

Company Announcement no. 13/2015

To: NASDAQ OMX Copenhagen A/S

Hørsholm, Denmark, 20 May, 2015

Veloxis Pharmaceuticals announces financial results for the first three months of 2015

Highlights:

- Veloxis has announced that once-daily Envarsus® XR, an investigational new drug under FDA review for the prevention of organ rejection in adult kidney transplant patients, demonstrated that a lower dose of once-daily Envarsus® XR in African-American kidney transplant patients is sufficient to achieve therapeutic tacrolimus blood concentrations, compared to twice-daily immediate release tacrolimus.
- The U.S. District Court for the District of Columbia has set a briefing schedule that enabled complete briefing in its pending case by 3 March, 2015. Veloxis is seeking an order requiring FDA to grant final approval to Envarsus® XR. While Veloxis currently expects the matter to be resolved by mid-year 2015, it is possible that delays may occur. There can be no assurance that Veloxis will be successful in its action against FDA.
- Veloxis is preparing for launch of Envarsus® XR in the US in the second half of 2015, either for the full indication that would include both *de novo* and conversion kidney transplant patients or for a more narrow initial indication in the conversion setting.
- Veloxis reported a net loss of DKK 27.0 million for the first quarter of 2015 compared to a net loss of DKK 20.0 million for the same period in 2014. The reported net loss is in line with expectations and the financial outlook for 2015 is maintained.
- For the first quarter of 2015, Veloxis' sales and marketing costs amounted to DKK 9.8 million. Research and development costs amounted to DKK 20.8 million compared to DKK 26.6 million during the same period in 2014.
- On 31 March, 2015, Veloxis had cash and cash equivalents of DKK 233.6 million.

Outlook for 2015

Veloxis maintains its 2015 outlook with an operating loss of DKK 200 - 240 million and a net loss of DKK 195 - 235 million for the financial year 2015.

On 31 March 2015, the Company's cash position equaled DKK 233.6 million, and on 31 December 2015, the Company's cash position is expected to be in the range of DKK 55 - 95 million.

Conference call

A conference call will be held tomorrow, 21 May, 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 32 71 16 60 (Denmark)

+44 (0) 20 3427 1913 (UK)

+1 212 444 0896 (USA)

Access code 7709988

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

Business update

Envarsus® in kidney transplant patients

Veloxis has conducted two Phase III studies of Envarsus® in kidney transplant recipients as the basis for its development programme for Envarsus® as a once-daily agent for the prophylaxis of organ rejection in kidney transplantation. The first of these studies, the 3001 Study, was a non-inferiority study performed in 326 stable kidney transplant recipients, and was successfully completed in 2011, meeting its primary efficacy and safety endpoints when compared to Prograf® (tacrolimus, Astellas Pharma Inc.). The second study, Study 3002 was a randomized, double-blind, multicenter study that compared once-daily Envarsus® against twice-daily Prograf® in 543 *de novo* adult kidney transplant patients and met its primary efficacy and primary safety endpoints. The primary endpoint of the study was a composite endpoint of treatment failure (biopsy-proven acute rejection, graft failure, loss to follow up or death) that was evaluated after a 12-month treatment period to demonstrate the non-inferiority of Envarsus® compared to Prograf®. The treatment failure rate for Envarsus® was 18.3% compared to 19.6% for Prograf®, and the difference between the treatments was well within the 10% pre-specified non-inferiority margin. The primary safety analyses were the differences between Envarsus® and Prograf® treatment groups at Month 12 (Day 360) with respect to the incidence of adverse events (AEs) and the incidence of predefined potentially clinically significant laboratory measures including: fasting plasma glucose; platelet count; white blood cell (WBC) count; aminotransaminases; total cholesterol; low density lipoprotein (LDL) cholesterol; triglycerides; and estimated glomerular filtration rate (eGFR). In all instances, there were no statistically significant differences between the two treatments. Specifically, renal function was similar between the two groups at 12 months, as was the incidence of malignancy, infections and new onset diabetes during this period. The study had a one-year extension period which produced similar outcomes.

