TRANSPLANTATION IS OUR

LIFE WORK

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at the Annual General Meeting on 3 April 2019

Chairman of the Meeting
Thomas Holst Laursen

2018 ANNUAL REPORT
For the period 1 January - 31 December 2018

Veloxis PHARMACEUTICALS


Challenges are what
makes life interesting;
overcoming them is what
makes life meaningful.
– Joshua J. Marine

CONTENT

Veloxis PHARMACEUTICALS

INTRODUCTION TO TRANSPLANTATION
LIFELONG PARTNERS – TRANSPLANTATION & HOPE

We have come a long way

In 1954, the kidney was the first human organ to be transplanted successfully. By the late 1960s, liver, heart, and pancreas transplants were successfully performed, while lung and intestinal organ transplant procedures were initiated in the 1980s.

Initially, organ rejection severely limited the success of transplants. Medical advances in the prevention of graft rejection in the early 1980s led to more successful transplants and an increase in demand of such surgeries. Since 1994, tacrolimus has been widely prescribed due to its effective prevention of transplant rejection, resulting in excellent short-term rates of graft and patient survival.

Thanks to increases in rates of organ donation over the last several years, improvements in the transplant network and immunosuppressant therapies, solid organ transplants in the US have increased to record highs. Today, solid organ transplants have saved and sustained the lives of more than 700,000 people in the US.

Partnering for a better future

We still have work to do though. According to United Network for Organ Sharing (UNOS), almost 114,000 people in the United States are currently on the waiting list for a lifesaving organ transplant and, on average, 20 people die every day from the lack of available organs for transplant.

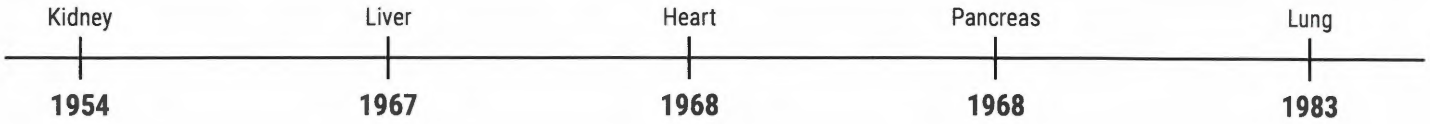
Efforts continue to increase organ availability, and at Veloxis, we are on a lifelong mission to deliver novel treatments that prevent graft rejection with less treatment complexity.

30% increase in US organ transplants between 2012–2018[1]

135,860 solid organ transplants worldwide in 2016[2]

80% of all organ transplants in the US are kidney and liver[1]

1 organ donor can save up to 8 lives

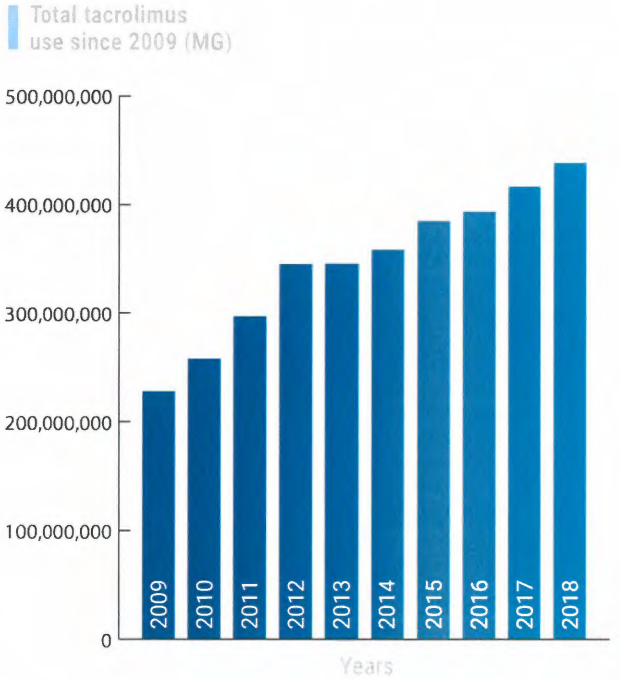



"I woke up around 4 AM the morning
after my transplant surgery ....
I started to notice changes almost immediately.
My skin was vibrantly glowing.
When I looked in the mirror,
my eyes were piercingly bright and full of life.
My energy level was through the roof, and
I felt like I could literally run a few laps.
It was in that moment that I realized how fatigued
I had become without even realizing it.
I cried happy tears every day
for the first three weeks."
Aniesa
-kidney transplant recipient
Double Lung
1986
Intestines
1987
Split-Liver
1988
Hand
1998
Face
2005

INTRODUCTION TO TACROLIMUS
LIFELONG IMMUNOSUPPRESSION

Immunosuppressive treatment to prevent graft rejection is the linchpin of transplantation. This means preventing acute rejection immediately following transplant and over the lifetime of the transplant recipient.

Tacrolimus was first approved by the US Food and Drug Administration (FDA) in 1994 for use in liver transplantation, followed by multiple additional indications, including kidney, heart, small bowel, pancreas, and lung transplants. For decades tacrolimus has been a critical part of immunosuppressant standard of care due to its consistent efficacy and tendency towards fewer cardiovascular side effects.



1994

Tacrolimus approved by the FDA for use in liver transplant followed by approvals for*:

- Kidney transplant
- Heart transplant
- Pancreas transplant
- Islet transplant
- Lung transplant
- Small bowel transplant
- Graft-versus-host disease

However, treatment with immediate release tacrolimus comes with challenges, including:

- Side effects such as diabetes, neurotoxicity, electrolyte disturbances, and nephrotoxicity
- Multiple does per day which has been associated with non-adherence
- Careful therapeutic drug monitoring to prevent under- and over-exposure
- An inconsistent pharmacokinetic profile impacted by a number of factors such as patient age, genotype, gender, race, and quality of the transplanted organ.

*Envarsus is not approved for liver, heart, pancreas, islet, lung, small bowel, graft-versus-host disease (approved for liver in the EU).

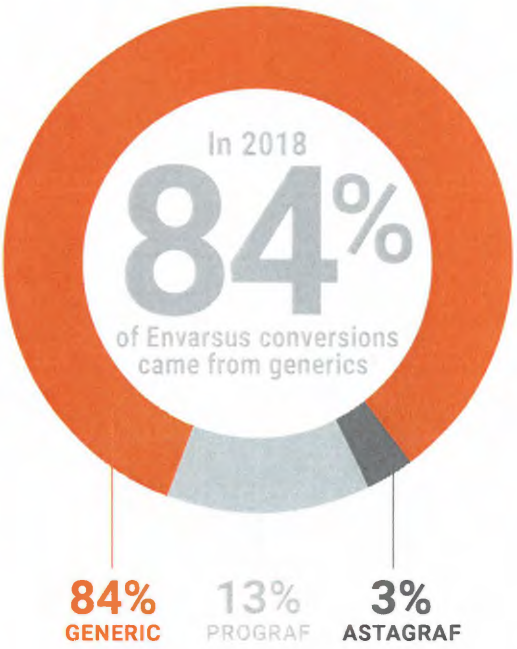
LIFE-CHANGING IMMUNOSUPPRESSION
ENVARSUS*

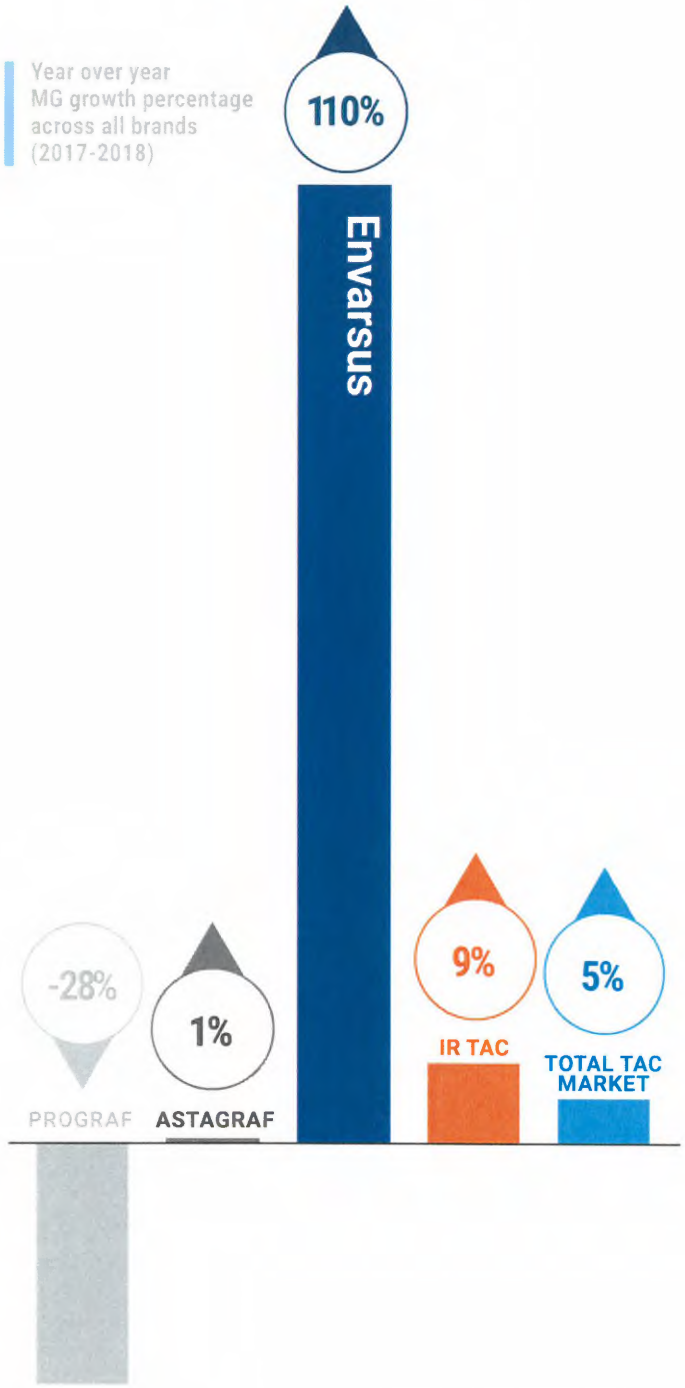
Envarsus® (tacrolimus extended-release tablet) is a novel formulation of tacrolimus designed using advanced technology which allows for increased bioavailability and a controlled, smooth delivery, resulting in:

- Once daily dosing
- A lower total daily dose requirement
- Lower peak concentrations and less fluctuation

In addition to the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus, Envarsus is now FDA-approved for use in de novo kidney transplant patients as of December 2018. That means more patients, including hard-to-treat patients such as rapid metabolizers, can benefit from once-daily controlled-release Envarsus.

Envarsus:
de novo approval
December 2018





*Envarsus is marketed as Envarsus XR® in the Unites States.

TO OUR SHAREHOLDERS

Dear Shareholders,

2018 was by all measurements an incredibly successful year for Veloxis Pharmaceuticals and the patients who experienced life-changing immunosuppression with Envarsus. In early 2018, we secured USD 60 million non-dilutive financing to enhance our cash position which provided us the requisite capital to execute on our commercial strategy for Envarsus. We delivered the Company's corporate strategy, by achieving solid top-line growth while continuing to expand the number of patients benefiting from Envarsus. The Company also remained active on the development front by obtaining a new indication for Envarsus in the US. In December 2018, the FDA approved Envarsus for use in de novo kidney transplant patients. We are excited about the impact the de novo indication will have on our growth and on the patients who can now benefit from Envarsus from the beginning of their immunosuppressive treatment journey.

The launch of Envarsus in the US has resulted in significant market penetration, with approximately 90% of adult transplant centers having utilized Envarsus since launch. Even more important, Envarsus is now approved on more than 50% of US transplant center hospital formularies and over 20% of US centers have added Envarsus to a formal protocol.

The formulary and protocol access we have generated within key transplant centers has resulted in an estimated 7,700 patients using Envarsus by year end, and more than 46,000 prescriptions of Envarsus in 2018.[3] Utilization of Envarsus grew by 110% compared to 2017, proving that healthcare providers and patients recognize the value that Envarsus delivers.

