

# ANNUAL REPORT 2015

Veloxis Pharmaceuticals A/S Agern Allé 24 2970 Hørsholm, Denmark CVR No.: 26 52 77 67

The Annual Report was presented and approved at the Annual General Meeting on / 06.04.2016

Thomas Holst Laursen

**Chairman of the meeting** 

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## To our shareholder

### Dear Shareholder,

Veloxis stands well prepared to meet new opportunities and to grow our business in 2016. We have recently hired Craig A. Collard as President and CEO who brings extensive commercial experience. We have a comfortable net-cash position and have secured additional financing The commercialization prospects for Envarsus® XR are good and we have a strong shareholder base.

2015 was a busy and eventful year for the Company/Veloxis. We achieved several significant milestones, most notably, the U.S. Food and Drug Administration (FDA) marketing approval in July of Envarsus® XR for kidney transplant patients who require or desire conversion from other twice-daily tacrolimus products to once-daily Envarsus® XR.

Following marketing approval, Envarsus® XR was granted Orphan Drug status by the FDA in August 2015. The Orphan Drug status allows the Company to have seven years of market exclusivity in the U.S. The product exclusivity is also protected by our patents surrounding our MeltDose technology which extends beyond 2022.

Veloxis launched Envarsus® XR in the U.S. market in December 2015 and is selling the product through our own sales force. The field-based team is supplemented by regional field-based reimbursement specialist, medical affairs personnel, and supported by our in-house sales, marketing, reimbursement and medical affairs team. Our commercial team consists of employees with extensive experience and skills in commercializing specialty products, specifically transplant products.

The commercialization of Envarsus® in Europe through our partnership with Chiesi is progressing as planned. The product was launched in 2015 in most of the EU countries and will be launched in the remaining countries in 2016. We have experienced solid uptake across countries with particularly good uptake in France and Spain.

At Veloxis, our medical efforts continually focus on further differentiating Envarsus®XR from our competitors' products through convincing clinical study results. We have generated successful results in demonstrating the potential of Envarsus®XR to reduce troubling tremors among patients who develop tremors while on competing products. In addition, the study data yielded evidence of potential superiority in two important patient subgroups: African-American patients and patients older than 65 years, both important demographic groups.

We thank our shareholders and employees for their support during 2015 and look forward to another successful year as we progress in our commercialization activities.

Yours sincerely, Mette Kirstine Agger

Mette Kirstine Agger Craig A. Collard
Chairman President & CEO

# Highlights 2015

### **Change in management**

10 December, Veloxis announced that Craig A. Collard had been hired as President and CEO. Craig A. Collard has more than 20 years' track record of strategic and tactical leadership within the pharmaceutical industry. He replaces William J. Polvino.

### Launch of Envarsus® XR for Treatment of Kidney Transplant Patients in U.S.

7 December, Veloxis announced the U.S. launch of Envarsus® XR (tacrolimus extended-release tablets) for the prophylaxis of rejection in kidney transplant patients who require or desire conversion from immediate release tacrolimus products to oncedaily Envarsus® XR.

### Establishment of Sponsored Level 1 ADR Program in U.S.

14 October, Veloxis announced the establishment of a sponsored Level 1 American depositary receipt (ADR) program in the U.S. The ADR trades under the symbol VXPZY.

Envarsus® XR Granted Orphan Drug Status by U.S. Food and Drug Administration for Kidney Transplant Rejection Prophylaxis 14 August, Veloxis announced that Envarsus® XR was granted Orphan Drug status by the U.S. Food and Drug Administration (FDA) for prophylaxis of organ rejection in patients who convert from immediate-release tacrolimus.

### FDA Approval of Envarsus® XR for Treatment of Kidney Transplant Patients

10 July, Veloxis announced FDA approval of Envarsus® XR for the prophylaxis of rejection in kidney transplant patients who require or desire conversion from other twice-daily tacrolimus products to once-daily Envarsus® XR.

# Envarsus® XR Demonstrated Differentiated Pharmacokinetic Profile Compared to Twice-Daily Prograf® or Once-Daily Astagraf XL® in Stable Kidney Transplant Patients

24 June, Veloxis announced top-line results of the ASTCOFF study, A STeady-state Pharmacokinetic COmparison Of all Formulations, demonstrating that once-daily Envarsus® XR achieved differentiated pharmacokinetics (PK) when compared to twice-daily tacrolimus (Prograf®) or a once-daily tacrolimus product (Astagraf XL®).

### Envarsus® XR Demonstrated Improved Pharmacokinetic Profile in African-American Transplant Recipients

4 May, Veloxis announced that once-daily Envarsus® XR 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.

# Outlook 2016

#### Outlook

We expect an operating loss of DKK 120 - 160 million compared to the realized operating loss of DKK 192 million in 2015. Net loss is also expected to be in the range of DKK 120 - 160 million compared to the net loss of DKK 175 million in 2015.

# Important events following the balance sheet date

### **Material events**

29 February, Veloxis announced that Alastair McEwan has been appointed as Chief Operating Officer. Alastair McEwan has been involved in pharmaceutical development and commercialization for over twenty years and brings substantial operational and financial experience to the Company.

Veloxis has 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 mat be utilized in tranches and repaid without penalty. It carries a 9.25% interest rate, payable annually in arrears.

# Veloxis business strategy

Veloxis is a specialty pharmaceutical company with a singular focus on meeting the needs of the global transplant community. Veloxis markets and sells Envarsus® XR (tacrolimus extended-release tablets) in the US, and supports the commercial efforts of our partner to sell Envarsus® in Europe, Turkey and CIS Countries.

Veloxis markets and sells Envarsus® XR in the US through our dedicated specialized commercial infrastructure that launched Envarsus® XR into the US marketplace in December 2015.

Veloxis has a partnership agreement with Chiesi in respect of the commercialization of Envarsus® in Europe, Turkey and CIS Countries. Chiesi has launched Envarsus® in most EU countries and will continue to roll out launches through 2016 and beyond.

# Commercial update

Veloxis launched Envarsus® XR into the U.S. market in December 2015, selling the product through the company's own specialized dedicated transplant sales force. The commercial infrastructure includes field based sales personnel, supplemented by regional field-based reimbursement and medical affairs personnel, and supported by an in-house marketing, reimbursement and medical affairs team. The commercial team includes people with extensive experience and skill in commercializing specialty, and specifically transplant products.

Prior to launch, the sales force was trained and tasked with visiting all 200 transplant centers in the US by year end, a goal that was achieved. Within those centers, the field force has interacted with the decision makers for drug formulary inclusion as well as the key members of the transplant team (surgeons, nephrologists, transplant pharmacists, nurse coordinators, financial advisors and social workers). The months of October and November were used to educate the centers on the approval of Envarsus® XR in the US and to set up appointments to discuss the product in detail once officially launched with the intent of driving rapid use of the brand in 2016. Upon approval the field-force began performing regular sales calls to the target transplant centers and physicians and has seen strong initial interest in the product.

Market access and reimbursement are challenges in the current day U.S. healthcare landscape and this has been a priority area of focus for the Veloxis commercial team. Our access and reimbursement team has been working diligently to ensure that Envarsus® XR is available to providers and patients. One-month post launch we are very pleased to report that Envarsus® XR enjoys unrestricted access in > 60 % of commercially insured lives across the US. Additionally, we have been engaged with all the appropriate state and federal agencies to continue to expand Envarsus® XR formulary coverage and maximize patient and provider access for this critical medication.

