

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

Highlights

- FDA approves label enhancement for Envarsus XR® which establishes dosing and PK profile in African-Americans and rapid metabolizers of tacrolimus
- Favorable signal in cardiovascular outcomes in African-Americans from ASERTAA trial, and two-year safety results from STRATO trial presented at American Transplant Congress
- 34% of US transplant centers have prescribed Envarsus®

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

“In the first half of 2016, we have focused on the US launch of Envarsus through the establishment of a new commercial management team and have transitioned Danish activities to the US. Envarsus is on a clear growth trajectory in the US and EU markets.”

Summary

Net revenue for the first half of 2016 totaled 3,267 tUSD compared with 1,431 tUSD in first half of 2015, reflecting the US market launch in December 2015 and successful adoption of Envarsus XR in the US. Chiesi, under its license for European commercialization, continues to grow European sales and to launch Envarsus XR in additional European countries. Veloxis reported a net loss of 16,407 tUSD for the first half of 2016 compared to a net loss of 9,879 tUSD for the same period in 2015. The reported net loss is higher than for the same period in 2015 due to the launch and commercialization costs incurred in the US and is in line with expectations. Our financial outlook for 2016 is maintained as below.

Outlook for 2016

Veloxis has revised its 2016 outlook to an operating loss and net loss of USD 25.0 – 31.0 Million compared to the previously reported USD 17.6 – 23.4 Million.

The revision to the outlook is the result of increased costs due to the continued restructuring of the company from a development organization with headquarters in Denmark to a commercial organization with all major activities in the US. Further the outlook is impacted by additional costs related to warrant schemes for Management and new employees. The

costs related to warrants is a non cash item and does not result in any cash consideration being paid by the company nor does it affect the company's ability to continue to fund its operations within its loan facility.

Conference Call

A conference call will be held tomorrow, 25 August 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: 4376388

UK: +44(0)20 3427 1909

US: +1646 254 3361

DK: +4532 71 16 59

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

Business Update

The U.S. market opportunity for Envarsus XR is estimated at \$1.6 billion USD, with the treatable population growing at a CAGR of over 4%. As previously reported, Veloxis launched Envarsus XR into the U.S. market in December 2015 utilizing the company's own specialized transplant sales force. After two full quarters of promotion in the U.S., early adoption of Envarsus XR continues to be driven by differentiating the smooth pharmacokinetic profile of once-daily Envarsus XR when compared to twice-daily immediate-release tacrolimus. Account penetration in the U.S. has reached 34% of transplant centers, up from 20% at the end of the first quarter of 2016. In addition, the number of prescribers in the U.S. continues to increase, with 159 physicians prescribing the product at least once since launch.

On June 29th, Veloxis announced the FDA approval of label enhancements related to the pharmacokinetics (PK) and pharmacogenomics (PG) studied in the ASERTAA trial, one of the largest trials of tacrolimus PK in African-American kidney transplant patients ever conducted. African-American kidney transplant patients historically experience poorer outcomes as compared to other ethnic groups and this has been associated in part due to their expression of the CYP3A5*1 genotype, which codes for a cytochrome p450 enzyme that metabolizes tacrolimus, and shown to be present in approximately 80% of African-Americans. Patients expressing this genotype may be considered "rapid metabolizers" as they metabolize tacrolimus much more rapidly and as a result typically require higher tacrolimus doses. This may hinder efforts to obtain a therapeutic level and potentially increases the risk of organ rejection. The ASERTAA trial demonstrated that patients on Envarsus XR achieved therapeutic drug levels with a 30% lower peak concentration and 20% lower average dose compared to tacrolimus immediate-release regardless of genotype status. Based upon these findings, the FDA-approved label now contains ethnicity-specific dosing and unique genotyping guidance. Importantly, this guidance which is specific to Envarsus XR clarifies that the expected PK profile for these difficult populations remains the same as with other populations. There is a substantial market opportunity for meeting the unmet need among rapid metabolizers. Based upon published studies, we estimate that rapid metabolizers represent over 30% of the U.S. kidney transplant population, representing over \$500 million USD in market opportunity.