We are excited by the results of our partnership with Chiesi Farmaceutici S.p.A. for commercialization of Envarsus in Europe. Chiesi estimates that over 13,500 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 of Envarsus in the territory.

In 2019, 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 and also has patent protection that runs through 2028 in the US and 2031 in the EU. The Company plans to continue our business development efforts with the goal of expanding our pipeline and current product offering in transplant.

To our employees, we want to offer our sincere thanks for your commitment and hard work in 2018. Your efforts are truly what make Veloxis a success and improve the lives of transplant recipients. We are excited about our future opportunities and ongoing innovation in transplant therapy and look forward to sharing our progress throughout the year.

Yours sincerely,

Michael T. Heffernan
Chairman

Craig A. Collard
President & CEO

HIGHLIGHTS 2018

February

Veloxis Pharmaceuticals A/S obtained USD 60 million of capital from funds managed by Athyrium Capital Management, LP ("Athyrium"), in the form of a five-year, floating rate, interest only note, with USD 60 million available immediately upon closing.

March

Veloxis Pharmaceuticals A/S submitted a supplemental New Drug Application (sNDA) to the US Food and Drug Administration (FDA) seeking de novo indication for Envarsus.

October

Ira Duarte promoted to Chief Financial Officer of Veloxis Pharmaceuticals A/S.

November

Craig Collard, Chief Executive Officer, presented at the Jefferies 2018 London Healthcare Conference.

December

The FDA approved the new indication for Envarsus to prevent organ rejection in de novo kidney transplant recipients.

OUTLOOK 2019

OUTLOOK

Veloxis Pharmaceuticals anticipates 2019 total revenues to be in the range of USD 58–68 million and 2019 operating income before accounting for stock compensation to be in the range of USD 4–10 million. Our outlook for 2018 as disclosed in our June 30, 2018 quarterly report anticipated revenues to be in the range of USD 36–42 million and operating loss before stock compensation to be in the range of USD 2–6 million. Actual revenues for 2018 were USD 39 million, and actual operating loss before accounting for stock compensation was USD 2 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 payment of the Athyrium note.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Veloxis's documents, including this 2018 Annual Report, may contain "forward-looking statements." Words such as "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "future," "likely," "may," "should," "will" and similar references to future periods identify forward-looking statements. Examples of such forward-looking statements include, but are not limited to, the following:

- statements of targets, plans, objectives or goals for future operations;
- statements containing projections of or targets for revenues, costs, income (or loss), and other financial measures;
- statements regarding future economic performance, future actions and outcome of contingencies;
- statements regarding the assumptions underlying or relating to such statements.

In this 2018 Annual Report, examples of forward-looking statements can be found under the heading Outlook 2019 and elsewhere.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements.

For an overview of some, but not all, of the risks that could adversely affect Veloxis's results or the accuracy of forward-looking statements in this 2018 Annual Report, reference is made to the overview of risk factors in the Risk Management section on pp. 32-33 of this 2018 Annual Report.

Any forward-looking statement made by us in this report is based only on information currently available to us and speaks only as of the date on which it is made. Unless required by law, Veloxis is under no duty and undertakes no obligation to update or revise any forward-looking statement after the distribution of this 2018 Annual Report whether as a result of new information, future developments or otherwise.

VELOXIS BUSINESS STRATEGY

A LIFELONG COMMITMENT

Veloxis Pharmaceuticals is a biopharmaceutical company committed to improving the lives of transplant patients by identifying, developing, and commercializing products in transplantation. Utilizing our proprietary drug delivery technology (MeltDose®), Veloxis has developed and obtained FDA and European Medicines Agency (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 sales force 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.

In the US, our direct sales force is supplemented by field-based reimbursement, medical affairs personnel, and in-house marketing 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. In order to increase patient access to Envarsus, Veloxis has established specialty distribution and patient services to optimize the experience for patients and providers.

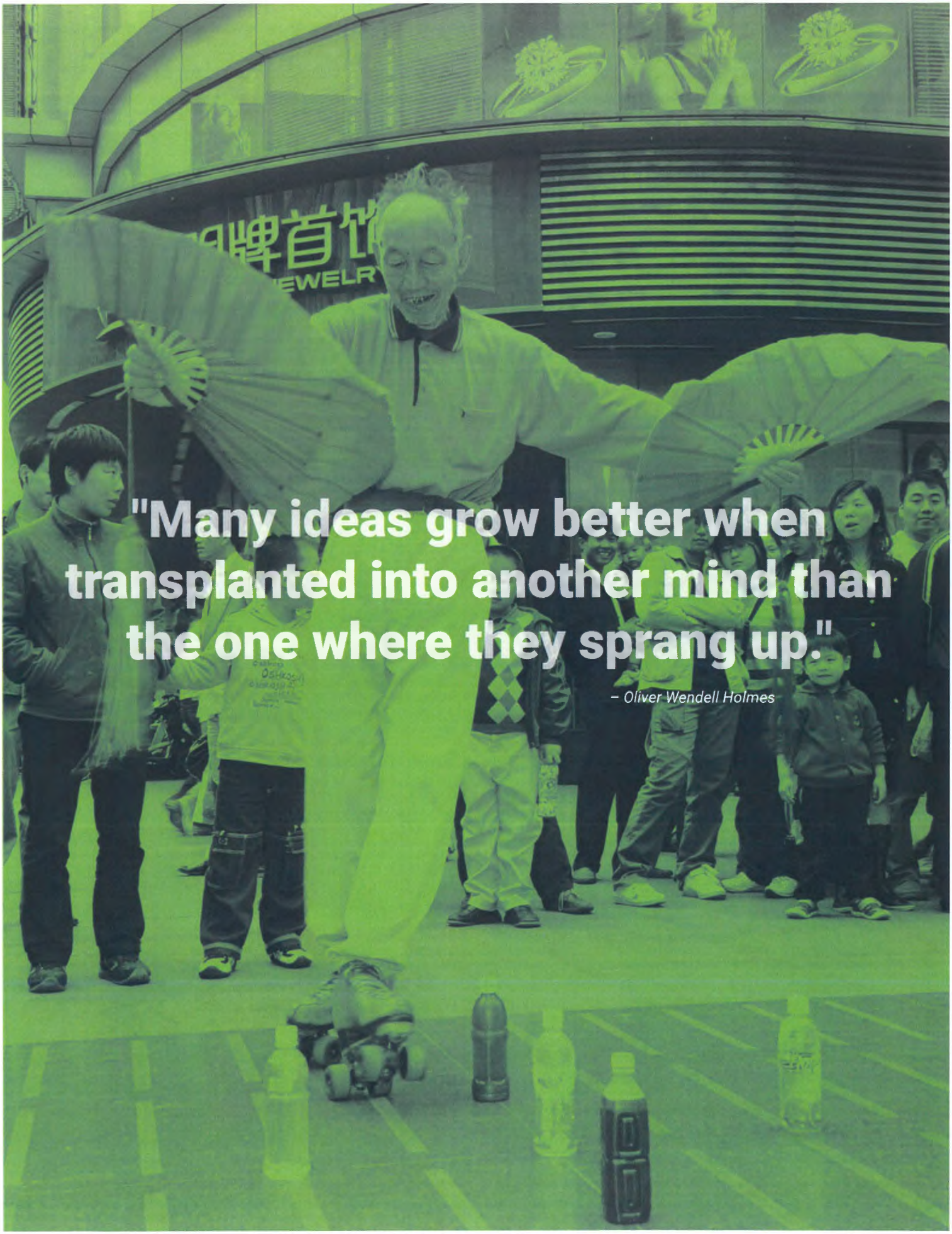
Envarsus is now licensed in
71 countries around the world.

ENVARSUS IS NOW LICENSED IN

71

COUNTRIES AROUND THE WORLD

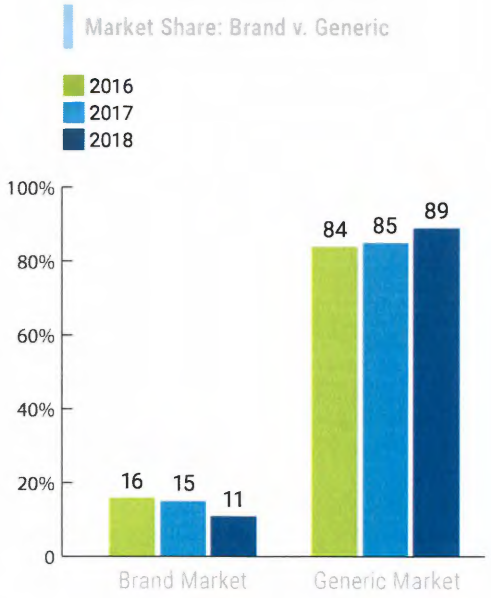
ALGERIA
AUSTRIA
BAHRAIN
BELGIUM
BULGARIA
CANADA
CHINA
CYPRUS
CZECH REPUBLIC
DENMARK
EGYPT
ESTONIA
FINLAND
FRANCE
GERMANY
GREECE
HUNGARY
IRAQ
IRELAND
ITALY
JORDAN
KINGDOM OF SAUDI ARABIA
KUWAIT
LATVIA
LEBANON
LITHUANIA
LUXEMBOURG
MALTA
NETHERLANDS
OMAN
POLAND
PORTUGAL
QATAR
ROMANIA
SLOVAKIA
SLOVENIA
SPAIN
SWEDEN
TUNISIA
UNITED ARAB EMIRATES
UNITED KINGDOM
UNITED STATES

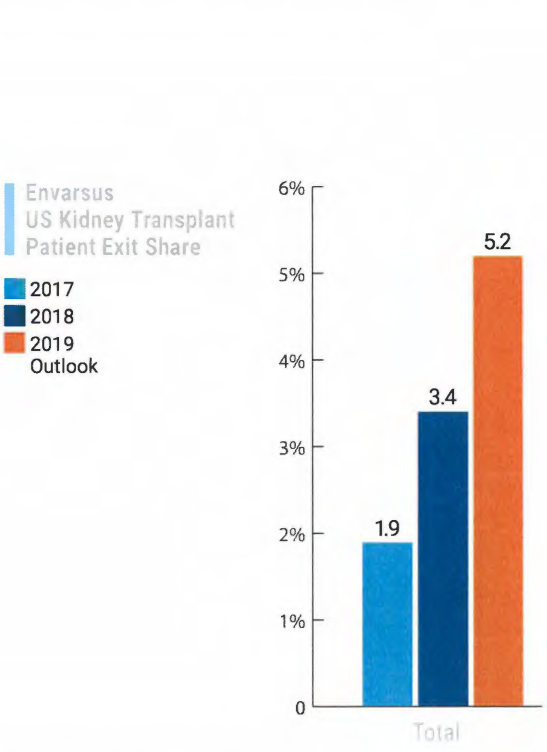

"Many ideas grow better when transplanted into another mind than the one where they sprang up."
– Oliver Wendell Holmes

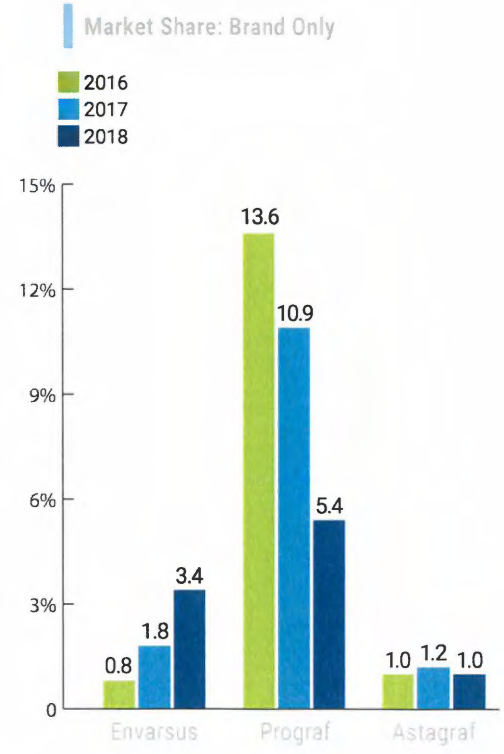
COMMERCIAL UPDATE

THE US MARKET

The US Kidney Transplant market consists of approximately 200 transplant centers. Patients are on multiple drugs to ensure adequate immunosuppression, but the mainstay of the treatment is tacrolimus. Approximately 95% of kidney transplant patients are on some form of tacrolimus. The tacrolimus market is made up of 3 branded formulations consisting of brand Prograf®, Astagraf®*, and Envarsus along with several manufacturers of generic Prograf (IR-TAC) in the US market. The US Kidney retail market consists of ~210,000 patients living with a kidney transplant and ~20,000 "de novo" new patients receiving a kidney transplant in 2018. The tacrolimus market has been growing at a CAGR of 4% since 2009 and de novo transplants have shown consistent growth each year as well. The existing patients are largely on generic tacrolimus which makes up ~90% of the retail market for kidney transplantation. Brand Prograf has been steadily declining since its loss of exclusivity in 2009, however it has maintained a significant amount of market share 10 years post generic entry. Since it's US launch, in December 2015, Envarsus has been growing share based largely on its indication for conversion from IR-TAC.







