

Corporate Release

Copenhagen, Denmark, 16 November 2016



INTERIM REPORT FOR THE PERIOD 1 JANUARY TO 30 SEPTEMBER 2016

Veloxis Pharmaceuticals Announces Financial Results for the First Nine Months of 2016 and Provides Corporate Update

Highlights

- Envarsus XR reaches an estimated 1,200 patients on therapy in the U.S. and an estimated 2,000 patients in EU countries
- Total net revenues for Veloxis grew 27% in the third quarter of 2016 over the second quarter of 2016 as launch activities for Envarsus XR in the U.S. continue to increase the number of transplant centers, new prescribers, and patients

In connection with the financial report, Veloxis President and CEO, Craig A. Collard, said:

“We continue to be pleased with the response to Envarsus XR in the U.S. There is a steady upward trajectory for key metrics as we work to establish Envarsus XR as a valuable option for treating kidney transplant patients with tacrolimus.”

Summary

Net revenue for the third quarter of 2016 totaled 2,239 tUSD compared with 1,767 tUSD in the second quarter of 2016, as the company continues the launch of Envarsus XR in the U.S. Veloxis reported a net loss of 7,554 tUSD for the third quarter of 2016 compared to a net loss of 9,298 tUSD for the second quarter of 2016 and 7,300 tUSD for the third quarter of 2015.

Outlook for 2016

Veloxis maintains its 2016 outlook of an operating loss and net loss of USD 25.0 – 31.0 Million, as noted in the Interim Report for the period 1 January to 30 June 2016.

Conference Call

A conference call will be held tomorrow, 17 November 2016 at 3:00 PM CEST (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:

Confirmation Code: 3090135

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

Financial Highlights

	YTD 2016 USD'000	YTD 2015 USD'000	Q3 2016 USD'000	Q3 2015 USD'000	Year 2015 USD'000
Income Statement					
Revenue	5,506	1,934	2,239	503	2,103
Production costs	(1,967)	(1,116)	(413)	(250)	(2,250)
Gross profit	3,539	818	1,826	253	(147)
Selling, general and administrative costs	(26,956)	(12,131)	(8,894)	(5,098)	(17,808)
Research and development costs	(397)	(8,360)	(222)	(2,512)	(11,345)
Operating result	(23,814)	(19,673)	(7,290)	(7,357)	(29,300)
Net financial income / (expenses)	(147)	1,948	(264)	(42)	2,168
Result before tax	(23,961)	(17,725)	(7,554)	(7,399)	(27,132)
Tax for the period	-	662	-	221	953
Net result for the period	(23,961)	(17,063)	(7,554)	(7,178)	(26,179)
Balance Sheet					
Cash and cash equivalents	5,295	23,665	5,295	23,665	15,763
Total assets	12,691	29,072	12,691	29,072	21,809
Share capital	25,508	24,986	25,508	24,986	24,360
Total equity	(4,589)	22,330	(4,589)	22,330	13,127
Investment in property, plant and equipment	125	48	44	7	48
Cash Flow Statement					
Cash flow from operating activities	(26,595)	(18,054)	(7,057)	(4,976)	(25,998)
Cash flow from investing activities	(125)	(48)	(44)	(7)	(48)
Cash flow from financing activities	16,090	39	5,147	21	48
Cash and cash equivalents at period end	5,295	23,665	5,295	23,665	15,763
Financial Ratios					
Basic and diluted EPS	(0.01)	(0.01)	(0.00)	(0.00)	(0.02)
Weighted average number of shares	1,684,161,541	1,663,194,517	1,699,576,055	1,663,408,929	1,663,334,241
Average number of employees (FTEs)	50	34	49	42	38
Assets/equity	(2.77)	1.30	(2.77)	1.30	1.66
Share price	1.18 DKK	1.22DKK	1.18 DKK	1.22DKK	1.75DKK

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

Revenue

For the first nine months of 2016 Veloxis recognized revenue of 5,506 tUSD compared to 1,934 tUSD in the same period of 2015. Revenue in 2016 relates to commercial sales of Envarsus XR in the US as well as to Chiesi Farmaceutici S.p.A (Chiesi). Revenue in 2015 consists only of commercial sales to Chiesi for the European market.