In addition to the pivotal Phase III studies, Veloxis is conducting a series of Phase IIIb/IV studies to further evaluate potential differences in clinical profile provided by Envarsus®' unique PK profile. The first study completed was the STRATO (Switching kidney TRAnsplant patients with Tremor to LCP-tacrO) study of Envarsus® in kidney transplant recipients experiencing drug-induced tremors. The STRATO study was designed to explore whether a conversion of patients who have symptomatic tremor from treatment with standard immediate release twice-daily tacrolimus capsules to extended release once-daily Envarsus® tablets leads to a measurable improvement in tremor. Results from this study demonstrated that patients switched to Envarsus® demonstrated a statistically significant improvement in hand tremors based on improvement in the FTM Tremor rating scale. Additionally, both the patient- and physician-reported global assessments demonstrated significant overall improvements following the switch to Envarsus®.

Additionally, the ASERTAA (A Study of Extended Release Tacrolimus in African-Americans) Phase IIIb study of Envarsus[®] in kidney transplant recipients is ongoing. The ASERTAA study is designed to compare the pharmacokinetics of Envarsus[®] given once-daily to immediate-release twice daily tacrolimus capsules (IR-Tac) in stable African-American renal transplant patients. Primary pharmacokinetic results from this study were presented at the American Transplant Congress in Philadelphia on 3 May, 2015. The key outcomes from this study were:

- The overall PK differences (increased absorption [$p < 0.0001$], lower peak blood concentrations [$p < 0.0001$], less peak-to-trough fluctuation in blood levels [$p < 0.0001$]) between Envarsus XR and IR-Tac capsules seen previously in studies of kidney transplant recipients were also confirmed in this exclusively African-American patient population.
- The optimal conversion ratio for once-daily extended release Envarsus XR was shown to be approximately 20% lower than the total IR-Tac.
- Peak tacrolimus concentration (C_{max}) was reduced 30% for patients on Envarsus while intra-day fluctuation was reduced 50%.
- Envarsus XR's PK parameters were less impacted by CYP3A5 genotype. IR-Tac was more affected by the presence of the *1 allele, driven primarily by the need to increase dose to achieve therapeutic trough levels, which also resulted in an incremental increase in tacrolimus intra-day peak levels.
- Conversion of African-American patients from IR-Tac to Envarsus XR was demonstrated to be readily achieved with a reduction in dose of approximately 20% without concern for genotype status.

In addition, the ASTCOFF (A Steady-state Pharmacokinetic Comparison Of all FK-506 Formulations) Phase IIIb study is ongoing. This study looks to examine the pharmacokinetic differences between Envarsus and the other two tacrolimus formulations commercially available, namely Astagraf XL and Prograf. Primary results from this study are anticipated during 2Q 2015.

Envarsus[®] Regulatory Strategy

On 29 April, 2013 a Marketing Authorization Application (MAA) was submitted by Veloxis to the European Medicines Agency (EMA) seeking approval to market Envarsus[®] for the prevention of organ rejection in transplant patients in the European Union. The MAA submission was based on the favourable results of the Envarsus[®] Phase III 3001 Study in stable kidney transplant patients and data from an extensive Phase I and II clinical programme and has been accepted for review by the EMA. On 28 July, 2014, it was announced that the European Commission granted marketing authorization for Envarsus[®] for the prevention of organ rejection in adult kidney and liver transplant patients in the European Union (EU). Veloxis' marketing and distribution partner Chiesi Farmaceutici launched Envarsus in the EU in late 2014, with launches in Germany and the Netherlands, followed by launch in the UK and Denmark in 2015. Additional launches are anticipated for the majority of the major EU countries during 2015, once local requirements such as pricing negotiations have been completed.

Veloxis submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for the marketing and sale of Envarsus[®] XR in the US for the prevention of organ rejection in kidney transplant recipients on 30 December, 2013. On 30 October, 2014 the FDA granted Tentative Approval for Envarsus[®] XR for the prophylaxis of rejection in kidney transplant patients. FDA stated that the final approval of Envarsus[®] XR will be delayed until expiration of the exclusivity period for Astellas' Astagraf XL[®], for the treatment of newly transplanted ('*de novo*') patients. The tentative approval notification received from FDA included agreement with manufacturing post-marketing commitments as previously proposed by Veloxis during NDA review as well as agreement on final labeling for the product. Veloxis disagrees that exclusivity for Astagraf XL[®], which was not identified as a listed drug or relied upon to support approval of Envarsus[®] XR, should require delay in the formal approval of Envarsus[®] XR. On 16 December, 2014, Veloxis announced

that it has filed an action against the FDA, seeking an order requiring FDA to grant final approval to Envarsus® XR. The U.S. District Court for the District of Columbia has set a briefing schedule that enabled complete briefing in this case by 3 March, 2015. Veloxis currently expects the matter to be resolved by mid-year 2015, but it is possible that delays may occur.