Veloxis has a partnership agreement with Chiesi in respect of the commercialization of Envarsus® in Europe, Turkey and CIS Countries. Chiesi launched Envarsus® in most EU countries during 2015, with the remaining countries expected to launch in 2016 once local pricing requirements are addressed. Envarsus® has seen solid uptake across the launched countries, with particularly good uptake seen in France and Spain which launched in the second half of 2015.

### Regulatory

On 10 July, 2015, the FDA granted marketing approval of Envarsus® XR (tacrolimus extended-release tablets) for the prophylaxis of rejection in kidney transplant patients who require or desire conversion from other twice-daily tacrolimus products to oncedaily Envarsus® XR.

On 14 August, 2015, Envarsus® XR was granted Orphan Drug status by the FDA for prophylaxis of organ rejection in patients who convert from immediate-release tacrolimus.

# Envarsus® for transplantation

Envarsus® 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® 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® 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	Phase II - <i>De novo</i> liver transplant patients	Completed 4Q 2010
(Not in active development)	Phase II - Stable liver transplant patients	Completed 3Q 2009

### Clinical overview and update

### Kidney - Phase III clinical studies

A Phase III programme in kidney transplant patients was initiated in the second half of 2008. The programme 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.

### 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 enrolment 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 hrs compared to both Prograf and Astagraf. The data from this study was presented at the European Society for Transplantation in September, 2015.

## **Financial Review**

#### Revenue

During 2015, Veloxis recognized revenue from commercial sales of DKK 14.2 million compared to DKK 3.2 million in 2014. Revenue in 2014 also consist of DKK 120.2 million of up-front and milestone payments under Veloxis' distribution agreement with Chiesi Farmaceutici S.p.A.

### Sales & marketing cost

Sales and marketing costs increased from DKK 41.3 million in 2014 to DKK 66.2 million in 2015. This reflects the hiring and building of the marketing and sales infrastructure in the U.S. Envarsus® XR was launched in the U.S. in December 2015.

On an overall basis, sales and marketing costs account for 33.8% of total cost of operations.

### Research & development cost

Research and development costs decreased from DKK 90.1 million in 2014 to DKK 76.3 million in 2015. The reduction in cost is associated with the overall reduction in study activity as studies are being completed.

On an overall basis, research and development costs account for 38.9% of total cost of operations. The comparable figure for 2014 was 50.4%.

### **Administrative expenses**

Administrative expenses increased from DKK 47.4 million in 2014 to DKK 53.6 million in 2015.

### **Share-based compensation cost**

During 2015, a total of DKK 12.3 million was recognized as share-based compensation. The comparable number for 2014 was DKK 9.7 million.

### **Operating result**

During 2015, Veloxis recognized DKK 197.1 million in operating loss compared to DKK 58.6 million in 2014.

### **Financial items**

Net financial items decreased by DKK 6.3 million, from an income of DKK 20.9 million in 2014 to an income of DKK 14.6 million in 2015. The income in 2015 is mainly attributable to exchange rate gains due to the increase in the USD/DKK exchange rate.

#### **Net result**

During 2015, Veloxis recognized DKK 176.1 million in net loss compared to DKK 36.3 million in 2014.

The net loss is in line with management's expectations for 2015 as reported on 26 August 2015 in connection with the second quarter interim report, which projected a net loss of DKK 155 - 185 million.

### Management review

### **Cash Flow**

As per 31 December 2015, the balance sheet reflects cash and cash equivalents of DKK 107.7 million compared to DKK 270.4 million as per 31 December 2014. The decrease in cash position reflects the changes in operating activities in 2015.

The cash position is in line with management's expectations for 2015, which projected a cash position at the end of 2015 of DKK 100 - 130 million.

### **Balance sheet**

As per 31 December 2015, total assets were DKK 149.0 million compared to DKK 293.7 million at the end of 2014.

Shareholders' equity equaled DKK 89.7 million as of 31 December 2015, compared to DKK 253.2 million at the end of 2014.

# Financial highlights - Consolidated

DKK'000	2015	2014	2013	2012	2011
Income Statement					
Revenue	14,150	123,395	38,148	6,868	-
Production costs	(15,139)	(3,247)	-	-	-
Gross profit	(989)	120,148	38,148	6,868	-
Sales and marketing costs	(66,192)	(41,278)	-	-	-
Research and development costs	(76,319)	(90,111)	(146,512)	(210,739)	(222,053)
Administrative expenses	(53,600)	(47,363)	(27,771)	(36,889)	(47,814)
Operating result before restructuring cost	(197,100)	(58,604)	(136,135)	(240,760)	(269,867)
Restructuring cost	-	-	-	(21,462)	-
Operating result	(197,100)	(58,604)	(136,135)	(262,222)	(269,867)
Net financial income / (expenses)	14,586	20,903	(4,426)	(850)	16,048
Result before tax	(182,514)	(37,701)	(140,561)	(263,072)	(253,819)
Tax for the period	6,408	1,382	1,250	363	1,193
Net result for the period	(176,106)	(36,319)	(139,311)	(262,709)	(252,626)
Statement of Financial Position					
Cash and cash equivalents	107,658	270,434	328,652	496,834	297,727
Total assets	148,953	293,723	348,863	509,271	320,927
Share capital	166,379	166,300	166,057	165,932	452,543
Total equity	89,659	253,248	279,042	409,737	255,900
Investment in property, plant and equipment	324	1,805	1,055	260	2,981
Cash Flow Statement					
Cash flow from operating activities	(177,348)	(77,243)	(157,747)	(205,870)	(234,637)
Cash flow from investing activities	(324)	(2,547)	(1,055)	169,712	(169,778)
Cash flow from financing activities	323	989	(3,227)	404,304	(5,948)
Cash and cash equivalents at period end	107,658	270,434	328,652	496,834	297,727
Financial Ratios					
Basic and diluted EPS (DKK)	(0.11)	(0.02)	(0.08)	(0.43)	(0.56)
Weighted average number of shares	1,663,334,241	1,662,266,639	1,660,353,248	607,511,489	452,542,480
Average number of employees (FTEs)	38	26	26	48	52
Assets/equity	1.66	1.16	1.25	1.24	1.25
Share price	1.75	1.15	0.70	0.34	0.83

# People

At year end 2015 Veloxis employed 50 people in our two locations in Hørsholm, Denmark and New Jersey, USA. 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 of 31 December 2015, 50% of the employees were in sales & marketing (S&M), 38% were in research and development (R&D) and 12% were in general and administration (G&A).

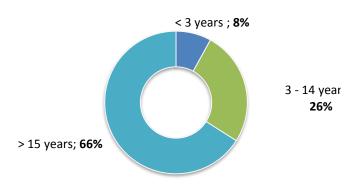
### **Educational background**

It is a prerequisite for Veloxis' activities that our employees are both highly motivated and well educated. 54% of Veloxis' employees have a university degree at a master's level or above. Our team is also highly experienced in that 66% of our employees have been employed in the biotech or pharmaceutical industry for more than 15 years.



