

# ANNUAL REPORT 2017

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

The Annual Report was presented and approved at the Annual General Meeting on 13 April, 2018

Christian Th. Kjølbye

Chairman of the Meeting

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# **To Our Shareholders**

# Dear Shareholders,

2017 was another successful year for Veloxis Pharmaceuticals. We executed on the Company's corporate strategy delivering solid top-line growth while continuing to expand the number of patients that are benefiting from Envarsus<sup>®</sup>. We also expanded the geographical reach of Envarsus by completing three different out-licensing transactions with partners in China, the Middle East North Africa region and Canada. The Company also remained active on the corporate development front by evaluating a broad range of acquisition and licensing opportunities.

The launch of Envarsus in the US has resulted in significant penetration, with approximately 77% of adult transplant centers and over 900 prescribers having utilized Envarsus in 2017. This resulted in an estimated 3,600 patients using Envarsus by year end, and over 32,500 prescriptions of Envarsus in the second year after launch.

We are excited by the results of our partnership with Chiesi Farmaceutici S.p.A. (Chiesi) for commercialization of Envarsus in Europe. Chiesi estimates that over 7,500 patients have been placed on Envarsus in Europe, and the product is on a strong trajectory for continued growth. We are also pleased that Chiesi has committed substantial financial and clinical resources towards ongoing clinical studies of Envarsus in Europe, signaling a long-term strategy for growth for Envarsus in the territory.

In 2018, we look forward to delivering on key financial and commercial goals that have the potential to drive significant value for our shareholders. We have a great lead product in Envarsus which is improving the daily lives of transplant patients as well as having orphan status and patent protection that runs through 2028 in the US. The Company plans to continue our business development efforts which we believe will lead to the Company completing a transaction that expands our current product offering.

Regarding the de novo indication, we are still in the process of assessing the impact that adding the indication would have on our current orphan drug exclusivity. We hope to complete our assessment and make a decision on this matter in the near future.

To our employees, we want to offer our sincere thanks for your commitment and hard work in 2017. Your efforts are truly what make Veloxis a success.

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

Yours sincerely,

Michael Heffernan Chairman Craig A. Collard President & CEO

# Highlights 2017

# February

- Veloxis Pharmaceuticals A/S agreed to amend and restate the terms of its previously announced loan and security agreement with Lundbeckfond Invest A/S and Novo Holdings A/S. The terms of the amended and restated agreement make available an additional USD 10 million in financing at an interest rate of 12%, payable annually in arrears.
- Veloxis Pharmaceuticals, Inc., closed its office in Edison, New Jersey. It now operates solely out of its office in Cary, NC.

# March

• Veloxis Pharmaceuticals, Inc., entered into an exclusive license, supply and distribution agreement with Taiba Healthcare to register, commercialize and distribute Envarsus in certain countries throughout the Middle East and North Africa region (MENA).

### June

- Veloxis Pharmaceuticals, Inc., entered into an exclusive license, supply and distribution agreement with Endo Ventures Limited to register, commercialize and distribute Envarsus in Canada.
- Veloxis Pharmaceuticals, Inc., entered into an exclusive license, supply and distribution agreement with Chiesi Farmaceutici, S.p.A. to register, commercialize and distribute Envarsus in China.

### September

• Ulf Meier-Kriesche, MD joined Veloxis Pharmaceuticals, Inc., as Chief Scientific Officer, bringing substantial clinical transplant experience and senior industry medical affairs experience within transplantation and immunology.

# Outlook 2018

# Outlook

Veloxis Pharmaceuticals anticipates 2018 total revenues to be in the range of USD 32 - 40 million and 2018 operating loss before accounting for stock compensation to be in the range of USD 6 - 12 million.

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

# Important Events Following the Balance Sheet Date

# **Material Events**

14 February: Veloxis Pharmaceuticals A/S obtained USD 60 million of capital from funds managed by Athyrium Capital Management, LP ("Athyrium"), a leading healthcare-focused investment firm. This financing is in the form of a five-year, floating rate, interest only note. The initial principal balance doubles the amount of debt at substantially the same cost of capital versus the previous debt instrument. The funds are structured with USD 60 million available immediately upon closing of the transaction to Veloxis Pharmaceuticals, Inc., and guaranteed by Veloxis Pharmaceuticals A/S. The previous loan with Lundbeckfond Invest A/S and Novo Holdings A/S was paid off in connection with obtaining the new loan from Athyrium.

# **Veloxis Business Strategy**

Veloxis Pharmaceuticals is a biopharmaceutical company focused on improving patient lives by identifying, developing, and commercializing meaningful products in transplantation and adjacent therapies. Utilizing our proprietary drug delivery technology (MeltDose®), Veloxis has developed and obtained FDA and EMA approval for our product, Envarsus (tacrolimus extended-release tablets), to aid in the prophylaxis of organ rejection in transplant recipients. Our strategy is to continue to commercialize Envarsus in the US with a direct salesforce and to license rights to Envarsus to proven commercial partners in other territories around the world. In addition to expanding use of Envarsus Veloxis is actively seeking business development and licensing targets within the areas of transplantation and adjacent specialties, and therapeutics for rare or severe disease for which chronic therapy is initiated in the large hospital setting.

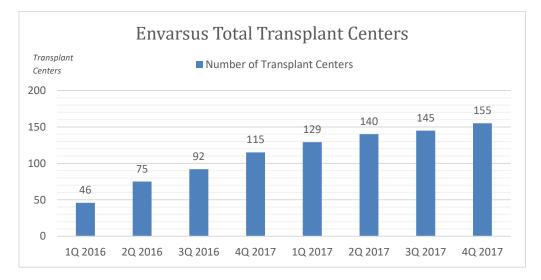
In the US, our direct salesforce is supplemented by field-based reimbursement and medical affairs personnel, and supported by inhouse marketing, medical affairs, and operations personnel. Our commercial strategy is to reach the organ transplant market by promoting within transplant centers which are typically located in the large hospital setting. A secondary focus is to reach transplant patients in need of Envarsus through promotion to large specialty practices which refer patients to transplant centers for organ transplantation. Direct sales efforts are complemented by specialty pharmaceutical marketing practices to ensure broad reach of brand awareness and core message delivery. Veloxis has established specialty distribution and patient services to optimize the experience for patients and providers and to offer patient access to Envarsus whenever possible.

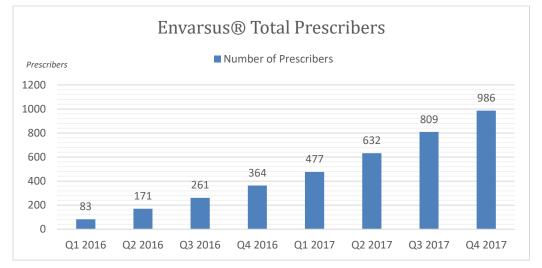
Envarsus is now licensed in 43 countries around the world. Previously, Veloxis had licensed Envarsus to Chiesi in Europe, Turkey and Commonwealth of Independent States countries, and in 2017 we expanded the partnership to include licensure for development, registration and commercialization in China. In March of 2017, Veloxis entered into an exclusive license, supply and distribution agreement with Taiba Healthcare, to register, commercialize and distribute Envarsus in the Middle East and North Africa (MENA) region. In June of 2017, Veloxis entered into an exclusive license, supply and distribution agreement with Endo Ventures Limited to register, commercialize and distribute Envarsus in Canada through the partner's affiliate, Paladin Labs Inc. Veloxis intends to license Envarsus for other key markets in the future.

# **Commercial Update**

Envarsus launched in Europe in November of 2014 through our licensed partner Chiesi Farmaceutici S.p.A., and in the US in December of 2015 by Veloxis utilizing a direct sales force with substantial experience in organ transplantation. Based upon available sales data, we estimate that there are now over 11,000 patients on Envarsus worldwide (7,500 in EU, 3,600 in US).

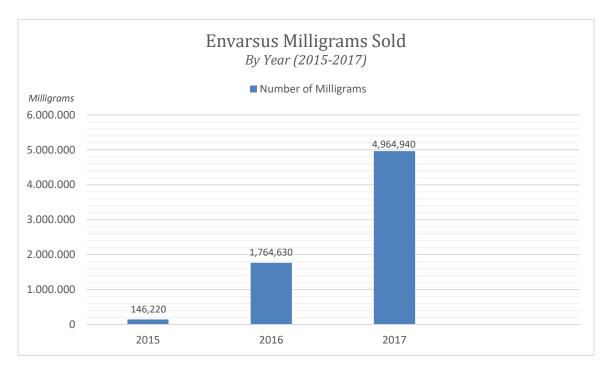
Key performance indicators in the US market demonstrate that 2017 was a successful year for achieving adoption of Envarsus within transplant centers. 77% of the 200 US transplant centers utilized Envarsus in the month of December 2017 compared to 53% in December 2016. Furthermore, over 900 transplant physicians prescribed Envarsus in the US in 2017, representing a three-fold increase in the number of prescribers versus 2016. Prescriptions of Envarsus also grew three-fold over 2016, totaling 32,500 in 2017.

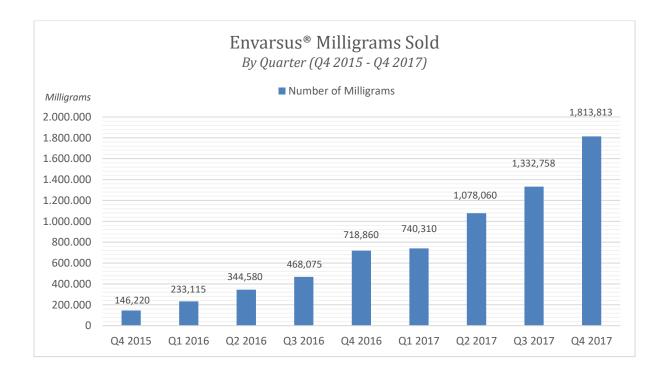




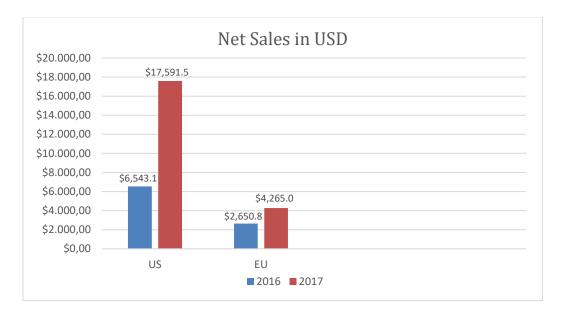
# **Management Review**

Total milligrams of Envarsus sold in 2017 increased from 1.765 million milligrams sold in 2016 to 4.965 million milligrams, which represents a growth of 192% over 2016. Moreover, Envarsus quarter over quarter growth averaged 27% in 2017.





