

Company Announcement no. 23/2015

To: NASDAQ OMX Copenhagen A/S

Hørsholm, Denmark, 11 November, 2015

# Veloxis Pharmaceuticals announces financial results for the first nine months of 2015

## Highlights:

- On 30 September, 2015, Veloxis had cash and cash equivalents of DKK 157.6 million, and the Company's cash position is expected to be in the range of DKK 100 130 million at year-end. The Company is currently engaged in a process to secure additional financing primarily through debt structure. The Company expects that the financing cost will be in the range of a high yield bond for similar life science companies and the proceeds will be used primarily to support US product launch.
- On 14 October, 2015, a sponsored Level 1 American depositary receipt (ADR) program in the U.S. was established. The ADR trades under the symbol VXPZY.
- Envarsus<sup>®</sup> XR has been issued a unique reimbursement J-code by the Centers for Medicare and Medicaid Services (CMS) for 2016 onwards.
- Envarsus<sup>®</sup> XR has been granted Orphan Drug status by the U.S. Food and Drug Administration (FDA) for prophylaxis of organ rejection in patients who convert from immediate-release tacrolimus.
- Veloxis has received U.S. Food and Drug Administration (FDA) approval of Envarsus® XR (tacrolimus extendedrelease tablets) for the prophylaxis of rejection in kidney transplant patients who require or desire conversion from other twice-daily tacrolimus products to once-daily Envarsus® XR. Veloxis expects Envarsus® XR to be available to patients in the United States and their physicians by the end of 2015.
- Veloxis reported a net loss of DKK 114.3 million for the nine months of 2015 compared to a net profit of DKK 12.9 million for the same period in 2014. The reported net loss is in line with expectations.
- For the first nine months of 2015, Veloxis recognized revenue of DKK 13.0 million compared to DKK 120.2 million in the same period of 2014. Revenue in 2015 consist of commercial sales to Chiesi Farmaceutici S.p.A. Revenue in 2014 consist of up-front and milestone payments under Veloxis' distribution agreement with Chiesi Farmaceutici S.p.A. Envarsus is currently launched in Germany, Netherlands, UK, Denmark, Austria, Ireland, France, Slovenia and the Czech Republic.
- For the first nine months of 2015, Veloxis' sales and marketing costs amounted to DKK 40.9 million compared to DKK 24.0 million during the same period in 2014. Research and development costs amounted to DKK 56.0 million compared to DKK 70.4 million during the same period in 2014.



## Outlook for 2015

Veloxis maintains its 2015 outlook with an operating loss in the range of DKK 175 - 205 million, and a net loss in the range of DKK 155 - 185 million for the financial year 2015.

On 30 September 2015, the Company's cash position equaled DKK 157.6 million, and on 31 December 2015, the Company's cash position is expected to be in the range of DKK 100 – 130 million.

## **Conference call**

A conference call will be held tomorrow, 12 November, 2015 at 3:00 PM CET (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: +45 38 48 75 13 (Denmark) +44 (0) 20 7136 2055 (UK) +1 718 354 1359 (USA) Access code 1720884

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

## **Business update**

## Envarsus® Market and Regulatory Strategy

On 28 July, 2014, it was announced that the European Commission granted marketing authorization for Envarsus<sup>®</sup> for the prevention of organ rejection in adult kidney and liver transplant patients in the European Union (EU). Veloxis' marketing and distribution partner in EU Chiesi Farmaceutici launched Envarsus<sup>®</sup> in late 2014, with launches in Germany and the Netherlands, followed by launch in the UK, Denmark, Austria, Eire, France, Slovenia and the Czech Republic in 2015. Additional launches are anticipated for the majority of the major EU countries during 2015 and into 2016, once local requirements such as pricing and reimbursement negotiations have been completed.

On 12 June, 2015, Veloxis announced that the U.S. District Court for the District of Columbia had ruled in favor of the FDA in the lawsuit filed by Veloxis against the FDA. The Court's ruling left intact FDA's 30 October, 2014 tentative approval of Envarsus<sup>®</sup> XR (tacrolimus extended-release tablets), which delayed full approval for use in newly transplanted kidney transplant recipients ("*de novo*" patients). Veloxis submitted revised labeling to FDA with the goal of making Envarsus<sup>®</sup> XR available for kidney transplant patients who wish to convert from twice-daily tacrolimus products to once-daily Envarsus<sup>®</sup> XR.