G & A; 12% S & M; 50%

### Employees' experience in biotech or pharma



# Corporate governance & risk management

As a company listed on NASDAQ OMX Copenhagen, Veloxis must be in compliance with Danish securities law and it is Veloxis' intent to be guided by the Corporate Governance Recommendations designated by NASDAQ OMX Copenhagen. NASDAQ OMX Copenhagen has on a comply or explain basis designated the Danish Recommendations on Corporate Governance (May 2013 and updated November 2014) prepared by the Danish Committee on Corporate Governance. Veloxis' position and our compliance with these recommendations are summarized below and the full reporting of Veloxis' governance practice in accordance with the Danish Financial Statements Act, section 107b can be found on our webpage http://www.veloxis.com/governance.cfm.

### **Practices of the Board of Directors**

The Articles of Association stipulate that the Board of Directors is elected by the Company's shareholders at the annual general meeting and members are elected for one-year terms. Members may stand for re-election for successive terms. The Board of Directors shall consist of not less than three and no more than nine members elected by the Company's shareholders at the general meeting. The Board of Directors has established a Remuneration Committee, Nomination Committee and an Audit Committee.

In 2015, the Board met physically five times. All meetings were attended by all board members. In addition the Board had 17 meetings held as conference calls; all meetings were attended by all board members. Further the Audit Committee met physically four times during the year, and the Remuneration Committee had two meetings during the year.

### **Board composition**

In order to secure the right competencies and promote diversity, the following targets have been set for the composition of the Board of Directors:

- At least half of the board members shall be independent in accordance with the Danish Code on Corporate Governance
- · At least half of the shareholder-elected board members shall have substantial pharmaceutical experience
- One-third or more of the board members shall be female, and one-third or more of the board members shall be male

Bullet one and two were met in 2015.

Regarding bullet three on gender composition the Board of Directors has maintained its ambition and set out targets to be reached within a two-year period, to allow for continuity of the board. This fulfills the requirements of section 99b of the Danish Financial Statements Acts.

### Danish recommendations on corporate governance

- 1. Communication and interaction by the company with its investors and other stakeholders Veloxis complies with these recommendations.
- 2. Tasks and responsibilities of the board of directors

  Veloxis complies with these recommendations, with the following exceptions:
- 2.1 Overall tasks and responsibilities

Veloxis support equal opportunities for both sexes and annually discuss the company's activities to ensure diversity. Veloxis is a small company and do not intend to formalize objectives for the time being.

### 3. Composition and organization of the board of directors

Veloxis complies with these recommendations.

### 4. Remuneration of management

Veloxis complies with these recommendations, with the following exceptions:

### 4.1 Form and content of the remuneration policy

Veloxis believes that the ability to offer warrants as well as other forms of shares as incentive compensation is necessary to attract key people from the industry (whether as board members, managers or employees).

### 4.2 Disclosure of remuneration policy

The total remuneration to each member of the board and the executive management is not disclosed in the annual report. The total remuneration to the entire board and the entire executive management, respectively, is disclosed together with an explanation of the components. It is the company's judgment that disclosure of the remuneration paid to each individual member of the Executive Management will not add additional value for shareholders and other stakeholders.

### 5. Financial reporting, risk management and audits

Veloxis complies with these recommendations.

### **Guidelines for incentive pay**

### **Board members**

Members of the Board of Directors receive a fixed annual fee. The Chairman of the Board of Directors and the Chairman of the Audit Committee, Chairman of the Remuneration Committee and Chairman of the Nomination Committee receive a supplement to the fixed annual fee.

In addition to the fixed annual fee, the members of the Board of Directors are annually granted a fixed number of warrants. The estimated present value of warrants granted in a given financial year to the members of the Board of Directors is calculated in accordance with the International Financial Reporting Standards (IFRS). The general terms and conditions applying to the grant, vesting, exercise, etc. of the warrants must be within the general terms and conditions applying if warrants are to be granted to members of the Executive Management, cf. below, and which also apply to other employees in the Company which has been granted warrants.

### **Executives**

The Remuneration Committee performs an annual review of the remuneration package paid to members of the Executive Management.

The remuneration paid to members of the Executive Management consists of a fixed and a variable part. The fixed pay consists of cash salary, pension contribution and other benefits.

As an element of the variable pay, members of the Executive Management may receive an annual bonus, subject to achievement of certain benchmarks. The bonus proportion varies among the members of the Executive Management, but cannot exceed 100 % of the fixed annual cash salary. The actual bonus paid to the members of the Executive Management is disclosed in the Annual Report at an aggregated level. At the date of adoption of these guidelines, the bonus benchmarks comprise primarily of the

progress in the Company's development of its product candidates, but they may be changed by the Board of Directors. The remuneration paid to members of the Executive Management is disclosed on page 40.

In addition to the annual bonus (see above), the Board of Directors is authorised to offer the members of the Executive Management a bonus equal to 24 months' base salary in order to seek that the members of the Executive Management in question remain employed by the Company to ensure continuation of the Company operations.

Another element of the variable pay is made up of new warrants and is intended to ensure that the Executive Management's incentive correlates with creation of shareholder value. The estimated aggregated present value of new warrants granted in a given financial year to the members of the Executive Management may be up to 100 % of the aggregated fixed annual cash salary to the member of the Executive Management at the time of the grant. The estimated present value is calculated in accordance with the International Financial Reporting Standards (IFRS). The grant of new warrants may or may not be subject to achievement of defined benchmarks. The exercise price of the new warrants cannot be less than the market price of the Company's stock at the date of grant. The new warrants may have a maximum term of up to 7 years and the exercise of the new warrants may be subject to a vesting period of up to 4 years. New warrants may be granted on such terms that the gain is taxed as share income while the costs of the grant are not tax deductible for the Company. The number of new warrants granted to members of the Executive Management is disclosed on page 41.

### **Collaboration and license agreements**

Veloxis has not entered into any significant collaboration and license agreements with external parties, which are subject to renegotiation in case of a change of control event in Veloxis.

### Statutory report on corporate social responsibility

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

Veloxis is a speciality 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 support and promote a good working environment for employees, good business conduct, and reasonable environmental and social standards with those with whom we do business.

### **Working environment**

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

- Assessment of absent due to the working environment.
- Assessment of incidents and nearby incidents related to working environment.
- Established a WESO (Work Environment Safety Organization) group which meet three times a year.

Throughout the year only a few minor incidents have occurred and have been handled by the WESO organization as part of their work and oversight.

### **Business partners and suppliers**

Our policy for business partners and suppliers is incorporated into our quality assurance system. When entering into agreements with external business partners and suppliers we ensure that we have a right to make control visits to our external business partners and suppliers to ensure that our requirements are met.

During the year we have performed 9 visits and audits (11 in 2014) 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.

### **Risk management**

Veloxis is exposed to certain risks. Some of these may significantly affect our ability to execute our strategy. We categorize these as critical risks – and we have a program in place to ensure that we proactively identify, manage and mitigate them.

Veloxis is exposed to critical risks within such areas as commercialization, research and development, financial management, currency exposure, legal affairs and in relation to the financial reporting process.

