

Veloxis Pharmaceuticals Announces Financial Results for the First Six Months of 2017

Highlights

- Revenue reached tUSD 16,168 in the first half of 2017 representing an increase of 394% compared to the same period last year.
 - U.S. revenue increased 168% to tUSD 6,418
 - EU revenue increased 69% to tUSD 1,470
 - RoW upfront revenues were tUSD 8,250
- Signed outlicensing agreements for Envarsus XR with:
 - Endo Ventures Limited for the Canadian market (to be registered and commercialized by Paladin Labs, Inc.)
 - Chiesi Farmaceutici S.p.A. for China
 - Taiba Healthcare for Middle East and North Africa region (MENA)
- 69% of U.S. transplant centers have utilized Envarsus XR since launch.
- Veloxis reported a net loss of tUSD 4,247 for the first half of 2017 compared to a net loss of tUSD 16,407 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 with the continued strong sales growth of Envarsus and the execution of our RoW licensing efforts. We will continue to execute our commercial strategy in the second half of 2017."

Outlook for 2017

Veloxis narrows its 2017 outlook of operating loss before the recognition of income from license agreements and before accounting for stock compensation from USD 5 – 15 million to be in the range of USD 10 – 15 million.

Conference Call

A conference call will be held tomorrow, 17 August, 2017 at 3:00 PM CEST (Denmark); 1:00 PM GMT (London), 9:00 AM EST (New York).

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

Confirmation Code: 1870839

UK: +44(0)20 3427 0503

U.S.: +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					
	YTD 2017 USD'000	YTD 2016 USD'000	Q2 2017 USD'000	Q2 2016 USD'000	Year 2016 USD'000
Income Statement					
Revenue	16,168	3,267	12,168	1,767	9,194
Production costs	(2,128)	(1,554)	(1,237)	(790)	(3,019)
Gross profit	14,040	1,713	10,931	977	6,175
Selling, general and administrative costs	(16,354)	(18,062)	(8,157)	(10,462)	(34,407)
Research and development costs	(186)	(175)	(51)	(110)	(636)
Other operating income	-	-	-	-	100
Operating result	(2,500)	(16,524)	2,723	(9,595)	(28,768)
Net financial income / (expenses)	(824)	117	(430)	297	(45)
Result before tax	(3,324)	(16,407)	2,293	(9,298)	(28,813)
Tax for the period	(923)	-	(649)	-	18,678
Net result for the period	(4,247)	(16,407)	1,644	(9,298)	(10,135)
Balance Sheet					
Cash and cash equivalents	12,806	7,206	12,806	7,206	3,359
Total assets	41,464	14,354	41,464	14,354	29,884
Share capital	24,264	24,111	24,264	24,111	24,175
Total equity	7,989	843	7,989	843	10,195
Investment in property, plant and equipment	161	81	47	81	176
Cash Flow Statement					
Cash flow from operating activities	(2,820)	(19,538)	1,352	(8,939)	(28,057)
Cash flow from investing activities	(161)	(81)	(47)	(81)	(176)
Cash flow from financing activities	12,267	10,943	4,129	9,781	15,981
Cash and cash equivalents at period end	12,806	7,206	12,806	7,206	3,359
Financial Ratios					
Weighted average number of shares ('000)	1,705,979	1,676,370	1,708,224	1,688,478	1,688,679
Average number of employees (FTEs)	50	50	53	51	38
Assets/equity	5.19	17.03	5.19	17.03	2.93
Share price DKK	1.08	1.10	1.08	1.10	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 six months of 2017, Veloxis reached USD16,168 compared to USD 3,267 in the same period of 2016. The increase is driven by growth in commercial sales of Envarsus XR in the U.S. from USD 2,396 to USD 6,418, sales to Chiesi Farmaceutici S.p.A (“Chiesi”) in Europe from USD 871 to USD 1,470 and rest of world (RoW) upfront revenue of USD 8,250 with no comparable revenue in the prior year.

In the second quarter of 2017, revenue grew 589% and reached USD 12,168 compared to USD 1,767 in the comparable period of prior year. U.S. revenue reached USD 3,847, up 218% or USD 2,638 from the second quarter of 2016. Revenue to Chiesi reached USD 1,041, up 87% or USD 483 from the second quarter of 2016. In addition, rest of world upfront revenue of USD 7,250 was recognized with no comparable revenue in the second quarter of 2016.

See Revenue Note 2 for more detail.

Selling, General and Administrative Costs

For the first half of 2017, Veloxis’s selling, general and administrative costs amounted to USD 16,354 compared to USD 18,062 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 second quarter of 2017, selling, general and administrative costs were USD 8,157 compared to USD 10,462 in the second 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 half of 2017, Veloxis’s research and development costs amounted to USD 186 compared to USD 175 during the same period in 2016.

In the second quarter of 2017, research and development costs were USD 51 compared to USD 110 in the comparable period of 2016.