### **Management Review**



The three-fold increase in prescribers and prescriptions in 2017, as well as the significant increase in milligrams sold, demonstrates the broad adoption of Envarsus by the transplant community. Envarsus is now the leading once-daily product prescribed in the US capturing 2% of the kidney tacrolimus market.

An important driver of the uptake of Envarsus in the US has been the 2016 FDA approval of label enhancements which allow promotion of Envarsus for use in special populations which may benefit from increased bioavailability and controlled delivery of tacrolimus. African-American kidney transplant patients historically experience poorer outcomes as compared to other ethnic groups and this has been associated in part due to their expression of the CYP3A5\*1 genotype, which codes for a cytochrome p450 enzyme that metabolizes tacrolimus, and is shown to be present in approximately 80% of African-Americans. Patients expressing this genotype metabolize tacrolimus much more rapidly and as a result typically require higher tacrolimus doses which may hinder efforts to obtain a therapeutic level and thereby potentially increasing the risk of organ rejection. Envarsus has demonstrated a unique pharmacokinetic profile in this population, and we believe this data will continue to drive prescription growth in this important and difficult to treat subset of transplant patients.

# **Envarsus for Transplantation**

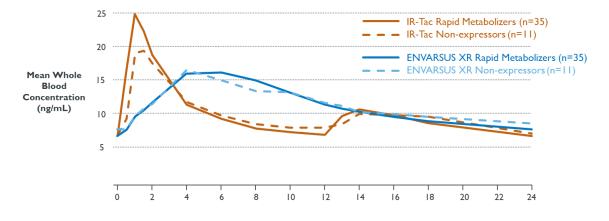
# ASERTAA (A Study of Extended Release Tacrolimus in African-Americans) Phase IIIb Study of Envarsus

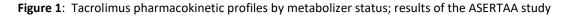
The ASERTAA Phase IIIb study of Envarsus in kidney transplant recipients compared the pharmacokinetics (PK) of Envarsus, a oncedaily tacrolimus tablet, to generic twice daily immediate-release tacrolimus capsules in stable African-American renal transplant recipients. This study was also one of the largest pharmacogenomics studies of African-American kidney transplant recipients ever conducted and the first of its kind for Envarsus. The results of this study were first presented at the American Transplant Congress in May 2015 and more recently accepted for publication in the American Journal of Kidney Disease in 2017.

Pharmacogenomics is the study of how genes affect a person's response to drugs; it combines the study of pharmacology (the science of drugs) and genomics (the study of genes and their functions) to help clinicians develop effective, safe medications and dosing regimens that can be tailored to a person's genetic makeup. This form of "personalized medicine" is of particular interest for drugs such as tacrolimus because it is what is known as a "narrow therapeutic index drug"; that is, one where small differences in the dose or blood concentration may lead to serious therapeutic failures and/or adverse drug reactions that are life-threatening or result in persistent or significant disability or incapacity. Previous pharmacogenomic studies of tacrolimus in African-Americans have been limited by the lack of a centralized laboratory, lack of standard tacrolimus dosing, and measurement of tacrolimus trough concentrations rather than stead-state 24-hour PK profiles. The ASERTAA study was specifically designed to overcome these barriers.

The ASERTAA study was an open-label, prospective, randomized, 2-sequence, 3-period, crossover, PK/pharmacogenetic study completed at three major, urban academic transplant centers in the United States. The purpose of this study was to advance understanding of the differences in tacrolimus exposure in patients who expressed a particular gene (CYP3A5\*1) that rendered them "rapid metabolizers" of tacrolimus. This term is used to describe patients who require significantly larger doses of tacrolimus in order to achieve equivalent exposure compared to those in whom the gene is not expressed. The CYP3A5\*1 allele was specifically chosen because it had been previously identified to be the most important genetic factor associated with risk of subtherapeutic tacrolimus concentrations in rapid metabolizer populations. African-Americans were enrolled in the ASERTAA study as the prevalence of the CYP3A5\*1 gene is significantly higher in this population, though it should be noted that race alone is not a sufficient predictor of metabolizer status. In fact, approximately one in three patients transplanted in the United States is a rapid metabolizer of tacrolimus.

The results of this 46-patient study confirmed the flatter PK curve previously seen with Envarsus was preserved in a population where 76% of evaluated patients were confirmed rapid metabolizers. More importantly, it elucidated important differences in the PK profile of Envarsus vs immediate-release tacrolimus capsules in a population of rapid metabolizers. Envarsus demonstrated a consistent PK profile regardless of a patient's metabolizer status. This is in contrast to immediate-release tacrolimus in which rapid metabolizers, who required higher doses to achieve therapeutic trough concentrations, were inadvertently exposed to higher peak levels than non-expressors of the CYP3A5\*1 allele. (See Figure 1)





Overall, patients treated with Envarsus demonstrated significantly lower peak concentrations by approximately 30%. This observation was even more pronounced in patients identified as rapid metabolizers given the higher peak obtained by this group on immediate-release tacrolimus capsules.

It is worth noting that pharmacogemonic testing is not standard in kidney transplant recipients for a variety of reasons: test results are often delayed, decreasing clinical utility; testing incurs an additional cost; and once obtained, little evidence exists to guide dosing for tacrolimus based on genotype. With a preserved pharmacokinetic profile that was not affected by the presence or absence of CYP3A5\*1 in this study, Envarsus provides clinicians with an alternative tacrolimus formulation which can be used in any population regardless of CYP3A5 expressor status.

# **Financial Review**

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

### Revenue

During 2017, Veloxis recognized revenue from commercial sales and upfront fees of USD 30,167 compared to USD 9,194 in 2016. The increase is driven by growth in commercial sales of Envarsus in the US from USD 6,543 in 2016 to USD 17,592 in 2017, sales to Chiesi Farmaceutici S.p.A ("Chiesi") in Europe from USD 2,651 in 2016 to USD 4,265 in 2017 and Rest of World (RoW) upfront revenue of USD 8,250 for 2017 with no comparable revenue in the prior year.

# Selling, General and Administrative Costs

Selling, general and administrative costs decreased from USD 34,407 in 2016 to USD 32,458 in 2017. The decrease is primarily attributable to cost efficiencies gained from consolidating the Company's operations to one location.

On an overall basis, selling, general and administrative costs account for 97% of total cost of operations.

### **Research & Development Cost**

Research and development costs increased from USD 636 in 2016 to USD 866 in 2017. The increase in cost is associated with qualifying a secondary source of supply.

On an overall basis, research and development costs account for 3% of total cost of operations. The comparable figure for 2016 was 1.8%.

### **Share-Based Compensation Cost**

During 2017, a total of USD 4,174 was recognized as share-based compensation. The comparable number for 2016 was USD 5,430.

### **Operating Result**

During 2017, Veloxis recognized USD 8,359 in operating loss compared with USD 28,768 in 2016.

The operating result is in line with Management's expectation as reported on 16 August 2017 in connection with the second quarter interim report, which provided a 2017 outlook of operating loss before the recognition of income from license agreements and before accounting for stock compensation to be in the range of USD 10 - 15 million. Operating loss adjusted for upfront fees from license agreements of USD 8,250 and stock compensation of USD 4,174 was USD 12,435.

### **Financial Items**

Net financial items increased by USD 2,045, from a loss of USD 45 in 2016 to a loss of USD 2,090 in 2017. The loss in 2016 and 2017 is primarily attributable to interest charges on the loan facility.

# **Management Review**

# Tax for the Year

Tax for the period was an income of USD 907 compared to USD 18,678 in 2016. In 2017 Veloxis recognized a tax income from revaluation of deferred tax assets of USD 1,509 and a tax expense of USD 602 due to payable taxes in Denmark and Italy. We expect to recognize tax income in the coming years in connection with revaluation and recognition of further deferred tax assets as our business continues to grow.

At 31 December 2017, the deferred tax asset was USD 20,187 compared to USD 18,678 at the end of 2016.

# **Net Result**

During 2017, Veloxis recognized USD 9,542 in net loss compared with USD 10,135 in 2016.

# **Cash Flow**

As of 31 December 2017, the balance sheet reflects cash and cash equivalents of USD 7,766 compared with USD 3,359 as per 31 December 2016 after drawing an additional USD 12,000 since 31 December 2016 under our current loan facility and receiving funds relating to the RoW agreements.

# **Balance Sheet**

As of 31 December 2017, total assets were USD 41,921 compared with USD 29,884 at the end of 2016.

As of 31 December 2017 the net debt was USD 28,839 up from USD 16,330 as of 31 December 2016. The difference relates primarily to drawing an additional USD 12,000 under the loan facility which was used to fund operations.

Shareholders' equity equaled USD 5,316 as at 31 December 2017, compared with USD 10,195 at the end of 2016.

