

Veloxis Pharmaceuticals Announces Financial Results for the First Six Months of 2018

Highlights

- Veloxis upgrades 2018 Outlook based on strong performance.
- Product revenue for first half of 2018 was USD 17.2 million, an increase of 117% compared to the same period last year.
 - U.S. revenue increased 129% to USD 14.7 million
 - EU revenue increased 69% to USD 2.5 million
- 88% of U.S. transplant centers have utilized Envarsus XR® since launch.
- FDA accepts Veloxis's supplemental New Drug Application for the *de novo* indication for Envarsus XR.
- Veloxis reported a net loss of USD 5.7 million for the first half of 2018 compared to a net loss of USD 4.2 million for the same period in 2017. The prior year included up-front revenues of USD 8.3 million with zero comparable revenue for the first half of 2018.

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

"We are very pleased with our performance in the first half of 2018. Product revenues are up significantly and, with the increasing number of transplant centers utilizing Envarsus, we believe we will continue to see strong growth for the remainder of the year. Therefore, we are very excited to be raising our Outlook to reflect the tremendous growth we are experiencing as a company."

Outlook for 2018

Veloxis revises its 2018 Outlook of revenues to be in the range of USD 36 – 42 million and operating loss before accounting for stock compensation in the range of USD 2 – 6 million. Veloxis's previously reported 2018 Outlook to be USD 32 – 40 million for revenues and operating loss before accounting for stock compensation in the range of USD 6 – 12 million.

Conference Call

A conference call will be held tomorrow, 14 August 2018 at 4:00 PM CET (Denmark); 10:00 AM EST (New York).

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

Confirmation Code: 5576829

U.S.: +1 929 477 0448

UK: +44 (0) 330 336 9126

DK: +45 35 15 80 49

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

Financial Highlights

	YTD 2018 USD'000	YTD 2017 USD'000	Q2 2018 USD'000	Q2 2017 USD'000	Year 2017 USD'000
Income Statement					
Revenue	17,161	16,168	9,896	12,168	30,167
Production costs	(3,402)	(2,128)	(2,061)	(1,237)	(5,202)
Gross profit	13,759	14,040	7,835	10,931	24,965
Selling, general and administrative costs	(18,275)	(16,354)	(9,163)	(8,157)	(32,458)
Research and development costs	(371)	(186)	(190)	(51)	(866)
Operating result	(4,887)	(2,500)	(1,518)	2,723	(8,359)
Net financial income / (expenses)	(2,877)	(824)	(1,689)	(430)	(2,090)
Result before tax	(7,764)	(3,324)	(3,207)	2,293	(10,449)
Tax for the period	2,100	(923)	1,574	(649)	907
Net result for the period	(5,664)	(4,247)	(1,633)	1,644	(9,542)
Balance Sheet					
Cash and cash equivalents	30,783	12,806	30,783	12,806	7,766
Total assets	70,525	41,464	70,525	41,464	41,921
Total equity	2,121	7,989	2,121	7,989	5,316
Investment in property, plant and equipment	150	161	-	47	564
Cash Flow Statement					
Cash flow from operating activities	(10,398)	(2,820)	(4,675)	1,352	(7,710)
Cash flow from investing activities	(150)	(161)	-	(47)	(564)
Cash flow from financing activities	33,632	12,267	-	4,129	12,435
Cash and cash equivalents at period end	30,783	12,806	30,783	12,806	7,766
Financial Ratios					
Weighted average number of shares ('000)	1,712,557	1,705,979	1,712,639	1,708,224	1,708,326
Average number of employees (FTEs)	54	50	54	53	51
Assets/equity	33.25	5.19	33.25	5.19	7.89
Share price DKK	0.92	1.08	0.92	1.08	0.86

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 first half of 2018, Veloxis reached revenue of USD 17,161 compared to USD 16,168 in the same period of 2017. The increase is driven by growth in commercial sales of Envarsus XR in the U.S. which increased by 117% to USD 14,672 compared to USD 6,418 for the first half of 2017. Sales to Chiesi Farmaceutici S.p.A (“Chiesi”) in Europe were USD 2,483 compared to USD 1,470 for the same period in 2017. There were zero upfront revenue compared to USD 8,250 in the prior year.