*Advagraf is marketed as Astagraf XL in the United States.

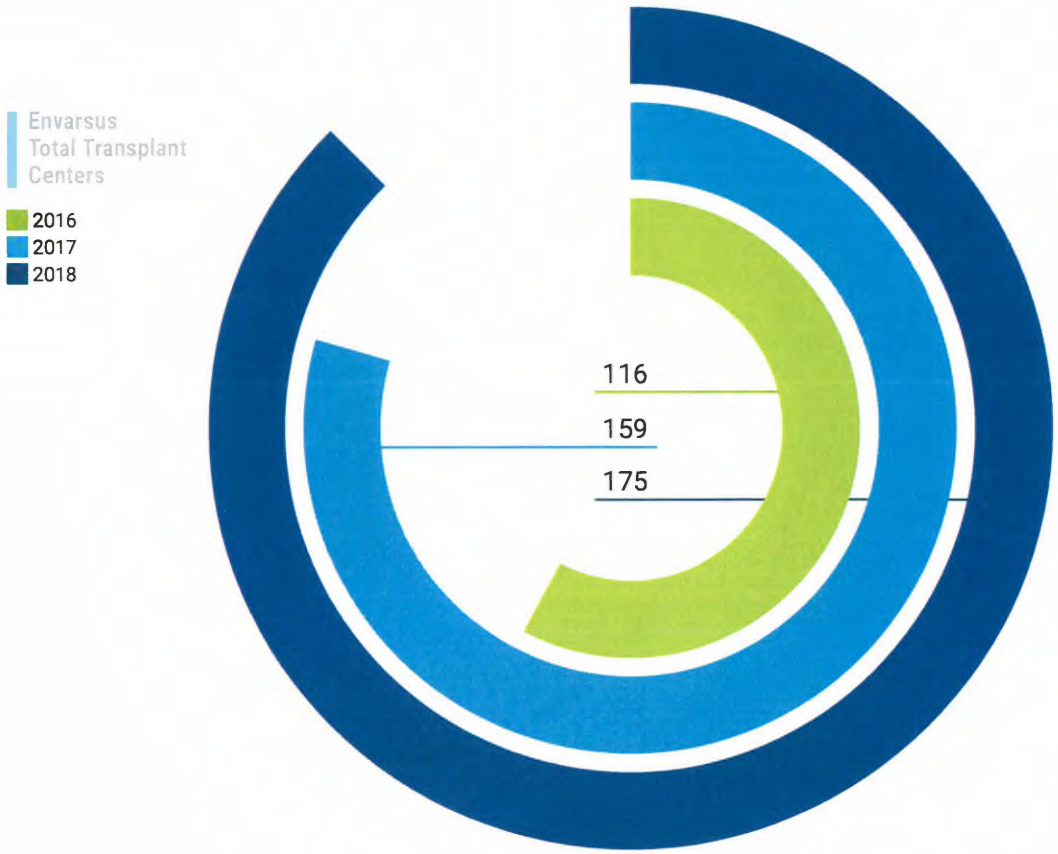
COMMERCIAL UPDATE

PARTNERSHIPS FOR SUCCESS

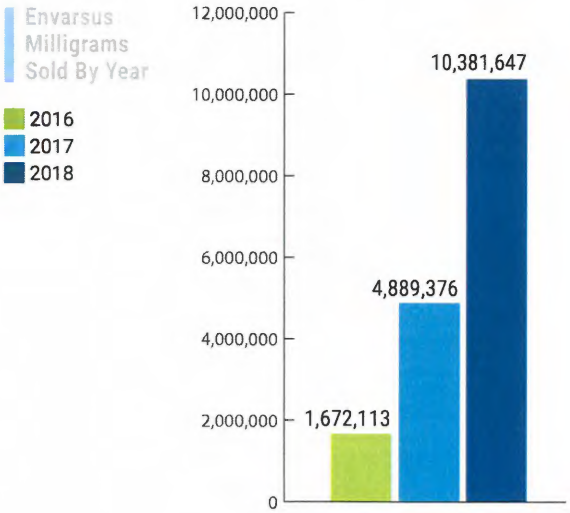
Envarsus launched in Europe in November of 2014 through our licensed partner Chiesi Farmaceutici S.p.A., and in the US in December of 2015. Veloxis utilizes it's own direct sales force that has substantial experience in organ transplantation. Based upon available sales data, we estimate that there are now over 21,000 patients on Envarsus worldwide (13,500 in EU and 7,700 in US).

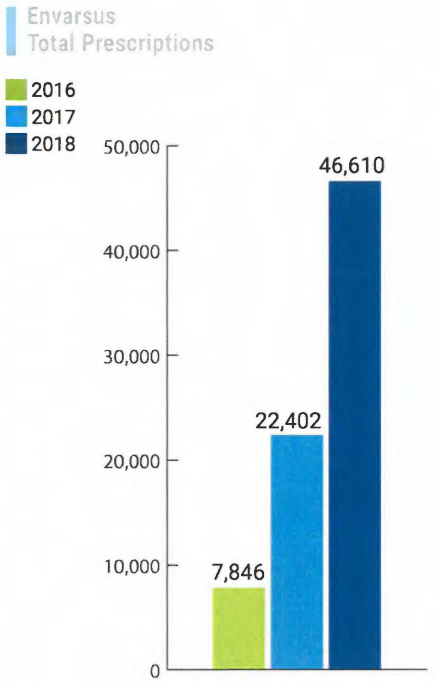
Key performance indicators in the US market demonstrate that 2018 was a successful year for achieving adoption of Envarsus within transplant centers. Approximately 90% of the 196 US transplant centers utilized Envarsus in 2018 compared to 81% in 2017.[3] Furthermore, prescriptions of Envarsus also grew over 100% compared to 2017, totaling 46,517 in 2018.[3] The two-fold increase in prescribers and prescriptions in 2018, 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 3.4% of the kidney tacrolimus market as of December 2018.[3]

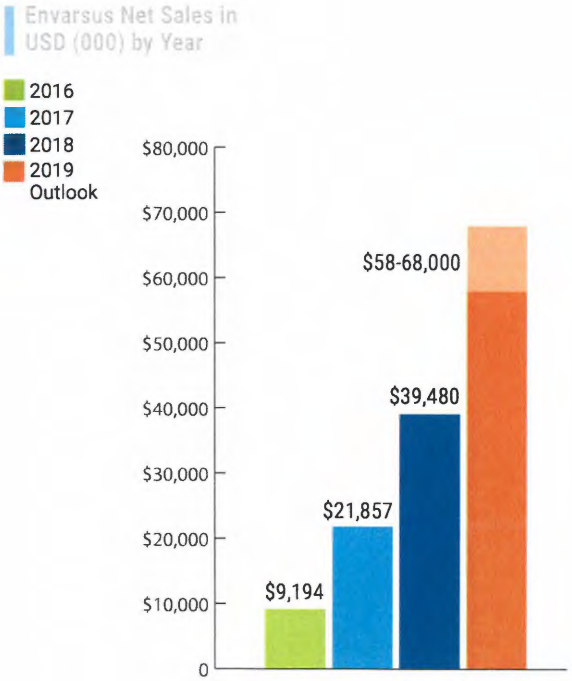
An important driver of the uptake of Envarsus in the US has been the 2017 FDA approval of label enhancements which allow promotion of Envarsus for use in special populations which may benefit from increased bioavailability and controlled delivery of tacrolimus. African-American kidney transplant patients historically experience poorer outcomes as compared to other ethnic groups. These out-



comes have 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 and upwards of 30% of transplant patients regardless of race. 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.



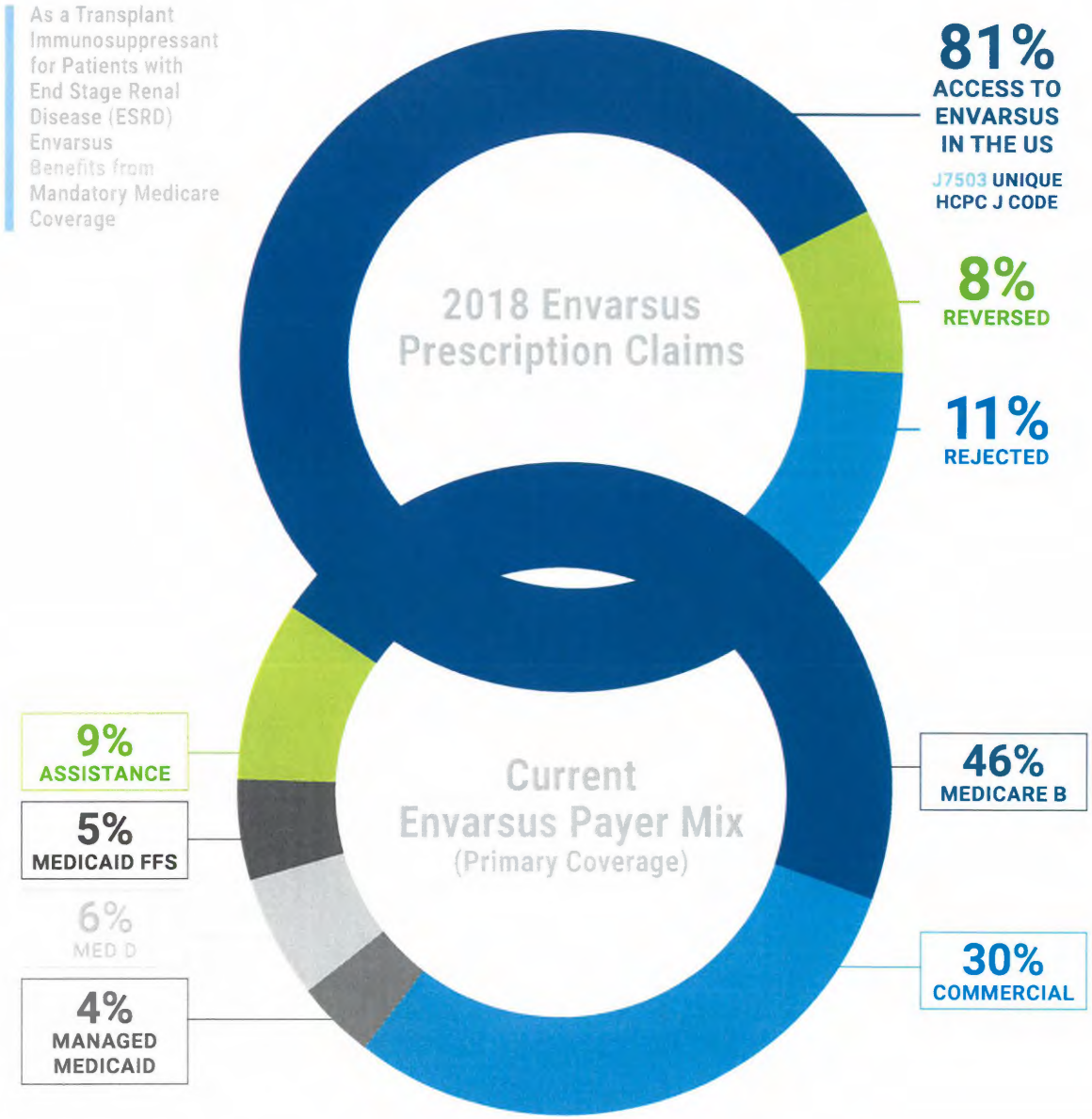




COMMERCIAL UPDATE

US MARKET ACCESS

Transplant patients in the US generally qualify for Medicare B coverage for immunosuppression therapy for up to 36 months post transplant. After 36 months, patients typically transition to commercial insurance, some other type of government funded program, or are eligible for disability and maintain Medicare coverage for life. Excluding Medicare where there is mandatory coverage of all immunosuppressants, 81% of patients have access to Envarsus in the US.