Two notable posters regarding Envarsus XR were presented at the American Transplant Congress in June of 2016. First, exploratory results from the ASERTAA Phase 3b trial in African-Americans favored Envarsus XR regarding its ability to potentially improve cardiovascular status among African-American kidney transplant patients. This is an important finding as cardiovascular death is the leading cause of mortality among kidney transplant patients. Secondly, the two-year safety results from the STRATO Phase 3b trial of switching of kidney transplant patients with tremor to Envarsus XR showed no unexpected safety concerns and consistent trough levels of blood concentration across the extended follow-up.

Veloxis licensed Envarsus XR to Chiesi Farmaceutici S.p.A for Europe, Turkey and CIS territories in 2012. Since 2014, Chiesi has launched Envarsus® in 17 EU countries, with 4 countries added in 2016. We estimate that over 1,400 patients have started therapy with Envarsus in EU countries, with substantial adoption in key countries such as Germany, France, Spain and Poland. Chiesi has proven to be a committed partner and has invested significantly in clinical trials of Envarsus across Europe.

With the U.S. and EU markets gaining momentum, Veloxis is actively seeking partners for Envarsus XR for remaining territories such as China, Japan, Latin America, Middle-East/North Africa, Canada, and other Asia Pacific countries.

Financial Highlights					
	YTD 2016 USD'000	YTD 2015 USD'000	Q2 2016 USD'000	Q2 2015 USD'000	Year 2015 USD'000
Income Statement					
Revenue	3,267	1,431	1,767	783	2,103
Production costs	(1,554)	(866)	(790)	(245)	(2,250)
Gross profit	1,713	565	977	538	(147)
Selling, general and administrative costs	(18,062)	(7,030)	(10,462)	(3,133)	(17,808)
Research and development costs	(175)	(5,849)	(110)	(2,716)	(11,345)
Operating result	(16,524)	(12,314)	(9,595)	(5,311)	(29,300)
Net financial income / (expenses)	117	1,992	297	(691)	2,168
Result before tax	(16,407)	(10,322)	(9,298)	(6,002)	(27,132)
Tax for the period	-	443	-	218	953
Net result for the period	(16,407)	(9,879)	(9,298)	(5,784)	(26,179)
Balance Sheet					
Cash and cash equivalents	7,206	28,656	7,206	28,656	15,763
Total assets	14,354	33,622	14,354	33,622	21,809
Share capital	25,356	24,947	25,356	24,947	24,360
Total equity	843	29,025	843	29,025	13,127
Investment in property, plant and equipment	81	41	81	40	48
Cash Flow Statement					
Cash flow from operating activities	(19,538)	(13,080)	(8,939)	(4,203)	(25,998)
Cash flow from investing activities	(81)	(41)	(81)	(40)	(48)
Cash flow from financing activities	10,943	18	9,781	13	48
Cash and cash equivalents at period end	7,206	28,656	7,206	28,656	15,763
Financial Ratios					
Basic and diluted EPS	(0.01)	(0.01)	(0.01)	(0.00)	(0.02)
Weighted average number of shares	1,676,369,590	1,663,085,535	1,688,478,176	1,663,167,653	1,663,334,241
Average number of employees (FTEs)	50	30	51	31	38
Assets/equity	17.03	1.16	17.03	1.16	1.66
Share price	1.10 DKK	0.86DKK	1.10 DKK	0.86DKK	1.75DKK

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

Revenue

For the first half of 2016 Veloxis recognized revenue of 3,267 tUSD compared to 1,431 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 half of 2016, Veloxis' selling, general and administrative costs amounted to 18,062 tUSD compared to 7,030 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 half of 2016, Veloxis' research and development costs amounted to 175 tUSD compared to 5,849 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. The limited ongoing spend on development relate to manufacturing process improvements.

Compensation Costs

For the first half of 2016, a total of 2,094 tUSD was recognized as share-based compensation. The cost is included in selling, general and administrative. The comparable cost for 2015 was 972 tUSD and was reflected in selling, general and administrative and in research and development costs.

In the second quarter of 2016, a total of 28,991,412 warrants have been cancelled, a total of 128,399 warrants have expired and a total of 13,567,340 warrants have been exercised (8,106,734 at an exercise price of DKK 0.35, 4,783,700 at an exercise price of DKK 0.36, 116,820 at an exercise price of DKK 0.95. 140,509 at an exercise price of DKK 1.03, 419,577 at an exercise price of DKK 1.05).

On 30 June, 2016, there were a total of 133,974,144 warrants outstanding at an average strike price of DKK 1.19. Members of the Board of Directors held 7,855,439 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 58,826,844 warrants at an average strike price of DKK 0.92.