In the second quarter of 2018, revenue, all of which was generated by product sales reached USD 9,896, an increase of 101% compared to product revenue of USD 4,918 for the same period of 2017. U.S. revenue reached USD 8,254 an increase of 115%, or USD 4,407, as compared to the second quarter of 2017. Revenue to Chiesi reached USD 1,642, an increase of 58%, or USD 601, as compared to the second quarter of 2017. There were zero upfront revenue for the second quarter of 2018 compared to USD 7,250 in the second quarter of 2017.

See Revenue Note 2 for more detail.

Selling, General and Administrative Costs

For the first half of 2018, Veloxis’s selling, general and administrative costs amounted to USD 18,275 compared to USD 16,354 during the same period in 2017. The increase reflects additional spends in our sales, marketing, and medical affairs department in our continued effort to maximize the growth of Envarsus XR.

In the second quarter of 2018, selling, general and administrative costs were USD 9,163 compared to USD 8,157 in the second quarter of 2017. The increase in costs is primarily due to additional efforts in our sales, marketing and medical affairs department to continue the growth momentum of Envarsus XR.

Research and Development Costs

For the first half of 2018, Veloxis’s research and development costs amounted to USD 371 compared to USD 186 for the same period in 2017.

In the second quarter of 2018, research and development costs were USD 190 compared to USD 51 for the same period in 2017.

Compensation Costs

For the first half of 2018, a total of USD 2,457 was recognized as share-based compensation. The cost is included in selling, general and administrative. The comparable cost for 2017 was USD 1,720.

In the second quarter of 2018, a total of 1,973,929 warrants were cancelled, 50,000 expired, and no warrants were exercised.

On 30 June 2018, there were a total of 190,038,029 warrants outstanding at an average strike price of DKK 1.12. Members of the Board of Directors held 19,445,908 warrants at an average strike price of DKK 1.06. Members of Executive Management held 92,417,373 warrants at an average strike price of DKK 1.22, while other current and former employees held 78,174,748 warrants at an average strike price of DKK 1.02.

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

Operating Loss

Veloxis's operating loss for the first half of 2018 was USD 4,887 compared to USD 2,500 for the same period in 2017. Veloxis had zero upfront revenue during the first half of 2018, compared to USD 8,250 of upfront revenue for the same period in 2017.

Financial Income

During the first half of 2018, the Company recognized net financial expense of USD 2,877 compared to net financial expense of USD 824 in the corresponding period of 2017. The increase in expense for 2018 is due to the increase of the loan facility to USD 60,000 in 2018.

Tax for the Period

Tax for the first half of 2018 was a benefit of USD 2,100 primarily related to the revaluation and recognition of further deferred tax assets. At 30 June 2018, the deferred tax asset was USD 22,364 compared to USD 20,187 at the end of 2017.

Net Loss

Veloxis's net loss for the first half of 2018 was USD 5,664 compared to USD 4,247 in the corresponding period of 2017.

Cash Flow

At 30 June 2018, the balance sheet reflected cash and cash equivalents of USD 30,783 compared to USD 7,766 at 31 December 2017. This increase in funds relates to Veloxis obtaining a USD 60,000 loan from Athyrium Capital Management, LP, in February 2018. Some of these proceeds were used to pay off the previous loan facility with Novo Holdings A/S and Lundbeckfond Invest A/S while the remaining funds will be used for operational purposes.

Balance Sheet

At 30 June 2018, total assets were USD 70,525 compared to USD 41,921 at the end of 2017. The majority of the increase in total assets relates to the higher cash balance of USD 30,783 in connection with the increase in the loan facility.

Shareholders' equity equaled USD 2,121 on 30 June 2018, compared to USD 5,316 at the end of 2017.

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 2017. 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 2017.

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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 S.p.A.

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 six months ended 30 June 2018 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, 13 August 2018

Executive Management

Craig A. Collard
President & CEO

Morten Marott
CFO

Board of Directors

Michael Heffernan
(Chairman)

Mette Kirstine Agger
(Deputy Chairman)