# **Financial Highlights - Consolidated**

**Financial Highlights** 

Total assets       41,921       29,884       21,809       47,983       64,453         Total equity       5,316       10,195       13,127       41,371       51,553         Investment in property, plant and equipment       564       176       48       295       195         Cash Flow Statement          48       295       195         Cash flow from operating activities       (7,710)       (28,057)       (26,392)       (13,050)       (28,089)         Cash flow from investing activities       (564)       (176)       (48)       (430)       (188         Cash flow from financing activities       12,435       15,981       48       167       (575         Cash and cash equivalents at period end       7,766       3,359       15,763       44,178       60,719         Financial Ratios           60,719       (0.02)       (0.02)       (0.08         Weighted average number of shares       1,708,325,635       1,688,679,397       1,663,334,241       1,662,266,639       1,660,353,248         Average number of employees (FTEs)       51       54       38       26       26         Assets/equity       7.89       2.93       1.66	USD'000	2017	2016	2015	2014	2013
Revenue         30,167         9,194         2,103         20,847         6,793           Production costs         (5,202)         (3,019)         (2,250)         (549)         -           Gross profit         24,965         6,175         (147)         20,299         6,793           Selling, general and administrative costs         (32,458)         (34,407)         (17,808)         (14,976)         (4,945           Research and development costs         (866)         (636)         (11,345)         (15,224)         (26,088           Other operating income         -         100         -         -         -         -           Operating result         (8,359)         (28,768)         (29,300)         (9,901)         (24,240           Net financial income / (expenses)         (2,090)         (45)         2,168         3,531         (788           Result before tax         (10,449)         (28,813)         (27,132)         (6,369)         (25,028           Tax for the period         907         18,678         953         234         223           Net result for the period         (9,542)         (10,135)         (26,179)         (6,136)         (24,806           Stah da cash equivalents         7,766	Income Statement					
Production costs       (5,202)       (3,019)       (2,250)       (549)       -         Gross profit       24,965       6,175       (147)       20,299       6,793         Selling, general and administrative costs       (3866)       (6136)       (11,345)       (14,976)       (4,945         Research and development costs       (866)       (6136)       (11,345)       (15,224)       (26,088         Other operating income       -       100       -       -       -       -         Operating result       (8,359)       (28,768)       (29,300)       (9,901)       (24,240         Net financial income / (expenses)       (2,090)       (45)       2,168       3,531       (788         Result before tax       (10,449)       (28,813)       (27,132)       (6,369)       (25,028         Tax for the period       907       18,678       953       234       223         Net result for the period       (9,542)       (10,135)       (26,179)       (6,136)       (24,806         Statement of Financial Position       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       - <t< td=""><td></td><td>30 167</td><td>9 19/</td><td>2 103</td><td>20 8/17</td><td>6 793</td></t<>		30 167	9 19/	2 103	20 8/17	6 793
Gross profit         24,965         6,175         (147)         20,299         6,793           Selling, general and administrative costs         (32,458)         (34,407)         (17,808)         (14,976)         (4,945)           Research and development costs         (866)         (636)         (11,345)         (15,224)         (26,088)           Operating income         -         100         -         -         -           Operating result         (8,359)         (28,768)         (29,300)         (9,901)         (24,240)           Net financial income / (expenses)         (2,090)         (45)         2,168         3,531         (788)           Result before tax         (10,449)         (28,813)         (27,132)         (6,369)         (25,028)           Tax for the period         907         18,678         953         234         2233           Net result for the period         (9,542)         (10,135)         (26,179)         (6,136)         (24,806)           Statement of Financial Position         Cash and cash equivalents         7,766         3,359         15,763         44,178         60,719           Total assets         41,921         29,884         21,809         47,983         64,453           Total a					,	0,795
Selling, general and administrative costs         (32,458)         (34,407)         (17,808)         (14,976)         (4,945)           Research and development costs         (866)         (6136)         (11,345)         (15,224)         (26,088)           Other operating income         -         100         -         -         -           Operating result         (8,359)         (28,768)         (29,300)         (9,901)         (24,240)           Net financial income / (expenses)         (2,090)         (45)         2,168         3,531         (788)           Result before tax         (10,449)         (28,813)         (27,132)         (6,369)         (24,803)           Net result for the period         (9,542)         (10,135)         (26,179)         (61,36)         (24,806)           Statement of Financial Position         Cash and cash equivalents         7,766         3,359         15,763         44,178         60,719           Total assets         41,921         29,884         21,809         47,983         64,453           Total equity         5,316         10,195         13,127         41,371         51,553           Investment in property, plant and equipment         564         176         (48)         (67,755				( )	( )	6 793
Research and development costs         (866)         (636)         (11,345)         (15,224)         (26,088           Other operating income         -         100         - <td>•</td> <td></td> <td>,</td> <td></td> <td>,</td> <td></td>	•		,		,	
Other operating income         -         100         -         -         -           Operating result         (8,359)         (28,768)         (29,300)         (9,901)         (24,240)           Net financial income / (expenses)         (2,090)         (45)         2,168         3,531         (788)           Result before tax         (10,449)         (28,813)         (27,132)         (6,69)         (25,028)           Tax for the period         (9,542)         (10,135)         (26,179)         (6,136)         (24,806)           Statement of Financial Position           Cash and cash equivalents         7,766         3,359         15,763         44,178         60,719           Total assets         41,921         29,884         21,809         47,983         64,453           Total equity         5,316         10,195         13,127         41,371         51,553           Investment in property, plant and equipment         564         176         48         295         195           Cash flow from operating activities         (564)         (176)         (48)         (430)         (188           Cash flow from financing activities         12,435         15,981         48         167         (575 <tr< td=""><td></td><td></td><td>. , ,</td><td></td><td></td><td></td></tr<>			. , ,			
Operating result         (8,359)         (28,768)         (29,300)         (9,901)         (24,240)           Net financial income / (expenses)         (2,090)         (45)         2,168         3,531         (788)           Result before tax         (10,449)         (28,813)         (27,132)         (6,636)         (25,028)           Tax for the period         907         18,678         953         234         223           Net result for the period         (9,542)         (10,135)         (26,179)         (6,136)         (24,806)           Statement of Financial Position         T,766         3,359         15,763         44,178         60,719           Total assets         41,921         29,884         21,809         47,983         64,453           Total assets         41,921         29,884         21,809         41,921         51,813           Investment in property, plant and equipment         564         176         48         295         195           Cash flow from operating activities         (7,710)         (28,057)         (26,392)         (13,050)         (28,089)           Cash flow from operating activities         (564)         (176)         (48)         (430)         (188)           Cash flow from inancing a		(000)		(11,545)	(13,224)	(20,000)
Net financial income / (expenses)       (2,090)       (45)       2,168       3,531       (788         Result before tax       (10,449)       (28,813)       (27,132)       (6,369)       (25,028         Tax for the period       907       18,678       953       234       223         Net result for the period       (9,542)       (10,135)       (26,179)       (6,136)       (24,806         Statement of Financial Position        (25,928       (25,928       (26,179)       (6,136)       (24,806         Statement of Financial Position         (20,135)       (26,179)       (6,136)       (24,806         Statement of Financial Position          (20,912)       (10,135)       (26,179)       (6,136)       (24,806         Statement of Financial Position          (26,179)       (6,136)       (24,806         Statement of property.plant and equipment       564       10,195       13,127       41,371       51,553         Investment in property, plant and equipment       564       176       (48)       (430)       (188         Cash flow from operating activities       (7,710)       (28,057)       (26,392)       (13,050)       (28,089		(8 359)		(29 300)	(9 901)	(24 240)
Result before tax       (10,449)       (28,813)       (27,132)       (6,369)       (25,028         Tax for the period       907       18,678       953       234       223         Net result for the period       (9,542)       (10,135)       (26,179)       (6,136)       (24,806         Statement of Financial Position          (0,719)       (0,719)       (0,719)         Total assets       41,921       29,884       21,809       47,983       64,453         Total assets       41,921       29,884       21,809       47,983       64,453         Total equity       5,316       10,195       13,127       41,371       51,553         Investment in property, plant and equipment       564       176       48       295       195         Cash flow from operating activities       (7,710)       (28,057)       (26,392)       (13,050)       (28,089         Cash flow from investing activities       15,643       (176)       (48)       (430)       (188         Cash flow from financing activities       12,435       15,981       48       167       (575         Cash and cash equivalents at period end       7,766       3,359       15,763       44,178       60,719 </td <td></td> <td></td> <td></td> <td></td> <td>., ,</td> <td></td>					., ,	
Tax for the period       907       18,678       953       234       223         Net result for the period       (9,542)       (10,135)       (26,179)       (6,136)       (24,806         Statement of Financial Position         Cash and cash equivalents       7,766       3,359       15,763       44,178       60,719         Total assets       41,921       29,884       21,809       47,983       64,453         Total assets       41,921       29,884       21,809       47,983       64,453         Total assets       41,921       29,884       21,809       47,983       64,453         Total assets       5,316       10,195       13,127       41,371       51,553         Investment in property, plant and equipment       564       176       48       295       195         Cash flow from operating activities       (7,710)       (28,057)       (26,392)       (13,050)       (28,089         Cash flow from investing activities       (564)       (176)       (48)       (430)       (188         Cash flow from financing activities       12,435       15,981       48       167       (575         Cash and cash equivalents at period end       7,766       3,359       15,763			· · · ·			
Net result for the period         (9,542)         (10,135)         (26,179)         (6,136)         (24,806)           Statement of Financial Position         Cash and cash equivalents         7,766         3,359         15,763         44,178         60,719           Total assets         41,921         29,884         21,809         47,983         64,453           Total assets         41,921         29,884         21,809         47,983         64,453           Total equity         5,316         10,195         13,127         41,371         51,553           Investment in property, plant and equipment         564         176         48         295         195           Cash flow from operating activities         (7,710)         (28,057)         (26,392)         (13,050)         (28,089)           Cash flow from investing activities         (564)         (176)         (48)         (430)         (188           Cash flow from financing activities         12,435         15,981         48         167         (575           Cash and cash equivalents at period end         7,766         3,359         15,763         44,178         60,719           Financial Ratios         Basic and diluted EPS (DKK)         (0.01)         (0.01)         (0.02)		( ) )		( ) )	., ,	