"When my anti-rejection medication caused me issues, I knew I had to talk to my transplant team to explore other options. After I explained my concerns, **my team recommended I switch to Envarsus**. They explained that the extended-release medication **would help keep my levels...level**. I would take it once a day and it would avoid medication spikes. **The idea of taking Envarsus once a day was perfect for me**. With classes and work, I wouldn't have to schedule time twice a day to take my meds."

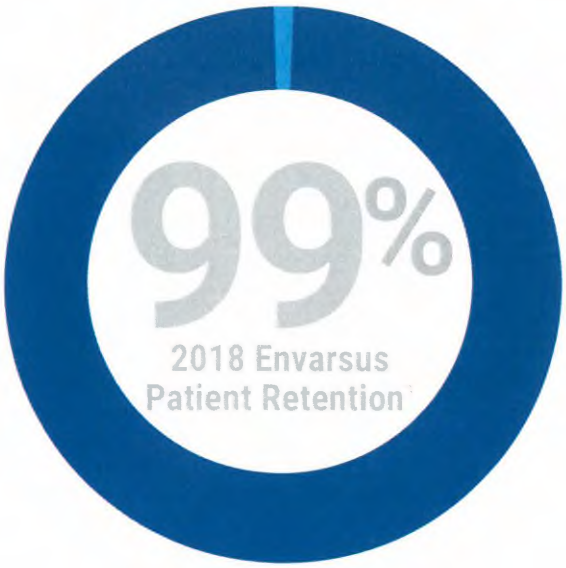
John
-kidney transplant recipient

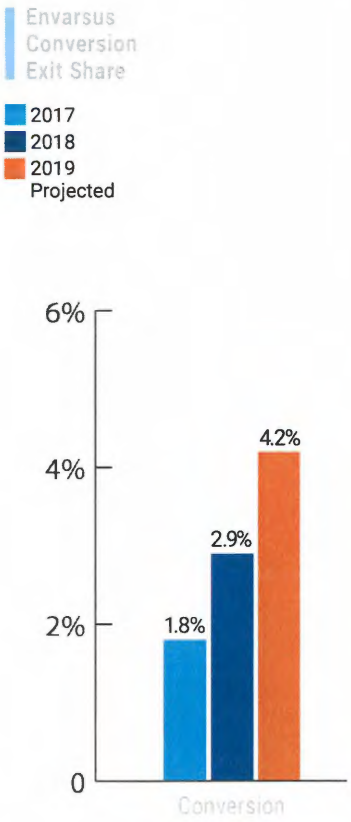
COMMERCIAL UPDATE

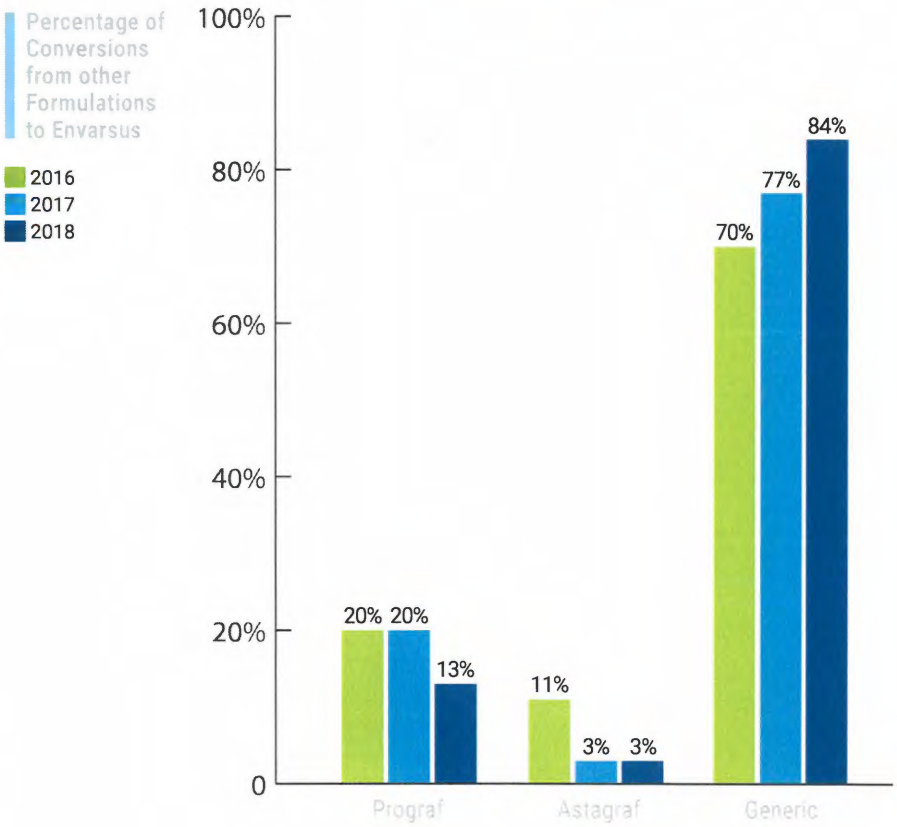
ENVARSUS IN CONVERSION

In the US, more than 80% of the patients who convert to Envarsus were on generic IR-TAC prior to converting. This is an important point as the market has recognized the potential benefits that Envarsus offers over the existing formulations and we see a significant amount of our conversions coming from generic formulations of tacrolimus.

An equally important measurement of the potential benefits of Envarsus is the patient's ability to stay on Envarsus after they switch to Envarsus from another formulation. 99% of patients who convert to Envarsus stay on Envarsus after conversion.







ENVARSUS IN THE DE NOVO SETTING

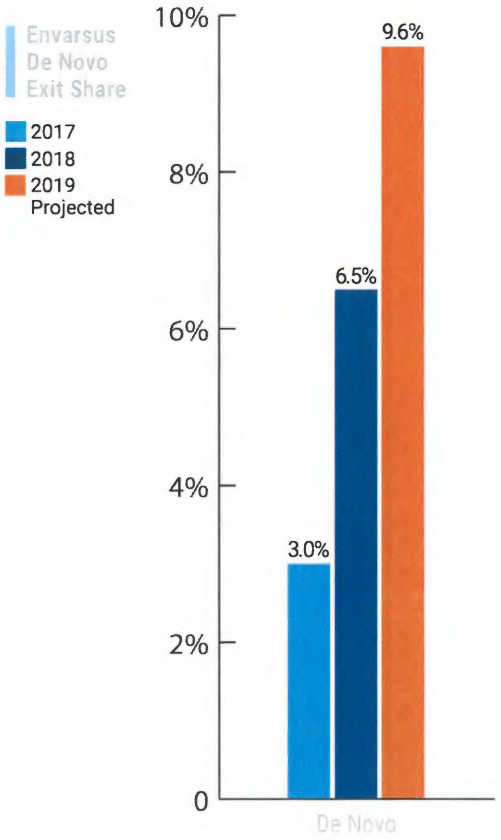
In December 2018, Envarsus was approved for use in the de novo kidney transplant population in the US. Veloxis engaged ZS Associates, a leading market research firm, to conduct a study to assess the potential impact of the new indication for Envarsus in de novo kidney transplant patients.

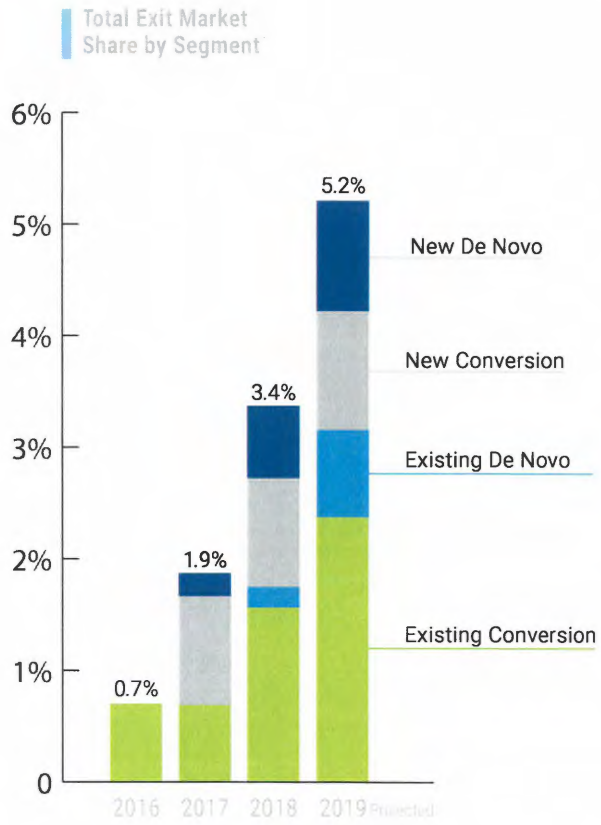
The study included 120 healthcare professional interviews (50 surgeons, 50 nephrologists and 20 pharmacists) all with specific transplant responsibility, defined as participating in or managing at least 5 kidney transplants per month within their institution.

The result of the study indicated that patient share nearly tripled among de novo kidney patients 3 years following approval of the de novo indication.

Envarsus exited 2018 with a 2.9% kidney patient share in conversion and 6.5% kidney patient share in the de novo setting (3.4% patient share total).

Our forecast assumes a growth in kidney patient share to 4.2% in conversion and 9.6% share in the de novo setting in 2019. Combining both indications for 2019 and forecasting current growth trends, we expect to exit 2019 with a 5.2% total kidney transplant patient share (conversion and de novo).





ENVARSUS FOR TRANSPLANTATION

SITUATION

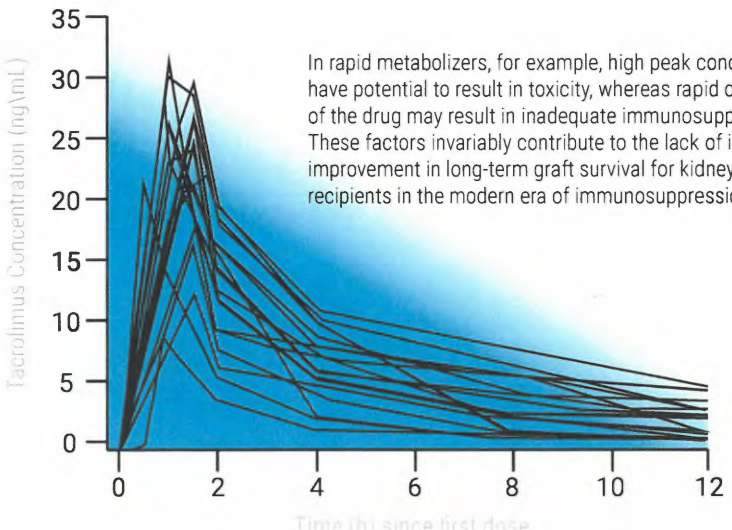
For over twenty years, the most commonly utilized maintenance immunosuppressive regimen among kidney transplant recipients has consisted of a combination of corticosteroids, mycophenolate (MPA) -based products, and a calcineurin-inhibitor (CNI). Since 2001 tacrolimus has been the most widely prescribed CNI, and even now continues to see its use continue to increase as the primary CNI.[5,6] Reasons for this include its greater potency for prophylaxis of transplant rejection, improved graft survival, and lesser tendency towards cardiovascular side effects in comparison to cyclosporine. Excellent short term rates of graft survival, patient survival, and low rates of acute rejection coupled with the lack of newer, effective immunosuppressants has led to wide acceptance of tacrolimus, MPA, and steroids as the "standard-of-care" for most kidney transplant recipients.