Selling, General and Administrative Costs

For the first nine months of 2016, Veloxis' selling, general and administrative costs amounted to 26,956 tUSD compared to 12,131 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 XR in the US.

Research and Development Costs

For the first nine months of 2016, Veloxis' research and development costs amounted to 397 tUSD compared to 8,360 tUSD during the same period in 2015. The reduction in cost is associated with completion of development work relating to Envarsus XR and launch of the product at the end of 2015.

Compensation Costs

For the first nine months of 2016, a total of 3,906 tUSD was recognized as share-based compensation. The cost is included in selling, general and administrative. The comparable cost for 2015 was 1,433 tUSD and was reflected in selling, general and administrative and in research and development costs.

In the third quarter of 2016, a total of 642,500 warrants have been cancelled, a total of 74,650 warrants have expired and a total of 2,800,000 warrants have been exercised at an exercise price of DKK 0.35.

On 30 September, 2016, there were a total of 134,466,994 warrants outstanding at an average strike price of DKK 1.21. Members of the Board of Directors held 7,825,579 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 59,221,154 warrants at an average strike price of DKK 0.97.

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 2016 was 23,814 tUSD compared to 19,673 tUSD in the corresponding period of 2015.

Financial Income

During the first nine months of 2016, the Company recognized net financial expense of 147 tUSD compared to net financial income of 1,948 tUSD in the corresponding period of 2015. The lower income is mainly due to lower realized currency gains in 2016 as compared to 2015.

Net Loss

Veloxis' net loss for the first nine months of 2016 was 23,961 tUSD compared to 17,063 tUSD in the corresponding period of 2015.

Cash Flow

On 30 September, 2016, the balance sheet reflects cash and cash equivalents of 5,295 tUSD compared to 15,763 tUSD on 31 December, 2015. This represents a decrease of 10,468 tUSD primarily related to the Company's completion of development programs and the establishment of sales and marketing infrastructure for the US launch.

Balance Sheet

On 30 September, 2016, total assets were 12,691 tUSD compared to 29,072 tUSD at the end of 2015.

Shareholders' equity equaled (4,589) tUSD on 30 September, 2016, compared to 22,330 tUSD at the end of 2015.

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 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.

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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 disclaims 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) 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 and maintains a second corporate office in Edison, New Jersey, 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 US, 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.

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 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.

Copenhagen, 16 November, 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)

Lars Kåre Viksmoen

Anders Götzsche

Paul K. Wotton

Robert Radie

Financial Highlights
Quarterly Numbers in USD

	Q3 2016 USD'000	Q2 2016 USD'000	Q1 2016 USD'000	Q4 2015 USD'000	Q3 2015 USD'000	Q2 2015 USD'000	Q1 2015 USD'000
Income Statement							
Revenue	2,239	1,767	1,500	170	503	783	647
Production costs	(413)	(790)	(764)	(1,129)	(250)	(245)	(626)
Gross profit	1,826	977	736	(959)	253	538	21
Selling, general and administrative costs	(8,894)	(10,462)	(7,600)	(5,672)	(5,098)	(3,133)	(3,905)
Research and development costs	(222)	(110)	(65)	(2,980)	(2,512)	(2,716)	(3,137)
Operating result	(7,290)	(9,595)	(6,929)	(9,611)	(7,357)	(5,311)	(7,021)
Net financial income / (expenses)	(264)	297	(180)	181	(42)	(691)	2,720
Result before tax	(7,554)	(9,298)	(7,109)	(9,430)	(7,399)	(6,002)	(4,301)
Tax for the period	-	-	-	290	220	219	224
Net result for the period	(7,554)	(9,298)	(7,109)	(9,140)	(7,179)	(5,783)	(4,077)
Balance Sheet							
Cash and cash equivalents	5,295	7,206	6,650	15,763	23,665	28,656	33,642
Total assets	12,691	14,354	12,207	21,809	29,072	33,622	37,832
Share capital	25,508	25,356	24,692	24,360	24,986	24,947	23,955
Total equity	(4,589)	843	7,998	13,127	22,330	29,025	32,943
Investment in property, plant and equipment	44	81	-	-	7	41	-
Cash Flow Statement							
Cash flow from operating activities	(7,057)	(8,939)	(10,599)	(8,543)	(4,976)	(4,203)	(8,276)
Cash flow from investing activities	(44)	(81)	-	(1)	(7)	(40)	-
Cash flow from financing activities	5,147	9,781	1,162	9	21	13	5
Cash and cash equivalents at period end	5,295	7,206	6,650	15,763	23,665	28,656	33,642
Financial Ratios							
Basic and diluted EPS	(0.00)	(0.01)	(0.00)	(0.01)	(0.00)	(0.00)	(0.00)
Weighted average number of shares	1,699,576,055	1,688,478,176	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)	49	51	53	50	42	31	30
Assets/equity	(2.77)	17.03	1.53	1.66	1.30	1.16	1.15