On 10 July, 2015, Veloxis received U.S. FDA approval of Envarsus<sup>®</sup> XR (tacrolimus extended-release tablets) for the prophylaxis of rejection in kidney transplant patients who require or desire conversion from other twice-daily tacrolimus products to once-daily Envarsus<sup>®</sup> XR.

Envarsus<sup>®</sup> XR has been issued a unique reimbursement J-code by the Centers for Medicare and Medicaid Services (CMS) for 2016 onwards. J-codes are used by providers to identify drugs to help facilitate reimbursement.

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The build and hiring of the full commercial infrastructure, including a sales team of approximately 18 individuals to call on the top 120 transplant centres in the US, to support launch of Envarsus<sup>®</sup> XR in the US is nearly complete and expected to be in place and operational for product launch in late 2015. The initial sales uptake in the US is expected to be gradual but steady as patients are converted from existing therapies to Envarsus XR.

In addition, Envarsus<sup>®</sup> XR has been granted Orphan Drug status by the U.S. Food and Drug Administration (FDA) for prophylaxis of organ rejection in patients who convert from immediate-release tacrolimus.

# Envarsus<sup>®</sup> study programme

Veloxis is conducting a series of Phase IIIb/IV studies to further evaluate potential differences in clinical profile provided by Envarsus<sup>®</sup> unique PK profile. The first study completed was the STRATO (Switching kidney TRAnsplant patients with Tremor to LCP-tacrO) study of Envarsus<sup>®</sup> in kidney transplant recipients experiencing drug-induced tremors which demonstrated significant overall improvements following the switch to Envarsus<sup>®</sup>. The results of this study were published in the journal *Clinical Transplantation*.

Additionally, the ASERTAA (A Study of Extended Release Tacrolimus in African-Americans) Phase IIIb study of Envarsus<sup>®</sup> in kidney transplant recipients has been completed. The ASERTAA primary pharmacokinetic results were presented at the American Transplant Congress in Philadelphia in May, 2015 and at the European Society of Organ Transplantation meeting in September, 2015. The key primary outcomes from this study were:

- The overall PK differences (increased absorption [p<0.0001], lower peak blood concentrations [p<0.0001], less peak-to-tough fluctuation in blood levels [p<0.0001]) between Envarsus XR and immediate-release tacrolimus (IR-Tac) capsules seen previously in studies of kidney transplant recipients were also confirmed in this exclusively African-American patient population.</li>
- The optimal conversion ratio for once-daily extended release Envarsus XR was shown to be approximately 20% lower than the total IR-Tac daily dose prior to conversion.
- Peak tacrolimus concentration (Cmax) was reduced 30% for patients on Envarsus while intra-day fluctuation was reduced 50%.

In addition, the ASTCOFF (A STeady-state Pharmacokinetic Comparison Of all FK-506 Formulations) Phase IIIb study has been completed and primary results were announced in June, 2015 and subsequently presented at the European Society of Organ Transplantation meeting in September, 2015. This study examined the pharmacokinetic differences between Envarsus and the other two tacrolimus formulations commercially available, namely Astagraf XL and Prograf. Primary results from this study confirmed previously published data for Envarsus and showed greater bioavailability (p<0.0001) and a flatter PK profile characterized by lower peak-to-trough fluctuation (p<0.001) and delayed time to peak concentrations of 6 hrs (p=<0.001) compared to both Prograf and Astagraf. At equivalent exposure, Envarsus achieves at least a 30% dose reduction requirement and a substantively lower peak blood concentration (p=<0.005) compared to the two comparator products.



