

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

Highlights

- Product revenue for Q1 2018 was tUSD 7,265 an increase of 142% compared to the same period last year.
 - U.S. revenue increased 150% to tUSD 6,418
 - EU revenue increased 96% to tUSD 841
- Over 79% of U.S. transplant centers have utilized Envarsus XR® since launch.
- Veloxis obtained USD 60 million of capital from funds managed by Athyrium Capital Management, LP, a leading healthcare-focused investment firm.
- Veloxis submitted a supplemental New Drug Application to the U.S. FDA seeking a new indication for Envarsus XR (tacrolimus extended-release tablets) for the prophylaxis of organ rejection in kidney transplant patients in combination with other immunosuppressants.
- Morten Marott joined Veloxis as Chief Financial Officer.
- Veloxis reported a net loss of tUSD 4,030 for the first quarter of 2018 compared to a net loss of tUSD 5,891 for the same period in 2017. The reported operating net loss is in line with expectations.

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

"2018 is off to a fantastic start with the filing of our sNDA for the *de novo* indication, the closing of our financing with Athyrium, the hiring of our new CFO, Morten Marott, and, most importantly, the continued growth of Envarsus."

Outlook for 2018

Veloxis maintains its 2018 outlook of revenues to be in the range of USD 32 – 40 million and operating loss before accounting for stock compensation in the range of USD 4 – 10 million.

Conference Call

A conference call will be held tomorrow, 15 May 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: 8366822

U.S.: +1 929 477 0275

DK: +45 35 15 80 50

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

Financial Highlights			
	Q1 2018 USD'000	Q1 2017 USD'000	Year 2017 USD'000
Income Statement			
Revenue	7,265	4,000	30,167
Production costs	(1,342)	(891)	(5,202)
Gross profit	5,923	3,109	24,965
Selling, general and administrative costs	(9,111)	(8,197)	(32,458)
Research and development costs	(180)	(135)	(866)
Operating result	(3,368)	(5,223)	(8,359)
Net financial income / (expenses)	(1,188)	(394)	(2,090)
Result before tax	(4,556)	(5,617)	(10,449)
Tax for the period	526	(274)	907
Net result for the period	(4,030)	(5,891)	(9,542)
Balance Sheet			
Cash and cash equivalents	35,587	7,243	7,766
Total assets	70,357	33,493	41,921
Total equity	2,406	5,369	5,316
Investment in property, plant and equipment	150	113	564
Cash Flow Statement			
Cash flow from operating activities	(5,723)	(4,172)	(7,710)
Cash flow from investing activities	(150)	(113)	(564)
Cash flow from financing activities	33,631	8,138	12,435
Cash and cash equivalents at period end	35,587	7,243	7,766
Financial Ratios			
Weighted average number of shares ('000)	1,712,474	1,703,708	1,708,326
Average number of employees (FTEs)	53	48	51
Assets/equity	29.25	6.24	7.89
Share price DKK	0.94	1.06	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 quarter of 2018, Veloxis reached revenue of USD 7,265 compared to USD 4,000 in the same period of 2017. The increase is driven by growth in commercial sales of Envarsus XR in the U.S. which resulted in revenues of USD 6,418 compared to USD 2,572 for the first quarter of 2017. Sales to Chiesi Farmaceutici S.p.A (“Chiesi”) in Europe were USD 841 compared to USD 428 for the same period in 2017. There were zero upfront revenue compared to USD 1,000 in the prior year.

See Revenue Note 2 for more detail.

Selling, General and Administrative Costs

For the first quarter of 2018, Veloxis’s selling, general and administrative costs amounted to USD 9,111 compared to USD 8,197 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.

Research and Development Costs

For the first quarter of 2018, Veloxis’s research and development costs amounted to USD 180 compared to USD 135 during the same period in 2017.

Compensation Costs

For the first quarter of 2018, a total of USD 1,108 was recognized as share-based compensation. The cost is included in selling, general and administrative. The comparable cost for 2017 was USD 873.

In the first quarter of 2018, a total of 21,655,065 warrants were cancelled, 300,000 expired, and a total of 200,000 warrants were exercised at an exercise price of DKK 0.35.