Tacrolimus also carries the endorsement of consensus groups in transplantation.[7]

The lack of newer immunosuppressive agents merits further explanation. Several barriers exist which prevent new drug development in transplantation. The major endpoints accepted by the US Food and Drug Administration (FDA) have been 1-year outcomes of patient and graft survival, and acute rejection.[8] These short-term outcomes have improved over the past decades and are now exceedingly difficult to demonstrate further improvement; thus the probability of showing superiority for any new agent is very low. This has led to "noninferiority" trial designs, requiring that a new drug only show that it is not worse than a standard-of-care agent for potential approval.

Moreover, the incentive is low for development of new therapies which are unlikely to show superiority over current therapies. These limitations result in failure to address long-term graft survival or comorbidities associated with immunosuppressants. Therefore, there is a misconception that current outcomes in transplantation are optimal and that current standard-of-care regimens cannot be improved.

Tacrolimus concentration of 13 patients after the first oral dose of IR-tacrolimus



In rapid metabolizers, for example, high peak concentrations have potential to result in toxicity, whereas rapid clearance of the drug may result in inadequate immunosuppression. These factors invariably contribute to the lack of incremental improvement in long-term graft survival for kidney transplant recipients in the modern era of immunosuppression.

PROBLEM

Despite the excellent short-term transplant outcomes achieved in kidney transplantation, the standard-of-care immunosuppressive strategy is not without shortcomings. Tacrolimus, for example, is associated with side effects such as diabetes, neurotoxicity, electrolyte disturbances, and nephrotoxicity. Multiple per-day dosing has been associated with medication non-adherence.[9] As a narrow therapeutic index drug, tacrolimus also requires close therapeutic drug monitoring to prevent under- and over-exposure. Complicating this is significant inconsistency in the pharmacokinetic profile of tacrolimus, which is impacted by a number of factors such as poor absorption, patient age, gender, presence of food, race, and genetic polymorphisms.[10] In fact, one study showed that interpatient exposure varied as much as 4-times after the first oral dose of tacrolimus in de novo kidney transplant recipients, demonstrating the challenges in tacrolimus management. In rapid metabolizers, for example, high peak concentrations have potential to result in toxicity, whereas rapid clearance of the drug may result in inadequate immunosuppression.[12-14] These factors invariably contribute to the lack of incremental improvement in long-term graft survival for kidney transplant recipients in the modern era of immunosuppression.

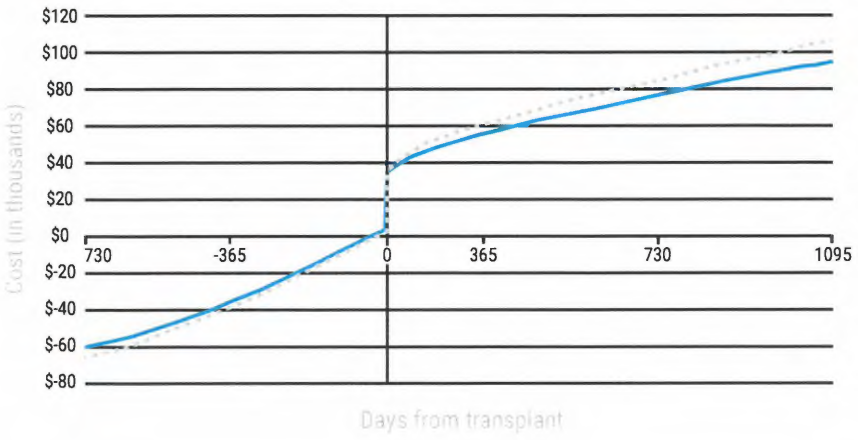
IMPLICATIONS

Treatment-related factors such as side effects and medication complexity are among the chief contributors to medication non-adherence with kidney transplant recipients exhibiting the highest rates of non-adherence compared to other organ types.[15-17] A cohort of kidney transplant recipients recently surveyed reported forgetfulness, interference with lifestyle, side effects, and problems with the evening dose as reasons for non-adherence.[18] Consequences of non-adherence are dire: poor adherence in kidney recipients has been associated with a 7-fold greater risk of graft loss, and a higher risk of mortality.[19,20] Furthermore, when potent immunosuppressive agents such as antilymphocytic therapies are administered for rejection, the risk of infectious complications, including opportunistic infections, is increased.[21]

Non-adherence to immunosuppression has economic implications as well. One study found that transplant recipients with poor adherence experienced medical costs which are approximately $33,000 higher after only 3 years compared to those with high adherence. Another study found that while lifetime cost estimates were higher in adherent patients than in non-adherent patients, this was due to the fact that adherent patients lived longer after transplantation.[23] Evaluating the economic implications from an alternative approach, multiple modeling analyses showed that in comparison to twice daily tacrolimus formulations, improved adherence through use of a once-daily tacrolimus formulation would reduce the rates of rejection and graft failure, thereby resulting in substantial cost-savings per patient.[24,25]

In an effort to avoid side effects, strategies to minimize or withdraw tacrolimus have been attempted. Two recent large prospective studies have demonstrated the detriment of such approaches, which increases risks of rejection, donor specific antibodies, and sub-clinical inflammation occurring in those with reduced exposure to tacrolimus.[26,27]

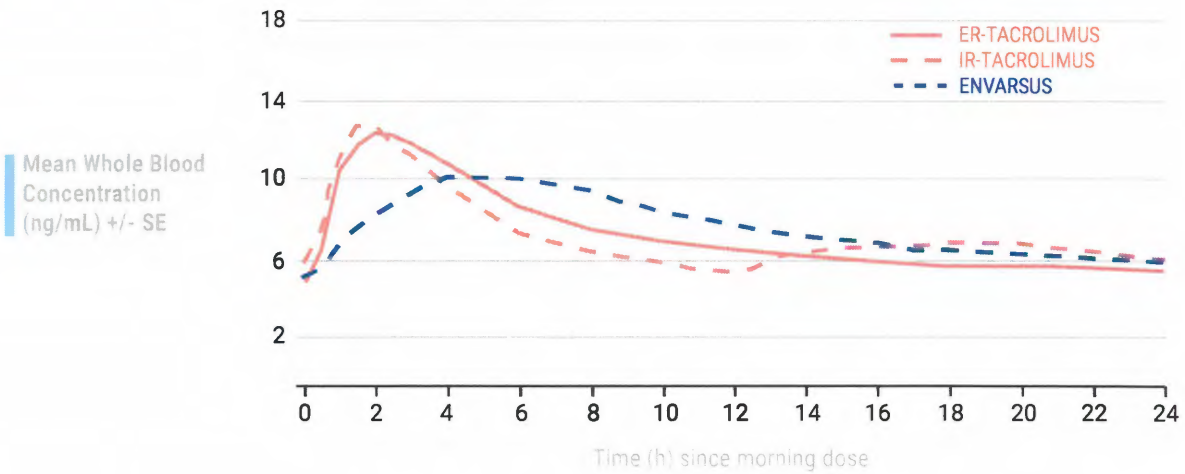
Medical costs over time by persistent high and low compliance



A PART OF THE SOLUTION

Envarsus is a novel formulation of tacrolimus designed using a technology which allows for increased bioavailability and a controlled delivery. This results in a lower total daily dose requirement, allows for once daily administration, lower peak concentrations and less fluctuation, resulting in a "flatter" pharmacokinetic profile compared to immediate-release tacrolimus (IR-tacrolimus).[28] Envarsus is indicated for the prophylaxis of organ rejection in kidney transplant patients converted from IR-tacrolimus formulations, in combination with other immunosuppressants. Importantly, the US Food and Drug Administration (FDA) does not stipulate a reason or time frame for conversion from IR-tacrolimus. This is important for those clinicians who feel that Envarsus may be the preferable agent for a given patient on IR-tacrolimus. Envarsus also carries an orphan drug status and has been issued a unique J-Code by CMS for reimbursement. Orphan drug designation is granted to a drug which may offer benefit to patients with rare diseases, defined as a prevalence of less than 200,000 persons, and that offer a medically plausible hypothesis for superiority over an existing formulation of that drug.[29]

ENVARSUS FOR TRANSPLANTATION



Envarsus is not interchangeable with other tacrolimus formulations, including other once-daily products. In fact, its unique development and delivery profile results in a completely distinct pharmacokinetic curve from once daily Astagraf XL® (extended-release tacrolimus capsules). In comparison to Astagraf XL, Envarsus demonstrated significantly less fluctuation (p=0.0004), lower peak concentrations (p=0.006), and a 36% lower dose requirement at equivalent exposure. The typical high initial peak, characteristic of twice daily IR-tacrolimus, was also observed with Astagraf XL but not with Envarsus, demonstrating the enhanced bioavailability and controlled-delivery of this agent vs other once-daily products.[30]

An important label enhancement after drug approval came as a result of findings from a prospective pharmacokinetic and pharmacogenomic study. In a cohort of kidney transplant recipients historically shown to have poorer outcomes due to genetic differences in the metabolism of tacrolimus, the study found that "rapid metabolizers" of tacrolimus experienced a 33% higher peak concentration compared to non-rapid metabolizers (p=0.04).[12,31-34] This difference was attenuated by Envarsus, and regardless of genotype status, Envarsus demonstrated similar exposure, significantly lower peak concentration, and increased bioavailability compared to immediate release tacrolimus.

Clinical benefits of the differences in Envarsus pharmacokinetics have not been established

A recent update is the filing of a supplemental new drug application to the FDA for prophylaxis of rejection in kidney transplant recipients in the de novo setting (immediately post-transplant). This application is based on data from a double-blind, double-dummy, multinational, phase 3 study in 543 patients that successfully demonstrated non-inferiority in this population.[35] An important finding in this study was the fact that patients on Envarsus were able to achieve therapeutic concentrations sooner than those on IR-tacrolimus. After initial dosing, 36.6% of patients on Envarsus vs. 18.5% of patients on IR-tacrolimus were within therapeutic concentrations. Importantly, no differences in adverse events were seen between the two groups. Early attainment of adequate tacrolimus exposure has been shown in several studies to reduce the risk of rejection.[36-38]

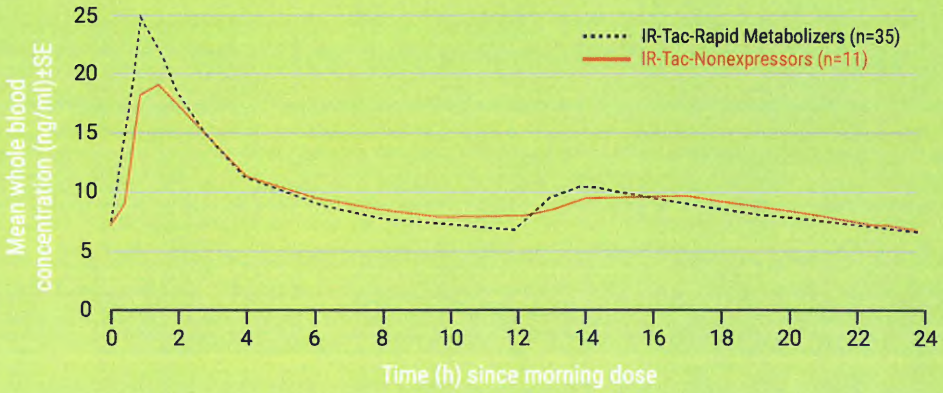
CLINICAL CONSIDERATIONS

The following summarizes potential subgroups of kidney transplant recipients where clinicians may consider Envarsus as the preferred tacrolimus formulation, as well as supporting literature.