# **Financial Highlights**

	VTD	VTD	01	03	Veer
	YTD 2015	YTD 2014	Q3 2015	Q3 2014	Year 2014
	DKK'000	2014 DKK'000	2015 DKK'000	2014 DKK'000	DKK'000
		DKK 000	DKK 000	DKK 000	DKK UUU
Income Statement					
Revenue	12,955	120,181	3,379	95,769	123,395
Production costs	(7,478)	-	(1,680)	-	(3,247)
Gross profit	5,477	120,181	1,699	95,769	120,148
Sales and marketing costs	(40,863)	(24,032)	(21,406)	(10,378)	(41,278)
Research and development costs	(55,988)	(70,435)	(16,861)	(19,391)	(90,111)
Administrative expenses	(40,387)	(27,988)	(12,814)	(10,256)	(47,363)
Operating result	(131,761)	(2,274)	(49,382)	55,744	(58,604)
Net financial income / (expenses)	13,048	15,238	(280)	13,332	20,903
Result before tax	(118,713)	12,964	(49,662)	69,076	(37,701)
Tax for the period	4,436	(106)	1,479	(3,095)	1,382
Net result for the period	(114,277)	12,858	(48,183)	65,981	(36,319)
Balance Sheet					
Cash and cash equivalents	157,579	310,571	157,579	310,571	270,434
Total assets	193,583	330,127	193,583	330,127	293,723
Share capital	166,374	166,300	166,374	166,300	166,300
Total equity	148,688	300,456	148,688	300,456	253,248
Investment in property, plant and equipment	322	657	50	540	1,805
Cash Flow Statement					
Cash flow from operating activities	(127,079)	(35,104)	(33,381)	32,023	(77,243)
Cash flow from investing activities	(127,079)	(53,104)	(55,381)	(540)	(77,243) (2,547)
Cash flow from financing activities	(322)	989	(30)	304	(2,347)
Cash and cash equivalents at period end	157,579	310,571	157,579	310,571	270,434
Cash and Cash equivalents at period end	137,379	510,571	137,373	510,571	270,434
Financial Ratios					
Basic and diluted EPS	(0.07)	0.01	(0.03)	0.04	(0.02)
Weighted average number of shares	1,663,194,517	1,662,020,404	1,663,408,929	1,662,680,554	1,662,266,639
Average number of employees (FTEs)	34	25	42	28	26
Assets/equity	1.30	1.10	1.30	1.10	1.16
Share price	1.22	2.07	1.22	2.07	1.15

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



## Revenue

For the first nine months of 2015 Veloxis recognized revenue of DKK 13.0 million compared to DKK 120.2 million in the same period of 2014. Revenue in 2015 consist of commercial sales to Chiesi Farmaceutici S.p.A. Revenue in 2014 consist of up-front and milestone payments under Veloxis' distribution agreement with Chiesi Farmaceutici S.p.A. Envarsus is currently launched in Germany, Netherlands, UK, Denmark, Austria, Ireland, France, Slovenia and the Czech Republic.

## Sales and marketing costs

For the first nine months of 2015, Veloxis' sales and marketing costs amounted to DKK 40.9 million compared to DKK 24.0 million during the same period in 2014. This reflects the building of the marketing and sales infrastructure in the US.

## **Research and development costs**

For the first nine months of 2015, Veloxis' research and development costs amounted to DKK 56.0 million compared to DKK 70.4 million during the same period in 2014. The reduction in cost is associated with the overall reduction in study activity as studies are being completed.

## Administrative expenses

For the first nine months of 2015, Veloxis' administrative cost amounted to DKK 40.4 million compared to DKK 28.0 million during the same period in 2014. The increase in cost is mainly attributable to legal fees in connection with legal actions against the FDA.

## **Compensation costs**

For the first nine months of 2015, a total of DKK 9.6 million was recognized as share-based compensation. The cost is included in sales & marketing, research & development and administrative cost. The comparable cost for 2014 was DKK 7.5 million.

In the third quarter of 2015, a total of 245,339 warrants have been cancelled, a total of 392,144 warrants have been exercised (386,606 at an exercise price of DKK 0.35, 1,386 at an exercise price of DKK 0.94, 4,152 at an exercise price of DKK 0.95), a total of 107,500 warrants have expired and a total of 5,990,000 warrants at a strike price of DKK 1.06 was granted to other employees.

On 30 September, 2015, there were a total of 132,205,917 warrants outstanding at an average strike price of DKK 0.70. Members of the Board of Directors held 5,107,815 warrants at an average strike price of DKK 0.90. Members of the Executive Management held 76,170,781 warrants at an average strike price of DKK 0.59, while other current and former employees held 50,927,321 warrants at an average strike price of DKK 0.85.

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

## **Operating loss**

Veloxis' operating loss for the first nine months of 2015 was DKK 131.8 million compared to DKK 2.3 million in the corresponding period of 2014.



# **Financial income**

During the first nine months of 2015, the Company recognized net financial income of DKK 13.0 million compared to net financial income of DKK 15.2 million in the corresponding period of 2014. The income is mainly due to unrealized currency gains following an increase in the USD / DKK currency rate during the first nine months of 2015.

## Net loss

Veloxis' net loss for the first nine months of 2015 was DKK 114.3 million compared to a net profit of DKK 12.9 million in the corresponding period of 2014.

## **Cash flow**

On 30 September, 2015, the balance sheet reflects cash and cash equivalents of DKK 157.6 million compared to DKK 270.4 million on 31 December, 2014. This represents a decrease of DKK 112.8 million primarily related to the Company's operating activities for the period.