Veloxis is preparing for launch of Envarsus® XR in the US in the second half of 2015, either for the full indication in kidney transplant recipients that would include both *de novo* and conversion patients or for a more narrow initial indication in the conversion setting.

In addition, the FDA granted Envarsus® Orphan Drug status for prophylaxis of organ rejection in patients receiving allogeneic kidney transplants. The designation is to encourage the development of drugs that may provide significant benefit to patients suffering from rare diseases.

Financial Highlights

	Q1 2015 DKK'000	Q1 2014 DKK'000	Year 2014 DKK'000
Income Statement			
Revenue	4,284	12,206	123,395
Production costs	(4,141)	-	(3,247)
Gross profit	143	12,206	120,148
Sales and marketing costs	(9,820)	-	(41,278)
Research and development costs	(20,764)	(26,624)	(90,111)
Administrative expenses	(16,024)	(7,749)	(47,363)
Operating result	(46,465)	(22,167)	(58,604)
Net financial income / (expenses)	18,000	677	20,903
Result before tax	(28,465)	(21,490)	(37,701)
Tax for the period	1,480	1,494	1,382
Net result for the period	(26,985)	(19,996)	(36,319)
Balance Sheet			
Cash and cash equivalents	233,568	296,237	270,434
Total assets	262,656	305,373	293,723
Share capital	166,309	166,252	166,300
Total equity	228,715	261,538	253,248
Investment in property, plant and equipment	-	285	1,805
Cash Flow Statement			
Cash flow from operating activities	(56,494)	(33,550)	(77,243)
Cash flow from investing activities	-	(285)	(2,547)
Cash flow from financing activities	33	684	989
Cash and cash equivalents at period end	233,568	296,237	270,434
Financial Ratios			
Basic and diluted EPS	(0.02)	(0.01)	(0.02)
Weighted average number of shares	1,663,002,504	1,660,833,074	1,662,266,639
Average number of employees (FTEs)	30	22	26
Assets/equity	1.15	1.17	1.16
Share price	0.90	0.97	1.15

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

Revenue

For the first quarter of 2015 Veloxis recognized revenue of DKK 4.3 million compared to DKK 12.2 million in the same period of 2014. Revenue in 2015 consist of commercial sales to Chiesi Farmaceutici S.p.A. and 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 and Denmark.

Sales and marketing costs

For the first quarter of 2015, Veloxis' sales and marketing costs amounted to DKK 9.8 million compared to DKK 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 quarter of 2015, Veloxis' research and development costs amounted to DKK 20.8 million compared to DKK 26.6 million during the same period in 2014. The reduction in cost is associated with the overall reduction in study activity as some studies have now been completed.

Administrative expenses

For the first quarter of 2015, Veloxis' administrative cost amounted to DKK 16.0 million compared to DKK 7.7 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 quarter of 2015, a total of DKK 2.7 million was recognized as share-based compensation. The cost is included in S&M, R&D and Admin. The comparable cost for 2014 was DKK 1.8 million.

In the first quarter of 2015, a total of 221,646 warrants have been cancelled, a total of 93,416 warrants have been exercised at an exercise price of DKK 0.35, and a total of 15,091,700 warrants were granted to Executive Management at a strike price of DKK 0.94, a total of 4,748,092 warrants at a strike price of DKK 0.86 was granted to Board of Directors and a total of 8,609,143 warrants at a strike price of DKK 0.94 was granted to other employees.

On 31 March, 2015, there were a total of 128,854,009 warrants outstanding at an average strike price of DKK 0.76. Members of the Board of Directors held 5,137,676 warrants at an average strike price of DKK 0.94. Members of the Executive Management held 76,370,781 warrants at an average strike price of DKK 0.59, while other current and former employees held 47,345,552 warrants at an average strike price of DKK 1.01.

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

Operating loss

Veloxis' operating loss for the first quarter of 2015 was DKK 46.5 million compared to DKK 22.2 million in the corresponding period of 2014.

Financial income

During the first quarter of 2015, the Company recognized net financial income of DKK 18.0 million compared to net financial income of DKK 0.7 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 quarter of 2015.

