

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

Highlights

- Product revenue for first nine months of 2018 was USD 27.8 million, an increase of 101% compared to the same period last year.
 - U.S. revenue increased 118% to USD 23.8 million
 - EU revenue increased 38% to USD 3.9 million
- 91% of U.S. transplant centers have utilized Envarsus XR® since launch.
- Cash balance, \$30.6 million on September 30.
- Veloxis reported a net loss of USD 4.1 million for the first nine months of 2018 compared to a net loss of USD 8.4 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 nine months of 2018.

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

"We are very excited about the wide-spread use of Envarsus among transplant centers. Veloxis has strong momentum as we move into the final quarter of 2018."

Outlook for 2018

Veloxis maintains 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.

Conference Call

A conference call will be held tomorrow, 15 November 2018 at 4:00 PM CET (Denmark); 10:00 AM EST (New York).

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

Confirmation Code: 3860316

U.S.: +1 929 477 0324

UK: +44 (0) 330 336 9411

DK: +45 35 15 81 21

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	Q3 2018 USD'000	Q3 2017 USD'000	Year 2017 USD'000
Income Statement					
Revenue	27,753	22,092	10,592	5,924	30,167
Production costs	(5,271)	(3,605)	(1,869)	(1,477)	(5,202)
Gross profit	22,482	18,487	8,723	4,447	24,965
Selling, general and administrative costs	(26,656)	(24,525)	(8,381)	(8,171)	(32,458)
Research and development costs	(501)	(636)	(130)	(450)	(866)
Other operating income	-	-	-	-	-
Operating result	(4,675)	(6,674)	212	(4,174)	(8,359)
Net financial income / (expenses)	(4,405)	(1,442)	(1,528)	(618)	(2,090)
Result before tax	(9,080)	(8,116)	(1,316)	(4,792)	(10,449)
Tax for the period	4,944	(305)	2,843	618	907
Net result for the period	(4,136)	(8,421)	1,527	(4,174)	(9,542)
Balance Sheet					
Cash and cash equivalents	30,564	8,983	30,564	8,983	7,766
Total assets	76,104	39,841	76,104	39,841	41,921
Total equity	4,307	5,186	4,307	5,186	5,316
Investment in property, plant and equipment	150	564	-	402	564
Cash Flow Statement					
Cash flow from operating activities	(10,621)	(6,386)	(223)	(3,567)	(7,710)
Cash flow from investing activities	(150)	(564)	-	(402)	(564)
Cash flow from financing activities	33,642	12,352	10	85	12,435
Cash and cash equivalents at period end	30,564	8,983	30,564	8,983	7,766
Financial Ratios					
Weighted average number of shares ('000)	1,712,613	1,707,268	1,712,723	1,709,803	1,708,326
Average number of employees (FTEs)	54	50	55	49	51
Assets/equity	17.67	7.68	17.67	7.68	7.89
Share price DKK	1.10	1.18	1.10	1.18	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 nine months of 2018, Veloxis reached revenue of USD 27,753 compared to USD 22,092 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 118% to USD 23,834 compared to USD 10,943 for the first nine months of 2017. Sales to Chiesi Farmaceutici S.p.A (“Chiesi”) in Europe were USD 3,913 compared to USD 2,839 for the same period in 2017. There were zero upfront revenue compared to USD 8,250 in the prior year.

In the third quarter of 2018, revenue reached USD 10,592, an increase of 79% compared to revenue of USD 5,924 for the same period of 2017. U.S. revenue reached USD 9,162 an increase of 103%, or USD 4,637, as compared to the third quarter of 2017. Revenue to Chiesi reached USD 1,430, an increase of 5%, or USD 61, as compared to the third quarter of 2017.

See Revenue Note 2 for more detail.

Selling, General and Administrative Costs

For the first nine months of 2018, Veloxis’s selling, general and administrative costs amounted to USD 26,656 compared to USD 24,525 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 third quarter of 2018, selling, general and administrative costs were USD 8,381 compared to USD 8,170 in the third 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 nine months of 2018, Veloxis’s research and development costs amounted to USD 501 compared to USD 636 for the same period in 2017.

In the third quarter of 2018, research and development costs were USD 130 compared to USD 450 for the same period in 2017.

Compensation Costs

For the first nine months of 2018, a total of USD 3,105 was recognized as share-based compensation. The cost is included in selling, general and administrative. The comparable cost for 2017 was USD 3,006.

In the third quarter of 2018, no warrants were cancelled, 88,466 warrants expired, and 200,000 warrants were exercised.