Commercial risk factors include risks related to market acceptance, effective commercialization, and competition related to Envarsus® and Envarsus® XR, as well as the ability to attract and retain employees and partners. We continuously monitor and evaluate the market development of, and the competitive landscape for, our products and product candidates to proactively manage applicable risks.

Veloxis has a whistleblower system that all employees can use anonymously if they experience non-compliance with Veloxis' policies and procedures. No incidents have been reported during the year.

As required under the Danish Financial Statements Act, Section 107b, we have on our webpage http://www.veloxis.com/governance.cfm. included Veloxis Pharmaceuticals' statutory report on Corporate Governance, which describes our risk management processes in greater details and how we manage these risks.

# Shareholder Information

Veloxis strives to maintain 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 where such information is considered important to the pricing of its shares.

Veloxis has during 2015 had several meetings with existing and potential shareholders, which includes meetings in in Europe as well as the US.

### **About our shares**

Veloxis' 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 SmallCap segment of the Danish companies on the NASDAQ OMX Copenhagen. Further Veloxis has a sponsored Level 1 American depositary receipt (ADR) program in the U.S. The ADR trades under the symbol VXPZY.

### **Share capital**

As of 31 December 2015 Veloxis had a registered share capital of DKK 166,378,357.50 with a nominal value of DKK 0.1 per share. 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 2016 to arrange for the Company to acquire its own shares up to a nominal value of 10% of the nominal share capital. The purchase price of such shares may not differ by more than 10% from the price quoted on the NASDAQ OMX Copenhagen at the time of purchase.

### **Ownership structure**

As of 31 December 2015, a total of 7,055 of Veloxis' shareholders were registered in the shareholder register. An increase from 6,373 shareholders as per 31 December 2014. Veloxis invites all shareholders to register in the Company's shareholder register.

The following shareholders have reported ownership of 5% or more of the Company's shares:

- Lundbeckfond Invest A/S 42.7% (100% owned by the Lundbeck Foundation), Denmark, municipality of Copenhagen
- Novo A/S 42.7% (100% owned by the Novo Nordisk Foundation), Denmark, municipality of Gentofte

### **Company announcements during 2015**

During 2015 the company issued 27 company announcements. These can be found on Veloxis' website: http://www.veloxis.com/releases.cfm.

### Financial calendar 2016

9 March, 2016 Annual report 2015 6 April, 2016 (1 PM) Annual General Meeting

Venue: Søhuset, Venlighedsvej 10, 2970 Hørsholm, Denmark

18 May, 2016 Interim report for the first three months of 2016
24 August, 2016 Interim report for the first six months of 2016
16 November, 2016 Interim report for the first nine months of 2016

### IR contact

Johnny Stilou Executive Vice President & CFO

Phone: +45 30 53 33 64 Email: jst@veloxis.com

# **Board of Directors & Management**

### **Board of Directors**

**Mette Kirstine Agger** 

Chairman

Board member since 2010

Independent board member

**Competences:** 

International Pharmaceutical experience

Managing Partner, Lundbeckfond

Ventures

**Directorships:** 

Klifo A/S

PsiOxis Therapeutics Ltd.

Cydan LLC.

scPharmaceuticals LLC

Thesan Pharmaceuticals Inc.

Vtesse Pharma

**Thomas Dyrberg** 

**Deputy Chairman** 

Chairman, Remuneration Committee

Board member since 2003

Independent board member

**Competences:** 

International Pharmaceutical experience

Managing Partner, Novo A/S

**Directorships:** 

Ophthotech Corp

**Delenex Therapeutics AG** 

**Galera Therapeutics** 

**Nuvelution Pharmaceuticals** 

Panoptica Inc

**Anders Götzsche** 

Chairman, Audit Committee Board member since 2008 Independent board member

**Competences:** Financial expert

EVP & CFO, H. Lundbeck A/S

**Directorships:** 

Rosborg Møbler A/S

**Michael Heffernan** 

Chairman, Nomination Committee

Board member since 2015 Independent board member

**Competences:** 

Registered pharmacist

**Directorships:** 

Ocata Therapeutics Inc.

### **Executive Management**

**Craig A. Collard**President & CEO
Employed since 2015

Alastair McEwan
Executive Vice President & COO
Employed since 2016

**Johnny Stilou** Executive Vice President & CFO Employed since 2008

# Executive Management's and Board of Directors' Statement on the annual report

The Executive Management and the Board of Directors have considered and adopted the Annual Report of Veloxis Pharmaceuticals A/S for the financial year 2015.

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

Further, the Consolidated financial statements, the Financial statements of the parent company and Management's Review are prepared in accordance with additional Danish disclosure requirements for listed companies.

In our opinion, the Consolidated financial statements and the Financial statements of the parent company give a true and fair view of the financial position at 31 December 2015, the results of the Group's and parent company's operations, and cash flows for the financial year 2015. 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.

Hørsholm, 9 March, 2016

### **Executive Management**

Craig A. Collard
President & CEO

Alastair McEwan
Executive Vice President & COO

Johnny Stilou

**Executive Vice President & CFO** 

### **Board of Directors**

Mette Kirstine Agger Chairman Thomas Dyrberg Deputy Chairman

Anders Götzsche

Michael Heffernan

# Independent auditor's report

To the Shareholders of Veloxis Pharmaceuticals A/S

### Report on consolidated financial statements and parent company financial statements

We have audited the Consolidated Financial Statements and the Parent Company Financial Statements of Veloxis

Pharmaceuticals A/S for the financial year 1 January to 31 December 2015, which comprise income statement, statement of
comprehensive income, statement of financial position, cash flow statement, statement of changes in equity and notes, including
summary of significant accounting policies, for the Group as well as for the Parent Company. The Consolidated Financial
Statements and the Parent Company Financial Statements are prepared in accordance with International Financial Reporting
Standards as adopted by the EU and Danish disclosure requirements for listed companies.

### Management's responsibility for the consolidated financial statements and the parent company 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 Danish disclosure requirements for listed companies, and for such internal control as Management determines is necessary to enable the preparation of Consolidated Financial Statements and Parent Company Financial Statements that are free from material misstatement, whether due to fraud or error.

### Auditor's responsibility

Our responsibility is to express an opinion on the Consolidated Financial Statements and the Parent Company Financial Statements based on our audit. We conducted our audit in accordance with International Standards on Auditing and additional requirements under Danish audit regulation. This requires that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance whether the Consolidated Financial Statements and the Parent Company Financial Statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the Consolidated Financial Statements and the Parent Company Financial Statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the Consolidated Financial Statements and the Parent Company Financial Statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the Company's preparation of Consolidated Financial Statements and Parent Company Financial Statements that give a true and fair view 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 Company's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by Management, as well as evaluating the overall presentation of the Consolidated Financial Statements and the Parent Company Financial Statements.

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

The audit has not resulted in any qualification.

### **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 2015 and of the results of the Group's and the Parent

Management statement and Auditor's report

Company's operations and cash flows for the financial year 1 January to 31 December 2015 in accordance with International Financial Reporting Standards as adopted by the EU and Danish disclosure requirements for listed companies.

### Statement on management's review

We have read Management's Review in accordance with the Danish Financial Statements Act. We have not performed any procedures additional to the audit of the Consolidated Financial Statements and the Parent Company Financial Statements. On this basis, in our opinion, the information provided in Management's Review is consistent with the Consolidated Financial Statements and the Parent Company Financial Statements.