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

Operating Loss

Veloxis' operating loss for the first half of 2016 was 16,524 tUSD compared to 12,314 tUSD in the corresponding period of 2015.

Financial Income

During the first half of 2016, the Company recognized net financial income of 117 tUSD compared to net financial income of 1,992 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 half of 2016 was 16,407 tUSD compared to 9,879 tUSD in the corresponding period of 2015.

Cash Flow

On 30 June, 2016, the balance sheet reflects cash and cash equivalents of 7,206 tUSD compared to 15,763 tUSD on 31 December, 2015. This represents a decrease of 8,557 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 June, 2016, total assets were 14,354 tUSD compared to 33,622 tUSD at the end of 2015.

Shareholders' equity equaled 843 tUSD on 30 June, 2016, compared to 29,025 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.

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 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, formerly LifeCycle Pharma 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 6 months ended 30 June 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, 25 August, 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

	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	1,767	1,500	170	503	783	647
Production costs	(790)	(764)	(1,129)	(250)	(245)	(626)
Gross profit	977	736	(959)	253	538	21
Selling, general and administrative costs	(10,462)	(7,600)	(5,672)	(5,098)	(3,133)	(3,905)
Research and development costs	(110)	(65)	(2,980)	(2,512)	(2,716)	(3,137)
Operating result	(9,595)	(6,929)	(9,611)	(7,357)	(5,311)	(7,021)
Net financial income / (expenses)	297	(180)	181	(42)	(691)	2,720
Result before tax	(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	(9,298)	(7,109)	(9,140)	(7,179)	(5,783)	(4,077)
Balance Sheet						
Cash and cash equivalents	7,206	6,650	15,763	23,665	28,656	33,642
Total assets	14,354	12,207	21,809	29,072	33,622	37,832
Share capital	25,356	24,692	24,360	24,986	24,947	23,955
Total equity	843	7,998	13,127	22,330	29,025	32,943
Investment in property, plant and equipment	81	-	-	7	41	-
Cash Flow Statement						
Cash flow from operating activities	(8,939)	(10,599)	(7,247)	(4,973)	(4,203)	(8,276)
Cash flow from investing activities	(81)	-	(1)	(7)	(40)	-
Cash flow from financing activities	9,781	1,162	9	21	13	5
Cash and cash equivalents at period end	7,206	6,650	15,763	23,665	28,656	33,642
Financial Ratios						
Basic and diluted EPS	(0.01)	(0.00)	(0.01)	(0.00)	(0.00)	(0.00)
Weighted average number of shares	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)	51	53	50	42	31	30
Assets/equity	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	Q2 2016	Q2 2015	Year 2015
Revenue	3,267	1,431	1,767	783	2,103
Production costs	(1,554)	(866)	(790)	(245)	(2,250)
Gross profit	1,713	565	977	538	(147)
Selling, general and administrative costs	(18,062)	(7,030)	(10,462)	(3,133)	(17,808)
Research and development costs	(175)	(5,849)	(110)	(2,716)	(11,345)
Operating result	(16,524)	(12,314)	(9,595)	(5,311)	(29,300)
Financial income	197	2,009	377	-	2,205
Financial expenses	(80)	(16)	(80)	(691)	(37)
Result before tax	(16,407)	(10,322)	(9,298)	(6,002)	(27,132)
Tax for the period	-	443	-	218	953
Net result for the period	(16,407)	(9,879)	(9,298)	(5,784)	(26,179)
Basic and diluted EPS	(0.01)	(0.01)	(0.01)	(0.00)	(0.02)
Weighted average number of shares	1,676,369,590	1,663,085,535	1,688,478,176	1,663,167,653	1,663,334,241
Statements of comprehensive income		Consolidated			
(USD'000)	YTD 2016	YTD 2015	Q2 2016	Q2 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	(16,407)	(9,879)	(9,298)	(5,784)	(26,179)
Other comprehensive income for the period	(192)	(37)	(701)	2	(12)
Total comprehensive income for the period	(192)	(37)	(701)	2	(12)
	(16,599)	(9,916)	(9,999)	(5,782)	(26,191)