Statement of Financial Position           Cash and cash equivalents         7,766         3,359         15,763         44,178         60,719           Total assets         41,921         29,884         21,809         47,983         64,453           Total equity         5,316         10,195         13,127         41,371         51,553           Investment in property, plant and equipment         564         176         48         295         195           Cash Flow Statement         Cash flow from operating activities         (7,710)         (28,057)         (26,392)         (13,050)         (28,089           Cash flow from investing activities         (564)         (176)         (48)         (430)         (188           Cash flow from financing activities         12,435         15,981         48         167         (575           Cash and cash equivalents at period end         7,766         3,359         15,763         44,178         60,719           Financial Ratios         Basic and diluted EPS (DKK)         (0.01)         (0.01)         (0.02)         (0.02)         (0.08           Weighted average number of shares         1,708,325,635         1,688,679,397         1,663,334,241         1,662,266,639         1,660,353,248           A					-	-
Cash and cash equivalents7,7663,35915,76344,17860,719Total assets41,92129,88421,80947,98364,453Total equity5,31610,19513,12741,37151,553Investment in property, plant and equipment56417648295195Cash Flow StatementCash flow from operating activities(7,710)(28,057)(26,392)(13,050)(28,089Cash flow from investing activities(564)(176)(48)(430)(188Cash and cash equivalents at period end7,7663,35915,76344,17860,719Financial RatiosBasic and diluted EPS (DKK)(0.01)(0.01)(0.02)(0.02)(0.08Weighted average number of shares1,708,325,6351,688,679,3971,663,334,2411,662,266,6391,660,353,248Average number of employees (FTEs)5154382626Assets/equity7.892.931.661.161.25Share price DKK0.861.081.751.150.70Average exchange rates DKK/USD6.53016.69406.72695.61905.6160		(0)01=)	(10)1007	(=0)=707	(0)2007	(2.)000
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Total equity       5,316       10,195       13,127       41,371       51,553         Investment in property, plant and equipment       564       176       48       295       195         Cash Flow Statement       Cash flow from operating activities       (7,710)       (28,057)       (26,392)       (13,050)       (28,089)         Cash flow from investing activities       (564)       (176)       (48)       (430)       (188         Cash flow from financing activities       12,435       15,981       48       167       (575         Cash and cash equivalents at period end       7,766       3,359       15,763       44,178       60,719         Financial Ratios       Example       Example       Example       Example       Example       Example         Sais and diluted EPS (DKK)       (0.01)       (0.01)       (0.02)       (0.02)       (0.08         Weighted average number of shares       1,708,325,635       1,688,679,397       1,663,334,241       1,662,266,639       1,660,353,248         Average number of employees (FTEs)       51       54       38       26       26         Assets/equity       7.89       2.93       1.66       1.16       1.25         Share price DKK       0.86       1.08 <td>Cash and cash equivalents</td> <td>7,766</td> <td>3,359</td> <td>15,763</td> <td>44,178</td> <td>60,719</td>	Cash and cash equivalents	7,766	3,359	15,763	44,178	60,719
Investment in property, plant and equipment         564         176         48         295         195           Cash Flow Statement         Cash flow from operating activities         (7,710)         (28,057)         (26,392)         (13,050)         (28,089)           Cash flow from investing activities         (564)         (176)         (48)         (430)         (188)           Cash flow from financing activities         12,435         15,981         48         167         (575)           Cash and cash equivalents at period end         7,766         3,359         15,763         44,178         60,719           Financial Ratios         Basic and diluted EPS (DKK)         (0.01)         (0.01)         (0.02)         (0.02)         (0.08           Weighted average number of shares         1,708,325,635         1,688,679,397         1,663,334,241         1,662,266,639         1,660,353,248           Average number of employees (FTEs)         51         54         38         26         26           Assets/equity         7.89         2.93         1.66         1.16         1.25           Share price DKK         0.86         1.08         1.75         1.15         0.70           Average exchange rates DKK/USD         6.5301         6.6940         6.7269	Total assets	41,921	29,884	21,809	47,983	64,453
Cash Flow Statement         Cash flow from operating activities       (7,710)       (28,057)       (26,392)       (13,050)       (28,089)         Cash flow from investing activities       (564)       (176)       (48)       (430)       (188         Cash flow from financing activities       12,435       15,981       48       167       (575         Cash and cash equivalents at period end       7,766       3,359       15,763       44,178       60,719         Financial Ratios       Basic and diluted EPS (DKK)       (0.01)       (0.01)       (0.02)       (0.02)       (0.08         Weighted average number of shares       1,708,325,635       1,688,679,397       1,663,334,241       1,662,266,639       1,660,353,248         Average number of employees (FTEs)       51       54       38       26       26         Assets/equity       7.89       2.93       1.66       1.16       1.25         Share price DKK       0.86       1.08       1.75       1.15       0.70         Average exchange rates DKK/USD       6.5301       6.6940       6.7269       5.6190       5.6160	Total equity	5,316	10,195	13,127	41,371	51,553
Cash flow from operating activities       (7,710)       (28,057)       (26,392)       (13,050)       (28,089)         Cash flow from investing activities       (564)       (176)       (48)       (430)       (188         Cash flow from financing activities       12,435       15,981       48       167       (575         Cash and cash equivalents at period end       7,766       3,359       15,763       44,178       60,719         Financial Ratios         Basic and diluted EPS (DKK)       (0.01)       (0.01)       (0.02)       (0.02)       (0.08         Weighted average number of shares       1,708,325,635       1,688,679,397       1,663,334,241       1,662,266,639       1,660,353,248         Average number of employees (FTEs)       51       54       38       26       26         Assets/equity       7.89       2.93       1.66       1.16       1.25         Share price DKK       0.86       1.08       1.75       1.15       0.70         Average exchange rates DKK/USD       6.5301       6.6940       6.7269       5.6190       5.6160	Investment in property, plant and equipment	564	176	48	295	195
Cash flow from investing activities       (564)       (176)       (48)       (430)       (188)         Cash flow from financing activities       12,435       15,981       48       167       (575)         Cash and cash equivalents at period end       7,766       3,359       15,763       44,178       60,719         Financial Ratios         Basic and diluted EPS (DKK)       (0.01)       (0.01)       (0.02)       (0.02)       (0.08         Weighted average number of shares       1,708,325,635       1,688,679,397       1,663,334,241       1,662,266,639       1,660,353,248         Average number of employees (FTEs)       51       54       38       26       26         Assets/equity       7.89       2.93       1.66       1.16       1.25         Share price DKK       0.86       1.08       1.75       1.15       0.70         Average exchange rates DKK/USD       6.5301       6.6940       6.7269       5.6190       5.6160	Cash Flow Statement					
Cash flow from investing activities       (564)       (176)       (48)       (430)       (188)         Cash flow from financing activities       12,435       15,981       48       167       (575)         Cash and cash equivalents at period end       7,766       3,359       15,763       44,178       60,719         Financial Ratios         Basic and diluted EPS (DKK)       (0.01)       (0.01)       (0.02)       (0.02)       (0.08         Weighted average number of shares       1,708,325,635       1,688,679,397       1,663,334,241       1,662,266,639       1,660,353,248         Average number of employees (FTEs)       51       54       38       26       26         Assets/equity       7.89       2.93       1.66       1.16       1.25         Share price DKK       0.86       1.08       1.75       1.15       0.70         Average exchange rates DKK/USD       6.5301       6.6940       6.7269       5.6190       5.6160	Cash flow from operating activities	(7,710)	(28,057)	(26,392)	(13,050)	(28,089)
Cash and cash equivalents at period end       7,766       3,359       15,763       44,178       60,719         Financial Ratios	Cash flow from investing activities	(564)	(176)	(48)	(430)	(188
Financial Ratios           Basic and diluted EPS (DKK)         (0.01)         (0.01)         (0.02)         (0.02)           Weighted average number of shares         1,708,325,635         1,688,679,397         1,663,334,241         1,662,266,639         1,660,353,248           Average number of employees (FTEs)         51         54         38         26         26           Assets/equity         7.89         2.93         1.66         1.16         1.25           Share price DKK         0.86         1.08         1.75         1.15         0.70           Average exchange rates DKK/USD         6.5301         6.6940         6.7269         5.6190         5.6160	Cash flow from financing activities	12,435	15,981	48	167	(575)
Basic and diluted EPS (DKK)       (0.01)       (0.01)       (0.02)       (0.02)       (0.08         Weighted average number of shares       1,708,325,635       1,688,679,397       1,663,334,241       1,662,266,639       1,660,353,248         Average number of employees (FTEs)       51       54       38       26       26         Assets/equity       7.89       2.93       1.66       1.16       1.25         Share price DKK       0.86       1.08       1.75       1.15       0.70         Average exchange rates DKK/USD       6.5301       6.6940       6.7269       5.6190       5.6160	Cash and cash equivalents at period end	7,766	3,359	15,763	44,178	60,719
Basic and diluted EPS (DKK)       (0.01)       (0.01)       (0.02)       (0.02)       (0.08         Weighted average number of shares       1,708,325,635       1,688,679,397       1,663,334,241       1,662,266,639       1,660,353,248         Average number of employees (FTEs)       51       54       38       26       26         Assets/equity       7.89       2.93       1.66       1.16       1.25         Share price DKK       0.86       1.08       1.75       1.15       0.70         Average exchange rates DKK/USD       6.5301       6.6940       6.7269       5.6190       5.6160	Financial Ratios					
Weighted average number of shares       1,708,325,635       1,688,679,397       1,663,334,241       1,662,266,639       1,660,353,248         Average number of employees (FTEs)       51       54       38       26       26         Assets/equity       7.89       2.93       1.66       1.16       1.25         Share price DKK       0.86       1.08       1.75       1.15       0.70         Average exchange rates DKK/USD       6.5301       6.6940       6.7269       5.6190       5.6160		(0.01)	(0.01)	(0.02)	(0.02)	(0.08)
Average number of employees (FTEs)         51         54         38         26         26           Assets/equity         7.89         2.93         1.66         1.16         1.25           Share price DKK         0.86         1.08         1.75         1.15         0.70           Average exchange rates DKK/USD         6.5301         6.6940         6.7269         5.6190         5.6160			· · ·	( )		•
Assets/equity         7.89         2.93         1.66         1.16         1.25           Share price DKK         0.86         1.08         1.75         1.15         0.70           Average exchange rates DKK/USD         6.5301         6.6940         6.7269         5.6190         5.6160						26
Share price DKK         0.86         1.08         1.75         1.15         0.70           Average exchange rates DKK/USD         6.5301         6.6940         6.7269         5.6190         5.6160		-	÷ .		-	-
Average exchange rates DKK/USD         6.5301         6.6940         6.7269         5.6190         5.6160					-	-
	•			_		5.6160
						5.4127