Lars Kåre Viksmoen

Anders Götzsche

Paul K. Wotton

Robert S. Radie

Financial Highlights						
	Q2 2018 USD'000	Q1 2018 USD'000	Q4 2017 USD'000	Q3 2017 USD'000	Q2 2017 USD'000	Q1 2017 USD'000
Income Statement						
Revenue	9,896	7,265	8,074	5,924	12,168	4,000
Production costs	(2,061)	(1,342)	(1,597)	(1,477)	(1,237)	(891)
Gross profit	7,835	5,923	6,478	4,447	10,931	3,109
Selling, general and administrative costs	(9,163)	(9,111)	(7,934)	(8,170)	(8,157)	(8,197)
Research and development costs	(190)	(180)	(230)	(450)	(51)	(135)
Operating result	(1,518)	(3,368)	(1,685)	(4,174)	2,723	(5,223)
Net financial income / (expenses)	(1,689)	(1,188)	(648)	(618)	(430)	(394)
Result before tax	(3,207)	(4,556)	(2,332)	(4,792)	2,293	(5,617)
Tax for the period	1,574	526	1,212	618	(649)	(274)
Net result for the period	(1,633)	(4,030)	(1,120)	(4,174)	1,644	(5,891)
Balance Sheet						
Cash and cash equivalents	30,783	35,587	7,766	8,983	12,806	7,243
Total assets	70,525	70,357	41,921	39,841	41,464	33,493
Share capital	24,314	24,314	24,311	24,288	24,264	24,227
Total equity	2,121	2,406	5,316	5,186	7,989	5,369
Investment in property, plant and equipment	-	150	-	402	49	113
Cash Flow Statement						
Cash flow from operating activities	(4,675)	(5,723)	(1,323)	(3,567)	1,352	(4,172)
Cash flow from investing activities	-	(150)	-	(402)	(49)	(113)
Cash flow from financing activities	-	33,631	84	85	4,129	8,138
Cash and cash equivalents at period end	30,783	35,587	7,766	8,983	12,806	7,243
Financial Ratios						
Basic EPS	(0.00)	(0.00)	(0.00)	(0.00)	0.00	(0.00)
Diluted EPS (DEPS)	(0.00)	(0.00)	(0.00)	(0.00)	0.00	(0.00)
Weighted average number of shares EPS	1,712,638,531	1,712,474,087	1,711,464,794	1,709,803,414	1,708,224,400	1,703,708,460
Weighted average number of shares DEPS	1,712,638,531	1,712,474,087	1,711,464,794	1,709,803,414	1,716,197,626	1,703,708,460
Average number of employees (FTEs)	54	53	52	51	53	48
Assets/equity	33.25	29.25	7.89	7.68	5.19	6.24

Income Statement and Statement of Comprehensive Income

Income Statement		Consolidated			
(USD'000)	YTD 2018	YTD 2017	Q2 2018	Q2 2017	Year 2017
Revenue - Net	17,161	16,168	9,896	12,168	30,167
Production costs	(3,402)	(2,128)	(2,061)	(1,237)	(5,202)
Gross profit	13,759	14,040	7,835	10,931	24,965
Selling, general and administrative costs	(18,275)	(16,354)	(9,163)	(8,157)	(32,458)
Research and development costs	(371)	(186)	(190)	(51)	(866)
Operating result	(4,887)	(2,500)	(1,518)	2,723	(8,359)
Financial income	62	152	(47)	133	199
Financial expenses	(2,939)	(976)	(1,642)	(563)	(2,289)
Result before tax	(7,764)	(3,324)	(3,207)	2,293	(10,449)
Tax for the period	2,100	(923)	1,574	(649)	907
Net result for the period	(5,664)	(4,247)	(1,633)	1,644	(9,542)
Basic EPS	(0.00)	(0.00)	(0.00)	0.00	(0.01)
Diluted EPS	(0.00)	(0.00)	(0.00)	0.00	(0.01)
Weighted average number of shares EPS	1,712,556,763	1,705,978,905	1,712,638,531	1,708,224,400	1,708,325,635
Weighted average number of shares DEPS	1,712,556,763	1,705,978,905	1,712,638,531	1,716,197,626	1,708,325,635

Statements of comprehensive income		Consolidated			
(USD'000)	YTD 2018	YTD 2017	Q2 2018	Q2 2017	Year 2017
Net result for the period	(5,664)	(4,247)	(1,633)	1,644	(9,542)
Other comprehensive income: <i>Items that may be subsequently reclassified to profit or loss:</i>					
Currency translation differences, net of tax	-	-	-	-	-
Other comprehensive income for the period	-	-	-	-	-
Total comprehensive income for the period	(5,664)	(4,247)	(1,633)	1,644	(9,542)