Balance sheet

Assets	Consolidated		
(USD'000)	30 June 2016	30 June 2015	31 Dec. 2015
Patent rights and software	130	163	146
Intangible assets	130	163	146
Property, plant and equipment	496	589	488
Property, plant and equipment	496	589	488
Non-current assets	626	752	634
Inventories	3,366	1,570	2,487
Trade receivables	1,290	284	862
Tax receivables	877	1,406	860
Other receivables	151	793	599
Prepayments	838	161	604
Receivables	3,156	2,644	2,925
Cash	7,206	28,656	15,763
Cash and cash equivalents	7,206	28,656	15,763
Current assets	13,728	32,870	21,175
Assets	14,354	33,622	21,809

Balance sheet

Equity & Liabilities	Consolidated		
(USD'000)	30 June 2016	30 June 2015	31 Dec. 2015
Share capital	25,356	24,947	24,360
Special reserve	60,781	61,084	59,632
Translation reserves	54	227	246
Retained earnings/loss	(85,348)	(57,233)	(71,111)
Equity	843	29,025	13,127
Trade payables	1,373	1,033	2,957
Tax payables	-	102	-
Deferred revenue	-	-	539
Other payables	3,138	3,462	5,186
Current liabilities	4,511	4,597	8,682
Loan payable	9,000	-	-
Non-current liabilities	9,000	-	-
Liabilities	13,511	4,597	8,682
Equity and liabilities	14,354	33,622	21,809

Cash flow statements

Cash Flow Statement	Consolidated				
(USD'000)	YTD 2016	YTD 2015	Q2 2016	Q2 2015	Year 2015
Operating result	(16,524)	(12,314)	(9,603)	(5,311)	(29,300)
Share-based payment	2,094	972	1,785	565	1,797
Depreciation and amortization	101	107	45	53	219
Changes in working capital	(5,209)	(1,828)	(1,166)	503	372
Cash flow from operating activities before interest	(19,538)	(13,063)	(8,939)	(4,190)	(26,912)
Interest received	-	-	-	-	21
Interest paid	-	(17)	-	(13)	(37)
Corporate tax received	-	-	-	-	930
Corporate tax paid	-	-	-	-	-
Cash flow from operating activities	(19,538)	(13,080)	(8,939)	(4,203)	(25,998)
Purchase of property, plant and equipment	(81)	(41)	(81)	(40)	(48)
Cash flow from investing activities	(81)	(41)	(81)	(40)	(48)
Proceeds from loan	9,000	-	9,000	-	-
Proceeds from issuance of shares, net	1,943	18	781	13	48
Cash flow from financing activities	10,943	18	9,781	13	48
Increase/(decrease) in cash	(8,676)	(13,103)	761	(4,230)	(25,998)
Cash at beginning of period	15,763	39,595	6,650	33,642	39,595
Exchange gains/(losses) on cash	119	2,164	(205)	(756)	2,166
Cash at end of period	7,206	28,656	7,206	28,656	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					(9,879)	(9,879)
Other comprehensive income for the period				(37)		(37)
Total comprehensive income				(37)	(9,879)	(9,917)
Warrant exercises	343,416	5			13	18
Share-based payment					952	952
Currency adjustment		593	1,452	6	(1,158)	893
Other transactions	343,416	598	1,452	6	(193)	1,863
Equity as of 30 June 2015	1,663,340,730	24,947	61,084	227	(57,233)	29,025
Net result for the period					(16,300)	(16,300)
Other comprehensive income for the period				25		25
Total comprehensive income				25	(16,300)	(16,275)
Warrant exercises	442,845	7			23	30
Share-based payment					846	846
Currency adjustment		(594)	(1,452)	(6)	1,553	(499)
Other transactions	442,845	(587)	(1,452)	(6)	2,422	377
Equity as of 31 Dec. 2015	1,663,783,575	24,360	59,632	246	(71,111)	13,127
Net result for the period					(16,407)	(16,407)
Other comprehensive income for the period				(192)		(192)
Total comprehensive income				(192)	(16,407)	(16,599)
Warrant exercises	35,290,306	533			1,410	1,943
Share-based payment					2,094	2,094
Currency adjustment		463	1,149	-	(1,334)	278
Other transactions	35,290,306	996	1,149	-	2,170	4,315
Equity as of 30 June 2016	1,699,073,881	25,356	60,781	54	(85,348)	843

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 = 6.69 DKK for the first half of 2015, 1 USD = 6.94 DKK at 31 March 2015 and 1 USD = 6.67 DKK at 30 June 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.