Compensation Costs

For the first half of 2017, a total of USD 1,720 was recognized as share-based compensation. The cost is included in selling, general and administrative. The comparable cost for 2016 was USD 2,094.

In the second quarter of 2017, a total of 800,114 warrants were cancelled, none expired and a total of 2,500,000 warrants were exercised at an exercise price of DKK 0.35.

On 30 June 2017, there were a total of 155,736,516 warrants outstanding at an average strike price of DKK 1.22. 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 59,972,701 warrants at an average strike price of DKK 1.05.

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 half of 2017 was USD 2,500 compared to USD 16,524 in the corresponding period of 2016.

Financial Income

During the first half of 2017, the Company recognized net financial expense of USD 824 compared to net financial income of USD 117 in the corresponding period of 2016.

Net Loss

Veloxis's net loss for the first half of 2017 was USD 4,247 compared to USD 16,407 in the corresponding period of 2016.

Cash Flow

On 30 June 2017, the balance sheet reflects cash and cash equivalents of USD 12,806 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 June 2017, total assets were USD 41,464 compared to USD 29,884 at the end of 2016.

Shareholders' equity equaled USD 7,989 on 30 June, 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.

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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[®], 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.

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 6 months ended 30 June 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, 16 August, 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

	Q2 2017 USD'000	Q1 2017 USD'000	Q4 2016 USD'000	Q3 2016 USD'000	Q2 2016 USD'000	Q1 2016 USD'000
Income Statement						
Revenue	12,168	4,000	3,688	2,239	1,767	1,500
Production costs	(1,237)	(891)	(1,052)	(413)	(790)	(764)
Gross profit	10,931	3,109	2,636	1,826	977	736
Selling, general and administrative costs	(8,157)	(8,197)	(7,451)	(8,894)	(10,462)	(7,600)
Research and development costs	(51)	(135)	(239)	(222)	(110)	(65)
Other operating income	-	-	100	-	-	-
Operating result	2,723	(5,223)	(4,954)	(7,290)	(9,595)	(6,929)
Net financial income / (expenses)	(430)	(394)	102	(264)	297	(180)
Result before tax	2,293	(5,617)	(4,852)	(7,554)	(9,298)	(7,109)
Tax for the period	(649)	(274)	18,678	-	-	-
Net result for the period	1,644	(5,891)	13,826	(7,554)	(9,298)	(7,109)
Balance Sheet						
Cash and cash equivalents	12,806	7,243	3,359	5,295	7,206	6,650
Total assets	41,464	33,493	29,884	12,691	14,354	12,207
Share capital	24,264	24,227	24,175	25,508	25,356	23,910
Total equity	7,989	5,369	10,195	(4,589)	843	7,998
Investment in property, plant and equipment	47	113	51	44	81	-
Cash Flow Statement						
Cash flow from operating activities	1,352	(4,172)	(1,462)	(7,057)	(8,939)	(10,599)
Cash flow from investing activities	(47)	(113)	(51)	(44)	(81)	-
Cash flow from financing activities	4,129	8,138	(109)	5,147	9,781	1,162
Cash and cash equivalents at period end	12,806	7,243	3,359	5,295	7,206	6,650
Financial Ratios						
Basic	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	1,708,224,400	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	1,716,197,626	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)	53	48	47	49	51	30
Assets/equity	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	Q2 2017	Q2 2016	Year 2016
Revenue - Net	16,168	3,267	12,168	1,767	9,194
Production costs	(2,128)	(1,554)	(1,237)	(790)	(3,019)
Gross profit	14,040	1,713	10,931	977	6,175
Selling, general and administrative costs	(16,354)	(18,062)	(8,157)	(10,462)	(34,407)
Research and development costs	(186)	(175)	(51)	(110)	(636)
Other operating income	-	-	-	-	100
Operating result	(2,500)	(16,524)	2,723	(9,595)	(28,768)
Financial income	152	197	133	377	643
Financial expenses	(976)	(80)	(563)	(80)	(688)
Result before tax	(3,324)	(16,407)	2,293	(9,298)	(28,813)
Tax for the period	(923)	-	(649)	-	18,678
Net result for the period	(4,247)	(16,407)	1,644	(9,298)	(10,135)
Basic EPS	(0.00)	(0.01)	0.00	(0.01)	(0.01)
Diluted EPS	(0.00)	(0.01)	0.00	(0.01)	(0.01)
Weighted average number of shares EPS	1,705,978,905	1,676,369,590	1,708,224,400	1,688,478,176	1,688,679,397
Weighted average number of shares DEPS	1,705,978,905	1,676,369,590	1,716,197,626	1,688,478,176	1,688,679,397

Statements of comprehensive income		Consolidated			
(USD'000)	YTD 2017	YTD 2016	Q2 2017	Q2 2016	Year 2016
Net result for the period	(4,247)	(16,407)	1,644	(9,298)	(10,135)
Other comprehensive income: <i>Items that may be subsequently reclassified to profit or loss:</i>					
Currency translation differences, net of tax	-	86	-	(423)	(392)
Other comprehensive income for the period	-	86	-	(423)	(392)
Total comprehensive income for the period	(4,247)	(16,321)	1,644	(9,721)	(10,527)