On 30 September 2018, a total of 193,449,563 warrants were 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 81,586,282 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 nine of 2018 was USD 4,675 compared to USD 6,674 for the same period in 2017. Veloxis had zero upfront revenue during the first nine months of 2018, compared to USD 8,250 of upfront revenue for the same period in 2017.

Financial Income

During the first nine months of 2018, the Company recognized net financial expense of USD 4,405 compared to net financial expense of USD 1,442 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 nine months of 2018 was a benefit of USD 4,944 primarily related to the revaluation and recognition of further deferred tax assets. At 30 September 2018, the deferred tax asset was USD 25,646 compared to USD 20,187 at the end of 2017.

Net Loss

Veloxis's net loss for the first nine months of 2018 was USD 4,136 compared to USD 8,421 in the corresponding period of 2017.

Cash Flow

At 30 September 2018, the balance sheet reflected cash and cash equivalents of USD 30,564 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 September 2018, total assets were USD 76,104 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 30,564 in connection with the increase in the loan facility.

Shareholders' equity equaled USD 4,307 on 30 September 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:

Craig A. Collard
President & CEO
Phone: +1 919 591 3090
Email: cac@veloxis.com

Ira Duarte
CFO
Phone: +1 919 591 3090
Email: idu@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 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 nine months ended 30 September 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 November 2018

Executive Management

Craig A. Collard
President & CEO

Ira Duarte
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

	Q3 2018 USD'000	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	10,592	9,896	7,265	8,074	5,924	12,168	4,000
Production costs	(1,869)	(2,061)	(1,342)	(1,597)	(1,477)	(1,237)	(891)
Gross profit	8,723	7,835	5,923	6,478	4,447	10,931	3,109
Selling, general and administrative costs	(8,381)	(9,163)	(9,111)	(7,934)	(8,171)	(8,157)	(8,197)
Research and development costs	(130)	(190)	(180)	(230)	(450)	(51)	(135)
Operating result	212	(1,518)	(3,368)	(1,685)	(4,174)	2,723	(5,223)
Net financial income / (expenses)	(1,528)	(1,689)	(1,188)	(648)	(618)	(430)	(394)
Result before tax	(1,316)	(3,207)	(4,556)	(2,332)	(4,792)	2,293	(5,617)
Tax for the period	2,843	1,574	526	1,212	618	(649)	(274)
Net result for the period	1,527	(1,633)	(4,030)	(1,120)	(4,174)	1,644	(5,891)
Balance Sheet							
Cash and cash equivalents	30,564	30,783	35,587	7,766	8,983	12,806	7,243
Total assets	76,104	70,525	70,357	41,921	39,841	41,464	33,493
Share capital	24,317	24,314	24,314	24,311	24,288	24,264	24,227
Total equity	4,307	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	(223)	(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	10	-	33,631	84	85	4,129	8,138
Cash and cash equivalents at period end	30,564	30,783	35,587	7,766	8,983	12,806	7,243
Financial Ratios							
Basic	0.00	(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	(0.00)
Weighted average number of shares EPS ('000)	1,712,723	1,712,639	1,712,474	1,711,465	1,709,803	1,708,224	1,703,708
Weighted average number of shares DEPS ('000)	1,721,539	1,712,639	1,712,474	1,711,465	1,709,803	1,716,198	1,703,708
Average number of employees (FTEs)	55	54	53	52	51	53	48
Assets/equity	17.67	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	Q3 2018	Q3 2017	Year 2017
Revenue - Net	27,753	22,092	10,592	5,924	30,167
Production costs	(5,271)	(3,605)	(1,869)	(1,477)	(5,202)
Gross profit	22,482	18,487	8,723	4,447	24,965
Selling, general and administrative costs	(26,656)	(24,525)	(8,381)	(8,171)	(32,458)
Research and development costs	(501)	(636)	(130)	(450)	(866)
Other operating income	-	-	-	-	-
Operating result	(4,675)	(6,674)	212	(4,174)	(8,359)
Financial income	185	191	124	39	199
Financial expenses	(4,590)	(1,633)	(1,652)	(657)	(2,289)
Result before tax	(9,080)	(8,116)	(1,316)	(4,792)	(10,449)
Tax for the period	4,944	(305)	2,843	618	907
Net result for the period	(4,136)	(8,421)	1,527	(4,174)	(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 ('000)	1,712,613	1,707,268	1,712,723	1,709,803	1,708,326
Weighted average number of shares DEPS ('000)	1,712,613	1,707,268	1,721,539	1,709,803	1,708,326