On 31 March 2018, there were a total of 158,297,425 warrants outstanding at an average strike price of DKK 1.15. 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 74,777,196 warrants at an average strike price of DKK 1.27, while other current and former employees held 69,388,675 warrants at an average strike price of DKK 1.03.

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 quarter of 2018 was USD 3,368 compared to USD 5,223 in the corresponding period of 2017.

Financial Income

During the first quarter of 2018, the Company recognized net financial expense of USD 1,188 compared to net financial expense of USD 394 in the corresponding period of 2017.

Tax for the Period

Net tax for the first quarter of 2018 was income of USD 526 primarily related to the revaluation and recognition of further deferred tax assets. At 31 March 2018, the deferred tax asset was USD 20,774 compared to USD 20,187 at the end of 2017.

Net Loss

Veloxis's net loss for the first quarter of 2018 was USD 4,030 compared to USD 5,891 in the corresponding period of 2017.

Cash Flow

On 31 March 2018, the balance sheet reflects cash and cash equivalents of USD 35,587 compared to USD 7,766 on 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

On 31 March 2018, total assets were USD 70,357 compared to USD 41,921 at the end of 2017.

Shareholders' equity equaled USD 2,406 on 31 March 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.

For More Information, Please Contact:

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President & CEO
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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[®], 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 three months ended 31 March 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, 14 May 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

	Q1 2018 USD'000	Q4 2017 USD'000	Q3 2017 USD'000	Q2 2017 USD'000	Q1 2017 USD'000
Income Statement					
Revenue	7,265	8,074	5,924	12,168	4,000
Production costs	(1,342)	(1,597)	(1,477)	(1,237)	(891)
Gross profit	5,923	6,478	4,447	10,931	3,109
Selling, general and administrative costs	(9,111)	(7,934)	(8,170)	(8,157)	(8,197)
Research and development costs	(180)	(230)	(450)	(51)	(135)
Operating result	(3,368)	(1,685)	(4,174)	2,723	(5,223)
Net financial income / (expenses)	(1,188)	(648)	(618)	(430)	(394)
Result before tax	(4,556)	(2,332)	(4,792)	2,293	(5,617)
Tax for the period	526	1,212	618	(649)	(274)
Net result for the period	(4,030)	(1,120)	(4,174)	1,644	(5,891)
Balance Sheet					
Cash and cash equivalents	35,587	7,766	8,983	12,806	7,243
Total assets	70,357	41,921	39,841	41,464	33,493
Share capital	24,314	24,311	24,288	24,264	24,227
Total equity	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	(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	35,587	7,766	8,983	12,806	7,243
Financial Ratios					
Basic EPS	(0.00)	(0.00)	(0.00)	0.00	(0.00)
Diluted EPS (DEPS)	(0.00)	(0.00)	(0.00)	0.00	(0.00)
Weighted average number of shares EPS	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	1,712,474,087	1,711,464,794	1,709,803,414	1,716,197,626	1,703,708,460
Average number of employees (FTEs)	53	52	51	53	48
Assets/equity	29.25	7.89	7.68	5.19	6.24

Income Statement and Statement of Comprehensive Income

Income Statement	Consolidated		
(USD'000)	Q1 2018	Q1 2017	Year 2017
Revenue - Net	7,265	4,000	30,167
Production costs	(1,342)	(891)	(5,202)
Gross profit	5,923	3,109	24,965
Selling, general and administrative costs	(9,111)	(8,197)	(32,458)
Research and development costs	(180)	(135)	(866)
Operating result	(3,368)	(5,223)	(8,359)
Financial income	109	19	199
Financial expenses	(1,297)	(413)	(2,289)
Result before tax	(4,556)	(5,617)	(10,449)
Tax for the period	526	(274)	907
Net result for the period	(4,030)	(5,891)	(9,542)
Basic EPS	(0.00)	(0.00)	(0.01)
Diluted EPS	(0.00)	(0.00)	(0.01)
Weighted average number of shares EPS	1,712,474,087	1,703,708,460	1,708,325,635
Weighted average number of shares DEPS	1,712,474,087	1,703,708,460	1,708,325,635