# People

At year-end 2017, Veloxis employed 52 people, all of which are located in the US. The organization is built to support our strategy and we will continue to strengthen the organization with focus on the commercialization of Envarsus in the US.

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

As at 31 December 2017, 100% of our employees were in selling, general and administration (SG&A).

# **Corporate Governance**

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

Veloxis has chosen to disclose the mandatory annual corporate governance report and statutory statement pursuant to Section 99 b of the Danish Financial Statement Act at <u>http://www.veloxis.com/governance.cfm</u>.

# **Risk Management**

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

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

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

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

Additionally, Veloxis relies on third party contract manufacturers to manufacture its products. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, Veloxis's business may be adversely affected.

# **Management Review**

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

#### **Market Risks**

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

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

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

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

#### **Financial Risks**

Veloxis has interest-bearing debt with variable interest rates. Our interest rate risk also extends to our cash and cash equivalent balances. In order to mitigate such risk, Veloxis's treasury policy allows the Company to hold excess cash at deposits with major Danish and US banks and in short-term Danish and US government bonds or Danish mortgage bonds with limited duration.

#### Legal Risks

Biotechnology and pharmaceutical companies are often involved in legal proceedings concerning a variety of issues including product liability claims, regulatory violations and infringement of intellectual property rights. As at 31 December 2017, the Company was not a party to any pending legal proceedings.

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

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

### **Reputational Risks**

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

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

Veloxis maintains a Code of Ethics that helps ensure that all employees comply with applicable international laws and regulations. This Code of Ethics is crucial to sustaining Veloxis's culture of compliance. It helps our employees comply with applicable laws and regulations, pharmaceutical industry standards and corporate requirements. We provide regular training and revise our Code of Ethics and related procedures to meet changing regulations, implement best practices and to respond to audit observations.

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

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

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

# **Working Environment**

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

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

In 2017, the Company did not experience any workplace safety incidents.

# **Anti-Bribery and Corruption**

Governments around the world play a key role in Veloxis's industry either as regulators, purchasers or payors. Additionally, Veloxis retains the services of scientists and doctors for consulting and research activities, many of whom are government employees or employees of public institutions. Most countries in which Veloxis does business have laws that forbid making, offering or promising payments or anything of value to a government employee when such payment is intended to influence an official act or decision to obtain or retain business or secure an unfair business advantage. Veloxis's Code of Ethics specifically requires that all employees comply with all federal, state and local laws relating to anti-bribery and corruption.

### **Business Partners**

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

During the year we have performed 20 visits and audits (12 in 2016) 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.

# **Shareholder Information**

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

In 2017, Veloxis met several times with existing and potential shareholders. These meetings took place in both the US and Europe.

# **About Our Shares**

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

# **Share Capital**

As at 31 December 2017 Veloxis had a registered share capital of USD 24,311 with a nominal value of DKK 0.1 per share (USD 0.014). Please see note 12 on page 48 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 2018, to arrange for the Company to acquire its own shares up to 10% of the share capital. Such acquisition must be in accordance with section 197 of the Danish Companies Act and may be financed by funds that may be distributed as ordinary dividends. The purchase price of such shares may not differ by more than 10% from the price quoted on the NASDAQ Copenhagen A/S at the time of purchase.

# **Ownership Structure**

As at 31 December 2017, a total of 8,040 of Veloxis's shareholders were registered in the shareholder register; a slight decrease from 8,064 shareholders as at 31 December 2016. Veloxis invites all shareholders to register in the Company's shareholder register.

As at 31 December 2017, the following shareholders have reported ownership of 5% or more of the Company's shares:

- Lundbeckfond Invest A/S 41.4% (100% owned by the Lundbeck Foundation), Denmark, municipality of Copenhagen
- Novo Holdings A/S 41.4% (100% owned by the Novo Nordisk Foundation), Denmark, municipality of Gentofte

### 2017 Company Announcements

During 2017, the Company issued 27 Company Announcements. These can be found on Veloxis's website: <u>http://www.veloxis.com/releases.cfm</u>.

# Management Review

# Financial Calendar 2018

27 February 2018	2017 Annual Report
01 March 2018	Deadline for Receipt of Shareholder Proposals for 2018 Annual General Meeting
13 April 2018	Annual General Meeting
14 May 2018	Interim Report for the First Three Months of 2018
13 August 2018	Interim Report for the First Six Months of 2018
14 November 2018	Interim Report for the First Nine Months of 2018

# **IR Contact**

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

# **Board of Directors & Management**

# **Board of Directors**

# Michael T. Heffernan

Chairman

Male Age: 53 Elected at the 2015 AGM Current term expires 13 April 2018 Nomination Committee (C) Remuneration Committee (M) Independent

# **Competences:**

Registered Pharmacist CEO, Collegium Pharmaceutical, Inc.

# Directorships:

Collegium Pharmaceutical, Inc. Keryx Biopharmaceuticals, Inc. Trevi Therapeutics, Inc.

# **Mette Kirstine Agger**

Deputy Chairman

Female Age: 53 Elected at 2010 AGM Current term expires 13 April 2018 Audit Committee (M) Remuneration Committee (M) Independent

# **Competences:**

International Pharmaceutical Experience Managing Partner, Lundbeckfonden Ventures

# Directorships:

Klifo A/S PsiOxus Therapeutics Ltd. Cydan Inc. scPharmaceuticals, Inc. Thesan Pharmaceuticals Inc. Imara Inc. Trevi Therapeutics, Inc.

# **Anders Götzsche**

# Member

Male Age: 50 Elected at 2008 AGM Current term expires 13 April 2018 Audit Committee (C) Independent

**Competences:** Interim CEO, EVP & CFO, H. Lundbeck A/S

**Directorships:** Rosborg Møbler A/S

# Lars Kåre Viksmoen

Member

Male Age: 69 Elected at July 2016 EGM Current term expires 13 April 2018 Nominating Committee (M) Independent

# **Competences:**

Doctor of Medicine Former CEO, GN ReSound A/S Former CEO, Biotec Phamacon ASA 20+ Years with Merck & Co. Inc. in EU, Africa and USA

# Directorships:

PCI Biotech

# Robert S. Radie

Member

Male Age: 54 Elected at July 2016 EGM Current term expires 13 April 2018 Audit Committee (M) Independent

**Competences:** CEO, Egalet Corporation

Directorships:

Egalet Corporation Paratek Pharmaceuticals Horse Power for Life Life Sciences Pennsylvania

# Paul K. Wotton

Member

Male Age: 57 Elected at July 2016 EGM Current term expires 13 April 2018 Remuneration Committee (C) Independent

# Competences:

Ph.D., Pharmaceutical Sciences CEO, Sigilon Inc.

Directorships:

Sigilon, Inc. Vericel Corp. Cynata Therapeutics Limited (C)

AGM = Annual General Meeting, EGM = Extraordinary General Meeting, C = Chairman, M = Member.

# **Executive Management**

# Craig A. Collard

President & CEO

Joined Veloxis in 2015

# 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 2017.

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

Management's Review are prepared in accordance with the Danish Financial Statements Act.

In our opinion, the Consolidated Financial Statements and the Parent Company Financial Statements give a true and fair view of the financial position at 31 December 2017, the results of the Group's and Parent Company's operations, and cash flows for the financial year 2017. Furthermore, in our opinion, Management's Review includes a true and fair account of the development in the operations and financial circumstances, of the results for the year, and of the financial position of the Group and the Parent Company as well as a description of the most significant risks and elements of uncertainty facing the Group and the Parent Company.

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

Copenhagen, 27 February 2018

# **Executive Management**

Craig A. Collard President & CEO

# **Board of Directors**

Michael Heffernan Chairman	Mette Kristine Agger Deputy Chairman
Anders Götzsche	Robert Radie
Lars Kåre Viksmoen	Paul K. Wotton

# Independent Auditor's Report

### To the Shareholders of Veloxis Pharmaceuticals A/S

### **Our Opinion**

In our opinion, the Consolidated Financial Statements and the Parent Company Financial Statements give a true and fair view of the Group's and the Parent Company's financial position at 31 December 2017 and of the results of the Group's and the Parent Company's operations and cash flows for the financial year 1 January to 31 December 2017 in accordance with International Financial Reporting Standards as adopted by the EU and further requirements in the Danish Financial Statements Act.

Our opinion is consistent with our Auditor's Long-form Report to the Audit Committee and the Board of Directors.

#### What we have audited

The Consolidated Financial Statements and Parent Company Financial Statements of Veloxis Pharmaceuticals A/S for the financial year 1 January to 31 December 2017 comprise income statement, statement of comprehensive income, balance sheet, 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. Collectively referred to as the "Financial Statements".

#### **Basis for opinion**

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

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

#### Independence

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

To the best of our knowledge and belief, prohibited non-audit services referred to in Article 5(1) of Regulation (EU) No 537/2014 were not provided.

#### Appointment

Following the admission of the shares of Veloxis Pharmaceuticals A/S for listing on Nasdaq Copenhagen on November 13, 2006, we were first appointed auditors of Veloxis Pharmaceuticals A/S on April 24, 2007. We have been reappointed annually by shareholder resolution for a total period of engagement of 11 years including the financial year 2017. We were reappointed following a tendering procedure at the General Meeting on April 7, 2017.

#### **Key audit matters**

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the Financial Statements for 2017. These matters were addressed in the context of our audit of the Financial Statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

business outlook of the Group

assets.

accuracy of budgets.

recognition of deferred tax assets.

#### **Key audit matters**

#### How our audit addressed the key audit matters

We discussed deferred tax asset recognition principles with

management and we inquired with management on the

We obtained financial budget for 2018 and forecasts for 2019 - 2022 underpinning the valuation of deferred tax

We critically challenged management's key assumptions and projections, by comparing Management's assessment

to evidence obtained, such as business plans and historical

We performed substantive audit procedures on the

#### Valuation of Deferred Tax Asset

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

Recognition of deferred tax assets depend on probable future taxable income will be available, against which the deferred tax assets can be utilized.

Significant judgement is required by Management in projections in financial budget for 2018 and forecasts for 2019 – 2022, especially expectations for revenue growth and gross margin, particularly when marketing a new product and transforming to a commercial company.

We focused on deferred tax assets because the recognition of deferred tax assets requires significant judgement and estimation by Management.

Reference is made to note 2 and 8 in the Consolidated Financial Statements.

#### Statement on Management's Review

Management is responsible for Management's Review.