Income statement and statement of comprehensive income

Income Statement		Consolidated			
(USD'000)	YTD 2016	YTD 2015	Q3 2016	Q3 2015	Year 2015
Revenue	5,506	1,934	2,239	503	2,103
Production costs	(1,967)	(1,116)	(413)	(250)	(2,250)
Gross profit	3,539	818	1,826	253	(147)
Selling, general and administrative costs	(26,956)	(12,131)	(8,894)	(5,098)	(17,808)
Research and development costs	(397)	(8,360)	(222)	(2,512)	(11,345)
Operating result	(23,814)	(19,673)	(7,290)	(7,357)	(29,300)
Financial income	178	1,976	(19)	-	2,205
Financial expenses	(325)	(27)	(245)	(42)	(37)
Result before tax	(23,961)	(17,725)	(7,554)	(7,399)	(27,132)
Tax for the period	-	662	-	221	953
Net result for the period	(23,961)	(17,063)	(7,554)	(7,178)	(26,179)
Basic and diluted EPS	(0.01)	(0.01)	(0.00)	(0.00)	(0.02)
Weighted average number of shares	1,684,161,541	1,663,194,517	1,699,576,055	1,663,408,929	1,663,334,241
Statements of comprehensive income		Consolidated			
(USD'000)	YTD 2016	YTD 2015	Q3 2016	Q3 2015	Year 2015
Net result for the period					
Other comprehensive income:					
<i>Items that may be subsequently reclassified to profit or loss:</i>					
Currency translation differences, net of tax	(23,961)	(17,063)	(7,554)	(7,178)	(26,179)
Other comprehensive income for the period	(41)	(21)	151	15	(12)
Total comprehensive income for the period	(41)	(21)	151	15	(12)
	(24,002)	(17,084)	(7,403)	(7,163)	(26,191)

Balance sheet

Assets	Consolidated		
(USD'000)	30 Sep 2016	30 Sep. 2015	31 Dec. 2015
Patent rights and software	124	155	146
Intangible assets	124	155	146
Property, plant and equipment	490	549	488
Property, plant and equipment	490	549	488
Non-current assets	614	704	634
Inventories	3,067	1,526	2,487
Trade receivables	1,641	-	862
Tax receivables	881	1,643	860
Other receivables	123	728	599
Prepayments	1,070	806	604
Receivables	3,715	3,177	2,925
Cash	5,295	23,665	15,763
Cash and cash equivalents	5,295	23,665	15,763
Current assets	12,077	28,368	21,175
Assets	12,691	29,072	21,809

Balance sheet

Equity & Liabilities	Consolidated		
(USD'000)	30 Sep. 2016	30 Sep. 2015	31 Dec. 2015
Share capital	25,508	24,986	24,360
Special reserve	61,044	61,165	59,632
Translation reserves	94	243	246
Retained earnings/loss	(91,235)	(64,064)	(71,111)
Equity	(4,589)	22,330	13,127
Trade payables	371	2,343	2,957
Tax payables	-	114	-
Deferred revenue	-	-	539
Other payables	2,909	4,285	5,186
Current liabilities	3,280	6,742	8,682
Loan payable	14,000	-	-
Non-current liabilities	14,000	-	-
Liabilities	17,280	6,742	8,682
Equity and liabilities	12,691	29,072	21,809