Statements of comprehensive income	Consolidated		
(USD'000)	Q1 2018	Q1 2017	Year 2017
Net result for the period	(4,030)	(5,891)	(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	(4,030)	(5,891)	(9,542)

Balance Sheet

Assets	Consolidated		
	(USD'000)	31 Mar. 2018	31 Mar. 2017
Patent rights and software	72	106	80
Intangible assets	72	106	80
Property, plant and equipment	987	551	875
Tangible fixed assets	987	551	875
Deferred tax asset	20,774	18,425	20,187
Financial assets	20,774	18,425	20,187
Non-current assets	21,833	19,082	21,142
Inventories	7,869	5,041	6,781
Trade receivables	3,446	1,434	4,354
Other receivables	23	62	55
Prepayments	1,600	631	1,823
Receivables	5,068	2,127	6,232
Cash	35,587	7,243	7,766
Cash and cash equivalents	35,587	7,243	7,766
Current assets	48,525	14,411	20,779
Assets	70,357	33,493	41,921

Balance Sheet Cont.

Equity & Liabilities	Consolidated		
(USD'000)	31 Mar. 2018	31 Mar. 2017	31 Dec. 2017
Share capital	24,314	24,227	24,311
Special reserve	57,804	57,804	57,804
Translation reserves	(4,052)	(4,052)	(4,052)
Retained earnings/loss	(75,660)	(72,610)	(72,747)
Equity	2,406	5,369	5,316
Loan	59,670	21,776	25,818
Non-current liabilities	59,670	21,776	25,818
Trade payables	765	1,987	2,428
Tax payables	223	22	-
Other payables	7,294	4,339	8,359
Current liabilities	8,281	6,348	10,787
Liabilities	67,951	28,124	36,605
Equity and liabilities	70,357	33,493	41,921

Cash Flow Statements

Cash Flow Statement	Consolidated		
(USD'000)	Q1 2018	Q1 2017	Year 2017
Operating result	(3,369)	(5,223)	(8,359)
Share-based payment	1,108	873	4,174
Depreciation and amortization	46	52	205
Changes in working capital	(766)	126	(2,517)
Cash flow from operating activities before interest	(2,981)	(4,172)	(6,497)
Interest paid	(2,742)	-	(1,213)
Cash flow from operating activities	(5,723)	(4,172)	(7,710)
Purchase of property, plant and equipment	(150)	(113)	(564)
Cash flow from investing activities	(150)	(113)	(564)
Proceeds from borrowings	60,000	8,000	12,000
Repayment of loan principal	(26,000)		
Cost of borrowings	(380)	(54)	(54)
Proceeds from issuance of shares	12	192	489
Cash flow from financing activities	33,631	8,138	12,435
Increase/(decrease) in cash	27,758	3,853	4,161
Cash at beginning of period	7,766	3,359	3,359
Exchange gains/(losses) on cash	63	31	246
Cash at end of period	35,587	7,243	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					(5,891)	(5,891)
Total comprehensive income					-	(5,891)
Warrant exercises	3,619,750	52			140	192
Share-based payment					873	873
Other transactions	3,619,750	52	-	-	1,013	1,065
Equity as of 31 March 2017	1,706,993,631	24,227	57,804	(4,052)	(72,610)	5,369
Net result for the year					(3,651)	(3,651)
Total comprehensive income					-	(3,651)
Warrant exercises	5,444,900	84			213	297
Share-based payment					3,301	3,301
Other transactions	5,444,900	84	-	-	3,514	3,598
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					(4,030)	(4,030)
Total comprehensive income					-	(4,030)
Warrant exercises	200,000	3			9	12
Share-based payment					1,108	1,108
Other transactions	200,000	3	-	-	1,117	1,120
Equity as of 31 March 2018	1,712,638,531	24,314	57,804	(4,052)	(75,660)	2,406

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:

	Q1	
<u>(USD'000)</u>	<u>2018</u>	<u>2017</u>
Europe	841	428
United States	6,418	2,572
RoW	6	-
Upfront revenue	-	1,000
Total	7,265	4,000