

# **ANNUAL REPORT 2016**

**Veloxis Pharmaceuticals A/S  
c/o Plesner Advokatfirma  
Amerika Plads 37  
DK-2100 Copenhagen  
CVR No.: 26 52 77 67**

**The Annual Report was presented and  
approved at the Annual General Meeting  
on /**

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**Chairman of the meeting**

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# To Our Shareholders

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## Dear Shareholder,

2016 marked a truly transformational year at Veloxis Pharmaceuticals as we launched our internally developed product, Envarsus XR® in the US market. We made a number of significant changes this year which include relocating our corporate operations to Cary, North Carolina, hiring of a new management team, expanding our Board of Directors and transitioning the Company to commercialization.

The launch of Envarsus XR in the US has resulted in significant penetration, with approximately 56% of adult transplant centers and over 350 prescribers having utilized Envarsus in 2016. This resulted in an estimated 1,750 patients using Envarsus by year end, and over 11,000 prescriptions of Envarsus in the first full year after launch.

An important driver of uptake of Envarsus XR in the US has been FDA's approval of label enhancements allowing promotion of Envarsus XR for use in special populations which may benefit from increased bioavailability and controlled delivery of tacrolimus. African-American kidney transplant patients historically experience poorer outcomes as compared to other ethnic groups and this has been associated in part due to their expression of the CYP3A5\*1 genotype, which codes for a cytochrome p450 enzyme that metabolizes tacrolimus, and shown to be present in approximately 80% of African-Americans. Patients expressing this genotype metabolize tacrolimus much more rapidly and as a result typically require higher tacrolimus doses. This may hinder efforts to obtain a therapeutic level potentially increasing the risk of organ rejection.

In regards to the de novo indication, the exclusivity period for Astagraf XL® expired on July 19, 2016. Veloxis is now eligible to apply for approval of the de novo indication for Envarsus XR. We intend to make a decision in the near future once it can be determined how approval for this indication will impact our current orphan drug exclusivity for Envarsus XR.

We are excited by the results of our partnership with Chiesi Farmaceutici S.p.A. (Chiesi) for commercialization of Envarsus® in Europe. Chiesi estimates that over 3,300 patients have been placed on Envarsus in Europe, and the product is on a strong trajectory for continued growth. We are also pleased that Chiesi has committed substantial financial and clinical resources towards ongoing clinical studies of Envarsus in Europe, signaling a long-term strategy for growth for Envarsus in the territory.

As we look beyond 2016, our future at Veloxis looks bright. We have a great lead product in Envarsus XR which is improving the daily lives of transplant patients as well as having orphan status and patent protection that runs through 2028. However, we believe our greatest asset is our people. Our team at Veloxis comprises industry veterans with experience in all areas of commercialization including clinical development, marketing, manufacturing and business development.

To our employees, I want to offer my sincere thanks for your results oriented attitude and for all your efforts in 2016.

We are excited about our future opportunities and look forward to sharing our progress with our shareholders throughout the year.

Yours sincerely,

Michael Heffernan  
Chairman

Craig A. Collard  
President & CEO

# Highlights 2016

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## February

- Veloxis announced that Alastair McEwan was hired as Chief Operating Officer. Mr. McEwan has been involved in pharmaceutical development and commercialization for over twenty years. He has broad general management, financial and M&A expertise derived from his past roles including President, Global Clinical at Inveresk Research and CFO of Cornerstone Therapeutics during its expansion and integration of EKR Therapeutics and its subsequent sale to Chiesi Farmaceutici. At the same time, Veloxis announced that John Weinberg had stepped down as Chief Operating Officer of Veloxis.

## March

- Veloxis entered into a five-year loan and security agreement with Lundbeckfond Invest A/S and Novo A/S for up to USD 20 million in financing. The facility may be utilized in tranches and repaid without penalty. It carries a 9.25% interest rate, payable annually in arrears.
- Veloxis announced the decision to close its office in Hørsholm, Denmark, and move all activities to the US where most of the company's current activities are already located, but that it will continue to be a Danish company listed on Nasdaq Copenhagen A/S. Completion of closure of the office in Hørsholm, Denmark was announced on 31 August.

## April

- Veloxis announced that Johnny Stilou will step down as EVP & Chief Financial Officer at the end of August 2016 as part of the Company's decision to close down all Danish activities and move to the US.

## June

- Veloxis announced that the company had received FDA approval for label enhancements to Envarsus XR related to the pharmacokinetics and pharmacogenomics studied in the ASERTAA trial. As previously reported, the ASERTAA trial demonstrated that patients on Envarsus XR achieved therapeutic drug levels with a 30% lower peak concentration and 20% lower average dose compared to tacrolimus immediate-release regardless of genotype status. Based upon these findings, the FDA-approved label now contains ethnicity-specific dosing and unique genotyping guidance to Envarsus XR as summarized below:
  - The pharmacokinetics (PK) of Envarsus XR converted from tacrolimus immediate-release to Envarsus XR indicated that an 80% dose conversion factor is appropriate for African-American patients
  - Regardless of genotype status, the PK data collected for Envarsus XR demonstrated similar exposure, lower C<sub>max</sub>, prolonged T<sub>max</sub>, and increased bioavailability when compared to tacrolimus immediate-release

## Management Review

### July

- Veloxis held an Extraordinary General Meeting at which Paul Kevin Wotton, Robert Samuel Radie and Lars Kåre Viksmoen were elected to the Board of Directors and that Thomas Peter Dyrberg had resigned as a member of the Board of Directors.

### August

- Envarsus XR demand in the US reaches and surpasses 1,000,000 milligrams in the tenth month since launch.

### November

- One year after launch of Envarsus XR in the US the drug's penetration reached and surpassed 50% of transplant centers.

### December

- Chiesi estimates that over 3,300 patients are being treated with Envarsus in European countries.

# Outlook 2017

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## Outlook

Veloxis Pharmaceuticals anticipates 2017 operating loss before the recognition of income from new license agreements and before accounting for stock compensation to be in the range of USD 5 – 15 million.

We continue to progress with out-licensing initiatives for Envarsus in new territories and we expect that these will generate revenue and income by way of milestone payments during 2017. The value of such payments cannot be accurately predicted at this time and they may be subject to differing accounting treatments depending on the final structure of any successful transactions.

## Going Concern

The Company's Board of Directors and Executive Management have reviewed the Company's financial projections, taking into account matters such as the progress of Envarsus in the US and European markets, the ongoing expenses associated with sales, marketing, product support, development and the administration of the Company. On that basis, the Board of Directors and Executive Management has come to the conclusion that the Company's funding arrangements are sufficient to meet its funding requirement through the period until cash flows generated by its operations are sufficient to cover its expenses and to repay sums drawn down under the existing loan arrangement.

# Important Events Following the Balance Sheet Date

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## Material Events

8 February: Veloxis announced that it has agreed to amend and restate the terms of the previously entered into long-term loan and security agreement with Lundbeckfond Invest A/S and Novo A/S. The terms of the amended and restated agreement make available an additional USD 10 million in financing at an interest rate of 12%, payable annually in arrears. Like the original USD 20 million facility, the new USD 10 million facility may be utilized in tranches and repaid without penalty. The amended and restated agreement also provides for a third additional facility in the amount of USD 5 million to be made available at the discretion of Lundbeckfond Invest A/S and Novo A/S if requested by Veloxis.

## Veloxis Business Strategy

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Veloxis Pharmaceuticals is a specialty pharmaceutical company focused on the therapeutic area of solid organ transplant. Utilizing its proprietary drug delivery technology (MeltDose®), Veloxis has developed and obtained FDA and EMA approval for Envarsus XR (tacrolimus extended-release tablets) to aid in the prophylaxis of organ rejection in transplant recipients.

Our strategy is to commercialize Envarsus XR in the US with a direct salesforce and to license rights to Envarsus to proven commercial partners in other territories around the world. Veloxis has licensed Envarsus to Chiesi in Europe, Turkey and Commonwealth of Independent States countries. Veloxis is actively evaluating partners for other territories.

In addition to direct commercialization of Envarsus XR in the US, Veloxis is actively evaluating business development & licensing targets within the areas of organ transplant or adjacent specialties, and pharmaceuticals for severe or uncommon conditions for which chronic therapy is initiated in the large hospital setting of care.

## Commercial Update

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Veloxis launched Envarsus XR into the US market in December of 2015, utilizing a direct specialized sales force with substantial experience in the therapeutic area of organ transplant. The salesforce is supplemented by field-based reimbursement and medical affairs personnel, and supported by in-house marketing, medical affairs, and operations personnel. Our commercial strategy is to reach the organ transplant market by promoting within transplant centers which are typically located in the large hospital setting. A secondary focus is to reach transplant patients in need of Envarsus through promotion to large specialty practices which refer patients to transplant centers for organ transplantation. Direct sales efforts are complemented by modern specialty pharmaceutical marketing practices to ensure broad reach of brand awareness and core message delivery. As pharmaceuticals for organ transplant patients are largely distributed through specialty pharmacies, Veloxis has established well-benchmarked specialty distribution and patient services to optimize the experience for patients and providers and to offer patient access to Envarsus XR whenever possible.

The launch of Envarsus XR in the US has resulted in significant penetration, with approximately 56% of adult transplant centers and over 350 prescribers having utilized Envarsus in 2016. This resulted in an estimated 1,750 patients using Envarsus by year end, and over 11,000 prescriptions of Envarsus in the first full year after launch.

An important driver of uptake of Envarsus XR in the US has been FDA approval of label enhancements allowing promotion of Envarsus XR for use in special populations which may benefit from increased bioavailability and controlled delivery of tacrolimus. African-American kidney transplant patients historically experience poorer outcomes as compared to other ethnic groups and this has been associated in part due to their expression of the CYP3A5\*1 genotype, which codes for a cytochrome p450 enzyme that metabolizes tacrolimus, and shown to be present in approximately 80% of African-Americans. Patients expressing this genotype metabolize tacrolimus much more rapidly and as a result typically require higher tacrolimus doses. This may hinder efforts to obtain a therapeutic level potentially increasing the risk of organ rejection.

These label enhancements are related to the pharmacokinetics (PK) and pharmacogenomics (PG) studied in the ASERTAA trial, one of the largest trials of tacrolimus PK in African-American kidney transplant patients ever conducted. As previously reported, the ASERTAA trial demonstrated that patients on Envarsus achieved therapeutic drug levels with a 30% lower peak concentration and 20% lower average dose compared to tacrolimus immediate-release regardless of genotype status. The importance of these label enhancements is that the dosing recommendations and expected PK profile even for these difficult populations remain the same as with other populations.

Veloxis has licensed Envarsus to Chiesi Farmaceutici S.p.A. in Europe, Turkey and Commonwealth of Independent States countries. Chiesi has launched Envarsus in 17 countries and has plans to launch in additional countries in the future. Uptake in utilization of Envarsus in these countries has been substantial, with an estimated 3,300 patients on therapy at the end of 2016. Key drivers of uptake in these countries include the unique pharmacokinetics of Envarsus and the benefits of a proven once-daily formulation.

# Envarsus for Transplantation

Envarsus XR is a once-daily dosage tablet version of tacrolimus for the treatment of kidney transplant patients. Compared with Astellas Pharma Inc.’s Prograf®, a twice-daily dosage capsule version of tacrolimus, Veloxis believes that Envarsus XR has the following potential benefits:

- once-daily dosing;
- improved systemic absorption;
- improved bioavailability; and
- reduced variability in the concentration of tacrolimus in the blood over a 24 hour period (“peak-to-trough” fluctuation).