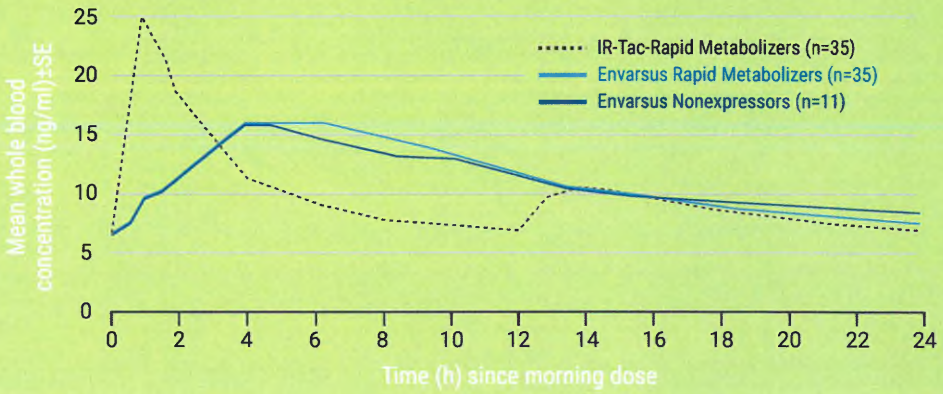
Non-adherent patients, or patients at risk of non-adherence

This includes but is not limited to younger patients, patients further out post-transplant, patients experiencing side effects or with increased complexity of the immunosuppressive regimen, and those in whom the evening dose interferes with their lifestyle.[15-18] Pharmacoeconomic and modeling analyses have demonstrated positive financial implications as well as improved rates of rejection and graft survival with the use of once-daily tacrolimus formulations.[24,25]

Mean tacrolimus whole blood concentration for rapid metabolizers vs nonexpressors on IR-tacrolimus[34]



Mean tacrolimus whole blood concentration for rapid metabolizers and nonexpressors on Envarsus and IR-tacrolimus[34]



ENVARSUS FOR TRANSPLANTATION

Rapid Metabolizers of tacrolimus

Extensive data indicate that "rapid metabolizers" require higher dosages of tacrolimus and are still at risk for suboptimal tacrolimus exposure, potentially resulting in inferior outcomes.[12-14,33] In particular, patients of African descent are frequently deemed rapid metabolizers. In rapid metabolizers, high dose requirements can result in supratherapeutic peak concentrations, nearly 33% higher than non-rapid metabolizers. This difference was attenuated by Envarsus, and regardless of genotype status the classical pharmacokinetic profile of Envarsus was preserved.[34]

ASERTAA

A Study of Extended Release Tacrolimus in African-Americans • **Phase IIIb Study of Envarsus**

Patients of African descent

As mentioned above, this group of patients is most likely to demonstrate rapid metabolism, resulting in high dose requirements, supratherapeutic peak concentrations, and rapid clearance. The pharmacokinetics of Envarsus have been shown to be less impacted by these pharmacogenomic differences.[34]

Patients with challenges to adhering to a twice daily fixed schedule

While Envarsus is recommended to be taken consistently in the morning, missed doses can be taken up to 15 hours following the regularly administered time.[39] In addition, due to its pharmacokinetic profile, the therapeutic monitoring window of Envarsus may allow for flexibility in trough monitoring, which may improve the monitoring experience for both patients and care providers alike.[40]

Clinical benefits of the differences in Envarsus pharmacokinetics have not been established.

Patients taking drugs known to interact with tacrolimus

While tacrolimus formulations are known to be subject to numerous drug interactions, very limited data on drug interactions with Envarsus exists. Recently, a randomized, cross-over design phase I pharmacokinetic study in 18 healthy volunteers was conducted to determine the influence of voriconazole, a medication known to increase tacrolimus exposure, on either IR-tacrolimus or Envarsus.[41] The exposure to IR-tac was increased by 6.02-fold and was highly variable in the presence of voriconazole. In contrast, the increased exposure for Envarsus was 2.62-fold higher ($p<0.01$), with less variability. This data suggests that Envarsus appears to be less susceptible to drug-drug interactions than IR-tacrolimus. This is an important finding given the frequency of interacting medication use in kidney transplant recipients, and potential adverse drug reactions which occur due to interactions.[42]

CONCLUSION

It is important to remember that many kidney transplant recipients will experience an optimal post-transplant experience on traditional IR-tacrolimus based regimens. Furthermore, there are patients who may not be able to take Envarsus, such as those who are unable to swallow tablets whole or those requiring liquid or sublingual formulations of tacrolimus. Therefore, IR-tacrolimus formulations are expected to remain as the standard-of-care tacrolimus products in many kidney transplant recipients. Prior to the availability of Envarsus, management of tacrolimus-related side effects consisted of lowering the dosage, which has been associated with adverse graft outcomes, or switching to an alternative agent with potentially inferior efficacy. With the availability of Envarsus, the transplant community now has a novel formulation which is distinct enough to be considered a preferred option for certain subgroups of recipients, while having the same active ingredient that has demonstrated efficacy for over 20 years.

Envarsus represents a novel, uniquely designed formulation of the same trusted and efficacious immunosuppressive agent that has been used for decades. Importantly, no equivalent product exists and substitution of Envarsus with any other tacrolimus product is not permitted, including generics or other once-daily products. Envarsus therefore represents a unique immunosuppressant medication in the armamentarium of transplant clinicians and an attractive alternative in a therapeutic area with limited options.

FINANCIAL REVIEW

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

Revenue

During 2018, Veloxis recognized revenue of USD 39,494 compared to USD 30,167 in 2017. The increase is driven by growth in commercial sales of Envarsus in the US, which increased by 91% from USD 17,592 in 2017 to USD 33,667 in 2018, and sales to Chiesi Farmaceutici S.p.A ("Chiesi") in Europe increased from USD 4,265 in 2017 to USD 5,813 in 2018. There was zero upfront revenue in 2018 compared to USD 8,250 in the prior year.

Selling, General and Administrative Costs

Selling, general and administrative costs increased from USD 32,458 in 2017 to USD 35,611 in 2018. The increase is due to the growth in the business, and additional spends in our sales, marketing and medical affairs departments in our continued efforts to maximize the growth of Envarsus.

On an overall basis, selling, general and administrative costs account for 95% of total cost of operations.

Research & Development Cost

Research and development costs increased from USD 866 in 2017 to USD 1,801 in 2018. The increase in costs is associated with regulatory approval of a new production facility and production optimization.

On an overall basis, research and development costs account for 5% of total cost of operations. The comparable figure for 2017 was 3%.

Share-Based Compensation Cost

We recognized USD 3,830 of share-based compensation in 2018 compared to USD 4,174 in 2017.

Operating Result

During 2018, Veloxis recognized USD 5,836 in operating loss compared with a USD 8,359 operating loss in 2017.

The operating result is in line with Management's expectation as reported on 14 November 2018 in connection with the third quarter interim report, which provided a 2018 outlook of operating loss before accounting for stock compensation to be in the range of USD 2 – 6 million. Operating loss adjusted for stock compensation of USD 3,830 was USD 2,006.

Financial Items

Net financial items increased by USD 3,926, from a loss of USD 2,090 in 2017 to a loss of USD 6,016 in 2018. The loss in 2017 and 2018 is primarily attributable to interest charges on the loan facility, which increased due to the $60M balance of the loan with Athyrium Capital Management, LP executed in February 2018, compared to the prior year loan balance of $26M with Lundbeckfond Invest A/S and Novo Holdings A/S.

Tax for the Year

Tax for the period was a benefit of USD 6,567 compared to USD 907 in 2017. In 2018 Veloxis recognized a tax benefit from revaluation of deferred tax assets of USD 7,014 and a tax expense of USD 447 due to payable taxes in Denmark. 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 2018, the deferred tax asset was USD 27,201 compared to USD 20,187 at the end of 2017.

Net Result

During 2018, Veloxis recognized a net loss of USD 5,285 compared with a net loss of USD 9,542 in 2017.

Cash Flow

As of 31 December 2018, the balance sheet reflects cash and cash equivalents of USD 30,520 compared with USD 7,766 as of 31 December 2017, with the increase primarily related to funds received upon execution of the Athyrium note offset by repayment of the principal on the previous Lundbeckfond Invest A/S and Novo Holdings A/S loan as discussed in note 13.

Balance Sheet

As of 31 December 2018, total assets were USD 77,117 compared with USD 41,921 at the end of 2017.

As of 31 December 2018, the net debt was USD 59,905 up from USD 25,818 as of 31 December 2017, primarily related to the execution of the Athyrium note as discussed in note 13.

Shareholders' equity equaled USD 4,614 as of 31 December 2018, compared with USD 5,316 at the end of 2017.

FINANCIAL HIGHLIGHTS - CONSOLIDATED

Financial Highlights

USD'000	2018	2017	2016	2015	2014
Income Statement					
Revenue	39,494	30,167 *	9,194	2,103	20,847 *
Production costs	(7,918)	(5,202)	(3,019)	(2,250)	(549)
Gross profit	31,576	24,965	6,175	(147)	20,299
Selling, general and administrative costs	(35,611)	(32,458)	(34,407)	(17,808)	(14,976)
Research and development costs	(1,801)	(866)	(636)	(11,345)	(15,224)
Other operating income	-	-	100	-	-
Operating result	(5,836)	(8,359)	(28,768)	(29,300)	(9,901)
Net financial income / (expenses)	(6,016)	(2,090)	(45)	2,168	3,531
Result before tax	(11,852)	(10,449)	(28,813)	(27,132)	(6,369)
Tax for the period	6,567	907	18,678	953	234
Net result for the period	(5,285)	(9,542)	(10,135)	(26,179)	(6,136)
Statement of Financial Position					
Cash and cash equivalents	30,520	7,766	3,359	15,763	44,178
Total assets	77,117	41,921	29,884	21,809	47,983
Total equity	4,614	5,316	10,195	13,127	41,371
Investment in property, plant and equipment	251	564	176	48	295
Cash Flow Statement					
Cash flow from operating activities	(11,265)	(7,710)	(28,057)	(26,392)	(13,050)
Cash flow from investing activities	(251)	(564)	(176)	(48)	(430)
Cash flow from financing activities	34,371	12,435	15,981	48	167
Cash and cash equivalents at period end	30,520	7,766	3,359	15,763	44,178
Financial Ratios					
Basic and diluted EPS (DKK)	(0.00)	(0.01)	(0.01)	(0.02)	(0.02)
Weighted average number of shares	1,713,188,778	1,708,325,635	1,688,679,397	1,663,334,241	1,662,266,639
Average number of employees (FTEs)	55	51	54	38	26
Assets/equity	16.71	7.89	2.93	1.66	1.16
Share price DKK	2.19	0.86	1.08	1.75	1.15
Average exchange rates DKK/USD	6.3521	6.5301	6.6940	6.7269	5.6190
Period End exchange rate DKK/USD	6.5204	6.2019	7.0460	6.8300	6.1214

* These revenue amounts include upfront payments of USD 8,250 for 2017 and milestone payments of USD 20,304 for 2014.

PEOPLE
CORPORATE GOVERNANCE

PEOPLE

At year-end 2018, Veloxis employed 58 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 2018, 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 99b of the Danish Financial Statement Act at http://ir.veloxis.com/corporate-governance.

RISK MANAGEMENT

Veloxis is exposed to certain risks, some of which may significantly affect the Company's operations and ability to execute it's commercial strategy. 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, Third-Party Manufacturing Risks and Reputational Risks.

The following examples highlight these key 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 2018, the Company was not a party to any pending legal proceedings.

Veloxis maintains broad insurance coverage to deal with a number of legal risks. The appropriateness of this insurance coverage, including products liability coverage, is assessed on an annual basis by the Board of Directors.

Third Party Manufacturing Risks

Veloxis contracts with third-party manufacturers and component suppliers to produce Envarsus. Failures or delays may occur at production sites or throughout the supply chain for components. This could be due to equipment breakdowns or quality issues at key suppliers' production facilities. If Veloxis is unable to supply Envarsus to the market, pharmacies and hospitals could face product shortages.

Veloxis mitigates its third-party manufacturing risks in a number of ways. Veloxis performs regular audits of its suppliers and manufacturers to ensure compliance with applicable regulations and quality standards. Additionally, Veloxis maintains an additional safety stock of Envarsus and critical components that are necessary for product manufacture. Lastly, Veloxis is pursuing the qualification of a secondary manufacturer for its product.