## **Balance sheet**

On 30 September, 2015, total assets were DKK 193.6 million compared to DKK 293.7 million at the end of 2014.

Shareholders' equity equalled DKK 148.7 million on 30 September, 2015, compared to DKK 253.2 million at the end of 2014.

## 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 2014. 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 2014.



#### 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 disclaim 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.

## Envarsus® XR (tacrolimus extended-release tablets) – Important Safety Information

## BOXED WARNING: MALIGNANCIES AND SERIOUS INFECTIONS

Increased risk for developing serious infections and malignancies with ENVARSUS XR or other immunosuppressants that may lead to hospitalization or death

## INDICATIONS AND USAGE

ENVARSUS XR is indicated for the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations, in combination with other immunosuppressants. Limitation of Use: ENVARSUS XR extended-release tablets are not interchangeable or substitutable with other tacrolimus

extended-release or immediate release products

#### CONTRAINDICATIONS

ENVARSUS XR is contraindicated in patients with known hypersensitivity to tacrolimus.

#### WARNINGS AND PRECAUTIONS

Immunosuppressants, including ENVARSUS XR, increase the risk of developing lymphomas and other malignancies, particularly of the skin.

Post-transplant lymphoproliferative disorder (PTLD), associated with Epstein-Barr Virus (EBV), has been reported in immunosuppressed organ transplant patients.

Immunosuppressants, including ENVARSUS XR, increase the risk of developing bacterial, viral, fungal, and protozoal infections, including opportunistic infections. These infections may lead to serious, including fatal, outcomes.

ENVARSUS XR is not interchangeable or substitutable with tacrolimus immediate-release products or other tacrolimus extended-release products.

Avoid the use of live attenuated vaccines during treatment with ENVARSUS XR. Inactivated vaccines noted to be safe for administration after transplantation may not be sufficiently immunogenic during treatment with ENVARSUS XR.

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Cases of pure red cell aplasia (PRCA) have been reported in patients treated with tacrolimus.

#### ADVERSE REACTIONS

Most common adverse reactions (incidence ≥10%) reported with ENVARUS XR are: diarrhea and blood creatinine increased.

For full Prescribing Information, see the US Package Insert and Medication Guide at www.envarsusxr.com

#### About Envarsus®

Tacrolimus is a leading immunosuppression drug used for the prevention of transplant allograft rejection after organ transplantation. Envarsus<sup>®</sup> (tacrolimus prolonged-release tablets) has received marketing authorization in the EU for prophylaxis of organ rejection in kidney and liver transplant recipients. In the U.S., Envarsus<sup>®</sup>, known as Envarsus<sup>®</sup> XR (tacrolimus extended-release tablets), is approved for the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations. Envarsus<sup>®</sup> XR has received orphan drug designation in the U.S. Veloxis plans to commercialize Envarsus<sup>®</sup> XR in the U.S. through its own sales force and in the EU through its partnership with Chiesi Farmaceutici SpA.

#### About Veloxis Pharmaceuticals

Based in Hørsholm, Denmark, with an office in New Jersey, Veloxis Pharmaceuticals A/S, or Veloxis, is a specialty pharmaceutical company. Veloxis' unique, patented delivery technology, MeltDose<sup>®</sup>, is designed to enhance the absorption and bioavailability of select orally administered drugs. 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 9 months ended 30 September 2015 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 the management 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.

Hørsholm, 11 November, 2015

#### **Executive Management**

Dr. William J. Polvino
President & CEO

Johnny Stilou Executive Vice President & CFO

**Board of Directors** 

Mette Kirstine Agger (Chairman) Thomas Dyrberg (Deputy Chairman)