## Envarsus XR development status and milestones

Disease indications	Clinical studies	Status
Organ transplant–Kidney	Phase III - <i>De novo</i> kidney transplant patients	Completed 3Q 2014
	Phase III - Stable kidney transplant patients	Completed 2Q 2011
	Phase II - <i>De novo</i> kidney transplant patients	Completed 3Q 2010
	Phase II - Stable kidney transplant patients	Completed 1Q 2008
	Phase IIIb/IV - STRATO	Completed 2Q 2013
	Phase IIIb/IV - ASERTAA	Completed 2Q 2015
	Phase IIIb/IV - ASTCOFF	Completed 2Q 2015
Organ transplant–Liver (Not in active development)	Phase II - <i>De novo</i> liver transplant patients	Completed 4Q 2010
	Phase II - Stable liver transplant patients	Completed 3Q 2009

## Clinical Overview and Update

### Kidney – Phase III Clinical Studies

A Phase III program in kidney transplant patients was initiated in the second half of 2008. The program consisted of one successfully completed conversion (switch) study in stable kidney transplant patients with Prograf as the comparator, as well as one *de novo* kidney transplant study versus Prograf. In addition, the Company has conducted three Phase IIIb/IV studies: STRATO, ASERTAA and ASTCOFF.



## Management Review

### **Envarsus in Kidney Transplant Patients (*de novo* patients, Study 3002)**

Study 3002 was a Phase III randomized, double-blind and double-dummy study in 543 *de novo* kidney transplant recipients, with Prograf as the comparator, which met its primary efficacy and primary safety endpoints. This clinical Phase III study in *de novo* kidney transplant patients was initiated in October 2010. Patient enrollment was completed in the first quarter of 2012, with 543 patients enrolled. One-year data from this study was presented at the European Society for Organ Transplantation congress held in Vienna in September 2013.

The primary endpoint of the study was a composite endpoint of treatment failure (biopsy-proven acute rejection or BPAR, 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, well within the 10% pre-specified non-inferiority margin. The study had a one-year extension period which produced similar outcomes.

### **Envarsus in Kidney Transplant Patients (stable patients, Study 3001)**

This Phase III study successfully demonstrated non-inferiority in predefined endpoints compared to Prograf. The Phase III open-label conversion (switch) study in 326 stable kidney transplant patients, with Prograf as the comparator, met all its primary efficacy and safety endpoints. Results of this study were published in the *American Journal of Transplantation* in 2013.

### **Additional Studies in Order to Identify Potential Additional Characteristics of Envarsus Compared to Prograf**

Veloxis has completed three Phase IIIb/IV studies:

#### **STRATO (Switching kidney TRANSplant patients with Tremor to LCP-tacrO) Phase IIIb study of Envarsus**

This was an open-label study of Envarsus in kidney transplant patients experiencing tremors on standard tacrolimus formulations. It was designed to explore whether converting patients who have symptomatic tremor from treatment with standard twice-daily tacrolimus capsules (such as Prograf) to sustained release once-daily Envarsus tablets, leads to a measurable improvement in tremor. The STRATO Study demonstrated that Envarsus may reduce a troubling side effect of tacrolimus, tremor, and improve the quality of life of kidney transplant recipients. The results of this study were published in *Clinical Transplantation* in September 2015.

#### **ASERTAA (A Study of Extended Release Tacrolimus in African-Americans) Phase IIIb Study of Envarsus**

The ASERTAA Phase IIIb study of Envarsus in kidney transplant recipients compared the pharmacokinetics (PK) of Envarsus, a once-daily tacrolimus tablet, to generic twice daily tacrolimus capsules in stable African-American renal transplant patients. The results of this study 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 results of this study were presented at the American Transplant Congress in May 2015.

### **ASTCOFF (A Steady-state Pharmacokinetic COmparison Of all FK-506 Formulations) Phase IIIb Study of Envarsus**

The ASERTAA Phase IIIb study compared the pharmacokinetic parameters of all three currently commercially available formulations of tacrolimus, demonstrating that once-daily Envarsus XR (tacrolimus extended-release tablets), achieved differentiated pharmacokinetics (PK) when compared to twice-daily tacrolimus (Prograf) or a once-daily tacrolimus product (Astagraf XL). This study confirmed previously published data for Envarsus and showed greater bioavailability) and a flatter PK profile characterized by lower peak-to-trough fluctuation) and delayed time to peak concentrations of 6 hours compared to both Prograf and Astagraf XL. The data from this study was presented at the European Society for Transplantation in September 2015.

# Financial Review

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**(in thousands USD, except share and per share data)**

## **Revenue**

During 2016, Veloxis recognized revenue from commercial sales of USD 9,194 compared to USD 2,103 in 2015. Revenue in 2015 consisted mostly of commercial sales to Chiesi Farmaceutici S.p.A for the European market while 2016 revenue consisted of USD 6,543 for US sales and USD 2,651 for European sales.

## **Selling, General and Administrative Costs**

Selling, general and administrative costs increased from USD 17,808 in 2015 to USD 34,407 in 2016. This reflects the hiring and building of the marketing and sales infrastructure in the US Envarsus XR was launched in the US in December 2015.

On an overall basis, selling, general and administrative costs account for 98.2% of total cost of operations.

## **Research & Development Cost**

Research and development costs decreased from USD 11,345 in 2015 to USD 636 in 2016. The reduction in cost is associated with completion of development work relating to Envarsus XR and the launch of the product at the end of 2015. The limited ongoing spend on development relate to manufacturing process improvements.

On an overall basis, research and development costs account for 1.8% of total cost of operations. The comparable figure for 2015 was 38.9%.

## **Share-Based Compensation Cost**

During 2016, a total of USD 5,430 was recognized as share-based compensation. The comparable number for 2015 was USD 1,797.

## **Operating Result**

During 2016, Veloxis recognized USD 28,768 in operating loss compared with USD 29,300 in 2015.

## Management Review

### Financial Items

Net financial items decreased by USD 2,213, from an income of USD 2,168 in 2015 to a loss of USD 45 in 2016. The income in 2015 was mainly attributable to exchange rate gains due to the increase in the USD/DKK exchange rate. The loss in 2016 is primarily attributable to interest charges on the loan facility.

### Tax for the Year

As the launch of Envarsus has progressed it is considered probable that future taxable profits will be available against which tax losses can be utilized. As a consequence, Veloxis has recognized a tax income of USD 18,678 related to assessment of deferred tax assets.

### Net Result

During 2016, Veloxis recognized USD 10,135 in net loss compared with USD 26,179 in 2015.

The net loss, before incorporation of the entries recognizing the Company's deferred tax asset, is in line with Management's expectations for 2016 as reported on 24 August 2016 in connection with the second quarter interim report, which provided a 2016 outlook of a net loss of USD 25,000 – 31,000.

### Cash Flow

As at 31 December 2016, the balance sheet reflects cash and cash equivalents of USD 3,359 compared with USD 15,763 as per 31 December 2015. The decrease in cash position reflects the changes in operating activities in 2016 as offset by drawdowns against the five-year loan and security agreement with Lundbeckfond Invest A/S and Novo A/S.

### Balance Sheet

As at 31 December 2016, total assets were USD 29,884 compared with USD 21,809 at the end of 2015.

Shareholders' equity equaled USD 10,195 as at 31 December 2016, compared with USD 13,127 at the end of 2015.

# Financial Highlights - Consolidated

Financial Highlights					
USD'000	2016	2015	2014	2013	2012
<b>Income Statement</b>					
Revenue	9,194	2,103	20,847	6,793	1,185
Production costs	(3,019)	(2,250)	(549)	-	-
Gross profit	6,175	(147)	20,299	6,793	1,185
Selling, general and administrative costs	(34,407)	(17,808)	(14,976)	(4,945)	(6,363)
Research and development costs	(636)	(11,345)	(15,224)	(26,088)	(36,352)
Other operating income	100	-	-	-	-
Operating result before restructuring cost	(28,768)	(29,300)	(9,901)	(24,240)	(41,530)
Restructuring cost	-	-	-	-	(3,702)
Operating result	(28,768)	(29,300)	(9,901)	(24,240)	(45,232)
Net financial income / (expenses)	(45)	2,168	3,531	(788)	(147)
Result before tax	(28,813)	(27,132)	(6,369)	(25,028)	(45,379)
Tax for the period	18,678	953	234	223	63
Net result for the period	(10,135)	(26,179)	(6,136)	(24,806)	(45,316)
<b>Statement of Financial Position</b>					
Cash and cash equivalents	3,359	15,763	44,178	60,719	87,794
Total assets	29,884	21,809	47,983	64,453	89,992
Total equity	10,195	13,127	41,371	51,553	72,403
Investment in property, plant and equipment	176	48	295	195	46
<b>Cash Flow Statement</b>					
Cash flow from operating activities	(28,057)	(26,392)	(13,050)	(28,089)	(35,512)
Cash flow from investing activities	(176)	(48)	(430)	(188)	29,275
Cash flow from financing activities	15,981	48	167	(575)	69,741
Cash and cash equivalents at period end	3,359	15,763	44,178	60,719	87,794
<b>Financial Ratios</b>					
Basic and diluted EPS (DKK)	(0.01)	(0.02)	(0.02)	(0.08)	(0.43)
Weighted average number of shares	1,688,679,397	1,663,334,241	1,662,266,639	1,660,353,248	607,511,489
Average number of employees (FTEs)	54	38	26	26	48
Assets/equity	2.93	1.66	1.16	1.25	1.24
Share price DKK	1.08	1.75	1.15	0.70	0.34
Average exchange rates DKK/USD	6.6940	6.7269	5.6190	5.6160	5.7972
Period End exchange rate DKK/USD	7.0460	6.8300	6.1214	5.4127	5.6591

## People

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At year-end 2016, Veloxis employed 45 people, all of which are located in the US. The organization is built to support our strategy and we will continue to strengthen the organization with focus on the commercialization of Envarsus XR in the US.

Attracting and retaining the best talent is crucial to our success and continues to be a company-wide focus.

As at 31 December 2016, 100% of our employees were in selling, general and administration (SG&A).

## Corporate Governance

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Corporate governance at Veloxis concerns the way in which our company is managed and controlled, while creating value for our company and shareholders.

Veloxis has chosen to disclose the mandatory annual corporate governance report at <http://www.veloxis.com/governance.cfm>.

## Risk Management

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Veloxis is exposed to certain risks, some of which may significantly affect the Company's operations and ability to execute strategically. Close monitoring, systemic risk assessments and the ability to respond to a changing environment are essential for an effective risk management process at Veloxis.

The principal aim of Veloxis's risk management process is to strike the right balance between risk exposure and value creation. Our risk management processes are continually updated and adapted to match internal and external requirements. This gives our Executive Management an accurate and complete overview of the Company's activities and resources, and a clear basis for decision-making on Veloxis's overall risk exposure.

Veloxis assesses the likelihood of an event occurring and its potential impact on the Company in terms of financial loss or reputational damage. Risk identification, evaluation, qualification, recording and reporting are carried out by Executive Management and are continually reviewed throughout the year. The overall risk exposure is then evaluated in consultation with the Board of Directors.

Veloxis is exposed to critical risks within such areas as Market Risks, Financial Risks, Legal Risks and Reputational Risks.

The following are examples of these risks and how they are addressed:

## Management Review

### Market Risks

In general, the global pharmaceutical market is characterized by a number of risk factors including risks related to market acceptance, effective commercialization and competition, as well as the ability to attract and retain employees and partners.