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 is proud of its commitment to the transplant community and our goal of conducting our business in a way that makes a positive and meaningful impact on health, science, and society overall. While Veloxis has no formal, Company-wide policies and reporting relating to corporate social responsibility, human rights or environmental issues, we remain committed to the support and betterment of our communities through corporate giving, and are supportive of our employee's volunteerism efforts, philanthropy, and relationships with non-profits.

Please refer to page 12 for a description of the Company's business model and pages 32-33 for a description of the risks related to the Company's activities.

Environmental Impacts

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 quite limited. However, Veloxis conducts its activities with deep respect for its stakeholders and with a focus on minimizing its environmental impact. The Company has not drawn up any formal policy in this regard.

Working Environment

Our employees are the backbone of our Company, and their well-being, health, and safety in the workplace are crucial to our success as a business. The objective of our working environment activities is to continually improve upon 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 2018, 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. Simply put, bribery of any kind is illegal worldwide, is inconsistent with Veloxis's values and is strictly prohibited by the Company.

In 2018, Veloxis reviewed its Code of Ethics and updated it as necessary to reflect changes in applicable law and industry practice. All employees received the most recently updated Code of Ethics, acknowledged their understanding of the Code of Ethics, and reaffirmed their adherence to the provisions contained therein.

Social and Staff Matters

Our employees' well-being, health, and safety in the work-place is of paramount importance to us. While the Company does not have a formal policy for social and staff matters, the Company is committed to securing and maintaining a safe working environment that ensures our employees feel safe, motivated and productive.

As such, every year we solicit feedback from our employees on the working environment and other social and staff matters through an annual review. We also conduct health and safety training, annually. In an effort to facilitate ideal social and staff matters, the Company has established a committee that meets regularly to organize quarterly team-building events. Every year, Veloxis organizes and sponsors different activities to show appreciation for our employee's efforts and dedication. The Company also has a dedicated, in-office, area for employee recreation during the workday.

In 2018, our team-building events included a culinary experience, an art class facilitated by an instructor, and the viewing of an art exhibition by a well-known international artist.

Veloxis assessed its risk in connection with social matters, and based on our current activity and staff level the Company does not have a formal social policy. The Company, however, realizes the importance of continuous community and social development. As such, Veloxis is committed to acting responsibly in pursuing our vision of building a sustainable future. The Company's approach is to engage and support local communities, wherever we operate, to build trusted relationships.

Climate

Veloxis does not have a formal policy in regard to impact on climate due to its small size at present. The Company intends to consider climate impacts generally in its decision-making where warranted.

Human Rights

Veloxis values diversity and provides equal opportunities to all in the recruitment and promotion process without regard to race, color, religion, sex (including pregnancy and gender identity), national origin, age, disability, genetic information, veteran status, and other protected classes. Veloxis does not tolerate harassment or discrimination in any circumstances and has adopted formal policies in this regard accordingly.

In 2018, Veloxis reviewed its Employee Handbook and updated it as necessary to reflect changes in applicable law and industry practice. The Employee Handbook contains several policies which impact human rights areas such as anti-harassment and equal opportunity employment. As part of the revision, employees acknowledged the updated policies and affirmed their adherence to comply with the provisions contained therein. Additionally, all employees attended mandatory training on sexual harassment, discrimination, and retaliation. Such training is a key element of the Company's onboarding program.

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 2018 Veloxis performed 4 audits of our approved vendors (20 visits and audits of our important partners and suppliers in 2017) 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 2018, 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 2018 Veloxis had a registered share capital of USD 24,399 with a nominal value of DKK 0.1 per share (USD 0.015).* Please see note 12 for a more detailed description. Veloxis has only one share class and all shares have equal voting rights. The Board of Directors has determined that the current single-class share structure is in the best interest of the shareholders of the Company at the present time.

The Board of Directors is authorized, until the Annual General Meeting in 2019, 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 2018, a total of 8,723 of Veloxis's shareholders were registered in the shareholder register; an increase from 8,040 shareholders as at 31 December 2017. Veloxis invites all shareholders to register in the Company's shareholder register.

As at 31 December 2018, the following shareholders have reported ownership of 5% or more of the Company's shares:

- Lundbeckfond Invest A/S 41.2% (100% owned by the Lundbeck Foundation), Denmark, municipality of Copenhagen
- Novo Holdings A/S 41.2% (100% owned by the Novo Nordisk Foundation), Denmark, municipality of Gentofte

2018 Company Announcements

During 2018, the Company issued 27 Company Announcements. These can be found on Veloxis's website: http://ir.veloxis.com/press-releases.

Financial Calendar 2019

19 February 2019
Deadline for Receipt of Shareholder Proposals for 2019 Annual General Meeting

27 February 2019
2018 Annual Report

3 April 2019
Annual General Meeting

6 May 2019
Interim Report for the First Three Months of 2019

8 August 2019
Interim Report for the First Six Months of 2019

12 November 2019
Interim Report for the First Nine Months of 2019

IR Contacts

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CFO
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* The differences between the USD reported share capital and the DKK registered share capital are explained by the measurement of share capital at historical costs translated using the exchange rate at the date of the transaction.

BOARD OF DIRECTORS & MANAGEMENT

Board of Directors

Michael T. Heffernan
Chairman

Male
Age: 54
Elected at the 2015 AGM
Current term expires 03 April 2019
Nomination Committee (C)
Remuneration Committee (M)
Independent

Competences:
Registered Pharmacist
Former CEO, Collegium Pharmaceutical, Inc.

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

Mette Kirstine Agger
Deputy Chairman

Female
Age: 54
Elected at 2010 AGM
Current term expires 03 April 2019
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.
Tiburio Therapeutics
Imara Inc.
Trevi Therapeutics, Inc.

Robert S. Radie
Member

Male
Age: 55
Elected at July 2016 EGM
Current term expires 03 April 2019
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: 58
Elected at July 2017 EGM
Current term expires 03 April 2019
Remuneration Committee (C)
Independent

Competences:
Ph.D., Pharmaceutical Sciences
Former CEO, Sigilon Inc.

Directorships:
Vericel Corp.
Cynata Therapeutics Limited (C)

Anders Götzsche
Member

Male
Age: 51
Elected at 2008 AGM
Current term expires 03 April 2019
Audit Committee (C)
Independent

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

Directorships:
Rosborg Møbler A/S
DFDS A/S

Lars Kåre Viksmoen
Member

Male
Age: 70
Elected at July 2017 EGM
Current term expires 03 April 2019
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

Executive Management

Craig A. Collard
President & CEO

Joined Veloxis in 2015

Ira Duarte
CFO

Joined Veloxis in 2016

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

EXECUTIVE MANAGEMENT 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 2018.

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 2018, the results of the Group's and Parent Company's operations, and cash flows for the financial year 2018. 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 2019

Executive Management

Craig A. Collard
President & CEO

Ira Duarte
CFO

Board of Directors

Michael T. Heffernan
Chairman

Mette Kirstine Agger
Deputy Chairman

Anders Götzsche
Member

Robert S. Radie
Member

Paul K. Wotton
Member

Lars Kåre Viksmoen
Member

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 2018 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 2018 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 2018 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 12 years including the financial year 2018. We were reappointed following a tendering procedure at the General Meeting on April 7, 2017.

INDEPENDENT AUDITOR'S REPORT

Key audit matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the Financial Statements for 2018. These matters were addressed in the context of our audit of the Financial Statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Key audit matter	How our audit addressed the key audit matter
Valuation of Deferred Tax Asset	
The Group has significant recognized and unrecognized deferred tax assets mainly related to tax losses carried forward due to significant losses in previous years.	We discussed deferred tax asset recognition principles with management and we inquired with management on the business outlook of the Group.
Recognition of deferred tax assets depend on probable future taxable income will be available, against which the deferred tax assets can be utilized.	We obtained financial budget for 2019 and forecasts for 2020 – 2023 underpinning the valuation of deferred tax assets.
Significant judgment is required by Management in projections in financial budget for 2019 and forecasts for 2020–2023, especially expectations for revenue growth and gross margin, particularly when marketing a new product and transforming to a commercial company.	We critically challenged management's key assumptions and projections, by comparing Management's assessment to evidence obtained, such as business plans and historical accuracy of budgets.
We focused on deferred tax assets because the recognition of deferred tax assets requires significant judgment and estimation by Management.	We performed substantive audit procedures on the recognition of deferred tax assets.

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 judgment 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.

INDEPENDENT AUDITOR'S REPORT

- 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.