Cash flow statements

Cash Flow Statement	Consolidated				
(USD'000)	YTD 2016	YTD 2015	Q3 2016	Q3 2015	Year 2015
Operating result	(23,814)	(19,673)	(7,290)	(7,357)	(29,300)
Share-based payment	3,906	1,433	1,812	462	1,797
Depreciation and amortization	159	163	58	57	219
Changes in working capital	(6,846)	50	(1,637)	1,873	372
Cash flow from operating activities before interest	(26,595)	(18,027)	(7,057)	(4,965)	(26,912)
Interest received	-	-	-	-	21
Interest paid	-	(27)	-	(11)	(37)
Corporate tax received	-	-	-	-	930
Corporate tax paid	-	-	-	-	-
Cash flow from operating activities	(26,595)	(18,054)	(7,057)	(4,976)	(25,998)
Purchase of property, plant and equipment	(125)	(48)	(44)	(7)	(48)
Cash flow from investing activities	(125)	(48)	(44)	(7)	(48)
Proceeds from loan	14,000	-	5,000	-	-
Proceeds from issuance of shares, net	2,090	39	147	21	48
Cash flow from financing activities	16,090	39	5,147	21	48
Increase/(decrease) in cash	(10,630)	(18,063)	(1,954)	(4,962)	(25,998)
Cash at beginning of period	15,763	39,595	7,206	28,656	39,595
Exchange gains/(losses) on cash	162	2,133	43	(29)	2,166
Cash at end of period	5,295	23,665	5,295	23,665	15,763

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
Equity as of 1 Jan. 2015	1,662,997,314	24,349	59,632	258	(47,161)	37,078
Net result for the period					(17,063)	(17,063)
Other comprehensive income for the period				(21)		(21)
Total comprehensive income				(21)	(17,063)	(17,084)
Warrant exercises	735,560	11			27	38
Share-based payment					1,406	1,406
Currency adjustment		626	1,533	6	(1,273)	892
Other transactions	735,560	598	1,452	6	160	2,336
Equity as of 30 Sep. 2015	1,663,732,874	24,986	61,165	243	(64,064)	22,330
Net result for the period					(9,117)	(9,117)
Other comprehensive income for the period				9		9
Total comprehensive income				9	(9,117)	(9,108)
Warrant exercises	50,701	1			8	9
Share-based payment					392	392
Currency adjustment		(627)	(1,533)	(6)	1,670	(496)
Other transactions	50,701	(626)	(1,533)	(6)	2,070	(95)
Equity as of 31 Dec. 2015	1,663,783,575	24,360	59,632	246	(71,111)	13,127
Net result for the period					(23,961)	(23,961)
Other comprehensive income for the period				(41)		(41)
Total comprehensive income				(41)	(23,961)	(24,002)
Warrant exercises	38,090,306	575			1,515	2,090
Share-based payment					3,906	3,906
Currency adjustment		573	1,412	(111)	(1,584)	290
Other transactions	38,090,306	1,148	1,412	(111)	3,837	6,286
Equity as of 30 Sep. 2016	1,701,873,881	25,508	61,044	94	(91,235)	(4,589)

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.

Effective January 2016 the presentation currency of Veloxis was 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, 1 USD = 6.76 DKK for Q2 2015, 1 USD = 6.71 DKK for Q3 2015, 1 USD = 6.70 DKK for the first nine months of 2015, 1 USD = 6.94 DKK at 31 March 2015, 1 USD = 6.67 DKK at 30 June 2015 and 1 USD = 6.66 DKK at 30 September 2015. 1 USD = 6.73 DKK for total 2015 and 1 USD = 6.83 DKK as at 31 December 2015.

2. Research and Development Costs

With the launch of Envarsus XR late in 2015 Veloxis Pharmaceuticals changed from a development company to a commercial company. Management does not expect significant development costs in the foreseen future and have reclassified the majority of costs identified as research and development costs during Q1 2016 as selling, general and administrative costs. Some of these costs have historically been classified as development costs but now are functioning to support the routine commercialization of our product and therefore will be classified as selling, general and administrative expenses.

3. Revenue Recognition

We changed our method for revenue recognition to ex-factory recognition, effective 1st January 2016.