Recently, the global pharmaceutical market has been subject to attempts by authorities to cap or reduce increasing healthcare costs. These cost containment measures may be structured in a number of ways, such as price controls or lengthy and resource-consuming market access processes in each country.

We continuously monitor and evaluate the market development of, and the competitive landscape for, our products and product candidates to proactively manage applicable market risks.

Additionally, our business strategy provides us with the freedom to seek partners for certain product candidates and develop our own sales and marketing organization for others.

### Financial Risks

Our expenses are primarily in US dollars (USD). However, our revenues and expenses include currencies other than USD, including EUR and DKK. Therefore, our expenses and income may be vulnerable to fluctuations in exchange rates.

We actively mitigate such fluctuations by placing some of our cash position in demand deposits in EUR and DKK. If we fail to adequately manage foreign exchange risk, the results of our operations and expectations, and the value of Veloxis, may be adversely affected.

Veloxis has interest-bearing debt with fixed interest rates. Our interest rate risk is therefore limited to our cash and cash equivalent balances. Veloxis's treasury policy allows the Company to hold excess cash at deposits with major Danish and US banks and in short-term Danish and US government bonds or Danish mortgage bonds with limited duration.

### Legal Risks

Biotechnology and pharmaceutical companies are often involved in legal proceedings concerning a variety of issues including product liability claims, regulatory violations and infringement of intellectual property rights. As at 31 December 2016, the Company was not a party to any pending legal proceedings.

The appropriateness of Veloxis's insurance coverage, including products liability coverage, is assessed on an annual basis by the Board of Directors.

Veloxis maintains a detailed quality assurance system for in-house company activities as well as for our external partners and suppliers.

### Reputational Risks

Strong corporate governance is essential to maintaining Veloxis's reputation. Accordingly, Veloxis has implemented systems and processes to ensure proactive risk management.

Marketing of pharmaceutical products is strictly regulated and Veloxis is committed to complying with these regulations. Our employees and third parties involved in the marketing of our products are trained to comply with all relevant laws and regulations.

Veloxis maintains a Code of Conduct that helps ensure that all employees comply with applicable international laws and regulations. Our internal procedures are continually updated to address changing regulations and implement best practices.

## Management Review

Veloxis is committed to having an open and honest dialogue about ethical dilemmas. Accordingly, Veloxis has a whistleblower system that all employees may use anonymously if they experience non-compliance with Veloxis's policies and procedures.

No incidents were reported during 2016.

# Statutory Report on Corporate Social Responsibility

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Veloxis has no formal policies and reporting relating to corporate social responsibility, human rights or environmental issues.

Veloxis is a specialty pharmaceutical company without either laboratories or production facilities and hence the Group's consumption of energy, other natural resources, and its discharges of substances into the air and water are limited.

Veloxis supports a good working environment for employees and promotes reasonable environmental and social standards with those with whom we do business.

## Working Environment

The objective of our working environment activities is to improve the safety, health and satisfaction of our employees. In order to ensure that Veloxis remains a safe workplace, we continuously monitor our performance in the following ways:

- Assessment of absence due to the working environment.
- Assessment of incidents and nearby incidents related to working environment.
- Established a WESO (Work Environment Safety Organization) group which meets as needed throughout the year.

In 2016, the company did not experience any workplace safety incidents.

## Business Partners

Our policy for business partners is incorporated into our quality assurance system. When entering into agreements with external business partners, Veloxis ensures that it has adequate rights to inspect our external business partners and ensure that our standards are met.

During the year we have performed 12 visits and audits (9 in 2015) at our important partners and suppliers in the US, Asia and Europe, to ensure that all of our quality requirements were adhered to. The visits did not result in any material remarks.

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# Shareholder Information

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Veloxis maintains an open and continuous dialogue with existing and potential shareholders, stakeholders and the general public. The Company aims for a high degree of openness and effective communication, respecting the principle of equal treatment of all market players. Veloxis will publish quarterly reports on the Company's development, including relevant financial information. In addition, Veloxis will publish details about the Company and its activities where such information is considered likely to have a significant effect on the prices of the Company's securities.

In 2016, Veloxis met several times with existing and potential shareholders. These meetings took place in both the US and Europe.

## About Our Shares

Veloxis's shares were admitted to trading and official listing on the NASDAQ OMX Copenhagen on 13 November 2006 after our IPO of 12.65 million new shares. The symbol is "VELO" and the securities identification code (ISIN) is DK0060048148. Veloxis is included in the Mid Cap segment of the Danish companies on the NASDAQ OMX Copenhagen. Veloxis has a sponsored Level 1 American depository receipt (ADR) program in the US. The ADR trades under the symbol VXPZY.

## Share Capital

As at 31 December 2016 Veloxis had a registered share capital of USD 24,175 with a nominal value of DKK 0.1 per share (USD 0.014). Please see note 12 on page 44 for a more detailed description. Veloxis has only one share class and all shares have equal voting rights.

The Board of Directors is authorized, until the Annual General Meeting in 2017, to arrange for the Company to acquire its own shares up to 10% of the share capital. Such acquisition must be in accordance with section 197 of the Danish Companies Act and may be financed by funds that may be distributed as ordinary dividends. The purchase price of such shares may not differ by more than 10% from the price quoted on the NASDAQ Copenhagen A/S at the time of purchase.

## Ownership Structure

As at 31 December 2016, a total of 8,064 of Veloxis's shareholders were registered in the shareholder register. An increase from 7,055 shareholders as at 31 December 2015. Veloxis invites all shareholders to register in the Company's shareholder register.

As at 31 December 2016, the following shareholders have reported ownership of 5% or more of the Company's shares:

- Lundbeckfond Invest A/S 42.9% (100% owned by the Lundbeck Foundation), Denmark, municipality of Copenhagen
- Novo A/S 42.9% (100% owned by the Novo Nordisk Foundation), Denmark, municipality of Gentofte

## 2016 Company Announcements

During 2016, the company issued 27 company announcements. These can be found on Veloxis's website: <http://www.veloxis.com/releases.cfm>.



## Management Review

### Financial Calendar 2017

28 February 2017	2016 Annual Report
7 April 2017	Annual General Meeting
16 May 2017	Interim Report for the First Three Months of 2017
16 August 2017	Interim Report for the First Six Months of 2017
14 November 2017	Interim Report for the First Nine Months of 2017

### IR Contact

Alastair McEwan  
Executive Vice President & COO  
Phone: +1 919 591 3090  
Email: [asm@veloxis.com](mailto:asm@veloxis.com)

# Board of Directors & Management

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## Board of Directors\*

### Michael T. Heffernan

*Chairman*

Male

Age: 52

Elected at the 2015 AGM

Current term expires 6 April 2017

Nomination Committee (C)

Remuneration Committee (M)

Independent

#### **Competences:**

Registered Pharmacist

CEO, Collegium Pharmaceutical, Inc.

#### **Directorships:**

Collegium Pharmaceutical, Inc.

Keryx Biopharmaceuticals, Inc.

### Mette Kirstine Agger

*Deputy Chairman*

Female

Age: 52

Elected at 2010 AGM

Current term expires 6 April 2017

Audit Committee (M)

Remuneration Committee (M)

Independent

#### **Competences:**

International Pharmaceutical Experience

Managing Partner, Lundbeckfond Ventures

#### **Directorships:**

Klifo A/S

PsiOxus Therapeutics Ltd.

Cydan LLC

scPharmaceuticals LLC

Thesan Pharmaceuticals Inc.

Vtesse Pharma Inc.

Imara Inc.

## Management Review

### Anders Götzsche

*Member*

Male

Age: 49

Elected at 2008 AGM

Current term expires 6 April 2017

Audit Committee (C)

Independent

#### **Competences:**

Financial Expert

EVP & CFO, H. Lundbeck A/S

#### **Directorships:**

Rosborg Møbler A/S

### Robert S. Radie

*Member*

Male

Age: 53

Elected at July 2016 EGM

Current term expires 6 April 2017

Audit Committee (M)

Independent

#### **Competences:**

CEO, Egalet Corporation

#### **Directorships:**

Egalet Corporation

Paratek Pharmaceuticals

Horse Power for Life

### Lars Kåre Viksmoen

*Member*

Male

Age: 68

Elected at July 2016 EGM

Current term expires 6 April 2017

Nominating Committee (M)

Independent

#### **Competences:**

Doctor of Medicine

Former CEO, GN ReSound A/S

Former CEO, Biotec Phamacon ASA

### Paul K. Wotton

*Member*

Male

Age: 56

Elected at July 2016 EGM

Current term expires 6 April 2017

Remuneration Committee (C)

Independent

#### **Competences:**

Ph.D., Pharmaceutical Sciences

CEO, Sigilon Inc.

#### **Directorships:**

Sigilon, Inc.

\* Information at 31 December 2016. AGM = Annual General Meeting, EGM = Extraordinary General Meeting, C = Chairman, M = Member.

## Management Review

### Executive Management\*

#### **Craig A. Collard**

*President & CEO*

Joined Veloxis in 2015

#### **Alastair McEwan**

*Executive Vice President & COO*

Joined Veloxis in 2016

\* Information at 31 December 2016.

# Executive Management's and Board of Directors' Statement on the Annual Report

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The Executive Management and the Board of Directors have considered and adopted the Annual Report of Veloxis Pharmaceuticals A/S for the financial year 2016.

The Consolidated Financial Statements and Parent Company Financial statements are prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU.

Further, the Consolidated Financial Statements, the Parent Company Financial statements and Management's Review are prepared in accordance with further requirements in the Danish Financial Statements Act.

In our opinion, the Consolidated Financial Statements and the Parent Company Financial Statements give a true and fair view of the financial position at 31 December 2016, the results of the Group's and Parent Company's operations, and cash flows for the financial year 2016. Furthermore, in our opinion, Management's Review includes a true and fair account of the development in the operations and financial circumstances, of the results for the year, and of the financial position of the Group and the Parent Company as well as a description of the most significant risks and elements of uncertainty facing the Group and the Parent Company.

We recommend that the Annual Report be adopted at the Annual General Meeting.

Copenhagen, 28 February, 2017

## Executive Management

Craig A. Collard  
President & CEO

Alastair McEwan  
Executive Vice President & COO

## Board of Directors

Michael Heffernan  
Chairman

Mette Kristine Agger  
Deputy Chairman

Anders Götzsche

Robert Radie

Lars Kåre Viksmoen

Paul K. Wotton

# Independent Auditor's Report

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## To the Shareholders of Veloxis Pharmaceuticals A/S

### Our Opinion

In our opinion, the Consolidated Financial Statements and the Parent Company Financial Statements give a true and fair view of the Group's and the Parent Company's financial position at 31 December 2016 and of the results of the Group's and the Parent Company's operations and cash flows for the financial year 1 January to 31 December 2016 in accordance with International Financial Reporting Standards as adopted by the EU and further requirements in the Danish Financial Statements Act.

### What We Have Audited

Veloxis Pharmaceuticals A/S's Consolidated Financial Statements and Parent Company Financial Statements for the financial year 1 January to 31 December 2016 comprise income statement, statement of comprehensive income, statement of financial position, cash flow statement, statement of changes in equity and notes to the financial statements, including summary of significant accounting policies for the Group as well as for the Parent Company. Collectively referred to as the "financial statements".

### Basis for Opinion

We conducted our audit in accordance with International Standards on Auditing (ISAs) and the additional requirements applicable in Denmark. Our responsibilities under those standards and requirements are further described in the *Auditor's Responsibilities for the Audit of the Financial Statements* section of our report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### Independence

We are independent of the Group in accordance with International Ethics Standards Board for Accountants' Code of Ethics for Professional Accountants (IESBA Code) and the ethical requirements that are relevant to our audit of the financial statements in Denmark. We have also fulfilled our other ethical responsibilities in accordance with the IESBA Code.