Copenhagen, 9 March, 2016 PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab CVR nr. 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

		Consol	idated	Parent			
(DKK'000)	Note	2015	2014	2015	2014		
Revenue	3	14,150	123,395	14,150	123,395		
Production costs		(15,139)	(3,247)	(15,139)	(3,247)		
Gross profit		(989)	120,148	(989)	120,148		
Sales and marketing costs	4.5	(66,192)	(41,278)	(61,611)	(39,065)		
Research and development costs	4.5	(76,319)	(90,111)	(76,081)	(90,741)		
Administrative expenses	4.5	(53,600)	(47,363)	(51,636)	(46,987)		
Operating result		(197,100)	(58,604)	(190,317)	(56,645)		
Financial income	6	14,832	21,098	14,832	21,098		
Financial expenses	7	(246)	(195)	(276)	(157)		
Result before tax		(182,514)	(37,701)	(175,761)	(35,704)		
Tax for the year	8	6,408	1,382	5,875	2,072		
Net result for the year		(176,106)	(36,319)	(169,886)	(33,632)		
Basic and diluted EPS		(0.11)	(0.02)	(0.10)	(0.02)		
Weighted average number of shares		1,663,334,241	1,662,266,639	1,663,334,241	1,662,266,639		

The Board of Directors proposes the net result for the year to be carried forward to next year

### Statement of comprehensive income

For the period 1 January – 31 December

	Consoli	dated	Parent		
(DKK'000)	2015	2014	2015	2014	
Net result for the period	(176,106)	(36,319)	(169,886)	(33,632)	
Other comprehensive income:					
Items that may be subsequently reclassified					
to profit or loss:					
Currency translation differences, net of tax	(83)	(208)	-		
Other comprehensive income for the period	(83)	(208)	-		
Total comprehensive income for the period	(176,189)	(36,527)	(169,886)	(33,632)	

# **Statement of financial position**

### Assets at 31 December

		Consoli	dated	Par	ent
(DKK'000)	Note	2015	2014	2015	2014
Patent rights and software	9	995	1,134	333	392
Intangible assets		995	1,134	333	392
Property, plant and equipment	9	3,335	4,247	3,148	4,098
Tangible fixed assets	_	3,335	4,247	3,148	4,098
Equity interest in subsidiary	10	_		2,592	2,592
Financial fixed assets		_	_	2,592	2,592
Non-current assets		4,330	5,381	6,073	7,082
Inventories	11	16,984	4,764	16,984	4,764
			<u>,                                      </u>		<u> </u>
Trade receivables		5,887	25	2,001	25
Tax receivables		5,875	6,250	5,875	6,250
Other receivables		4,089	2,677	3,765	2,318
Prepayments		4,130	4,192	1,363	3,543
Receivables		19,981	13,144	13,004	12,136
Cash		107,658	270,434	103,878	267,883
Cash and cash equivalents		107,658	270,434	103,878	267,883
Current assets		144,623	288,342	133,866	284,783
Assets		148,953	293,723	139,939	291,865

# Statement of financial position

### **Equity and liabilities at 31 December**

		Consoli	dated	Par	Parent		
(DKK'000)	Note	2015	2014	2015	2014		
Share capital	12	166,379	166,300	166,379	166,300		
Special reserve		407,289	407,289	407,289	407,289		
Translation reserves		1,677	1,760	-	-		
Retained earnings/loss		(485,686)	(322,101)	(477,816)	(320,451)		
Equity		89,659	253,248	95,852	253,138		
Trade payables		20,195	17,875	20,184	17,873		
Tax payables		20,195	470	20,164	17,075		
Deferred revenue		2 694	470	-	-		
		3,684	-	10.100	- - 007		
Debt to subsidiary		25 445	-	10,180	6,987		
Other payables		35,415	22,130	13,723	13,867		
Current liabilities		59,294	40,475	44,087	38,727		
Liabilities		59,294	40,475	44,087	38,727		
Equity and liabilities		148,953	293,723	139,939	291,865		
	<u> </u>						
Financial risks	13						
Warrants	14						
Other Commitments	15						
Related parties	16						
Fees to auditors	18						

### **Cash flow statement**

### For the period 1 January – 31 December

		Consolida	Consolidated Pa			
(DKK'000)	Note	2015	2014	2015	2014	
Operating result		(197,100)	(58,604)	(190,317)	(56,645)	
Share-based payment	5	12,277	9,744	12,277	9,744	
Depreciation and amortization	4	1,474	993	1,236	981	
Changes in working capital	17	(144)	(26,194)	(11,296)	(28,310)	
Cash flow from operating activities before i	nterest	(183,493)	(74,061)	(188,100)	(74,230)	
Interest received		141	350	141	350	
Interest paid		(246)	(195)	(276)	(157)	
Corporate tax received		6,250	1,250	6,250	1,250	
Corporate tax paid		· -	(4,587)	-	(4,178)	
Cash flow from operating activities		(177,348)	(77,243)	(181,985)	(76,965)	
Purchase of property, plant and equipm	ent	(324)	(2,547)	(227)	(1,644)	
Payable to / receivable from subsidiary		-	-	3,193	(1,801)	
Cash flow from investing activities		(324)	(2,547)	2,966	(3,445)	
Proceeds from issuance of shares, net		323	989	323	989	
Cash flow from financing activities		323	989	323	989	
Increase/(decrease) in cash		(177,349)	(78,801)	(178,696)	(79,421)	
Cash at beginning of period		270,434	328,652	267,883	326,556	
Exchange gains/(losses) on cash		14,573	20,583	14,691	20,748	
Cash at end of period		107,658	270,434	103,878	267,883	

### Statement of changes in equity

### **Consolidated**

Consolidated						
	Number of		Special	Translation	Retained	
	Shares	Share Capital DKK'000	Reserves DKK'000	Reserves DKK'000	Earnings DKK'000	Total DKK'000
Equity as of 1 January 2014	1,660,572,426	166,057	407,289	1,968	(296,272)	279,042
Net result for the year					(36,319)	(36,319)
Other comprehensive income for	the year			(208)		(208)
Total comprehensive income				(208)	(36,319)	(36,527)
Warrant exercises	2,424,888	243			746	989
Share-based payment					9,744	9,744
Other transactions	2,424,888	243			10,490	10,733
Equity as of 31 December 2014	1,662,997,314	166,300	407,289	1,760	(322,101)	253,248
Net result for the year					(176,106)	(176,106)
Other comprehensive income for	the year			(83)		(83)
Total comprehensive income				(83)	(176,106)	(176,189)
Warrant exercises	786,261	79			244	323
Share-based payment					12,277	12,277
Other transactions	786,261	79			12,521	12,600
Equity as of 31 December 2015	1,663,783,575	166,379	407,289	1,677	(485,686)	89,659

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 or loss.