Net loss

Veloxis' net loss for the first quarter of 2015 was DKK 27.0 million compared to DKK 20.0 million in the corresponding period of 2014.

Cash flow

On 31 March, 2015, the balance sheet reflects cash and cash equivalents of DKK 233.6 million compared to DKK 270.4 million on 31 December, 2014. This represents a decrease of DKK 36.8 million primarily related to the Company's operating activities for the period.

Balance sheet

On 31 March, 2015, total assets were DKK 262.7 million compared to DKK 293.7 million at the end of 2014.

Shareholders' equity equalled DKK 228.7 million on 31 March, 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.

About Envarsus®

Tacrolimus is a leading immunosuppression drug used for the prevention of transplant allograft rejection after organ transplantation. Envarsus® (tacrolimus prolonged-release tablets) has received marketing authorization in the EU for prophylaxis of organ rejection in kidney and liver transplant recipients. In the US, Envarsus®, known as Envarsus® XR (tacrolimus extended-release tablets), has received Tentative Approval as a once-daily tablet version of tacrolimus for prophylaxis of organ rejection in kidney transplant patients in combination with other immunosuppressants. Envarsus® XR has received orphan drug designation in the U.S. Veloxis plans to commercialize Envarsus® XR in the US 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®, 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 3 months ended 31 March 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, 20 May, 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

Interim Report
for the 3 Months Ended 31 March, 2015
(20 May, 2015)



Financial Highlights					
Quarterly Numbers in DKK					
	Q1 2015 DKK'000	Q4 2014 DKK'000	Q3 2014 DKK'000	Q2 2014 DKK'000	Q1 2014 DKK'000
Income Statement					
Revenue	4,284	3,214	95,769	12,206	12,206
Production costs	(4,141)	(3,247)	-	-	-
Gross profit	143	(33)	95,769	12,206	12,206
Sales and marketing costs	(9,820)	(17,246)	(10,378)	(13,653)	-
Research and development costs	(20,764)	(19,677)	(19,391)	(24,420)	(26,624)
Administrative expenses	(16,024)	(19,375)	(10,256)	(9,983)	(7,749)
Operating result	(46,465)	(56,331)	55,744	(35,850)	(22,167)
Net financial income / (expenses)	18,000	5,666	13,332	1,228	677
Result before tax	(28,465)	(50,665)	69,076	(34,622)	(21,490)
Tax for the period	1,480	1,488	(3,095)	1,495	1,494
Net result for the period	(26,985)	(49,177)	65,981	(33,127)	(19,996)
Balance Sheet					
Cash and cash equivalents	233,568	270,434	310,571	264,240	296,237
Total assets	262,656	293,723	330,127	276,493	305,373
Share capital	166,309	166,300	166,300	166,252	166,252
Total equity	228,715	253,248	300,456	231,649	261,538
Investment in property, plant and equipment	-	1,149	540	(169)	285
Cash Flow Statement					
Cash flow from operating activities	(56,494)	(42,139)	32,023	(33,577)	(33,550)
Cash flow from investing activities	-	(1,891)	(540)	169	(285)
Cash flow from financing activities	33	-	304	-	684
Cash and cash equivalents at period end	233,568	270,434	310,571	264,240	296,237
Financial Ratios					
Basic and diluted EPS	(0.02)	(0.03)	0.04	(0.02)	(0.01)
Weighted average number of shares	1,663,002,504	1,662,997,314	1,662,680,554	1,662,527,283	1,660,833,074
Average number of employees (FTEs)	30	31	28	23	22
Assets/equity	1.15	1.16	1.10	1.19	1.17

Income statement and statement of comprehensive income

Income Statement		Consolidated		
(DKK'000)	Q1 2015	Q1 2014	Year 2014	
Revenue	4,284	12,206	123,395	
Production costs	(4,141)	-	(3,247)	
Gross profit	143	12,206	120,148	
Sales and marketing costs	(9,820)	-	(41,278)	
Research and development costs	(20,764)	(26,624)	(90,111)	
Administrative expenses	(16,024)	(7,749)	(47,363)	
Operating result	(46,465)	(22,167)	(58,604)	
Financial income	18,021	3,191	21,098	
Financial expenses	(21)	(2,514)	(195)	
Result before tax	(28,465)	(21,490)	(37,701)	
Tax for the period	1,480	1,494	1,382	
Net result for the period	(26,985)	(19,996)	(36,319)	
Basic and diluted EPS	(0.02)	(0.01)	(0.02)	
Weighted average number of shares	1,663,002,504	1,660,833,074	1,662,266,639	