### Key Audit Matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial statements for 2016. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

**Key Audit Matters**

**How Our Audit Addressed the Key Audit Matters**

*Revenue recognition*

Sales of Envarsus® in the US results in deductions to gross sales in arriving net sales and give rise to provide customers with rebates, discounts, chargebacks and returns under certain commercial and government mandated contracts and reimbursement arrangements in the US.

These areas are complex and require judgement and estimation by management in establishing appropriate accruals.

Reference is made to note 2 and 3 in the Consolidated Financial Statements.

We tested relevant controls and Management's review controls.

We tested that sale was recorded in the appropriate period. Furthermore, we substantive testing of revenue transactions, reconciliations and payments on account receivable balances and performed analytical procedures where appropriate.

We obtained Management's calculations for accruals under applicable schemes and compared to applicable contracts and third party data.

We tested to contracted prices. We also considered the accuracy of the Group's estimates in prior quarters in 2016.

We used our own specialists to evaluate the most significant elements of the accrual at 31 December 2016.

*Valuation of Deferred Tax Asset*

The Group has significant recognised and unrecognised deferred tax assets mainly related to tax losses carried forward due to significant losses related to research and development costs in previous years.

Transformation from a loss making research and development company to a profitable and tax paying commercial company is a process with uncertainty especially concerning revenue growth and gross margin.

Valuation of deferred tax assets depend on future earnings and require significant judgement and estimation by management. This judgement is particularly complex when marketing a new product.

Reference is made to note 1 and 8 in the Consolidated Financial Statements.

We tested the documentation supporting the valuation of the recognised deferred tax assets.

We also inquired with management on the business outlook of the Company and we challenged management's assumptions underpinning the valuation of deferred tax assets.

Moreover, we challenged management on other relevant expectations applied in their calculation, assessment and conclusions.

### **Statement on Management's Review**

Management is responsible for Management's Review.

Our opinion on the financial statements does not cover Management's Review, and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read Management's Review and, in doing so, consider whether Management's Review is materially inconsistent with the financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated.

Moreover, we considered whether Management's Review includes the disclosures required by the Danish Financial Statements Act.

Based on the work we have performed, in our view, Management's Review is in accordance with the Consolidated Financial Statements and the Parent Company Financial Statements and has been prepared in accordance with the requirements of the Danish Financial Statements Act. We did not identify any material misstatement in Management's Review.

### **Management's Responsibility for the Financial Statements**

Management is responsible for the preparation of Consolidated Financial Statements and Parent Company Financial Statements that give a true and fair view in accordance with International Financial Reporting Standards as adopted by the EU and further requirements in the Danish Financial Statements Act, and for such internal control as Management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, Management is responsible for assessing the Group's and the Parent Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless Management either intends to liquidate the Group or the Parent Company or to cease operations, or has no realistic alternative but to do so.

### **Auditor's Responsibilities for the Audit of the Financial Statements**

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and the additional requirements applicable in Denmark will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISAs and the additional requirements applicable in Denmark, we exercise professional judgement and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.



## Financial Statements

- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's and the Parent Company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by Management.
- Conclude on the appropriateness of Management's use of the going concern basis of accounting and based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's and the Parent Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group or the Parent Company to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide those charged with governance with a statement that we have complied with relevant ethical requirements regarding independence, and communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with those charged with governance, we determine those matters that were of most significance in the audit of the financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

Copenhagen, 28 February 2017

### **PricewaterhouseCoopers**

Statsautoriseret Revisionspartnerselskab

*CVR No 33 77 12 31*

Torben Jensen  
State Authorised Public Accountant

Henrik Ødegaard  
State Authorised Public Accountant

# Financial Statements

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## Income Statement

For the period 1 January – 31 December

(USD'000)	Note	Consolidated		Parent	
		2016	2015	2016	2015
Revenue	3	9,194	2,103	3,800	2,103
Production costs		(3,019)	(2,250)	-	(2,250)
<b>Gross profit</b>		<b>6,175</b>	<b>(147)</b>	<b>3,800</b>	<b>(147)</b>
Selling, general and administrative costs	4.5	(34,407)	(17,808)	(10,875)	(16,835)
Research and development costs	4.5	(636)	(11,345)	-	(11,310)
Other operating income		100	-	-	-
<b>Operating result</b>		<b>(28,768)</b>	<b>(29,300)</b>	<b>(7,075)</b>	<b>(28,292)</b>
Financial income	6	643	2,205	2,117	2,205
Financial expenses	7	(688)	(37)	(674)	(41)
<b>Result before tax</b>		<b>(28,813)</b>	<b>(27,132)</b>	<b>(5,632)</b>	<b>(26,128)</b>
Tax for the year	8	18,678	953	18,678	873
<b>Net result for the year</b>		<b>(10,135)</b>	<b>(26,179)</b>	<b>13,046</b>	<b>(25,255)</b>
Basic and diluted EPS		(0.01)	(0.02)		
Weighted average number of shares		1,688,679,397	1,663,334,241		

## Statement of Comprehensive Income

For the period 1 January – 31 December

(USD'000)	Consolidated		Parent	
	2016	2015	2016	2015
<b>Net result for the period</b>	<b>(10,135)</b>	<b>(26,179)</b>	<b>13,046</b>	<b>(25,255)</b>
<b>Other comprehensive income:</b>				
<i>Items that may be subsequently reclassified to profit or loss:</i>				
Currency translation differences, net of tax	(392)	(3,910)	(388)	(3,909)
<b>Other comprehensive income for the period</b>	<b>(392)</b>	<b>(3,910)</b>	<b>(388)</b>	<b>(3,909)</b>
<b>Total comprehensive income for the period</b>	<b>(10,527)</b>	<b>(30,089)</b>	<b>12,658</b>	<b>(29,164)</b>

## Statement of Financial Position

### Assets at 31 December

(USD'000)	Note	Consolidated		Parent	
		2016	2015	2016	2015
Patent rights and software	9	114	146	40	49
<b>Intangible assets</b>		<b>114</b>	<b>146</b>	<b>40</b>	<b>49</b>
Property, plant and equipment	9	482	488	308	461
<b>Tangible fixed assets</b>		<b>482</b>	<b>488</b>	<b>308</b>	<b>461</b>
Receivable from subsidiary		-	-	27,194	-
Equity interest in subsidiary	10	-	-	368	380
Deferred tax asset	8	18,678	-	18,678	-
<b>Financial assets</b>		<b>18,678</b>	<b>-</b>	<b>46,240</b>	<b>380</b>
<b>Non-current assets</b>		<b>19,274</b>	<b>634</b>	<b>46,588</b>	<b>889</b>
<b>Inventories</b>	11	<b>4,141</b>	<b>2,487</b>	<b>-</b>	<b>2,487</b>
Trade receivables		2,212	862	-	293
Tax receivables		-	860	-	860
Other receivables		96	598	55	551
Prepayments		802	605	192	200
<b>Receivables</b>		<b>3,110</b>	<b>2,925</b>	<b>247</b>	<b>1,904</b>
Cash		3,359	15,763	2,335	15,209
<b>Cash and cash equivalents</b>		<b>3,359</b>	<b>15,763</b>	<b>2,335</b>	<b>15,209</b>
<b>Current assets</b>		<b>10,610</b>	<b>21,175</b>	<b>2,582</b>	<b>19,600</b>
<b>Assets</b>		<b>29,884</b>	<b>21,809</b>	<b>49,170</b>	<b>20,489</b>

## Statement of Financial Position

### Equity and liabilities at 31 December

(USD'000)	Note	Consolidated		Parent	
		2016	2015	2016	2015
Share capital	12	24,175	23,578	24,175	23,578
Special reserve		57,804	57,804	57,804	57,804
Translation reserves		(4,052)	(3,660)	(4,297)	(3,909)
Retained earnings/loss		(67,732)	(64,595)	(43,395)	(63,439)
<b>Equity</b>		<b>10,195</b>	<b>13,127</b>	<b>34,287</b>	<b>14,034</b>
Loan	13	13,816	-	13,901	-
<b>Non-current liabilities</b>		<b>13,816</b>	<b>-</b>	<b>13,901</b>	<b>-</b>
Trade payables		957	2,957	118	2,955
Deferred revenue		-	539	-	-
Debt to subsidiary		-	-	-	1,490
Other payables		4,916	5,186	864	2,010
<b>Current liabilities</b>		<b>5,873</b>	<b>8,682</b>	<b>982</b>	<b>6,455</b>
<b>Liabilities</b>		<b>19,689</b>	<b>8,682</b>	<b>14,883</b>	<b>6,455</b>
<b>Equity and liabilities</b>		<b>29,884</b>	<b>21,809</b>	<b>49,170</b>	<b>20,489</b>
Financial risks	14				
Warrants	15				
Other Commitments	16				
Related parties	17				
Fees to auditors	19				

## Cash Flow Statement

### For the period 1 January – 31 December

(USD'000)	Note	Consolidated		Parent	
		2016	2015	2016	2015
<b>Operating result</b>		<b>(28,768)</b>	<b>(29,300)</b>	<b>(7,075)</b>	<b>(28,292)</b>
Share-based payment	5	5,430	1,797	5,430	1,797
Depreciation and amortization	4	208	219	153	184
Changes in working capital	18	(5,787)	(22)	526	(1,679)
<b>Cash flow from operating activities before interest</b>		<b>(28,917)</b>	<b>(27,306)</b>	<b>(966)</b>	<b>(27,990)</b>
Interest received		-	21	-	21
Interest paid		-	(37)	-	(42)
Corporate tax received		860	930	860	930
<b>Cash flow from operating activities</b>		<b>(28,057)</b>	<b>(26,392)</b>	<b>(106)</b>	<b>(27,081)</b>
Purchase of property, plant and equipment		(176)	(48)	-	(34)
Payable to / (receivable) from subsidiary		-	-	(28,683)	475
<b>Cash flow from investing activities</b>		<b>(176)</b>	<b>(48)</b>	<b>(28,683)</b>	<b>441</b>
Proceeds from bank borrowings		14,000	-	14,000	-
Cost of borrowings		(184)	-	(98)	-
Proceeds from issuance of shares		2,165	48	2,165	48
<b>Cash flow from financing activities</b>		<b>15,981</b>	<b>48</b>	<b>16,067</b>	<b>48</b>
<b>Increase/(decrease) in cash</b>		<b>(12,252)</b>	<b>(26,392)</b>	<b>(12,722)</b>	<b>(26,592)</b>
Cash at beginning of period		15,763	39,595	15,209	39,222
Exchange gains/(losses) on cash		(152)	2,560	(152)	2,579
<b>Cash at end of period</b>		<b>3,359</b>	<b>15,763</b>	<b>2,335</b>	<b>15,209</b>

Cash includes USD 315 of restricted cash in Consolidated numbers for 2016

## Statement of Changes in Equity

### Consolidated

Consolidated						
USD	Number of Shares	Share Capital USD'000	Special Reserves USD'000	Translation Reserves USD'000	Retained Earnings USD'000	Total USD'000
<b>Equity as of 1 January 2015</b>	<b>1,662,997,314</b>	<b>23,566</b>	<b>57,804</b>	<b>250</b>	<b>(40,249)</b>	<b>41,371</b>
Net result for the year					(26,179)	(26,179)
Currency adjustment				(3,910)		(3,910)
Total comprehensive income		-	-	(3,910)	(26,179)	(30,089)
Warrant exercises	786,261	12			36	48
Share-based payment					1,797	1,797
Other transactions	786,261	12			1,833	1,845
<b>Equity as of 31 December 2015</b>	<b>1,663,783,575</b>	<b>23,578</b>	<b>57,804</b>	<b>(3,660)</b>	<b>(64,595)</b>	<b>13,127</b>
Net result for the year					(10,135)	(10,135)
Currency adjustment				(392)		(392)
Total comprehensive income				(392)	(10,135)	(10,527)
Warrant exercises	39,590,306	597			1,568	2,165
Share-based payment					5,430	5,430
Other transactions	39,590,306	597	-	-	6,998	7,595
<b>Equity as of 31 December 2016</b>	<b>1,703,373,881</b>	<b>24,175</b>	<b>57,804</b>	<b>(4,052)</b>	<b>(67,732)</b>	<b>10,195</b>

At the general meeting of the company held on 18 April 2012 it was resolved to reduce the share capital of the company by decrease of the denomination of all shares. The capital decrease was made by transfer to a special reserve fund (Special reserves), which can only be paid out with prior approval by the shareholders in accordance with the Danish Companies Act section 189 (1).