### Statement of changes in equity

### **Parent Company**

Parent						
	Number of Shares	Share Capital DKK'000	Special Reserves DKK'000	Translation Reserves DKK'000	Retained Earnings DKK'000	Total DKK'000
Equity as of 1 January 2014	1,660,572,426	166,057	407,289	-	(297,309)	276,037
Net result for the year Other comprehensive income for	the year				(33,632)	(33,632)
Total comprehensive income					(33,632)	(33,632)
Warrant exercises Share-based payment	2,424,888	243			746 9,744	989 9,744
Other transactions	2,424,888	243			10,490	10,733
Equity as of 31 December 2014	1,662,997,314	166,300	407,289	-	(320,451)	253,138
Net result for the year Other comprehensive income for	the year				(169,886)	(169,886)
Total comprehensive income	•				(169,886)	(169,886)
Warrant exercises Share-based payment	786,261	79			244 12,277	323 12,277
Other transactions	786,261	79			12,521	12,600
Equity as of 31 December 2015	1,663,783,575	166,379	407,289	-	(477,816)	95,852

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**

### Note 1. Summary of significant accounting policies

#### General

The annual report of Veloxis Pharmaceuticals A/S for the year ended 31 December 2015, 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.

The financial statements are presented in Danish kroner (DKK), which is the functional currency of the parent company.

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 2015. 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)

At the time of publication of this annual report, a number of IFRS standards, amended standards and IFRIC interpretations, which are effective on or after 1 January 2016 have not been incorporated in the financial statements. Management anticipates that the adoption of these standards and interpretations will have no material impact on the financial statements in the coming years.

### 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 is transferred to the group.

The income statement for the foreign subsidiary 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 foreign subsidiary's shareholders' equity at the beginning of the year, and exchange rate differences arising as a result of the foreign subsidiary's income statement being translated at average exchange rates, are recorded in translation reserves in shareholders' equity.

### Foreign currency

Transactions in foreign currencies are translated at the exchange rates in effect at the date of the transaction.

Exchange rate gains and losses arising between the transaction date and the settlement date are recognized in the income statement as financial items.

Unsettled monetary assets and liabilities in foreign currencies are translated at the exchange rates in effect at the balance sheet date. Exchange rate gains and losses arising between the transaction date and the balance sheet date are recognized in the income statement as financial items.

### 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 exchange gains/losses arising from translating the financial statements of a foreign operation.

### **Income statement**

#### Revenues

Revenues comprise the value of sales of products and income derived from 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.

Revenues are stated less of VAT, charges and discounts.

### **Production costs**

Production costs comprise raw materials, trading goods and other costs incurred in order to obtain the net revenue for the year.

### Sales and marketing costs

Sales and marketing costs comprise advertising, promotions, seminars, salaries and other staff costs including pensions, and other costs including cost of premises, depreciation and amortization related to sales and marketing activities. Advertising costs are expensed as incurred.

### Research and development costs

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

Research 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.

### **General and administrative expenses**

General and administrative expenses comprise salaries and other staff costs including pensions, office supplies, cost of premises, and depreciation and amortization related to administrative activities.

General and administrative expenses 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.

On each balance sheet date, Veloxis reassesses its estimates of the number of warrants expected to be exercised. Veloxis recognizes any impact of such reassessment of the original estimates in the income statement (catch up) with a corresponding adjustment in equity over the remaining vesting period. Prior-year adjustments are recognized in the income statement in the adjustment year.

#### **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, it is the time to the approval at the general meeting.

### **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.

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, 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: 1-3 years

Depreciation, impairment losses and gains or losses on disposal of tangible fixed assets is recognized in the income statement as other (losses)/gains - net.

### 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.

#### Financial statements

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 as historical and anticipated futures sales compared to 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).

Translation reserves include exchange rate adjustments of equity investments in subsidiaries.

### **Non-current liabilities**

### **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 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.

### **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.

#### **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' 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.

**Total assets** 

Assets/Equity = 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' 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' 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.

Management is convinced that the company has sufficient capital resources and liquidity to support the current strategy even if one or more budget assumptions fail, and that other measures can be taken to ensure that sufficient capital resources are available as may be required also in the longer run.

### **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.

# Note 3. Revenue

	Consol	idated	Par	Parent			
(DKK'000)	2015	2014	2015	2014			
Sale of goods - EU	13,949	3,214	13,949	3,214			
Sale of goods - US	201	-	201	-			
Milestone payments	-	120,181	-	120,181			
Total	14,150	123,395	14,150	123,395			

Sale of goods - EU and Milestone payments relates to one customer.

# Note 4. Depreciation and amortization

	Consoli	idated	Par	Parent		
(DKK'000)	2015	2014	2015	2014		
Patent rights and software	222	102	59	102		
Property, plant and equipment	1,252	891	1,177	879		
Total	1,474	993	1,236	981		
Allocated by function:						
Sales and marketing costs	603	207	-	-		
Research and development costs	639	561	809	716		
General and administrative expenses	232	225	427	265		
Total	1,474	993	1,236	981		

Note 5. Staff costs

	Consoli	dated	Pare	ent
(DKK'000)	2015	2014	2015	2014
Wages and salaries	63,313	38,570	26,431	26,314
Pension contributions	1,820	1,692	1,099	1,285
Other social security costs	4,599	1,843	79	107
Share-based payment	12,263	9,682	3,587	2,849
Total	81,995	51,787	31,196	30,555
Allocated by function:				
Sales and marketing costs	28,723	11,417	3,608	3,112
Research and development costs	27,807	20,116	12,087	13,901
General and administrative expenses	25,465	20,254	15,501	13,542
Total	81,995	51,787	31,196	30,555
Average number of employees (FTEs)	38	26	12	15
Remuneration of board of directors, and executive management:				
Board of directors				
Cash remuneration	1,504	1,100	1,504	1,100
Share-based payment	1,019	98	1,019	98
	2,523	1,198	2,523	1,198
Executive management				
Gross salary	5,221	4,349	5,221	4,349
Severance (former CEO)	1,585	-	1,585	-
Bonus	6,808	5,273	6,808	5,273
Pension contributions	268	246	268	246
Share-based payment	6,063	5,642	6,063	5,642
	19,945	15,510	19,945	15,510

Members of the Board of Directors receive a fixed annual fee of USD 25,000. The Chairman of the Board of Directors receives a supplement of USD 50,000 to the fixed fee and the Chairman of respectively the Audit Committee and the Compensation Committee receives a supplement of USD 25,000 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 fixed number of 1,187,023 warrants.

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

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

Veloxis has implemented a company-wide (including management) 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. Further Veloxis has established a long term incentive plan for executive management and specific employees which include a stay-on bonus equivalent of up to 24 months' base salary.

Veloxis has implemented Incentive Guidelines, which has been adopted by the General Assembly and are in further detailed described on page 15 and on Veloxis' homepage www.veloxis.com/investors.