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

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

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

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

#### Management's responsibilities for the Financial Statements

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

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

### Auditor's responsibilities for the audit of the Financial Statements

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

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

- Identify and assess the risks of material misstatement of the Financial Statements, whether due to fraud or error, design
  and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to
  provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for
  one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the
  override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's and the Parent Company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by Management.
- Conclude on the appropriateness of Management's use of the going concern basis of accounting and based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's and the Parent Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the Financial Statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group or the Parent Company to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the Financial Statements, including the disclosures, and whether the Financial Statements represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the Consolidated Financial Statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

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

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

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

Copenhagen, 27 February 2018

**PricewaterhouseCoopers** Statsautoriseret Revisionspartnerselskab *CVR No 33 77 12 31* 

Søren Ørjan Jensen State Authorised Public Accountant mne33226 Henrik Ødegaard State Authorised Public Accountant mne31489

# **Financial Statements**

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# **Income Statement**

# For the period 1 January – 31 December

		Consoli	dated	Parent	t
(USD'000)	Note	2017	2016	2017	2016
Revenue	3	30,167	9,194	12,670	3,800
Production costs		(5,202)	(3,019)	-	-
Gross profit		24,965	6,175	12,670	3,800
Selling, general and administrative costs	4.5	(32,458)	(34,407)	(3,453)	(10,875)
Research and development costs Other operating income	4.5	(866)	(636) 100	-	-
Operating result		(8,359)	(28,768)	9,217	(7,075)
Financial income	6	199	643	3,372	2,117
Financial expenses	7	(2,289)	(688)	(2,269)	(674)
Result before tax		(10,449)	(28,813)	10,320	(5,632)
Tax for the year	8	907	18,678	1,348	18,678
Net result for the year		(9,542)	(10,135)	11,668	13,046
Basic and diluted EPS		(0.01)	(0.01)		
Weighted average number of shares		1,708,325,635	1,688,679,397		

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

	Consolida	ited	Parent		
(USD'000)	2017	2016	2017	2016	
Net result for the period	(9,542)	(10,135)	11,668	13,046	
Other comprehensive income: Items that may be subsequently reclassified to profit or loss:					
Currency translation differences, net of tax		(392)	-	(388)	
Other comprehensive income for the period		(392)		(388)	
Total comprehensive income for the period	(9,542)	(10,527)	11,668	12,658	

# **Balance Sheet**

# Assets at 31 December

		Consolida	ated	Paren	t
(USD'000)	Note	2017	2016	2017	2016
Patent rights and software	9	80	114	33	40
Intangible assets		80	114	33	40
Property, plant and equipment	9	875	482	202	308
Tangible fixed assets		875	482	202	308
Receivable from subsidiary		-	-	48,026	27,194
Equity interest in subsidiary	10	-	-	4,070	368
Deferred tax asset	8	20,187	18,678	20,187	18,678
Financial assets		20,187	18,678	72,283	46,240
Non-current assets		21,142	19,274	72,518	46,588
Inventories	11	6,781	4,141		-
Trade receivables		4,354	2,212	-	-
Other receivables		55	96	48	55
Prepayments		1,823	802	149	192
Receivables		6,232	3,110	197	247
Cash		7,766	3,359	6,139	2,335
Cash and cash equivalents		7,766	3,359	6,139	2,335
Current assets		20,779	10,610	6,336	2,582
Assets		41,921	29,884	78,854	49,170

Fees to auditors

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

		Consolidated		Parent	nt	
(USD'000)	Note	2017	2016	2017	2016	
Share capital	12	24,311	24,175	24,311	24,175	
Special reserve	12	57,804	57,804	57,804	57,804	
Translation reserves		(4,052)	(4,052)	(4,297)	(4,297)	
Retained earnings/loss		(72,747)	(67,732)	(27,200)	(43,395)	
Equity		5,316	10,195	50,618	34,287	
Loan	13	25,818	13,816	25,883	13,901	
Non-current liabilities		25,818	13,816	25,883	13,901	
Trade payables		2,428	957	107	118	
Other payables		8,359	4,916	2,246	864	
Current liabilities		10,787	5,873	2,353	982	
Liabilities		36,605	19,689	28,236	14,883	
Equity and liabilities		41,921	29,884	78,854	49,170	
Financial risks	14					
Warrants	15					
Other Commitments	16					
Related parties	17					

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# **Cash Flow Statement**

# For the period 1 January – 31 December

		Consolidated		Parent		
(USD'000)	Note	2017	2016	2017	2016	
Operating result		(8,359)	(28,768)	9,217	(7,075)	
Share-based payment	5	4,174	5,430	472	5,430	
Depreciation and amortization	4	205	208	113	153	
Changes in working capital	18	(2,517)	(5,787)	3,367	526	
Cash flow from operating activities before	interest	(6,497)	(28,917)	13,169	(966)	
Interest received		-	-	-	-	
Interest paid		(1,213)	-	(1,213)	-	
Corporate tax received		-	860	-	860	
Cash flow from operating activities	<u> </u>	(7,710)	(28,057)	11,956	(106)	
Purchase of property, plant and equipr	nent	(564)	(176)	-	-	
Payable to / (receivable) from subsidia	ry	-		(20,833)	(28,683)	
Cash flow from investing activities	<u> </u>	(564)	(176)	(20,833)	(28,683)	
Proceeds from bank borrowings		12,000	14,000	12,000	14,000	
Cost of borrowings		(54)	(184)	(54)	(98)	
Proceeds from issuance of shares		489	2,165	489	2,165	
Cash flow from financing activities		12,435	15,981	12,435	16,067	
Increase/(decrease) in cash		4,161	(12,252)	3,558	(12,722)	
Cash at beginning of period		3,359	15,763	2,335	15,209	
Exchange gains/(losses) on cash		246	(152)	246	(152)	
Cash at end of period		7,766	3,359	6,139	2,335	

Parent contributed USD 3,702 as a non-cash contribution through investment in sub Cash includes USD 315 of restricted cash in Consolidated numbers for 2017 and 2016

# Statement of Changes in Equity Consolidated

Consolidated						
USD	Number of Shares	Share Capital USD'000	Special Reserves USD'000	Translation Reserves USD'000	Retained Earnings USD'000	Total USD'000
Equity as of 1 January 2016	1,663,783,575	23,578	57,804	(3,660)	(64,595)	13,127
Net result for the year Currency adjustment				(392)	(10,135)	(10,135) (392)
Total comprehensive income		-	-	(392)	(10,135)	(10,527)
Warrant exercises Share-based payment	39,590,306	597			1,568 5,430	2,165 5,430
Other transactions	39,590,306	597	-	-	6,998	7,595
Equity as of 31 December 2016	1,703,373,881	24,175	57,804	(4,052)	(67,732)	10,195
Net result for the year					(9,542)	(9,542)
Total comprehensive income				-	(9,542)	(9,542)
Warrant exercises	9,064,650	136			353	489
Share-based payment					4,174	4,174
Other transactions	9,064,650	136	-	-	4,527	4,663
Equity as of 31 December 2017	1,712,438,531	24,311	57,804	(4,052)	(72,747)	5,316

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

Translation reserves may be subsequently reclassified to profit and loss.

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

# Statement of Changes in Equity Parent Company

Parent						
USD	Number of Shares	Share Capital USD'000	Special Reserves USD'000	Translation Reserves USD'000	Retained Earnings USD'000	Total USD'000
Equity as of 1 January 2016	1,663,783,575	23,578	57,804	(3,909)	(63,439)	14,034
Net result for the year Currency adjustment				(388)	13,046 -	13,046 (388)
Total comprehensive income		-	-	(388)	13,046	12,658
Warrant exercises Share-based payment	39,590,306	597			1,568 5,430	2,165 5,430
Other transactions	39,590,306	597	-	-	6,998	7,595
Equity as of 31 December 2016	1,703,373,881	24,175	57,804	(4,297)	(43,395)	34,287
Net result for the year					11,668	11,668
Total comprehensive income				-	11,668	11,668
Warrant exercises	9,064,650	136			353	489
Share-based payment					4,174	4,174
Other transactions	9,064,650	136	-	-	4,527	4,663
Equity as of 31 December 2017	1,712,438,531	24,311	57,804	(4,297)	(27,200)	50,618

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

# Notes

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

# **Note 1. Summary of Significant Accounting Policies**

# General

The Annual Report of Veloxis Pharmaceuticals A/S (the Parent Company) for the year ended 31 December 2017, 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 Consolidated Financial Statements include Veloxis Pharmaceuticals A/S 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").

Effective 1 January 2017, the functional and presentation currency are USD for both the Parent Company and the Consolidated Financial Statements because of the change of activity in the Parent and the related change in the currency of the Group's transactions.

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

# **Accounting Policy Changes**

### Adoption of new or amended IFRS's

Veloxis has adopted the following new or amended standards and interpretations from January 1, 2017:

Amendments to IAS 7 Disclosure Initiative was published in January 2016 and requires an entity to provide disclosures that enable users of financial statements to evaluate changes in liabilities arising from financing activities.

Besides the adopted standard described above, no new or amended or revised accounting standards and interpretations issued by the International Accounting Standards Board (IASB) and IFRS endorsed by the European Union have an effect on the Consolidated Financial Statements for 2017.

### **New Financial Standards Adopted**

In addition to the above, IASB has issued a number of new or amended and revised accounting standards and interpretations that have not yet come into effect. New or amended and revised standards are implemented when taking effect. The following standards are, in general, expected to cause the most significant changes to current accounting regulation:

IFRS 9 "Financial Instruments" will apply from the 2018 financial year. The standard contains amendments to the classification and measurement of financial instruments. Implementation of IFRS 9 is not expected to have a material effect on the Consolidated Financial Statements.

IFRS 15 "Revenue from contracts with customers" will apply from the 2018 financial year. The standard contains a revised model for the recognition of revenue and a number of additional disclosure requirements. Management has assessed the implementation of IFRS 15 and concluded that the effect on the Consolidated Financial Statements is expected to be limited.

IFRS 16 "Leases" will apply from the 2019 financial year. The standard requires that all leases must be recognized in the balance sheet with a corresponding lease liability, except for short-term assets and minor assets. Veloxis is currently analyzing the effects of implementing IFRS 16, but implementation is not expected to have a material effect on the Consolidated Financial Statements.

None of the other changed standards or interpretations are expected to have any significant monetary effect on the statements of the Group's results, assets and liabilities or the equity."

### **Consolidated Financial Statements**

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

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

### **Foreign Currency**

Items included in the Financial Statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates ('the functional currency'). The functional currency of the Company's operations is in USD. The financial statements are presented in USD, which is the Group's functional and presentation currency.