Translation reserves may be subsequently reclassified to profit and loss.

The overall difference between consolidated total equity and parent total equity is primarily attributable to the subsidiaries net loss.

## Statement of Changes in Equity

### Parent Company

Parent						
USD	Number of Shares	Share Capital USD'000	Special Reserves USD'000	Translation Reserves USD'000	Retained Earnings USD'000	Total USD'000
<b>Equity as of 1 January 2015</b>	<b>1,662,997,314</b>	<b>23,566</b>	<b>57,804</b>	<b>-</b>	<b>(40,017)</b>	<b>41,353</b>
Net result for the year					(25,255)	(25,255)
Currency adjustment				(3,909)		(3,909)
Total comprehensive income		-	-	(3,909)	(25,255)	(29,164)
Warrant exercises	786,261	12			36	48
Share-based payment					1,797	1,797
Other transactions	786,261	12			1,833	1,845
<b>Equity as of 31 December 2015</b>	<b>1,663,783,575</b>	<b>23,578</b>	<b>57,804</b>	<b>(3,909)</b>	<b>(63,439)</b>	<b>14,034</b>
Net result for the year					13,046	13,046
Currency adjustment				(388)	-	(388)
Total comprehensive income					13,046	12,658
Warrant exercises	39,590,306	597			1,568	2,165
Share-based payment					5,430	5,430
Other transactions	39,590,306	597	-	-	6,998	7,595
<b>Equity as of 31 December 2016</b>	<b>1,703,373,881</b>	<b>24,175</b>	<b>57,804</b>	<b>(4,297)</b>	<b>(43,395)</b>	<b>34,287</b>

At the general meeting of the company held on 18 April 2012 it was resolved to reduce the share capital of the company by decrease of the denomination of all shares. The capital decrease was made by transfer to a special reserve fund (Special reserves), which can only be paid out with prior approval by the shareholders in accordance with the Danish Companies Act section 189 (1).



## Notes

(in thousands USD, except share and per share data)

### Note 1. Summary of Significant Accounting Policies

#### General

The annual report of Veloxis Pharmaceuticals A/S for the year ended 31 December 2016, comprising the financial statements of the parent company and the consolidated financial statements (financial statements) has been prepared in accordance with the International Financial Reporting Standards (IFRS) as adopted by the EU and additional Danish disclosure requirements for annual reports of listed companies.

Effective 1 January 2016 the financial statements are presented in USD, which is the functional currency of the subsidiary. The functional currency of the parent company is Danish kroner (DKK). The year-end exchange rate used for 2016 was 7.046 DKK to USD and the average exchange rate used for conversion was 6.694 DKK to USD.

Effective 1 January 2017 both the functional and presentation currency will be USD for both the parent company and the consolidated financial statements because of the change of activity in the parent and the related change in the currency of the Group's transactions.

The financial statements are presented on a historical cost basis. Otherwise, the accounting policies are as described in the following.

The financial statements are presented in accordance with the new and revised Standards (IFRS/IAS) and the new Interpretations (IFRIC) that apply to financial years beginning 1 January 2016. The implementation of the new and revised Standards and Interpretations has not led to any changes in the accounting policies, and has not had any material impact on the amounts and disclosures reported for current or prior years.

#### New International Financial Reporting Standards (IFRS) and Interpretations (IFRIC)

Veloxis has assessed the effect of the new standards, amendments and interpretations. Veloxis has concluded that all standards, amendments and interpretations effective for financial years beginning on or after 1 January 2017 are either not relevant to the Group or have no significant effect on the Financial Statements of Group.

##### *IFRS 15*

The IASB has issued IFRS 15 "Revenue from contracts with customers", with an effective date of 1 January 2018. The standard is endorsed by the EU. Under the standard entities will apply a five step model to determine when, how and at what amount of revenue is to be recognized depending on whether certain criteria are met. Veloxis is performing an assessment of the standard to determine the potential impact of IFRS 15 on the financial statements. Veloxis plans to adopt IFRS 15 on the effective date.

##### *IFRS 9*

The IASB has issued IFRS 9 "Financial Instruments", with an effective date of 1 January 2018. The standard is endorsed by the EU. IFRS 9 addresses the classification, measurement and de-recognition of financial assets and financial liabilities and introduces new rules for hedge accounting. Veloxis is performing an assessment of the standard to determine the potential impact of IFRS 9 on the financial statements. Veloxis plans to adopt IFRS 9 on the effective date.

### *IFRS 16*

The IASB has issued IFRS 16 “Leasing”, with an effective date of 1 January 2019. The standard awaits endorsement by the EU. The standard requires that all leases be recognized in the balance sheet with a corresponding lease liability, except for short term assets and minor assets. Leased assets are amortized over the lease term, and payments are allocated between installments on the lease obligation and interest expense, classified as financial items. Veloxis is performing an assessment of the standard to determine the potential impact of IFRS 16 on the financial statements. Veloxis plans to adopt IFRS 16 on the effective date.

### **Consolidated Financial Statements**

The consolidated financial statements include Veloxis Pharmaceuticals A/S (the Parent Company) and subsidiaries in which the Parent Company directly or indirectly exercises a controlling interest through shareholding or otherwise. Accordingly, the consolidated financial statements include Veloxis Pharmaceuticals A/S and Veloxis Pharmaceuticals, Inc. (collectively referred to as the Group).

The Group’s consolidated financial statements have been prepared on the basis of the financial statements of the Parent Company and the subsidiary – prepared under the Group’s accounting policies – by combining similar accounting items on a line-by-line basis. On consolidation, intercompany income and expenses, intercompany receivables and payables, and unrealized gains and losses on transactions between the consolidated companies are eliminated.

The recorded value of the equity interests in the consolidated subsidiary is eliminated with the proportionate share of the subsidiary’s equity. The subsidiary is consolidated from the date when control was transferred to the Group.

The income statement for the Parent Company is translated into the Group’s reporting currency at the year’s weighted average exchange rate and the balance sheet is translated at the exchange rate in effect at the balance sheet date. Exchange rate differences arising from the translation of the Parent Company balance sheet at period end rates, and exchange rate differences arising as a result of the Parent Company income statement being translated at average exchange rates, are recorded in translation reserves in shareholders’ equity.

### **Foreign Currency**

Items included in the financial statements of each of the Group’s entities are measured using the currency of the primary economic environment in which the entity operates (“the functional currency”). The functional currency of the Company’s operations in Denmark and the United States of America, are DKK and USD, respectively. The financial statements are presented in USD, which is the Group’s presentation currency.

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized as operating expense in the income statement in financial income/expenses.

Group companies that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- Assets and liabilities for each balance sheet presented are translated at the closing rate at the date of that balance sheet.
- Income and expenses for each income statement are translated at the dates of the transactions.
- All resulting exchange rate differences are recognized in other comprehensive income.

### **Operating Lease Commitments**

Leases in which a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments made under operating leases (net of any incentives received from the lessor) are charged on a straight-line basis to the income statement as research and development costs or as selling, general and administrative expenses, depending on the use of the asset.

The total commitment under operating leases is disclosed in the notes to the financial statements.

### **Comprehensive Income**

Veloxis presents comprehensive income in two statements. An income statement and a statement of total comprehensive income which includes result for the year and income recognized in other comprehensive income. Other comprehensive income includes the difference between exchange rates used for converting balance sheet accounts and income statement accounts arising from translating the financial statements of the Parent Company.

### **Income Statement**

#### **Revenues**

Revenues comprises invoiced sales for the year less discounts. Moreover, revenue includes milestone payments, royalties and services rendered from research and development and commercialization agreements. Revenue is recognized when it is probable that future economic benefits will flow to the Company and these benefits can be measured reliably. Further, revenue recognition requires that all significant risks and rewards of ownership of the goods or services included in the transaction have been transferred to the buyer, and that Veloxis retains neither continuing managerial involvement to the degree usually associated with ownership nor effective control over the goods or services sold.

Sales are measured at the fair value of consideration received or receivable. When sales are recognized, the Company also records estimates for a variety of sales deductions, including product returns as well as rebates and discounts to government agencies, wholesalers, chargebacks, managed healthcare organizations and retail customers. Sales deductions are recognized as a reduction of gross sales to arrive at net sales.

#### **Production Costs**

Production costs comprise raw materials, shipping costs and other costs incurred directly attributable to the production of Envarsus XR. Also included are expenses for quality assurance of products and any write-down to net realizable value of unsaleable and slow-moving items.

#### **Selling, General and Administrative Costs**

Selling costs comprise costs incurred for the sale and distribution of the Group's product sold during the year. This includes costs incurred for sales campaigns, training and administration of the sales force and direct distribution, marketing and promotion. Also included are salaries and other costs for the sales, distribution and marketing functions.

General and administrative expenses comprise expenses incurred for the management and administration of the Group and include salaries and other expenses relating to various functions within the Group.

In addition, amortization/depreciation and impairment losses and other direct costs are included in this line item.

### Research and Development Costs

Research and development costs comprise costs by activity, as follows: (a) product and manufacturing development, (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 costs are recognized in the income statement in the period to which they relate. Development costs are recognized in the income statement when incurred if the criteria for capitalization have not been met.

A development project involves a single product candidate undergoing a high number of tests to illustrate its safety profile and effect on human beings prior to obtaining the necessary approval from the appropriate authorities. Considering the general risk related to the development of pharmaceutical products, management has concluded that the future economic benefits associated with the individual development projects cannot be estimated with sufficient certainty until the project has been finalized and the necessary market approval of the final product has been obtained. As a consequence, all development costs are recognized in the income statement in the period to which they relate.

### Share-Based Payment

Veloxis has established equity-settled share-based payment plans (warrants). The employee services received in exchange for the grant of the warrants or shares are recognized as an expense and allocated over the vesting period. The amount is determined as the fair value of the equity instruments granted. The total amount recognized over the vesting period corresponds to the fair value of the warrants or shares that actually vest. The fair value is determined at the grant date and is not adjusted subsequently.

Veloxis estimates a forfeiture rate for all warrants granted and therefore does not recognize any impact of any cancellations or forfeitures in the income statement once they happen. Forfeiture rates are reassessed annually and adjusted as necessary.

### Financial Items

Financial income and expenses include interest, dividend, gains and losses related to transactions denominated in foreign currencies and amortization of finance lease obligations.

Interest income and expenses are accrued with basis in the principal and the nominal interest rate.