#### Board of Directors and Executive Management's holdings of shares and warrants

	As per 31 De	As per 31 December 2015		ember 2014
	Shares	Warrants	Shares	Warrants
Board of directors				
Thomas Dyrberg	451,733	1,396,746	451,733	239,584
Anders Götzche	-	1,187,023	-	-
Mette Kirstine Agger	1,288	1,337,023	1,288	150,000
Michael Heffernan	-	1,187,023	-	-
Executive management				
Craig A. Collard	-	-	-	-
Johnny Stilou	-	20,847,552	<u> </u>	16,731,634

## Note 6. Financial income

	Consol	idated	Parent			
(DKK'000)	2015	2014	2015	2014		
Interest income	141	350	141	350		
Exchange rate gains	14,691	20,748	14,691	20,748		
Total	14,832	21,098	14,832	21,098		

# **Note 7. Financial expenses**

	Consol	idated	Par	ent
(DKK'000)	2015	2014	2015	2014
Interest expenses	246	195	246	-
Interest expense from group companies	-	-	30	157
Total	246	195	276	157

# Note 8. Tax and deferred tax

	Consol	idated	Par	Parent		
(DKK'000)	2015	2014	2015	2014		
To forth was an he make a fellow.						
Tax for the year can be explained as follows:	(102 514)	(27.704)	(175.761)	(25.704)		
Income / (loss) for the year before tax	(182,514)	(37,701)	(175,761)	(35,704)		
Tax rate	23.5%	24.5%	23.5%	24.5%		
Computed tax on income / (loss) for the year	(44,009)	(9,703)	(41,304)	(8,747)		
Change in tax losses carried forward not capitalized	44,009	9,703	41,304	8,747		
Tax benefit	5,875	6,250	5,875	6,250		
Witholding tax on milestone payment	-	(4,178)	-	(4,178)		
Commercial rent tax	-	(409)	-	-		
Tax re previous year	533	-	-	-		
Tax on profit in subsidiary	-	(281)	-			
Tax for the year	6,408	1,382	5,875	2,072		
	.,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		,-		
Tax rate	22.0%	22.0%	22.0%	22.0%		
Calculated deferred tax asset	(412.200)	292.470	(412.260)	202 470		
	(413,369)	382,470	(413,369)	·		
Write down to assessed value	413,369	(382,470)	413,369	(382,470)		
Carrying amount	-		-	<u>-</u>		

The deferred tax asset has been written down, as it is uncertain whether or not the tax asset will be realized in future earnings. The deferred tax asset can be carried forward without timing limitations.

Unrecognized tax loss carry forward amounts to DKK 1,716 million (2014 DKK 1,497 million).

Note 9. Intangible & tangible fixed assets

Consolidated	Patent rights & Software Property, Plant & Equipment		Leasehold Improvements			
(DKK'000)	2015	2014	2015	2014	2015	2014
				_		
Cost at 1 January	2,022	1,280	41,065	39,274	400	419
Additions	-	742	324	1,805	-	-
Exchange adjustment	86		99	(14)	105	(19)
Cost at 31 December	2,108	2,022	41,488	41,065	505	400
Amortization / Depreciation / Impairment						
loss at 1 January	(888)	(786)	(36,818)	(35,941)	(400)	(419)
Amortization / Depreciation	(222)	(102)	(1,252)	(891)	-	-
Exchange adjustment	(3)		(83)	14	(105)	19
Amortization / Depreciation / Impairment loss at						
31 December	(1,113)	(888)	(38,153)	(36,818)	(505)	(400)
Net book value at 31 December	995	1,134	3,335	4,247	-	-

Parent	Patent rights & Software		Property, Plant & Equipment		
(DKK'000)	2015	2014	2015	2014	
Cost at 1 January	1,280	1,280	40,598	38,954	
Additions	-		227	1,644	
Cost at 31 December	1,280	1,280	40,825	40,598	
Amortization / Depreciation / Impairment		<u> </u>			
loss at 1 January	(888)	(786)	(36,500)	(35,621)	
Amortization / Depreciation	(59)	(102)	(1,177)	(879)	
Amortization / Depreciation / Impairment loss at					
31 December	(947)	(888)	(37,677)	(36,500)	
Net book value at 31 December	333	392	3,148	4,098	

# Note 10. Investment in subsidiary

	Parent			
(DKK'000)	2015	2014		
Cost at 1 January Additions	2,592 -	2,592 -		
Cost at 31 December	2,592	2,592		

Veloxis Pharmaceuticals, Inc. was established as a wholly owned subsidiary as of 2 January 2007. This subsidiary is domiciled in New Jersey, USA and is primarily focused on commercial activities in the US and Canada on behalf of the Parent Company.

#### Note 11. Inventories

Consol	idated	Par	ent
2015	2014	2015	2014
12,850	3,718	12,850	3,718
4,134	1,046	4,134	1,046
16 09/	4 764	16 984	4,764
	<b>2015</b> 12,850	12,850 3,718 4,134 1,046	2015         2014         2015           12,850         3,718         12,850           4,134         1,046         4,134

The total consumption of materials included in cost of sales amounted to DKK 5.3 million (2014: DKK 2.4 million).

Cost of sales include an inventory write down of DKK 3.9 million (2014: DKK 0 million).

# Note 12. Share capital

On 31 December 2015 the total number of outstanding shares was 1,663,783,575. Each share has a nominal value of DKK 0.1 and one vote.

## Changes in share capital from 2010 to 2015

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

					Share pri	ce in DKK
			Share classes after	capital	pre bonus	post bonus
Date	Transaction	Share Capital	increase		shares	shares
		(1)				
25 November 2010	Cash contribution	395,974,670 <sup>(1)</sup>	452,542,480	shares	-	1.20
13 November 2012	Cash contribution	1,206,779,946	1,659,322,426	shares	-	0.35
6 March 2013	Cash contribution	1,250,000 (3)	1,660,572,426	shares	-	0.35
20 March 2014	Cash contribution	1,954,857 (4)	1,662,527,283	shares	-	0.35
1 September 2014	Cash contribution	256,639 <sup>(5)</sup>	1,662,783,922	shares	-	0.35
1 September 2014	Cash contribution	54,167 <sup>(5)</sup>	1,662,838,089	shares	-	0.58
1 September 2014	Cash contribution	9,225 (5)	1,662,847,314	shares	-	0.95
1 September 2014	Cash contribution	150,000 <sup>(5)</sup>	1,662,997,314	shares	-	1.16
27 March 2015	Cash contribution	93,416 (6)	1,663,090,730	shares	-	0.35
3 June 2015	Cash contribution	250,000 <sup>(7)</sup>	1,663,340,730	shares	-	0.35
15 September 2015	Cash contribution	386,606 (8)	1,663,727,336	shares	-	0.35
15 September 2015	Cash contribution	1,386 (8)	1,663,728,722	shares	-	0.94
15 September 2015	Cash contribution	4,152 (8)	1,663,732,874	shares	-	0.95
3 December 2015	Cash contribution	50,701 <sup>(9)</sup>	1,663,783,575	shares	-	1.23

#### Notes:

(1) Issuance of 395,974,670 shares in connection with rights issue on 29 October 2010.

- (2) Issuance of 1,206,779,946 shares in connection with rights issue on 13 November 2012.
- (3) Issuance of 1,250,000 shares in connection with subscription through the exercise of employee warrants.
- (4) Issuance of 1,954,857 shares in connection with subscription through the exercise of employee warrants.
- (5) Issuance of 470,031 shares in connection with subscription through the exercise of employee warrants.
- (6) Issuance of 93,416 shares in connection with subscription through the exercise of employee warrants.
- (7) Issuance of 250,000 shares in connection with subscription through the exercise of employee warrants.
- (8) Issuance of 392,144 shares in connection with subscription through the exercise of employee warrants.
- (9) Issuance of 50,701 shares in connection with subscription through the exercise of employee warrants.