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

### **Operating Lease Commitments**

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

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

### **Comprehensive Income**

Veloxis presents comprehensive income in two statements. An income statement and a statement of total comprehensive income which includes results for the year and income recognized in other comprehensive income. Prior to 2017, other comprehensive income included the difference between exchange rates used for converting balance sheet accounts and income statement accounts arising from translating the financial statements of the Parent Company.

# **Income Statement**

#### Revenues

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

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

#### **Production Costs**

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

#### Selling, General and Administrative Costs

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

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

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

### **Research and Development Costs**

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

Research costs are recognized in the income statement in the period to which they relate. Development costs are recognized in the income statement when incurred if the criteria for capitalization have not been met.

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

#### **Share-Based Payment**

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

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

#### **Financial Items**

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

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

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

#### **Corporate Tax**

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

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

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

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

# **Statement of Financial Position**

### **Non-Current Assets**

### **Intangible Assets**

Intangible assets comprise acquired patent rights and software.

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

Patent rights:	20 years
Software:	3-5 years

# **Tangible Fixed Assets**

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

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

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

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

Depreciation period and residual value are reassessed annually.

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

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

### **Current Assets**

#### Inventories

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

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

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

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

### **Trade Receivables**

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

#### **Other Receivables**

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

#### Prepayments

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

### **Cash and Cash Equivalents**

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

### **Shareholders' Equity**

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

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

# **Non-Current Liabilities**

#### Loan

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

### **Current Liabilities**

### **Trade Payables**

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

# **Deferred Revenue**

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

### **Other Liabilities**

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

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

### **Equity Interests in Subsidiaries**

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

# **Cash Flow Statement**

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

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

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

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

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

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

### **Segment Reporting**

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

#### **Financial Ratios**

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

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

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

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

Assets/Equity Ratio =

<u>Total Assets</u> Equity

# **Note 2. Critical Accounting Estimates and Judgments**

In preparing financial statements under IFRS, certain provisions in the standards require Management's judgments. Such judgments are considered important to understand the accounting policies and Veloxis's compliance with the standards. The following

### **Financial Statements**

summarizes the areas involving higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the financial statements.

### **Deferred Tax Assets**

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

# **Sales Deductions**

Sales deductions are estimated and provided for at the time the related sales are recorded. These estimates of unsettled obligations require use of judgement, as all conditions are not known at the time of sale. Accruals of sales deductions amounted to USD 0.8 – 1.3 million.

### Chargebacks

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

### Rebates

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

# Discounts, Sales Returns and Other Rebates

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

# Note 3. Revenue

The Group derives the following types of revenue:

	Consol	idated	Parent		
(USD'000)	2017	2016	2017	2016	
Sale of goods	21,917	9,194	-	-	
Royalty and upfront	8,250	-	12,670	3,800	
Total	30,167	9,194	12,670	3,800	

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

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

	Consoli	dated	Parent		
(USD'000)	2017	2016	2017	2016	
Europe	4,265	2,651	-	-	
United States	17,592	6,543	12,670	3,800	
RoW	8,310	-			
Total	30,167	9,194	12,670	-	

Revenue is comprised from the following major customers:

	Consol	idated	Pai	Parent		
<u>(USD'000)</u>	2017	2016	2017	2016		
Customer A revenue	6,278	2,307	-	-		
Customer B revenue	6,136	2,089	-	-		
Customer C revenue	131	1,315	-	-		
Customer D revenue	2,851	711	-	-		
Customer E revenue	4,265	2,651	-	-		
Other customer revenue	2,196	121	-	-		
Total	21,857	9,194	-	-		

# Note 4. Depreciation and Amortization

	Consol	idated	Parent		
<u>(USD'000)</u>	2017	2016	2017	2016	
Patent rights and software	35	27	7	4	
Property, plant and equipment	154	177	106	149	
Leasehold improvements	16	4	0	0	
Total	205	208	113	153	
Allocated by function: Selling, general and administrative expenses Research and development costs	205	208	113 -	153 	
Total	205	208	113	153	

# Note 5. Staff Costs

	Consolid	ated	Parer	Parent		
<u>(</u> USD'000)	2017	2016	2017	2016		
Wages and salaries	11,494	11,759	360	2,026		
Pension contributions	297	1,055	0	733		
Other social security costs	1,454	1,487	0	2		
Share-based payment	4,174	5,430	472	5,430		
Total	17,419	19,731	832	8,191		
Allocated by function:						
Selling, general and administrative	17,419	19,731	-	8,191		
Research and development costs	-	0	-	0		
Total	17,419	19,731	-	8,191		
Average number of employees (FTEs)	51	54_	-	5		
Remuneration of board of directors, and executive management:						
Board of directors						
Cash remuneration	360	325	360	325		
Share-based payment	382	225	382	225		
	742	550	742	550		
Executive management						
Gross salary	837	789	837	789		
Severance	193	555	193	555		
Bonus	345	618	345	618		
Pension contributions	22	22	22	22		
Share-based payment	2,092	3,903	2,092	3,903		
	3,489	5,887	3,489	5,887		

Members of the Board of Directors receive a fixed annual fee of USD 37.5. The Chairman of the Board of Directors receives a supplement of USD 50 to the fixed fee and the Chairman of respectively the Audit Committee, Nominating Committee and the Compensation Committee receives a supplement of USD 20, USD 15 and USD 10, respectively to the fixed annual fee.

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

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

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

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

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

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

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

	As per 31 Dec	As per 31 December 2017		ember 2016	
	Shares	Shares Warrants		Warrants	
Board of directors					
Anders Götzche	-	2,808,508	-	1,873,929	
Mette Kirstine Agger	1,288	2,958,508	1,288	2,023,929	
Michael Heffernan	-	2,808,508	-	1,873,929	
Paul K. Wotton	-	1,852,010	-	917,431	
Robert Radie	-	1,852,010	-	917,431	
Lars Kåre Viksmoen	-	1,852,010	-	917,431	
Executive management					
Craig A. Collard	-	74,777,196	-	50,565,196	

# Note 6. Financial Income

	Consol	idated	Parent		
(USD'000)	2017	2016	2017	2016	
Interest income	13	-	13	-	
Interest income from group companies	-	-	3,139	1,458	
Exchange rate	186	643	220	659	
Total	199	643	3,372	2,117	

# **Note 7. Financial Expenses**

	Consoli	dated	Parent		
(USD'000)	2017	2016	2017	2016	
Interest expenses	2,289	688	2,269	674	
Total	2,289	688	2,269	674	

# Note 8. Tax and Deferred Tax

	Consolida	ated	Parent		
_(USD'000)	2017	2016	2017	2016	
Actual Corporate tax	(602)	-	(161)	-	
Change in deferred tax	1,509	18,678	1,509	18,678	
Tax for the year	907	18,678	1,348	18,678	
Tax for the year can be explained as follows:					
Income / (loss) for the year before tax	(10,246)	(28,813)	10,964	1,239	
Tax rate	22.0%	22.0%	22.0%	22.0%	
Computed tax on income / (loss) for the year	2,254	6,339	(2,412)	1,239	
Deferred tax asset not recognized	(2,189)	(9,444)	-	-	
Reversal of writedon in previous years	3,670	18,592	3,671	18,592	
Foreign tax withholding	(480)		-		
Permanent differences	47	(1,181)	89	(1,153)	
Tax re previous year	-	(834)	-	-	
Deviation in foreign subsidiary tax rate	(2,395)	5,206	-	-	
Tax for the year	907	18,678	1,348	18,678	
Calculated deferred tax asset, beginning	68,169	61,033	58,724	60,522	
Exchange rate adjustment	8,148	(1,855)	8,149	(1,855)	
Change in deferred tax assets	(124)	8,991	(2,313)	57	
Calculated deferred tax asset, ending	76,193	68,169	64,560	58,724	
Write down to assessed value	(56,006)	(49,491)	(44,373)	(40,046)	
Carrying amount	20,187	18,678	20,187	18,678	

The remaining unrecognized tax loss carry-forward and temporary differences amounts to USD 247,873 (2016 USD 208,061).

# Note 9. Intangible & Tangible Fixed Assets

Consolidated	Patent rights & Software		Property, Plant & Equipment		Leasehold Improvements	
(USD'000)	2017	2016	2017	2016	2017	2016
Cost at 1 January	304	308	6,019	6,074	125	74
Additions	-	2	517	123	46	51
Exchange adjustment	-	(6)	-	(178)	-	-
Cost at 31 December	304	304	6,536	6,019	171	125
Amortization / Depreciation / Impairment loss at 1 January	(190)	(163)	(5,584)	(5,585)	(78)	(74)
Amortization / Depreciation	(35)	(27)	(154)	(177)	(16)	(4)
Exchange adjustment	-	-	-	178	-	-
Amortization / Depreciation / Impairment loss at 31 December	(225)	(190)	(5,738)	(5,584)	(94)	(78)
Net book value at 31 December	80	114	798	435	77	47

Parent	Patent rights & Software		Property, Plant & Equipment	
(USD'000)	2017	2016	2017	2016
Cost at 1 January	182	187	5,799	5,977
Additions	-	-	-	-
Exchange adjustment	-	(5)	(5)	(178)
Cost at 31 December	182	182	5,794	5,799
Amortization / Depreciation / Impairment loss at 1 January	(142)	(139)	(5,491)	(5,516)
Amortization / Depreciation	(7)	(4)	(106)	(149)
Exchange adjustment	-	-	5	174
An anti-stice / Demostration / Investment lass at 24 December	(1.40)	(4.42)	(5 503)	(5.404)
Amortization / Depreciation / Impairment loss at 31 December	(149)	(142)	(5,592)	(5,491)
Net book value at 31 December	33	40	202	308

# Note 10. Investment in Subsidiary

	Parent		
(USD'000)	2017	2016	
Cost at 1 January Addition	368 3,702	380	
Exchange adjustment	-	(12)	
Cost at 31 December	4,070	368	

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

# Note 11. Inventories

	Consolio	dated	Par	Parent	
(USD'000)	2017	2016	2017	2016	
Raw materials	3,837	3,134	-	-	
Work in Process	2,212	313	-	-	
Finished goods	732	694	-	-	
Total	6,781	4,141	-	-	

The total consumption of materials included in production costs amounted to USD 4,274 (2016: USD 1,944).