Dividend from equity interests in subsidiaries is recognized in the income statement of the Parent company in the financial income, when final right to the dividend has been acquired.

### Corporate Tax

Tax for the year, which consists of current tax for the year and changes in deferred tax, is recognized in the income statement by the portion attributable to the income for the year, and recognized directly in equity by the portion attributable to transactions recognized directly in equity. Current tax payable or receivable is recognized in the balance sheet as tax calculated on the taxable income for the year adjusted for prepaid tax.

## Financial Statements

Deferred tax is recognized and measured under the liability method on all temporary differences between the carrying amount and tax value of assets and liabilities. The tax value of the assets is calculated based on the planned use of each asset.

Deferred tax is calculated in accordance with the tax regulations and tax rates that are expected to be in effect, considering the laws in force at the balance sheet date, when the deferred tax is estimated to crystallize as current tax. Changes in deferred tax resulting from changed tax rates are recognized in the income statement.

Deferred tax assets, including the tax value of tax losses carried forward, are recognized in the balance sheet at their estimated realizable value, either as a set-off against deferred tax liabilities, if such set-off is permitted for tax purpose, or as net tax assets. Deferred tax assets which are not recognized in the balance sheet are disclosed in a note to the financial statements.

## Statement of Financial Position

### Non-Current Assets

#### Intangible Assets

Intangible assets comprise acquired patent rights and software.

Patent rights and software are measured at cost less accumulated amortization and impairment losses. The amortization period is determined based on the expected economic and technical useful life, and amortization is recognized on a straight-line basis over the expected useful life as follows:

Patent rights:	20 years
Software:	3-5 years

#### Tangible Fixed Assets

Tangible fixed assets comprise process plant and machinery, other fixtures and fittings, hardware and computers, tools and equipment and leasehold improvements. Tangible fixed assets are measured at cost less accumulated depreciation and impairment losses. Cost includes expenditures that are directly attributable to the acquisition of the assets. Subsequent costs are included in the carrying amount of the asset or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the assets will flow to the Company and the costs of the items can be measured reliably. All repair and maintenance costs are charged to the income statement during the financial periods in which they are incurred.

Depreciation of tangible fixed assets is calculated using the straight-line method to allocate the cost to the residual value of the assets over the expected useful life as follows:

Process plant and machinery:	7 years
Other fixtures and fittings, tools and equipment:	3-5 years
Leasehold improvements:	1-5 years
Hardware and computers:	1-3 years

Depreciation, impairment losses and gains or losses on disposal of tangible fixed assets is recognized in the income statement as part of selling, general and administrative costs.

Depreciation period and residual value are reassessed annually.

### **Impairment of Long-Lived Assets**

The carrying amount of long-lived assets is tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If there are such indications, an impairment test is performed. An impairment loss is recognized for the amount by which the carrying amount of the asset exceeds its recoverable amount. The recoverable amount is determined as the higher of an asset's net selling price and its value in use. Value in use is calculated as the net present value of future cash inflow generated from the asset. For the purposes of assessing impairment, assets are grouped at the lower levels for which there are separately identifiable cash flows (cash-generating units). For corporate assets the assessment is carried out at an entity level. Impairment losses are recognized in the income statement under the same line items as the related depreciation or amortization.

### **Current Assets**

#### **Inventories**

Inventories are valued at the lower of cost using FIFO and net realizable value.

Cost of goods for sale and raw materials comprises all costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition.

The net realizable value of inventory is measured at the selling price less cost related to the execution of sales. Furthermore, net realizable value is determined with regard to marketability, obsolescence and development in expected selling price.

Inventories are regularly evaluated for obsolescence and excess quantities, taking into account factors such as historical and anticipated futures sales compared with quantities on hand and the remaining shelf life of products.

#### **Trade Receivables**

Trade receivables are measured in the balance sheet at the lower of amortized cost and net realizable value, which corresponds to the nominal value less provisions for bad debts. Provisions for bad debts are determined on the basis of an individual assessment of each receivable.

#### **Other Receivables**

Other receivables are measured at fair value on initial recognition and subsequently measured at amortized cost according to the effective interest method less provision for impairment. Impairment losses are based on an individual evaluation of each amount collectible.

#### **Prepayments**

Prepayments comprise incurred costs related to a future financial period. Prepayments are measured at nominal value.

#### **Cash and Cash Equivalents**

Cash and cash equivalents comprise cash and deposits with financial institutions. Cash and cash equivalents are measured at amortized cost.

### Shareholders' Equity

The share capital comprises the nominal amount of the Company's ordinary shares, each at a nominal value of DKK 0.1. All shares are fully paid.

Special reserve can only be paid out with prior approval by the shareholders in accordance with the Danish Companies Act section 188 paragraph 1 (3).

### Non-Current Liabilities

#### Loan

Borrowings are initially recognized at fair value, net of transaction costs incurred. Borrowings are subsequently measured at amortized cost. Any difference between the proceeds (net of transaction costs) and the redemption amount is recognized in profit or loss over the period of the borrowings using the effective interest method. Fees paid on the establishment of loan facilities are recognized as transaction costs of the loan and are shown as an offset to the loan facility in the balance sheet. These fees are amortized over the period of the facility to which they relate.

#### Current Liabilities

##### Trade Payables

Trade payables are measured at amortized cost, which is considered to be equal to the fair value due to the short-term nature of the liabilities.

##### Deferred Revenue

Deferred revenue comprises invoiced sales where all significant risks have not been transferred to the customer. Deferred revenue is measured at cost.

##### Other Liabilities

Other liabilities are measured in the balance sheet at amortized cost, which is considered to be equal to the fair value due to the short-term nature of the liabilities.

Provision for sales rebates and discounts granted to government agencies, wholesalers, hospitals and other customers are recorded at the time the related revenues are recorded or when the incentives are offered. Provisions are calculated based on historical experience and the specific terms in the individual agreements.

##### Equity Interests in Subsidiaries

In the separate financial statements of the Parent Company, equity interests in subsidiaries are recognized and measured at cost. Equity interests in foreign currencies are translated to the reporting currency by use of historical exchange rates prevailing at the time of investment.

## Cash Flow Statement

The cash flow statement is presented using the indirect method with basis in operating result and shows cash flow from operating, investing and financing activities as well as the cash and cash equivalents at the beginning and end of each financial year.

Cash flows from operating activities are calculated as the operating profit/loss adjusted for non-cash operating items such as share-based payment, depreciation, amortization and impairment losses, working capital changes and financial income and expenses received or paid.

Cash flows from investing activities comprise cash flows from purchase and sale of intangible assets and property, plant and equipment.

Cash flows from financing activities comprise cash flows from issuance of shares net of costs, raising and repayment of non-current loans including installments on finance lease liabilities.

Cash and cash equivalents comprise cash at hand and deposits with financial institutions.

The cash flow statement cannot be derived solely from the financial statements.

## Segment Reporting

The Group is managed and operated as one business unit. No separate business areas or separate business units have been identified in relation to product candidates or geographical markets. Accordingly, Veloxis's management has concluded that it is not relevant to disclose segment information on business segments or geographical markets.

## Financial Ratios

Financial ratios have been calculated in accordance with the recommendations of the Association of Danish Financial Analysts.

Basic Earnings per share (EPS) is calculated as the net income/loss from continuing operations for the period divided by the weighted average number of ordinary shares outstanding.

Diluted earnings per share is calculated as the net income/ loss from continuing operations for the period divided by the weighted average number of ordinary shares outstanding adjusted for the dilutive effect of share equivalents.

As the income statement shows a net loss, no adjustment has been made for the dilutive effect.

Assets/Equity ratio =  $\frac{\text{Total assets}}{\text{Equity}}$

## Note 2. Critical accounting estimates and judgments

In preparing financial statements under IFRS, certain provisions in the standards require management's judgments. Such judgments are considered important to understand the accounting policies and Veloxis's compliance with the standards. The following summarizes the areas involving higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the financial statements.



### Capital Resources and Liquidity

Veloxis's financial statements are prepared on a going concern basis based on a budget which inherently is subject to a number of assumptions and uncertainties including most notably an assumption of continued growth in the company's sale of Envarsus, and associated uncertainties relating to the nature of the markets, which the company addresses. Management acknowledges that there are risks associated with achieving the budget.

The Company's Board of Directors and Executive Management have reviewed the Company's financial projections, taking into account matters such as the progress of Envarsus in the US and European markets, the ongoing expenses associated with sales, marketing, product support, development and the administration of the Company. On that basis, the Board of Directors and Executive Management has come to the conclusion that the Company's funding arrangements are sufficient to meet its funding requirement through the period until cash flows generated by its operations are sufficient to cover its expenses and to repay sums drawn down under the existing loan arrangement.

### Deferred Tax Assets

Deferred tax assets, including tax losses carried forward, are recognized with their expected value. The assessment of deferred tax assets regarding loss carry-forwards, which has been capitalized, is based on the expected, future taxable income of the respective company and the due date of their losses. For further details, please refer to note 8.

### Sales Deductions

Sales deductions are estimated and provided for at the time the related sales are recorded. These estimates of unsettled obligations require use of judgement, as all conditions are not known at the time of sale. Accruals of sales deductions amounted to USD 0.5 – 1 million.

### *Chargebacks*

Wholesale chargebacks relate to contractual arrangements between the company and indirect customers whereby products are sold at contract prices lower than the list price originally charged to wholesalers. A wholesaler chargeback represents the difference between the invoice price to the wholesaler and the indirect customer's contract price. Accruals are calculated for estimated chargebacks using a combination of factors such as historical experience, current wholesaler inventory levels, contract terms and the value of claims received but not yet processed. Wholesaler chargebacks are generally settled within 30 days of the liability being incurred.

### *Rebates*

Medicaid rebates have been calculated using a combination of historical experience, product and population growth, price increases, and the impact of contracting strategies. Further, the calculation involves interpretation of relevant regulations that are subject to changes in interpretative guidance from government authorities. Although provisions are made for Medicaid rebates at the time sales are recorded, the actual rebates related to specific sales will typically be invoiced to the company 3-6 months later. Due to the time lag, the rebate adjustments to sales in any particular period may incorporate adjustments of provisions from prior period.

### *Discounts, sales returns and other rebates*

Other discounts are provided to wholesalers, hospitals, pharmacies, etc. and are usually linked to sales volume or provided as cash discounts. Accruals are calculated based on historical data, and recorded as a reduction in gross sales at the time the related sales are recorded. Sales returns are related to damaged or expired products.

### Note 3. Revenue

The Group derives the following types of revenue:

	Consolidated		Parent	
	2016	2015	2016	2015
<b>(USD'000)</b>				
Sale of goods	9,194	2,103	-	2,103
Royalty	-	-	3,800	-
<b>Total</b>	<b>9,194</b>	<b>2,103</b>	<b>3,800</b>	<b>2,103</b>

Royalty is paid from the subsidiary to the parent at arm's length and is eliminated in consolidation.

