30 Sep. 2016</b>	<b>31 Dec. 2016</b>
Share capital	24,288	24,153	24,175
Special reserve	57,804	57,804	57,804
Translation reserves	(4,052)	(3,411)	(4,052)
Retained earnings/loss	(72,854)	(83,135)	(67,732)
<b>Equity</b>	<b>5,186</b>	<b>(4,589)</b>	<b>10,195</b>
Loan	25,804	14,000	13,816
<b>Non-current liabilities</b>	<b>25,804</b>	<b>14,000</b>	<b>13,816</b>
Trade payables	1,920	371	957
Tax payables	619	-	-
Other payables	6,313	2,909	4,916
<b>Current liabilities</b>	<b>8,852</b>	<b>3,280</b>	<b>5,873</b>
<b>Liabilities</b>	<b>34,656</b>	<b>17,280</b>	<b>19,689</b>
<b>Equity and liabilities</b>	<b>39,841</b>	<b>12,691</b>	<b>29,884</b>

## Cash Flow Statements

Cash Flow Statement	Consolidated				
(USD'000)	YTD 2017	YTD 2016	Q3 2017	Q3 2016	Year 2016
<b>Operating result</b>	<b>(6,675)</b>	<b>(23,814)</b>	<b>(4,175)</b>	<b>(7,290)</b>	<b>(28,768)</b>
Share-based payment	3,006	3,906	1,287	1,812	5,430
Depreciation and amortization	155	159	48	58	208
Changes in working capital	(1,659)	(6,846)	(725)	(1,637)	(5,787)
<b>Cash flow from operating activities before interest</b>	<b>(5,173)</b>	<b>(26,595)</b>	<b>(3,567)</b>	<b>(7,057)</b>	<b>(28,917)</b>
Interest paid	(1,213)	-	-	-	-
Corporate tax received	-	-	-	-	860
Corporate tax paid	-	-	-	-	-
<b>Cash flow from operating activities</b>	<b>(6,386)</b>	<b>(26,595)</b>	<b>(3,567)</b>	<b>(7,057)</b>	<b>(28,057)</b>
Purchase of property, plant and equipment	(564)	(125)	(402)	(44)	(176)
<b>Cash flow from investing activities</b>	<b>(564)</b>	<b>(125)</b>	<b>(402)</b>	<b>(44)</b>	<b>(176)</b>
Proceeds from borrowings	12,000	14,000	-	5,000	14,000
Cost of borrowings	(54)	-	-	-	(184)
Proceeds from issuance of shares	406	2,090	85	147	2,165
<b>Cash flow from financing activities</b>	<b>12,352</b>	<b>16,090</b>	<b>85</b>	<b>5,147</b>	<b>15,981</b>
<b>Increase/(decrease) in cash</b>	<b>5,402</b>	<b>(10,630)</b>	<b>(3,884)</b>	<b>(1,954)</b>	<b>(12,252)</b>
Cash at beginning of period	3,359	15,763	12,806	7,206	15,763
Exchange gains/(losses) on cash	222	162	61	43	(152)
<b>Cash at end of period</b>	<b>8,983</b>	<b>5,295</b>	<b>8,983</b>	<b>5,295</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					(23,961)	(23,961)
Currency adjustment				249		249
<b>Total comprehensive income</b>				<b>249</b>	<b>(23,961)</b>	<b>(23,712)</b>
Warrant exercises	38,090,306	575			1,515	2,090
Share-based payment					3,906	3,906
Other transactions	38,090,306	575	-	-	5,421	5,996
<b>Equity as of 30 September 2016</b>	<b>1,701,873,881</b>	<b>24,153</b>	<b>57,804</b>	<b>(3,411)</b>	<b>(83,135)</b>	<b>(4,589)</b>
Net result for the year					13,826	13,826
Currency adjustment				(641)		(641)
<b>Total comprehensive income</b>				<b>(641)</b>	<b>13,826</b>	<b>13,185</b>
Warrant exercises	1,500,000	22			53	75
Share-based payment					1,524	1,524
Other transactions	1,500,000	22	-	-	1,577	1,599
<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					(8,421)	(8,421)
Currency adjustment						-
<b>Total comprehensive income</b>				<b>-</b>	<b>(8,421)</b>	<b>(8,421)</b>
Warrant exercises	7,619,750	113			293	406
Share-based payment					3,006	3,006
Other transactions	7,619,750	113	-	-	3,299	3,412
<b>Equity as of 30 September 2017</b>	<b>1,710,993,631</b>	<b>24,288</b>	<b>57,804</b>	<b>(4,052)</b>	<b>(72,854)</b>	<b>5,186</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 September		Q3	
(USD'000)	2017	2016	2017	2016
Europe	2,839	1,503	1,369	632
United States	10,943	4,003	4,525	1,607
RoW	61	-	30	-
Upfront revenue	8,250	-	-	-
<b>Total</b>	<b>22,092</b>	<b>5,506</b>	<b>5,924</b>	<b>2,239</b>