Statements of comprehensive income		Consolidated		
(DKK'000)	Q1 2015	Q1 2014	Year 2014	
Net result for the period	(26,985)	(19,996)	(36,319)	
Other comprehensive income:				
<i>Items that may be subsequently reclassified to profit or loss:</i>				
Currency translation differences, net of tax	(259)	26	(208)	
Other comprehensive income for the period	(259)	26	(208)	
Total comprehensive income for the period	(27,244)	(19,970)	(36,527)	

Balance sheet

Assets	Consolidated		
	(DKK'000)	31 Mar. 2015	31 Mar. 2014
Patent rights and software	1,177	468	1,134
Intangible assets	1,177	468	1,134
Property, plant and equipment	3,967	3,442	4,247
Property, plant and equipment	3,967	3,442	4,247
Non-current assets	5,144	3,910	5,381
Inventories	8,172	-	4,764
Trade receivables	4,295	-	25
Tax receivables	7,812	-	6,250
Other receivables	2,232	4,350	2,677
Prepayments	1,433	876	4,192
Receivables	15,772	5,226	13,144
Cash	233,568	296,237	270,434
Cash and cash equivalents	233,568	296,237	270,434
Current assets	257,512	301,463	288,342
Assets	262,656	305,373	293,723

Interim Report
for the 3 Months Ended 31 March, 2015
(20 May, 2015)



Balance sheet

Equity & Liabilities	Consolidated		
(DKK'000)	31 Mar. 2015	31 Mar. 2014	31 Dec. 2014
Share capital	166,309	166,252	166,300
Special reserve	407,289	407,289	407,289
Translation reserves	1,501	1,994	1,760
Retained earnings/loss	(346,384)	(313,997)	(322,101)
Equity	228,715	261,538	253,248
Trade payables	11,817	8,250	17,875
Tax payables	620	-	470
Deferred revenue	-	24,412	-
Other payables	21,504	11,173	22,130
Current liabilities	33,941	43,835	40,475
Liabilities	33,941	43,835	40,475
Equity and liabilities	262,656	305,373	293,723

Cash flow statements

Cash Flow Statement	Consolidated		
(DKK'000)	Q1 2015	Q1 2014	Year 2014
Operating result	(46,465)	(22,167)	(58,604)
Share-based payment	2,678	1,782	9,744
Depreciation and amortization	354	202	993
Changes in working capital	(13,040)	(13,365)	(26,194)
Cash flow from operating activities before interest	(56,473)	(33,548)	(74,061)
Interest received	-	-	350
Interest paid	(21)	-	(195)
Corporate tax received	-	-	1,250
Corporate tax paid	-	(2)	(4,587)
Cash flow from operating activities	(56,494)	(33,550)	(77,243)
Purchase of property, plant and equipment	-	(285)	(2,547)
Cash flow from investing activities	-	(285)	(2,547)
Proceeds from issuance of shares, net	33	684	989
Cash flow from financing activities	33	684	989
Increase/(decrease) in cash	(56,461)	(33,151)	(78,801)
Cash at beginning of period	270,434	328,652	328,652
Exchange gains/(losses) on cash	19,595	736	20,583
Cash at end of period	233,568	296,237	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 year					(19,996)	(19,996)
Other comprehensive income for the year				26		26
Total comprehensive income				26	(19,996)	(19,970)
Warrant exercises	1,954,857	195			489	684
Share-based payment					1,782	1,782
Equity as of 31 Mar. 2014	1,662,527,283	166,252	407,289	1,994	(313,997)	261,538
Net result for the year					(16,323)	(16,323)
Other comprehensive income for the year				(234)		(234)
Total comprehensive income				(234)	(16,323)	(16,557)
Warrant exercises	470,031	48			257	305
Share-based payment					7,962	7,962
Equity as of 31 Dec. 2014	1,662,997,314	166,300	407,289	1,760	(322,101)	253,248
Net result for the year					(26,985)	(26,985)
Other comprehensive income for the year				(259)		(259)
Total comprehensive income				(259)	(26,985)	(27,244)
Warrant exercises	93,416	9			24	33
Share-based payment					2,678	2,678
Equity as of 31 Mar. 2015	1,663,090,730	166,309	407,289	1,501	(346,384)	228,715

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.