Production costs include an inventory write down of USD 305. (2016: USD 215).

# Note 12. Share Capital

On 31 December 2017 the total number of outstanding shares was 1,712,438,531. Each share has a nominal value of DKK 0.1 and one vote.

### Changes in Share Capital from 2013 to 2017

The table below sets forth the changes in our issued share capital since 2013:

					Share pri	ce in DKK
Year	Transaction	Share Capital	Share classes after increase	capital	pre bonus shares	post bonus shares range
		•				
2013	Cash contribution	1,250,000	1,660,572,426	shares	-	0.35
2014	Cash contribution	2,424,888	1,662,997,314	shares	-	0.35 - 1.16
2015	Cash contribution	786,261	1,663,783,575	shares	-	0.35 - 1.23
2016	Cash contribution	39,590,306	1,703,373,881	shares	-	0.35 - 1.05
2017	Cash contribution	9,064,650	1,712,438,531	shares	-	0.35 - 0.95

# Note 13. Non-Current Debt

Veloxis has entered into a five-year loan and security agreement with Lundbeckfond invest A/S and Novo Holdings A/S for up to USD 30,000 in financing. The facility may be utilized in tranches and repaid without penalty. It carries a 9.25% interest rate for balances up to USD 20,000 and a 12% interest rate for balances in excess of USD 20,000. Interest is payable annually in arrears and no principal payments are required until the maturity of 8 March, 2021. The amended and restated agreement also provides for a third additional facility in the amount of USD 5 million to be made available at the discretion of Lundbeckfond Invest A/S and Novo Holdings A/S if requested by Veloxis.

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

On February 14, 2018 Veloxis Pharmaceuticals A/S obtained USD 60 million of capital from funds managed by Athyrium Capital Management, LP ("Athyrium"), a leading healthcare-focused investment firm. This financing is in the form of a five-year interest only note with interest at 3-month Libor plus 8% per annum. The funds are structured with USD 60 million available immediately upon closing of the transaction to Veloxis Pharmaceuticals, Inc., and guaranteed by Veloxis Pharmaceuticals A/S. The previous loan with Lundbeckfond invest A/S and Novo Holdings A/S was paid off in connection with obtaining the new loan from Athyrium.

### **Liabilities Arising from Financing Activities**

	Consolidated	Parent
(USD'000)	2017	2017
Long-term debt at 1 January	14,000	14,000
Cash Flows	12,000	12,000
Long-term borrowings	26,000	26,000
Long-term debt at 31 December	26,000	26,000

# Note 14. Financial Risks

### **Interest Rate Risk**

Veloxis has interest-bearing debt with variable interest rates. Our interest rate risk also extends to our cash and cash equivalent balances. In order to mitigate such risk, Veloxis's Treasury Policy allows the Company to hold excess cash at deposits with major Danish and US banks and in short-term Danish and US government bonds or Danish mortgage bonds with limited duration.

### **Cash Management**

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

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### **Capital Structure**

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

# **Credit Risk**

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

### **Liquidity Risk**

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

### **Currency Exposure**

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

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

	Consol	Consolidated		Parent	
	2017	2017 2016 2017		2016	
EUR'000	858	964	858	964	
DKK'000	1,050	1,129	1,050	1,129	

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 an impact on the Company's operating results and cash flows. The Company is primarily exposed to such risk from currency fluctuations between USD and EUR. Based on the EURO position at the end of 2017, a 10% change in the USD/EUR rate will impact result and equity with approximately USD 103.

# Note 15. Warrants

Veloxis has established warrant programs for Board members, members of Executive Management and employees. All warrants have been issued by the Company's shareholders or by the board of directors pursuant to valid authorizations in Veloxis's Articles of Association.

# **Vesting Conditions**

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

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

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

# **Term of Granted Warrants**

The maximum term for all granted warrants is 7 years.

### **Exercise Periods**

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

# Warrant Activity

The following table specifies the warrant activity:

	Current and Former Employees	Executive management	Board of directors	Total	Weighted average exercise price DKK
Outstanding as of 1 January 2016	93,189,049	20,847,552	5,107,815	119,144,416	0.67
Granted in the year	19,202,073	67,420,261	5,499,917	92,122,251	1.40
Exercised in the year	(39,590,306)	-	-	(39,590,306)	0.36
Cancelled in the year	(38,281,833)	-	-	(38,281,833)	0.76
Expired in the year	(1,260,889)	-	(29,860)	(1,290,749)	3.55
Change between categories	22,901,344	(20,847,552)	(2,053,792)	-	
Outstanding as of 31 December 2016	56,159,438	67,420,261	8,524,080	132,103,779	1.21
Granted in the year	34,562,500	24,212,000	5,607,474	64,381,974	0.97
Exercised in the year	(9,064,650)	-	-	(9,064,650)	0.36
Cancelled in the year	(4,025,113)	-	-	(4,025,113)	1.14
Expired in the year	(2,943,500)	-	-	(2,943,500)	1.38
Change between categories	16,855,065	(16,855,065)	-	-	-
Outstanding as of 31 December 2017	91,543,740	74,777,196	14,131,554	180,452,490	1.17
Weighted average exercise price DKK	1.10	1.27	1.07	1.17	

As at 31 December 2017, a total of 180,452,490 warrants were outstanding with a weighted average exercise price of DKK 1.17. 97,364,511 of these warrants had vested and are exercisable as at 31 December 2017 with a weighted average exercise price of DKK 1.21. For comparison, as at 31 December 2016, a total of 132,103,779 warrants were outstanding with a weighted average exercise price of DKK 1.21.

# 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% to 52%, determined as the average of the stock price volatility based on Veloxis's historical share prices since its Initial Public Offering in November 2006; (ii) no payment of dividends; (iii) a risk free interest rate equaling the interest rate on a 5-year government bond on the date of grant; and (iv) a life of the warrants determined as the average of the date of becoming exercisable and the date of expiry.

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

During 2017, a total of USD 4,174 was recognized as share-based compensation compared with USD 5,430 in 2016.

The entire warrant compensation costs for 2017 was allocated to selling, general and administrative costs.

# Value of Granted Warrants

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

	Granted 1 March, 2017	Granted 21 June, 2017	Granted 31 October, 2017	Granted 22 December, 2017
		•	•	•
Share price at grant (DKK)	1.12	1.07	0.86	0.84
Volatility (%)	52	51	51	51
Exercise price (DKK)	1.12	1.07	0.86	0.84
Risk-free interest rate for options (%)	0%	0%	0%	0%
Annual dividend per share (DKK)	-	-	-	-
Years to expiry	7	7	7	7
Exercise period	2024	2024	2024	2024
Market value at grant (USD'000)	96	2,168	851	718

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

Year of grant	Number of granted warrants	Number of outstanding warrants	Weighted average exercise price (DKK)	Weighted average contractual life (months)	Exercise price range (DKK)
2010	22,230,855	-	1.28	0.00	1.05 - 2.03
2011	4,665,291	488,466	1.15	3.45	1.00 - 1.23
2012	59,047,200	5,596,800	0.35	22.45	0.35
2013	20,930,000	100,000	0.36	23.77	0.36 - 0.63
2014	26,004,829	7,181,860	1.03	39.15	0.95 - 1.86
2015	34,438,935	12,163,181	0.95	50.84	0.86 - 1.06
2016	91,889,590	90,539,590	1.40	63.70	0.95 - 1.43
2017	64,381,974	64,381,974	0.97	107.45	0.84 - 1.12
31 December 2017	323,588,674	180,451,871	0.94	76.00	

# **Note 16. Other Commitments**

	Consolidated		Pare	nt
(USD'000)	2017	2016	2017	2016
Operating lease commitments regarding offices Operating lease commitments regarding	1,204	1,482	-	-
property, plant and equipment	257	83	3	55
Total operating lease commitments	1,461	1,565	3	55
Total operating lease payments fall due:				
Within 1 year	335	343	3	55
From 1 to 5 years	1,126	1,222	-	-
After 5 years	-	-	-	-
Total	1,461	1,565	3	55
Expensed operating lease payments	330	451	12	106

# **Note 17. Related Parties**

# Shareholders with Significant Influence

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

During 2016 Veloxis entered into a loan and security agreement with Lundbeck Invest A/S and Novo Holdings A/S as discussed further in Note 13.

# Members of the Executive Management and Board of Directors

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

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

# Veloxis Pharmaceuticals, Inc.

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

During 2017, the subsidiary has performed managerial activities on behalf of the Parent Company, which has been remunerated in accordance with the service agreements between the companies. Total services amount to USD 1,000 for the year 2017 (2016: USD 981). In addition, the subsidiary has incurred interest expenses of USD 3,139 for the period 1 January to 31 December 2017 due to an internal loan between the two companies (2016: expenses of USD 1,457).

At 31 December 2017, the Parent Company had a net receivable from Veloxis Pharmaceuticals, Inc., totaling USD 48,026 (2016: USD 26,371).

# **Other Related Parties**

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

# Note 18. Changes in Working Capital

	Consoli	Consolidated		rent
(USD'000)	2017	2016	2017	2016
The design in the state	(2.1.12)	(4.250)		202
Trade receivables	(2,142)	(1,350)	-	293
Other receivables	41	502	7	508
Prepayments	(1,021)	(198)	43	8
Inventories	(2,640)	(1,654)	-	2,487
Trade payables	1,471	(2,000)	(11)	(2,838)
Deferred revenue	-	(539)	-	-
Other payables	1,574	(949)	3,328	(352)
Exchange gains/(losses)	200	401	-	420
Total	(2,517)	(5,787)	3,367	526

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

	Consolio	dated	Parent		
(USD'000)	2017	2016	2017	2016	
PricewaterhouseCoopers					
Audit	89	63	89	63	
Tax Services	81	59	81	59	
Other assurance engagements	-	3	-	3	
Other services	28	38	28	38	
Total	198	163	198	163	

Audit fees include the audit of the Consolidated Financial Statements and the Parent Company Financial Statements. Tax services relate primarily to incentives, German VAT and collection of information concerning transfer pricing request. Other services include IFRS accounting regarding revenue recognition and deferred tax assets, as well as other assistance such as digital filing (XBRL) etc.

# **Parent Company**

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