Revenue from sale of goods is generated from the sale of Envarsus to wholesalers, specialty pharmacies and other customers. The sales of Envarsus can be split into the following geographical segments:

	Consolidated		Parent	
	2016	2015	2016	2015
<b>(USD'000)</b>				
Europe	2,651	2,073	-	2,073
United States	6,543	30	-	30
<b>Total</b>	<b>9,194</b>	<b>2,103</b>	<b>-</b>	<b>2,103</b>

Revenue is comprised from the following major customers:

	Consolidated		Parent	
	2016	2015	2016	2015
<b>(USD'000)</b>				
Customer A revenue	2,307	-	-	-
Customer B revenue	2,089	-	-	-
Customer C revenue	1,315	-	-	-
Customer D revenue	711	-	-	-
Customer E revenue	2,651	2,073	-	2,073
Other customer revenue	121	30	-	30
<b>Total</b>	<b>9,194</b>	<b>2,103</b>	<b>-</b>	<b>2,103</b>

## Note 4. Depreciation and Amortization

(USD'000)	Consolidated		Parent	
	2016	2015	2016	2015
Patent rights and software	27	33	4	9
Property, plant and equipment	177	186	149	175
Leasehold improvements	4	0	0	0
<b>Total</b>	<b>208</b>	<b>219</b>	<b>153</b>	<b>184</b>
Allocated by function:				
Selling, general and administrative expenses	208	124	153	64
Research and development costs	-	95	-	120
<b>Total</b>	<b>208</b>	<b>219</b>	<b>153</b>	<b>184</b>

## Note 5. Staff Costs

(USD'000)	Consolidated		Parent	
	2016	2015	2016	2015
Wages and salaries	11,759	9,412	2,026	3,929
Pension contributions	1,055	271	733	164
Other social security costs	1,487	684	2	12
Share-based payment	5,430	1,797	5,430	533
<b>Total</b>	<b>19,731</b>	<b>12,164</b>	<b>8,191</b>	<b>4,638</b>
Allocated by function:				
Selling, general and administrative	19,731	8,030	8,191	2,841
Research and development costs	-	4,134	-	1,797
<b>Total</b>	<b>19,731</b>	<b>12,164</b>	<b>8,191</b>	<b>4,638</b>
Average number of employees (FTEs)	54	38	5	12
<b>Remuneration of board of directors, and executive management:</b>				
<b>Board of directors</b>				
Cash remuneration	325	224	325	224
Share-based payment	225	151	225	151
	<b>550</b>	<b>375</b>	<b>550</b>	<b>375</b>
<b>Executive management</b>				
Gross salary	789	776	789	776
Severance	555	236	555	236
Bonus	618	1,012	618	1,012
Pension contributions	22	40	22	40
Share-based payment	3,903	901	3,903	901
	<b>5,887</b>	<b>2,965</b>	<b>5,887</b>	<b>2,965</b>

Members of the Board of Directors receive a fixed annual fee of USD 25. The Chairman of the Board of Directors receives a supplement of USD 50 to the fixed fee and the Chairman of respectively the Audit Committee, Nominating Committee and the Compensation Committee receives a supplement of USD 25 to the fixed annual fee.

Travel and accommodation expenses in connection with board meetings and expenses associated with any relevant training are paid on submission of receipts to members of the Board of Directors.

In addition to the fixed annual fee, the members of the Board of Directors are annually granted a number of warrants that is to be equivalent to USD 150.

The severance/notice period for the Executive Management is 12 months.

Veloxis's and the Group's pension schemes are defined contribution schemes and Veloxis has no additional payment obligations.

Veloxis has implemented a company-wide remuneration policy with a bonus element including both a cash element and a warrant based element. Hence a certain percentage of each employee's remuneration is dependent on the employee and the company specified goals and objectives agreed upon at the beginning of each year.

Veloxis has implemented Incentive Guidelines in its Remuneration Policy, which has been adopted by the shareholders at the Annual General Meeting and are in further detailed on Veloxis's website at <http://www.veloxis.com/documents.cfm>.

### Board of Directors and Executive Management's Holdings of Shares and Warrants

	As per 31 December 2016		As per 31 December 2015	
	Shares	Warrants	Shares	Warrants
<b>Board of directors</b>				
Anders Götzche	-	1,873,929	-	1,187,023
Mette Kirstine Agger	1,288	2,023,929	1,288	1,337,023
Michael Heffernan	-	1,873,929	-	1,187,023
Paul K. Wotton	-	917,431	-	-
Robert Radie	-	917,431	-	-
Lars Kåre Viksmoen	-	917,431	-	-
<b>Executive management</b>				
Craig A. Collard	-	50,565,196	-	-
Alastair McEwan	-	16,855,065	-	-

### Note 6. Financial Income

(USD'000)	Consolidated		Parent	
	2016	2015	2016	2015
Interest income	-	21	-	21
Interest income from group companies	-	-	1,458	-
Exchange rate, net	643	2,184	659	2,184
<b>Total</b>	<b>643</b>	<b>2,205</b>	<b>2,117</b>	<b>2,205</b>

**Note 7. Financial Expenses**

	Consolidated		Parent	
	2016	2015	2016	2015
<b>(USD'000)</b>				
Interest expenses	688	37	674	37
Interest expense from group companies	-	-	-	4
<b>Total</b>	<b>688</b>	<b>37</b>	<b>674</b>	<b>41</b>

**Note 8. Tax and Deferred Tax**

	Consolidated		Parent	
	2016	2015	2016	2015
<b>(USD'000)</b>				
<b>Tax for the year can be explained as follows:</b>				
Income / (loss) for the year before tax	(28,813)	(27,132)	(5,632)	(26,128)
<b>Tax rate</b>	<b>22.0%</b>	<b>23.5%</b>	<b>22.0%</b>	<b>23.5%</b>
Computed tax on income / (loss) for the year	6,339	(6,376)	1,239	(6,140)
Change in tax losses carried forward	9,148	6,376	18,592	6,140
Tax benefit	-	873	-	873
Permanent differences	(1,181)	-	(1,153)	-
Tax re previous year	(834)	79	-	-
Deviation in foreign subsidiary tax rate	5,206	-	-	-
<b>Tax for the year</b>	<b>18,678</b>	<b>952</b>	<b>18,678</b>	<b>873</b>
Calculated deferred tax asset	68,169	61,033	58,724	60,522
Write down to assessed value	(49,491)	(61,033)	(40,046)	(60,522)
<b>Carrying amount</b>	<b>18,678</b>	<b>-</b>	<b>18,678</b>	<b>-</b>

As the launch of Envarsus has progressed it is considered probable that future taxable profits will be available against which tax losses can be utilized. As a consequence, Veloxis has recorded USD 18,678 in deferred tax asset as at 31, December 2016.

The remaining Unrecognized tax loss carry-forward amounts to USD 188,839 (2015 USD 245,458).

## Note 9. Intangible & Tangible Fixed Assets

Consolidated	Patent rights & Software		Property, Plant & Equipment		Leasehold Improvements	
	2016	2015	2016	2015	2016	2015
(USD'000)						
Cost at 1 January	308	296	6,074	6,012	74	59
Additions	2	-	123	47	51	-
Exchange adjustment	(6)	12	(178)	15	-	15
<b>Cost at 31 December</b>	<b>304</b>	<b>308</b>	<b>6,019</b>	<b>6,074</b>	<b>125</b>	<b>74</b>
Amortization / Depreciation / Impairment loss at 1 January	(163)	(130)	(5,585)	(5,391)	(74)	(59)
Amortization / Depreciation	(27)	(33)	(177)	(183)	(4)	-
Exchange adjustment	-	-	178	(11)	-	(15)
<b>Amortization / Depreciation / Impairment loss at 31 December</b>	<b>(190)</b>	<b>(163)</b>	<b>(5,584)</b>	<b>(5,585)</b>	<b>(78)</b>	<b>(74)</b>
<b>Net book value at 31 December</b>	<b>114</b>	<b>146</b>	<b>435</b>	<b>488</b>	<b>47</b>	<b>-</b>

Parent	Patent rights & Software		Property, Plant & Equipment	
	2016	2015	2016	2015
(USD'000)				
Cost at 1 January	187	187	5,977	5,944
Additions	-	-	-	33
Exchange adjustment	(5)	-	(178)	-
<b>Cost at 31 December</b>	<b>182</b>	<b>187</b>	<b>5,799</b>	<b>5,977</b>
Amortization / Depreciation / Impairment loss at 1 January	(139)	(130)	(5,516)	(5,344)
Amortization / Depreciation	(4)	(9)	(149)	(172)
Exchange adjustment	-	-	174	-
<b>Amortization / Depreciation / Impairment loss at 31 December</b>	<b>(142)</b>	<b>(139)</b>	<b>(5,491)</b>	<b>(5,516)</b>
<b>Net book value at 31 December</b>	<b>40</b>	<b>49</b>	<b>308</b>	<b>461</b>

## Note 10. Investment in Subsidiary

	Parent	
	2016	2015
(USD'000)		
Cost at 1 January	380	380
Exchange adjustment	(12)	-
<b>Cost at 31 December</b>	<b>368</b>	<b>380</b>

Veloxis Pharmaceuticals, Inc. was established as a wholly owned subsidiary as at 2 January 2007. This subsidiary is incorporated in Delaware and is the Group's vehicle for all commercial activities.

**Note 11. Inventories**

(USD'000)	Consolidated		Parent	
	2016	2015	2016	2015
Raw materials	3,134	1,881	-	1,881
Work in Process	313	-	-	-
Finished goods	694	606	-	606
<b>Total</b>	<b>4,141</b>	<b>2,487</b>	<b>-</b>	<b>2,487</b>

The total consumption of materials included in cost of sales amounted to USD 1,944 (2015: USD 788).

Cost of sales include an inventory write down of USD 215. (2015: USD 580).

**Note 12. Share Capital**

On 31 December 2016 the total number of outstanding shares was 1,703,373,881. Each share has a nominal value of DKK 0.1 and one vote.

**Changes in share capital from 2010 to 2016**

The table below sets forth the changes in our issued share capital since 2010:

Year	Transaction	Share Capital	Share classes after capital increase	Share price in DKK	
				pre bonus shares	post bonus shares range
2010	Cash contribution	395,974,670 <sup>(1)</sup>	452,542,480 shares	-	1.20
2012	Cash contribution	1,206,779,946 <sup>(2)</sup>	1,659,322,426 shares	-	0.35
2013	Cash contribution	1,250,000 <sup>(3)</sup>	1,660,572,426 shares	-	0.35
2014	Cash contribution	2,424,888 <sup>(4)</sup>	1,662,997,314 shares	-	0.35 - 1.16
2015	Cash contribution	786,261 <sup>(5)</sup>	1,663,783,575 shares	-	0.35 - 1.23
2016	Cash contribution	39,590,306 <sup>(6)</sup>	1,703,373,881 shares	-	0.35 - 1.05

**Notes:**

There were no transactions in 2011.

**Note 13. Non-Current Debt**

Veloxis has entered into a five-year loan and security agreement with Lundbeckfond invest A/S and Novo A/S for up to USD 30,000 in financing. The facility may be utilized in tranches and repaid without penalty. It carries a 9.25% interest rate for balances up to USD 20,000 and a 12% interest rate for balances in excess of USD 20,000. Interest is payable annually in areas and no principal



payments are required until the maturity of 8 March, 2021. The amended and restated agreement also provides for a third additional facility in the amount of USD 5 million to be made available at the discretion of Lundbeckfond Invest A/S and Novo A/S if requested by Veloxis.

The loan and security agreement carries with it several covenants regarding cash coverage and financial ratios as compared with the company's latest consolidated budget. Management monitors compliance with these covenants quarterly.

### **Note 14. Financial Risks**

#### **Interest Rate Risk**

Veloxis has interest-bearing debt with fixed interest rates. Our interest rate risk is therefore limited to our cash and cash equivalent balances. Veloxis's treasury policy allows the Company to hold excess cash at deposits with major Danish and US banks and in short-term Danish and US government bonds or Danish mortgage bonds with limited duration. All positions carry variable interest rates. At the end of 2016, Veloxis had limited cash position and none or insignificant interest rates making any interest rate fluctuations immaterial to financial income and equity.