#### Note 13. Financial risks

#### Interest rate risk

Veloxis has an investment policy with the purpose of preserving the Company's capital without significantly increasing the risks. Accordingly, the Company seeks to limit any risks related to the interest rate. The Company is primarily exposed to interest rate risk ascribable to its cash position. All positions carry variable interest rates. Based on the cash position at the end of 2015, a 1% point change in the interest rate will impact net financial income and equity of approximately DKK 2 million (2014 DKK 3 million).

#### **Capital structure**

During 2015, the Company's excess cash has been placed in short-term and long-term deposits with two major Danish banks, thereby reducing the fair value risk. The cash position at year end and the average interest rate is presented in the following table:

	Consolidated		Parent	
(DKK'000)	2015	2014	2015	2014
Cash	107,658	270,434	103,878	267,883
Average variable interest rate	-0.05%	0.12%	-0.06%	0.12%

#### **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. As regards cash deposits, the Company's bank has a credit rating of A2 according to Moody's. The credit risk ascribable to the Company's receivables is considered low as such receivables arise from collaboration agreements with large pharmaceutical companies.

#### 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 USD. Changes in exchange rates of such foreign currencies towards the Company's functional currency may affect the results and cash position.

The Company's net position (monetary items) in foreign currencies is stated below:

	Consolidated		Parent	
	2015	2014	2015	2014
USD'000	4,846	25,206	2,233	23,648
EUR'000	419	741	419	741
GBP'000	(2)	(32)	(2)	(32)
CAD'000	(2)	(5)	(2)	(5)

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 DKK. Based on the USD position at the end of 2015, a 10% change in the USD / DKK rate will impact result and equity with approximately DKK 3.3 million (2014 DKK 15 million).

#### Note 14. 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' 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. 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' preliminary annual report and Veloxis' quarterly interim reports.

### **Warrant activity**

The following table specifies the warrant activity during 2015:

	Employees	Executive management	Board of directors	Total	Weighted average exercise price DKK
Outstanding as of 1 January 2014	36,296,540	45,631,300	589,584	82,517,424	0.64
Granted in the year	9,874,975	15,647,781	250,000	25,772,756	1.03
Exercised in the year	(2,220,721)	-	(204,167)	(2,424,888)	0.41
Cancelled in the year	(4,752,501)	-	-	(4,752,501)	0.36
Expired in the year	(392,656)	-	-	(392,656)	11.99
Outstanding as of 31 December 2014	38,805,637	61,279,081	635,417	100,720,135	0.71
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)		
Outstanding as of 31 December 2015	93,189,049	20,847,552	5,107,815	119,144,416	0.67
Weighted average exercise price DKK	0.67	0.59	0.90	0.67	

In total, as of 31 December 2015, a total of 119,144,416 warrants were outstanding with a weighted average exercise price of DKK 0.67. 96,163,586 of these warrants had vested and are exercisable as of 31 December 2015 with a weighted average exercise price of DKK 0.59. For comparison, as of 31 December 2014, a total of 100,720,135 warrants were outstanding with a weighted average exercise price of DKK 0.71.

#### 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 51% - 52%, determined as the average of the stock price volatility based on Veloxis' 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.

During 2015, a total of DKK 12.3 million was recognized as share-based compensation compared to DKK 9.7 million in 2014.

The warrant compensation costs for 2015 were allocated to sales and marketing costs at DKK 1.1 million, research and development costs at DKK 3.9 million and to general and administrative expenses at DKK 7.3 million.

### 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 3 March, 2015	Granted 27 March, 2015	Granted 27 August, 2015
Share price at grant (DKK)	0.94	0.86	1.06
Volatility (%)	52	51	52
Exercise price (DKK)	0.94	0.86	1.06
Risk-free interest rate for options (%)	0%	0%	0%
Annual dividend per share (DKK)	-	-	-
Years to expiry	7	7	7
Exercise period	2022	2022	2022
Market value at grant (DKK'000)	9,100	1,600	2,600

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)
2009	4.948.753	1,290,758	3.56	3.73	1.96 - 4.45
2010	22,230,930	3,363,099	1.34	21.74	1.05 - 2.03
2011	4,665,291	628,975	1.15	29.14	1.00 - 1.23
2012	59,047,200	46,618,800	0.35	47.00	0.35
2013	20,930,000	20,780,000	0.36	49.06	0.36 - 0.63
2014	25,772,756	20,589,674	1.03	63.54	0.95 - 1.86
2015	34,438,935	25,873,110	0.95	76.15	0.86 - 1.06
31 December 2015	172,033,865	119,144,416	0.67	55.27	

Note 15. Other commitments

	Consolidated		Parent	
(DKK'000)	2015	2014	2015	2014
Occupation I amount in the control of the control o	070	1.010	244	460
Operating lease commitments regarding offices	870	1,018	244	468
Operating lease commitments regarding property, plant and equipment	872	1,353	816	1,265
property, prant and equipment	072	1,333	010	1,203
Total operating lease commitments	1,742	2,371	1,060	1,733
Total operating lease payments fall due:				
Within 1 year	1,358	1,589	690	1,001
From 1 to 5 years	384	782	370	732
After 5 years	-	-	-	
Total	1,742	2,371	1,060	1,733
Expensed operating lease payments	1,355	2,116	438	1,298

## Note 16. Related parties

## Shareholders with significant influence

- Lundbeckfond Invest A/S 42.7% (100% owned by the Lundbeck Foundation), Denmark, municipality of Copenhagen
- Novo A/S 42.7% (100% owned by the Novo Nordisk Foundation), Denmark, municipality of Gentofte

There have been no transactions with the shareholders in either 2014 or 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 14 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.

During 2015, the subsidiary has performed clinical, 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 DKK 74.3 million for the year 2015 (2014: DKK 35.8 million). Further, the Parent Company has paid interest expenses of DKK 30 thousand

for the period 1 January to 31 December 2015 due to internal transactions between the two companies (2014: expenses of DKK 157 thousand).

At 31 December 2015, the Parent Company had a net payable to Veloxis Pharmaceuticals, Inc. totaling DKK 10.2 million (2014: DKK 7.0 million).

#### Other related parties

Other related parties may exist as the members of Veloxis' 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 17. Changes in working capital

	Consol	Consolidated		Parent		
(DKK'000)	2015	2014	2015	2014		
Trade receivables	(5,862)	(25)	(1,976)	(25)		
Other receivables	(1,412)	11,388	(1,447)	11,594		
Prepayments	62	(2,978)	2,180	(2,339)		
Inventories	(12,220)	(4,764)	(12,220)	(4,764)		
Trade payables	2,320	4,849	2,311	4,847		
Deferred revenue	3,684	(36,617)	-	(36,617)		
Other payables	13,284	1,953	(144)	(1,006)		
		_				
Total	(144)	(26,194)	(11,296)	(28,310)		

# Note 18. Fees to auditors appointed by the annual general meeting

	Consolidated		Parent	
(DKK'000)	2015	2014	2015	2014
PricewaterhouseCoopers				
Audit	321	311	321	311
Tax Services	158	262	158	262
Other assurance engagements	14	35	14	35
Other services	372	199	372	199
Total	865	807	865	807

# **Parent company**

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