Anders Götzsche

Michael Heffernan



## Financial Highlights

Quarterly Numbers in DKK

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	Q3	Q2	Q1	Q4	Q3	Q2	Q1
	2015	2015	2015	2014	2014	2014	2014
	DKK'000	DKK'000	DKK'000	DKK'000	DKK'000	DKK'000	DKK'000
Income Statement							
Revenue	3,379	5,292	4,284	3,214	95,769	12,206	12,206
Production costs	(1,680)	(1,657)	(4,141)	(3,247)	-	-	-
Gross profit	1,699	3,635	143	(33)	95,769	12,206	12,206
Sales and marketing costs	(21,406)	(9,637)	(9 <i>,</i> 820)	(17,246)	(10,378)	(13,653)	-
Research and development costs	(16,861)	(18,363)	(20,764)	(19,677)	(19,391)	(24,420)	(26,624)
Administrative expenses	(12,814)	(11,549)	(16,024)	(19,375)	(10,256)	(9,983)	(7,749)
Operating result	(49,382)	(35,914)	(46,465)	(56,331)	55,744	(35,850)	(22,167)
Net financial income / (expenses)	(280)	(4,673)	18,000	5,666	13,332	1,228	677
Result before tax	(49,662)	(40,587)	(28,465)	(50,665)	69,076	(34,622)	(21,490)
Tax for the period	1,479	1,478	1,480	1,488	(3,095)	1,495	1,494
Net result for the period	(48,183)	(39,109)	(26,985)	(49,177)	65,981	(33,127)	(19,996)
Balance Sheet							
Cash and cash equivalents	157,579	191,064	233,568	270,434	310,571	264,240	296,237
Total assets	193,583	224,177	262,656	293,723	330,127	276,493	305,373
Share capital	166,374	166,334	166,309	166,300	166,300	166,252	166,252
Total equity	148,688	193,526	228,715	253,248	300,456	231,649	261,538
Investment in property, plant and							
equipment	50	272		1,149	540	(169)	285
Cash Flow Statement							
Cash flow from operating activities	(33,381)	(37,205)	(56,494)	(42,139)	32,023	(33,577)	(33,550)
			(50,494)				
Cash flow from investing activities	(50)	(272)	-	(1,891)	(540)	169	(285)
Cash flow from financing activities	141	88	33	-	304	-	684
Cash and cash equivalents at period end	157,579	191,064	233,568	270,434	310,571	264,240	296,237
Financial Ratios							
Basic and diluted EPS	(0.03)	(0.02)	(0.02)	(0.03)	0.04	(0.02)	(0.01)
Weighted average number of shares	1,663,408,929	1,663,167,653	1,663,002,504		1,662,680,554	1,662,527,283	1,660,833,074
Average number of employees (FTEs)	42	31	30	31	28	23	22
Assets/equity	1.30	1.16	1.15	1.16	1.10	1.19	1.17
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## Income statement and statement of comprehensive income

Income Statement			Consolidated		
(DKK'000)	YTD 2015	YTD 2014	Q3 2015	Q3 2014	Year 2014
_					
Revenue	12,955	120,181	3,379	95,769	123,395
Production costs	(7,478)	-	(1,680)	-	(3,247)
Gross profit	5,477	120,181	1,699	95,769	120,148
Sales and marketing costs	(40,863)	(24,032)	(21,406)	(10,378)	(41,278)
Research and development costs	(55,988)	(70,435)	(16,861)	(19,391)	(90,111)
Administrative expenses	(40,387)	(27,988)	(12,814)	(10,256)	(47,363)
Operating result	(131,761)	(2,274)	(49,382)	55,744	(58,604)
Financial income	13,232	15,432	-	13,526	21,098
Financial expenses	(184)	(194)	(280)	(194)	(195)
Result before tax	(118,713)	12,964	(49,662)	69,076	(37,701)
Tax for the period	4,436	(106)	1,479	(3,095)	1,382
Net result for the period	(114,277)	12,858	(48,183)	65,981	(36,319)
Basic and diluted EPS	(0.07)	0.01	(0.03)	0.04	(0.02)
Weighted average number of shares	1,663,194,517	1,662,020,404	1,663,408,929	1,662,680,554	1,662,266,639

Statements of comprehensive income			Consolidated		
(DKK'000)	YTD 2015	YTD 2014	Q3 2015	Q3 2014	Year 2014
<b>Net result for the period</b> <b>Other comprehensive income:</b> <i>Items that may be subsequently reclassified</i> <i>to profit or loss:</i>	(114,277)	12,858	(48,183)	65,981	(36,319)
Currency translation differences, net of tax	(144)	22	104	(52)	(208)
Other comprehensive income for the period	(144)	22	104	(52)	(208)
Total comprehensive income for the period	(114,421)	12,880	(48,079)	65,929	(36,527)



## **Balance sheet**

Assets		Consolidated				
(DKK'000)	30 Sep. 2015	30 Sep. 2014	31 Dec. 2014			
Patent rights and software	1,034	415	1,134			
Intangible assets	1,034	415	1,134			
Property, plant and equipment	3,654	3,411	4,247			
Property, plant and equipment	3,654	3,411	4,247			
Non-current assets	4,688	3,826	5,381			
Inventories	10,163	7,567	4,764			
Trade receivables	-	-	25			
Tax receivables Other receivables	10,937 4,845	- 7,568	6,250 2,677			
Prepayments	5,371	595	4,192			
Receivables	21,153	8,163	13,144			
Cash	157,579	310,571	270,434			
Cash and cash equivalents	157,579	310,571	270,434			
Current assets	188,895	326,301	288,342			
Assets	193,583	330,127	293,723			