Statements of comprehensive income		Consolidated			
(USD'000)	YTD 2018	YTD 2017	Q3 2018	Q3 2017	Year 2017
Net result for the period	(4,136)	(8,421)	1,527	(4,174)	(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	(4,136)	(8,421)	1,527	(4,174)	(9,542)

Balance Sheet

Assets	Consolidated		
(USD'000)	30 Sep. 2018	30 Sep. 2017	31 Dec. 2017
Patent rights and software	56	89	80
Intangible assets	56	89	80
Property, plant and equipment	912	916	875
Tangible fixed assets	912	916	875
Deferred tax asset	25,646	19,433	20,187
Financial assets	25,646	19,433	20,187
Non-current assets	26,614	20,437	21,142
Inventories	10,328	6,135	6,781
Trade receivables	7,127	3,355	4,354
Other receivables	51	70	55
Prepayments	1,420	861	1,823
Receivables	8,598	4,286	6,232
Cash	30,564	8,983	7,766
Cash and cash equivalents	30,564	8,983	7,766
Current assets	49,490	19,405	20,779
Assets	76,104	39,841	41,921

Balance Sheet Cont.

Equity & Liabilities	Consolidated		
(USD'000)	30 Sep. 2018	30 Sep. 2017	31 Dec. 2017
Share capital	24,317	24,288	24,311
Special reserve	57,804	57,804	57,804
Translation reserves	(4,052)	(4,052)	(4,052)
Retained earnings/loss	(73,762)	(72,854)	(72,747)
Equity	4,307	5,186	5,316
Loan	59,827	25,804	25,818
Non-current liabilities	59,827	25,804	25,818
Trade payables	2,736	1,920	2,428
Other payables	9,234	6,932	8,359
Current liabilities	11,970	8,852	10,787
Liabilities	71,797	34,656	36,605
Equity and liabilities	76,104	39,841	41,921

Cash Flow Statements

Cash Flow Statement	Consolidated				
(USD'000)	YTD 2018	YTD 2017	Q3 2018	Q3 2017	Year 2017
Operating result	(4,675)	(6,675)	212	(4,175)	(8,359)
Share-based payment	3,105	3,006	648	1,287	4,174
Depreciation and amortization	137	155	44	48	205
Changes in working capital	(3,307)	(1,659)	447	(725)	(2,517)
Cash flow from operating activities before interest	(4,741)	(5,173)	1,351	(3,567)	(6,497)
Interest paid	(5,880)	(1,213)	(1,574)	-	(1,213)
Cash flow from operating activities	(10,621)	(6,386)	(223)	(3,567)	(7,710)
Purchase of property, plant and equipment	(150)	(564)	-	(402)	(564)
Cash flow from investing activities	(150)	(564)	-	(402)	(564)
Proceeds from borrowings	60,000	12,000	-	-	12,000
Repayment of loan principal	(26,000)	-	-	-	-
Cost of borrowings	(381)	(54)	-	-	(54)
Proceeds from issuance of shares	22	406	10	85	489
Cash flow from financing activities	33,642	12,352	10	85	12,435
Increase/(decrease) in cash	22,871	5,402	(213)	(3,884)	4,161
Cash at beginning of period	7,766	3,359	30,783	12,806	3,359
Exchange gains/(losses) on cash	(73)	222	(6)	61	246
Cash at end of period	30,564	8,983	30,564	8,983	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					(8,421)	(8,421)
Total comprehensive income					-	(8,421)
Warrant exercises	7,619,750	113			293	406
Share-based payment					3,006	3,006
Other transactions	7,619,750	113	-	-	3,299	3,412
Equity as of 30 September 2017	1,710,993,631	24,288	57,804	(4,052)	(72,854)	5,186
Net result for the year					(1,121)	(1,121)
Total comprehensive income					-	(1,121)
Warrant exercises	1,444,900	23			60	83
Share-based payment					1,168	1,168
Other transactions	1,444,900	23	-	-	1,228	1,251
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					(4,136)	(4,136)
Total comprehensive income					-	(4,136)
Warrant exercises	400,000	6			16	22
Share-based payment					3,105	3,105
Other transactions	400,000	6	-	-	3,121	3,127
Equity as of 30 September 2018	1,712,838,531	24,317	57,804	(4,052)	(73,762)	4,307

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 September		Q3	
(USD'000)	2018	2017	2018	2017
Europe	3,913	2,839	1,430	1,369
United States	23,834	10,943	9,162	4,525
RoW	6	61	-	30
Upfront revenue	-	8,250	-	-
Total	27,753	22,092	10,592	5,924