#### **Cash Management**

The Company's Finance function ensures that Veloxis has sufficient and flexible financial resources at its disposal. Veloxis's short-term liquidity is managed with quarterly budget reviews to balance the demand for liquidity needs.

#### **Capital Structure**

It is the Company's aim to have an adequate capital structure in relation to the underlying operating results and commercialization activities, so that it is always possible to provide sufficient capital to support operations and its long term growth targets. The Board of Directors determined that the current capital and share structure is appropriate for the shareholders and the company.

#### **Credit Risk**

The credit terms on the Company's receivables are considered to be at market conditions, and the Company has not encountered any losses as a result of credit risk during the years presented. In regards to cash deposits, the Company's two major banks have credit ratings of A1 and Aa1 according to Moody's. The credit risk ascribable to the Company's receivables is considered low as such receivables arise from collaboration agreements with wholesale distributors.

#### **Liquidity Risk**

The Company is exposed to liquidity risk arising from short-term payables.

#### **Currency Exposure**

Veloxis is subject to currency risk, as the Company incurs income and expenses in a number of different currencies, mainly DKK and EUR. Changes in exchange rates of such foreign currencies towards the Company's functional currency may affect the results and cash position.

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The Company's cash balances in foreign currencies is stated below:

	Consolidated		Parent	
	2016	2015	2016	2015
USD'000	1,266	4,846	242	2,233
EUR'000	964	419	964	419
DKK'000	1,129	-	1,129	-
GBP'000	-	(2)	-	(2)
CAD'000	-	(2)	-	(2)

All net positions are current.

The carrying amount approximately equals the fair value. Changes in currencies may affect future income and expenses in such foreign currencies, and may have a significant impact on the Company's operating results and cash flows. The Company is primarily exposed to such risk from currency fluctuations between USD and EUR. Based on the USD position at the end of 2016, a 10% change in the USD / EUR rate will impact result and equity with approximately USD 127 (2015: USD 485).

### Note 15. Warrants

Veloxis has established warrant programs for board members, members of executive management and employees. All warrants have been issued by the Company's shareholders or by the board of directors pursuant to valid authorizations in Veloxis's articles of association.

#### Vesting Conditions

Warrants issued since May 2008 vest in general at 1/36 per month from the date of grant, subject to the employees continued employment. Warrants issued to executive management since 7 April 2016 vest 1/3 on 10 December 2016 with the remaining 2/3 vesting in twenty-four (24) equal monthly installments. However, some warrants are not subject to vesting conditions, but vest in full at the time of grant.

Warrants granted to employees in affiliates cease to vest upon termination of the employment relationship regardless of the reason for such termination. Warrants granted to employees employed in the parent company cease to vest from the date of termination in the event that (i) a warrant holder resigns without this being due to the Company's breach of contract, or (ii) if Veloxis terminates the employment relationship where the employee has given the Company good reason to do so. The warrant holder will, however, be entitled to exercise vested warrants in the first coming exercise period after termination.

Exercise of warrants issued to board members are conditional upon the warrant holder being connected to Veloxis on the date of exercise. However, if the warrant holder's position has been terminated without this being attributable to the warrant holder's actions or omissions, the warrant holder shall be entitled to exercise vested warrants in the pre-determined exercise periods.

#### Term of Granted Warrants

The maximum term for all granted warrants is 7 years.

#### Exercise Periods

Vested warrants may generally be exercised during four four-week periods following publication of Veloxis's preliminary annual report and Veloxis's quarterly interim reports.

### Warrant Activity

The following table specifies the warrant activity:

	Employees	Executive management	Board of directors	Total	Weighted average exercise price DKK
<b>Outstanding as of 1 January 2015</b>	<b>38,805,637</b>	<b>61,279,081</b>	<b>635,417</b>	<b>100,720,135</b>	<b>0.71</b>
Granted in the year	14,599,143	15,091,700	4,748,092	34,438,935	0.95
Exercised in the year	(586,261)	(200,000)	-	(786,261)	0.41
Cancelled in the year	(13,787,125)	-	-	(13,787,125)	0.98
Expired in the year	(1,411,407)	-	(29,861)	(1,441,268)	7.80
Change between categories	55,569,062	(55,323,229)	(245,833)	-	-
<b>Outstanding as of 31 December 2015</b>	<b>93,189,049</b>	<b>20,847,552</b>	<b>5,107,815</b>	<b>119,144,416</b>	<b>0.67</b>
Granted in the year	19,202,073	67,420,261	5,499,917	92,122,251	1.40
Exercised in the year	(39,590,306)	-	-	(39,590,306)	0.36
Cancelled in the year	(38,281,833)	-	-	(38,281,833)	0.76
Expired in the year	(1,260,889)	-	(29,860)	(1,290,749)	3.55
Change between categories	22,901,344	(20,847,552)	(2,053,792)	-	-
<b>Outstanding as of 31 December 2016</b>	<b>56,159,438</b>	<b>67,420,261</b>	<b>8,524,080</b>	<b>132,103,779</b>	<b>1.21</b>
<b>Weighted average exercise price DKK</b>	<b>0.98</b>	<b>1.43</b>	<b>1.08</b>	<b>1.21</b>	

As at 31 December 2016, a total of 132,103,779 warrants were outstanding with a weighted average exercise price of DKK 1.21. 57,383,970 of these warrants had vested and are exercisable as at 31 December 2016 with a weighted average exercise price of DKK 1.02. For comparison, as at 31 December 2015, a total of 119,144,416 warrants were outstanding with a weighted average exercise price of DKK 0.67.

### Warrant Compensation Costs

Warrant compensation costs are calculated at the date of grant by use of the Black-Scholes valuation model with the following assumptions: (i) a volatility of 52%, determined as the average of the stock price volatility based on Veloxis's historical share prices since its Initial Public Offering in November 2006; (ii) no payment of dividends; (iii) a risk free interest rate equaling the interest rate on a 5-year government bond on the date of grant; and (iv) a life of the warrants determined as the average of the date of becoming exercisable and the date of expiry.

Warrant compensation costs are recognized in the income statement over the vesting period of the warrants granted.

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During 2016, a total of USD 5,430 was recognized as share-based compensation compared with USD 1,797 in 2015.

The entire warrant compensation costs for 2016 was allocated to selling, general and administrative costs.

### Value of Granted Warrants

The fair value at the grant date has been calculated under the Black-Scholes option pricing model, adjusted for dilution of share capital, based on the following assumptions:

	Granted 7 April 2016	Granted 19 May 2016	Granted 25 August, 2016	Granted 17 November 2016
Share price at grant (DKK)	1.43	1.24	1.32	1.09
Volatility (%)	52	52	52	52
Exercise price (DKK)	1.43	1.24	1.32	1.09
Risk-free interest rate for options (%)	0%	0%	0%	0%
Annual dividend per share (DKK)	-	-	-	-
Years to expiry	7	7	7	7
Exercise period	2023	2023	2023	2023
Market value at grant (DKK'000)	48,390	1,849	2,170	1,246

The following table specifies the weighted average exercise price and the weighted average life of outstanding warrants:

Year of grant	Number of granted warrants	Number of outstanding warrants	Weighted average exercise price (DKK)	Weighted average contractual life (months)	Exercise price range (DKK)
2010	22,230,855	2,943,500	1.34	9.28	1.05 - 2.03
2011	4,665,291	488,466	1.15	15.45	1.00 - 1.23
2012	59,047,200	12,489,100	0.35	34.45	0.35
2013	20,930,000	2,235,900	0.36	37.28	0.36 - 0.63
2014	25,772,756	8,177,936	1.03	51.44	0.95 - 1.86
2015	34,438,935	14,982,835	0.95	63.51	0.86 - 1.06
2016	92,122,251	90,786,042	1.40	75.70	1.09 - 1.43
<b>31 December 2016</b>	<b>259,207,288</b>	<b>132,103,779</b>	<b>1.21</b>	<b>66.56</b>	

**Note 16. Other Commitments**

	Consolidated		Parent	
	2016	2015	2016	2015
<b>(USD'000)</b>				
Operating lease commitments regarding offices	1,482	127	-	36
Operating lease commitments regarding property, plant and equipment	83	128	55	119
<b>Total operating lease commitments</b>	<b>1,565</b>	<b>255</b>	<b>55</b>	<b>155</b>
<b>Total operating lease payments fall due:</b>				
Within 1 year	343	199	55	101
From 1 to 5 years	1,222	56	-	54
After 5 years	-	-	-	-
<b>Total</b>	<b>1,565</b>	<b>255</b>	<b>55</b>	<b>155</b>
Expensed operating lease payments	451	201	106	65

**Note 17. Related Parties****Shareholders with Significant Influence**

- Lundbeckfond Invest A/S 42.9% (100% owned by the Lundbeck Foundation), Denmark, municipality of Copenhagen
- Novo A/S 42.9% (100% owned by the Novo Nordisk Foundation), Denmark, municipality of Gentofte

During 2016 Veloxis entered into a loan and security agreement with Lundbeck Invest A/S and Novo A/S as discussed further in Note 13. There were no transactions with the shareholders in 2015.

**Members of the Executive Management and Board of Directors**

The members of the Executive Management and Board of Directors are considered related parties following their positions in the Company.

The Executive Management and the Board of Directors have received remuneration from Veloxis, including warrants, as described in note 5 and note 15 to the financial statements.

**Veloxis Pharmaceuticals, Inc.**

In the separate financial statements of the Parent Company, Veloxis Pharmaceuticals, Inc. is considered a related party, as this company is a wholly owned subsidiary of Veloxis Pharmaceuticals A/S.

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During 2016, the subsidiary has performed marketing and managerial activities on behalf of the Parent Company, which has been remunerated in accordance with the service agreements between the companies. Total services amount to USD 981 for the year 2016 (2015: USD 11,045). In addition, Further, the subsidiary has paid interest expenses of USD 1,457 for the period 1 January to 31 December 2016 due to internal transactions between the two companies (2015: expenses of USD 5).

At 31 December 2016, the Parent Company had a net receivable from Veloxis Pharmaceuticals, Inc. totaling USD 26,371 (2015: Debt USD 1,041).

### Other Related Parties

Other related parties may exist as the members of Veloxis's Board of Directors and Executive Management hold positions as Board members in other companies, and as the shareholders of Veloxis may also be shareholders of other companies. Except for the companies listed above, Veloxis has not identified any such parties as related parties and no transactions have been identified as related party transactions as we are not aware of such relationships.

### Note 18. Changes in Working Capital

(USD'000)	Consolidated		Parent	
	2016	2015	2016	2015
Trade receivables	(1,350)	(871)	293	(294)
Other receivables	502	(210)	508	(215)
Prepayments	(198)	9	8	324
Inventories	(1,654)	(1,817)	2,487	(1,817)
Trade payables	(2,000)	345	(2,838)	344
Deferred revenue	(539)	548	-	-
Other payables	(949)	1,975	(352)	(21)
Exchange gains/(losses)	401	-	420	-
<b>Total</b>	<b>(5,787)</b>	<b>(21)</b>	<b>526</b>	<b>(1,679)</b>

### Note 19. Fees to Auditors Appointed by the Annual General Meeting

(USD'000)	Consolidated		Parent	
	2016	2015	2016	2015
<b>PricewaterhouseCoopers</b>				
Audit	63	48	63	48
Tax Services	59	23	59	23
Other assurance engagements	3	2	3	2
Other services	38	55	38	55
<b>Total</b>	<b>163</b>	<b>128</b>	<b>163</b>	<b>128</b>

## Parent Company

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