Balance Sheet

Assets	Consolidated		
	(USD'000)	30 June 2017	30 June 2016
Patent rights and software	98	130	114
Intangible assets	98	130	114
Property, plant and equipment	551	496	482
Tangible fixed assets	551	496	482
Deferred tax asset	18,678	-	18,678
Financial assets	18,678	-	18,678
Non-current assets	19,327	626	19,274
Inventories	5,809	3,366	4,141
Trade receivables	2,931	1,290	2,212
Tax receivables	-	877	-
Other receivables	85	151	96
Prepayments	506	838	802
Receivables	3,522	3,156	3,110
Cash	12,806	7,206	3,359
Cash and cash equivalents	12,806	7,206	3,359
Current assets	22,137	13,728	10,610
Assets	41,464	14,354	29,884

Balance Sheet Cont.

Equity & Liabilities	Consolidated		
(USD'000)	30 June 2017	30 June 2016	31 Dec. 2016
Share capital	24,264	24,111	24,175
Special reserve	57,804	57,804	57,804
Translation reserves	(4,052)	(3,574)	(4,052)
Retained earnings/loss	(70,027)	(77,498)	(67,732)
Equity	7,989	843	10,195
Loan	25,790	9,000	13,816
Non-current liabilities	25,790	9,000	13,816
Trade payables	708	1,373	957
Tax payables	443	-	-
Other payables	6,534	3,138	4,916
Current liabilities	7,685	4,511	5,873
Liabilities	33,475	13,511	19,689
Equity and liabilities	41,464	14,354	29,884

Cash Flow Statements

Cash Flow Statement	Consolidated				
(USD'000)	YTD 2017	YTD 2016	Q2 2017	Q2 2016	Year 2016
Operating result	(2,500)	(16,524)	2,723	(9,603)	(28,768)
Share-based payment	1,720	2,094	847	1,785	5,430
Depreciation and amortization	107	101	55	45	208
Changes in working capital	(934)	(5,209)	(1,060)	(1,166)	(5,787)
Cash flow from operating activities before interest	(1,607)	(19,538)	2,565	(8,939)	(28,917)
Interest paid	(1,213)	-	(1,213)	-	-
Corporate tax received	-	-	-	-	860
Corporate tax paid	-	-	-	-	-
Cash flow from operating activities	(2,820)	(19,538)	1,352	(8,939)	(28,057)
Purchase of property, plant and equipment	(161)	(81)	(47)	(81)	(176)
Cash flow from investing activities	(161)	(81)	(47)	(81)	(176)
Proceeds from bank borrowings	12,000	9,000	4,000	9,000	14,000
Cost of borrowings	(54)	-	-	-	(184)
Proceeds from issuance of shares	321	1,943	129	781	2,165
Cash flow from financing activities	12,267	10,943	4,129	9,781	15,981
Increase/(decrease) in cash	9,286	(8,676)	5,434	761	(12,252)
Cash at beginning of period	3,359	15,763	7,243	6,650	15,763
Exchange gains/(losses) on cash	161	119	129	(205)	(152)
Cash at end of period	12,806	7,206	12,806	7,206	3,359

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. 2016	1,663,783,575	23,578	57,804	(3,660)	(64,595)	13,127
Net result for the year					(16,407)	(16,407)
Currency adjustment				86		86
Total comprehensive income				86	(16,407)	(16,321)
Warrant exercises	35,290,306	533			1,410	1,943
Share-based payment					2,094	2,094
Other transactions	35,290,306	533	-	-	3,504	4,037
Equity as of 30 June 2016	1,699,073,881	24,111	57,804	(3,574)	(77,498)	843
Net result for the year					6,272	6,272
Currency adjustment				(478)		(478)
Total comprehensive income				(478)	6,272	5,794
Warrant exercises	4,300,000	64			158	222
Share-based payment					3,336	3,336
Other transactions	4,300,000	64	-	-	3,494	3,558
Equity as of 31 Dec. 2016	1,703,373,881	24,175	57,804	(4,052)	(67,732)	10,195
Net result for the year					(4,247)	(4,247)
Currency adjustment						-
Total comprehensive income				-	(4,247)	(4,247)
Warrant exercises	6,119,750	89			232	321
Share-based payment					1,720	1,720
Other transactions	6,119,750	89	-	-	1,952	2,041
Equity as of 30 June 2017	1,709,493,631	24,264	57,804	(4,052)	(70,027)	7,989

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 June		Q2	
(USD'000)	2017	2016	2017	2016
Europe	1,470	871	1,041	558
United States	6,418	2,396	3,847	1,209
RoW	30	-	30	-
Upfront revenue	8,250	-	7,250	-
Total	16,168	3,267	12,168	1,767