Balance Sheet

Assets	Consolidated		
	(USD'000)	30 June 2018	30 June 2017
Patent rights and software	64	98	80
Intangible assets	64	98	80
Property, plant and equipment	948	551	875
Tangible fixed assets	948	551	875
Deferred tax asset	22,364	18,678	20,187
Financial assets	22,364	18,678	20,187
Non-current assets	23,376	19,327	21,142
Inventories	8,645	5,809	6,781
Trade receivables	5,473	2,931	4,354
Other receivables	1,313	85	55
Prepayments	935	506	1,823
Receivables	7,721	3,522	6,232
Cash	30,783	12,806	7,766
Cash and cash equivalents	30,783	12,806	7,766
Current assets	47,149	22,137	20,779
Assets	70,525	41,464	41,921

Balance Sheet Cont.

Equity & Liabilities	Consolidated		
(USD'000)	30 June 2018	30 June 2017	31 Dec. 2017
Share capital	24,314	24,264	24,311
Special reserve	57,804	57,804	57,804
Translation reserves	(4,052)	(4,052)	(4,052)
Retained earnings/loss	(75,945)	(70,027)	(72,747)
Equity	2,121	7,989	5,316
Loan	59,748	25,790	25,818
Non-current liabilities	59,748	25,790	25,818
Trade payables	512	708	2,428
Other payables	8,144	6,977	8,359
Current liabilities	8,656	7,685	10,787
Liabilities	68,404	33,475	36,605
Equity and liabilities	70,525	41,464	41,921

Cash Flow Statements

Cash Flow Statement	Consolidated					
	(USD'000)	YTD 2018	YTD 2017	Q2 2018	Q2 2017	Year 2017
Operating result		(4,887)	(2,500)	(1,518)	2,723	(8,359)
Share-based payment		2,457	1,720	1,349	847	4,174
Depreciation and amortization		93	107	47	55	205
Changes in working capital		(3,755)	(934)	(2,989)	(1,060)	(2,517)
Cash flow from operating activities before interest		(6,092)	(1,607)	(3,111)	2,565	(6,497)
Interest paid		(4,306)	(1,213)	(1,564)	(1,213)	(1,213)
Cash flow from operating activities		(10,398)	(2,820)	(4,675)	1,352	(7,710)
Purchase of property, plant and equipment		(150)	(161)	-	(47)	(564)
Cash flow from investing activities		(150)	(161)	-	(47)	(564)
Proceeds from bank borrowings		60,000	12,000	-	4,000	12,000
Repayment of loan principal		(26,000)	-	-	-	-
Cost of borrowings		(380)	(54)	-	-	(54)
Proceeds from issuance of shares		12	321	-	129	489
Cash flow from financing activities		33,632	12,267	-	4,129	12,435
Increase/(decrease) in cash		23,084	9,286	(4,675)	5,434	4,161
Cash at beginning of period		7,766	3,359	35,587	7,243	3,359
Exchange gains/(losses) on cash		(67)	161	(129)	129	246
Cash at end of period		30,783	12,806	30,783	12,806	7,766

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. 2017	1,703,373,881	24,175	57,804	(4,052)	(67,732)	10,195
Net result for the year					(4,247)	(4,247)
Total comprehensive income					-	(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
Net result for the year					(5,295)	(5,295)
Total comprehensive income					-	(5,295)
Warrant exercises	2,944,900	47			121	168
Share-based payment					2,454	2,454
Other transactions	2,944,900	47	-	-	2,575	2,622
Equity as of 31 Dec. 2017	1,712,438,531	24,311	57,804	(4,052)	(72,747)	5,316
Net result for the year					(5,664)	(5,664)
Total comprehensive income					-	(5,664)
Warrant exercises	200,000	3			9	12
Share-based payment					2,457	2,457
Other transactions	200,000	3	-	-	2,466	2,469
Equity as of 30 June 2018	1,712,638,531	24,314	57,804	(4,052)	(75,945)	2,121

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 2017.

2. Revenue

Revenue was comprised of the following:

	YTD June		Q2	
(USD'000)	2018	2017	2018	2017
Europe	2,483	1,470	1,642	1,041
United States	14,672	6,418	8,254	3,847
RoW	6	30	-	30
Upfront revenue	-	8,250	-	7,250
Total	17,161	16,168	9,896	12,168