#### **Balance sheet**

Equity & Liabilities	Consolidated				
(DKK'000)	30 Sep. 2015	30 Sep. 2014	31 Dec. 2014		
Share capital	166,374	166,300	166,300		
Special reserve	407,289	407,289	407,289		
Translation reserves	1,616	1,990	1,760		
Retained earnings/loss	(426,591)	(275,123)	(322,101)		
Equity	148,688	300,456	253,248		
Trade payables	15,598	10,650	17,875		
Tax payables	761	-	470		
Other payables	28,536	19,021	22,130		
Current liabilities	44,895	29,671	40,475		
Liabilities	44,895	29,671	40,475		
Equity and liabilities	193,583	330,127	293,723		



### **Cash flow statements**

Cash Flow Statement	Consolidated				
(DKK'000)	YTD 2015	YTD 2014	Q3 2015	Q3 2014	Year 2014
Operating result	(131,761)	(2,274)	(49,382)	55,744	(58,604)
Share-based payment	9,600	7,545	3,100	2,575	9,744
Depreciation and amortization	1,094	658	380	253	993
Changes in working capital	(5,828)	(36,873)	12,595	(22,175)	(26,194)
Cash flow from operating activities before interest	(126,895)	(30,944)	(33,307)	36,397	(74,061)
Interest received	-	212	-	(2)	350
Interest paid	(184)	(194)	(74)	(194)	(195)
Corporate tax received	-	-	-	-	1,250
Corporate tax paid	-	(4,178)	-	(4,178)	(4,587)
Cash flow from operating activities	(127,079)	(35,104)	(33,381)	32,023	(77,243)
Purchase of property, plant and equipment	(322)	(657)	(50)	(540)	(2,547)
Cash flow from investing activities	(322)	(657)	(50)	(540)	(2,547)
Proceeds from issuance of shares, net	261	989	141	304	989
Cash flow from financing activities	261	989	141	304	989
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Increase/(decrease) in cash	(127,140)	(34,772)	(33,290)	31,787	(78,801)
Cash at beginning of period	270,434	328,652	191,064	264,240	328,652
Exchange gains/(losses) on cash	14,285	16,691	(195)	14,544	20,583
Cash at end of period	157,579	310,571	157,579	310,571	270,434



## Statement of changes in equity

Consolidated Equity						
	Number of Shares	Share Capital DKK'000	Special Reserves DKK'000	Translation Reserves DKK'000	Retained Earnings DKK'000	Total DKK'000
Equity as of 1 Jan. 2014	1,660,572,426	166,057	407,289	1,968	(296,272)	279,042
Net result for the period					12,858	12,858
Other comprehensive income fo	r the period			22		22
Total comprehensive income				22	12,858	12,880
Warrant exercises	2,424,888	243			746	989
Share-based payment	_,,	2.0			7,545	7,545
Equity as of 30 Sep. 2014	1,662,997,314	166,300	407,289	1,990	(275,123)	300,456
Net result for the period					(49,177)	(49,177)
Other comprehensive income fo	r the period			(230)		(230)
Total comprehensive income				(230)	(49,177)	(49,407)
Share-based payment					2,199	2,199
Equity as of 31 Dec. 2014	1,662,997,314	166,300	407,289	1,760	(322,101)	253,248
Net result for the period					(114,277)	(114,277)
Other comprehensive income fo	r the period			(144)		(144)
Total comprehensive income	· · · · · · · · · · · · · · · · · · ·			(144)	(114,277)	(114,421)
Warrant exercises	735,560	74			187	261
Share-based payment					9,600	9,600
Equity as of 30 Sep. 2015	1,663,732,874	166,374	407,289	1,616	(426,591)	148,688



# 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 2014.

## 2. Research and development costs

We track research and development costs by activity, as follows: (a) product development and manufacturing, (b) medical and regulatory operations, and (c) direct preclinical and clinical programs. Research and development costs include personnel, manufacturing and quality operations, pharmaceutical and device development, research, clinical, regulatory, other preclinical and clinical activities, medical affairs and other costs including cost of premises, depreciation and amortization related to research and development activities. Research and development costs are charged to operations as incurred.