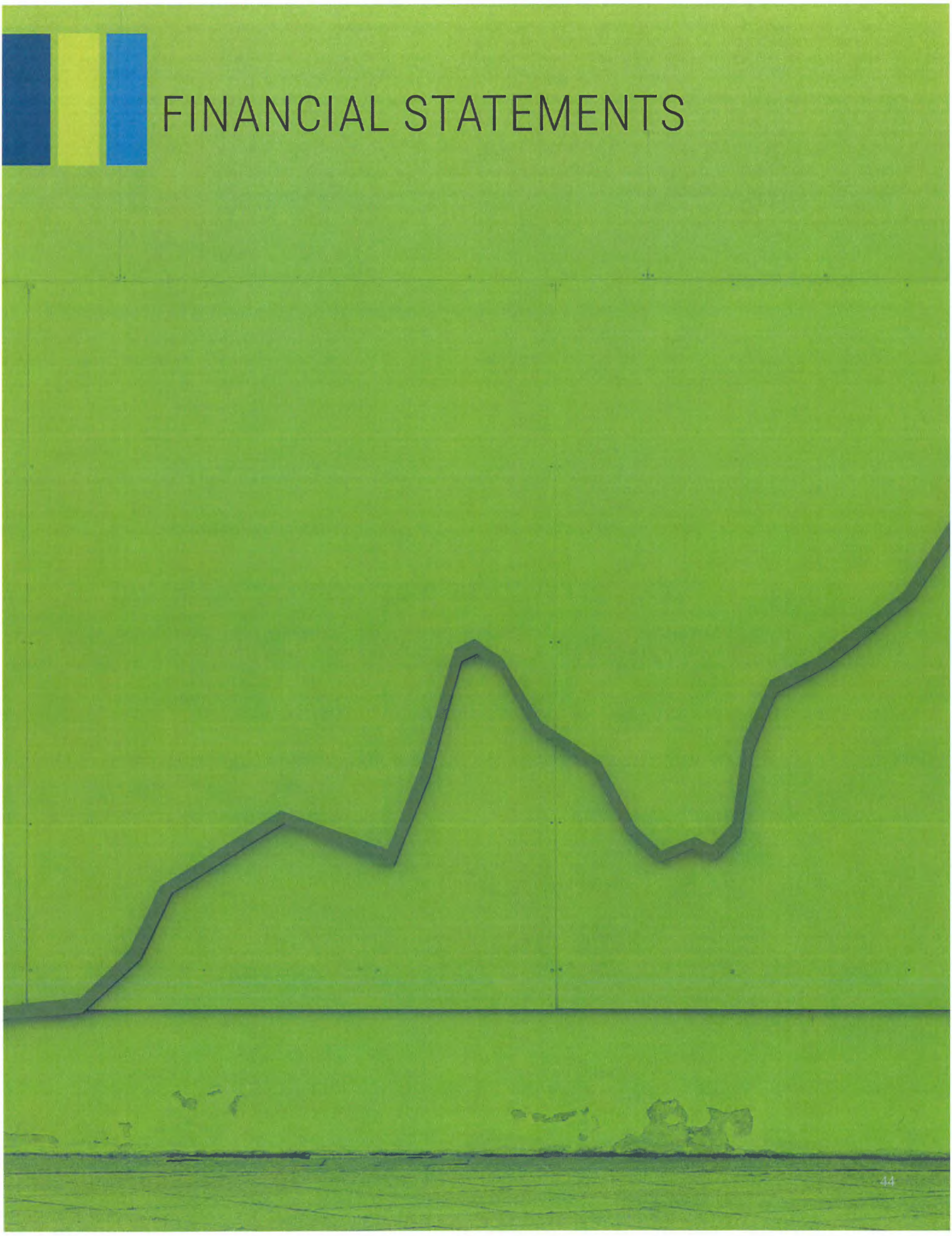
Copenhagen, 27 February 2019

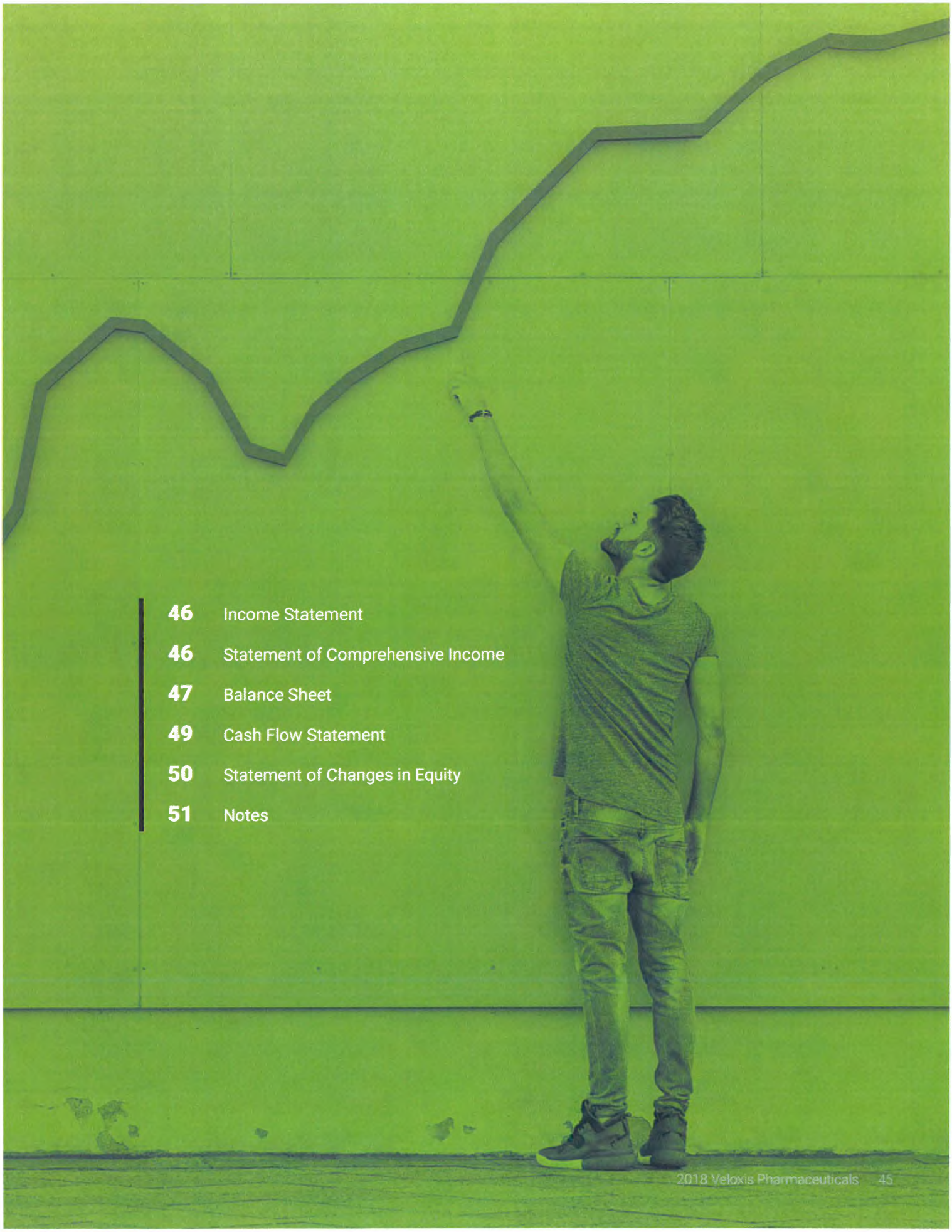
PricewaterhouseCoopers
Statsautoriseret Revisionspartnerselskab
CVR No 33 77 12 31

Søren Ørjan Jensen
State Authorised Public Accountant
mne33226

Henrik Ødegaard
State Authorised Public Accountant
mne31489

FINANCIAL STATEMENTS





FINANCIAL STATEMENTS

INCOME STATEMENT

For the period 1 January – 31 December

		Consolidated		Parent	
(USD'000)	Note	2018	2017	2018	2017
Revenue	3	39,494	30,167	16,587	12,670
Production costs		(7,918)	(5,202)	-	-
Gross profit		**31,576**	**24,965**	**16,587**	**12,670**
Selling, general and administrative costs	4, 5	(35,611)	(32,458)	(3,134)	(3,453)
Research and development costs	4, 5	(1,801)	(866)	-	-
Operating result		**(5,836)**	**(8,359)**	**13,453**	**9,217**
Financial income	6	347	199	2	3,372
Financial expenses	7	(6,363)	(2,289)	(517)	(2,269)
Result before tax		**(11,852)**	**(10,449)**	**12,938**	**10,320**
Tax for the year	8	6,567	907	6,567	1,348
Net result for the year		**(5,285)**	**(9,542)**	**19,505**	**11,668**
Basic and diluted EPS		(0.00)	(0.01)		
Weighted average number of shares		1,713,188,778	1,708,325,635		

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

	Consolidated		Parent	
(USD'000)	2018	2017	2018	2017
Net result for the period	**(5,285)**	**(9,542)**	**19,505**	**11,668**
Other comprehensive income for the period	-	-	-	-
Total comprehensive income for the period	**(5,285)**	**(9,542)**	**19,505**	**11,668**

BALANCE SHEET

Assets at 31 December

		Consolidated		Parent	
(USD'000)	Note	2018	2017	2018	2017
Patent rights and software	9	48	80	26	33
Intangible assets		**48**	**80**	**26**	**33**
Property, plant and equipment	9	965	875	127	202
Tangible fixed assets		**965**	**875**	**127**	**202**
Receivable from subsidiary		-	-	-	48,026
Equity interest in subsidiary	10	-	-	46,609	4,070
Deferred tax asset	8	27,201	20,187	27,201	20,187
Financial assets		**27,201**	**20,187**	**73,810**	**72,283**
Non-current assets		**28,214**	**21,142**	**73,963**	**72,518**
Inventories	**11**	**8,375**	**6,781**	**-**	**-**
Trade receivables		6,903	4,354	-	-
Other receivables		59	55	54	48
Prepayments		3,046	1,823	134	149
Receivables		**10,008**	**6,232**	**188**	**197**
Cash		30,520	7,766	1,650	6,139
Cash and cash equivalents		**30,520**	**7,766**	**1,650**	**6,139**
Current assets		**48,903**	**20,779**	**1,838**	**6,336**
Assets		**77,117**	**41,921**	**75,801**	**78,854**

FINANCIAL STATEMENTS

BALANCE SHEET

Equity and liabilities at 31 December

		Consolidated		Parent	
(USD'000)	**Note**	**2018**	**2017**	**2018**	**2017**
Share capital	12	24,399	24,311	24,399	24,311
Special reserve		-	57,804	-	57,804
Translation reserves		(4,052)	(4,052)	(4,297)	(4,297)
Retained earnings/loss		(15,733)	(72,747)	54,604	(27,200)
Equity		**4,614**	**5,316**	**74,706**	**50,618**
Loan	13	59,905	25,818	-	25,883
Non-current liabilities		**59,905**	**25,818**	**-**	**25,883**
Trade payables		1,996	2,428	43	107
Other payables		10,602	8,359	1,052	2,246
Current liabilities		**12,598**	**10,787**	**1,095**	**2,353**
Liabilities		**72,503**	**36,605**	**1,095**	**28,236**
Equity and liabilities		**77,117**	**41,921**	**75,801**	**78,854**

CASH FLOW STATEMENT

For the period 1 January – 31 December

		Consolidated		Parent	
(USD'000)	**Note**	**2018**	**2017**	**2018**	**2017**
Operating result		**(5,836)**	**(8,359)**	**13,453**	**9,217**
Share-based payment	5	3,830	4,174	407	472
Depreciation and amortization	4	193	205	82	113
Changes in working capital	18	(1,927)	(2,517)	(107)	3,367
Cash flow from operating activities before interest		**(3,740)**	**(6,497)**	**13,835**	**13,169**
Interest paid		(7,516)	(1,213)	(1,877)	(1,213)
Corporate tax paid		(9)	-	(9)	-
Cash flow from operating activities		**(11,265)**	**(7,710)**	**11,949**	**11,956**
Purchase of property, plant and equipment		(251)	(564)	-	-
Payable to / (receivable from) subsidiary		-	-	8,910	(20,833)
Cash flow from investing activities		**(251)**	**(564)**	**8,910**	**(20,833)**
Proceeds from bank borrowings		60,000	12,000	-	12,000
Repayment of principal		(26,000)	-	(26,000)	-
Cost of borrowings		(382)	(54)	-	(54)
Proceeds from issuance of shares		753	489	753	489
Cash flow from financing activities		**34,371**	**12,435**	**(25,247)**	**12,435**
Increase/(decrease) in cash		**22,855**	**4,161**	**(4,388)**	**3,558**
Cash at beginning of period		7,766	3,359	6,139	2,335
Exchange gains/(losses) on cash		(101)	246	(101)	246
Cash at end of period		**30,520**	**7,766**	**1,650**	**6,139**

Parent contributed USD 3,423 as a non-cash contribution through investment in sub in 2018 (3,702 in 2017).

Parent contributed USD 39,116 as a non-cash contribution through equity in 2018.

Cash includes USD 315 of restricted cash in Consolidated numbers for 2018 and 2017.

FINANCIAL STATEMENTS

STATEMENT OF CHANGES IN EQUITY

Consolidated

	Number of Shares	Share Capital	Special Reserves	Translation Reserves	Retained Earnings	Total
		USD'000	USD'000	USD'000	USD'000	USD'000
Equity as of 1 January 2017	**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**
Net result for the year					(5,285)	(5,285)
Total comprehensive income		-	-	-	(5,285)	(5,285)
Warrant exercises	5,756,817	88			665	753
Share-based payment					3,830	3,830
Transfer to retained earnings			(57,804)		57,804	-
Other transactions	5,756,817	88	(57,804)	-	62,299	4,583
Equity as of 31 December 2018	**1,718,195,348**	**24,399**	**-**	**(4,052)**	**(15,733)**	**4,614**

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). On December 31, 2018, the Company transferred the Special Reserves to Retained Earnings, as allowable by Danish Companies Act sections 188 and 189.

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

STATEMENT OF CHANGES IN EQUITY

Parent Company

	Number of Shares	Share Capital	Special Reserves	Translation Reserves	Retained Earnings	Total
		USD'000	USD'000	USD'000	USD'000	USD'000
Equity as of 1 January 2017	**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**
Net result for the year					19,505	19,505
Total comprehensive income		-	-	-	19,505	19,505
Warrant exercises	5,756,817	88			665	753
Share-based payment					3,830	3,830
Transfer to retained earnings			(57,804)		57,804	-
Other transactions	5,756,817	88	(57,804)	-	62,299	4,583
Equity as of 31 December 2018	**1,718,195,348**	**24,399**	**-**	**(4,297)**	**54,604**	**74,706**

NOTES

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 2018, 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.

FINANCIAL STATEMENTS

Accounting Policy Changes

Adoption of new or amended IFRS's

Veloxis has adopted the following new or amended standards and interpretations effective 1 January 2018:

IFRS 9 "Financial Instruments" was issued in 2014 and contains amendments to the classification and measurement of financial instruments. Implementation of this standard did not impact the Group's consolidated financial statements.

The Group has implemented IFRS 15 "Revenue from Contracts with Customers" using the modified retrospective approach. IFRS 15 replaces the current standards on revenue (IAS 11 "Construction Contracts" and IAS 18 "Revenue"). There is no significant effect on the financial statements from the implementation of the Standard.

Besides the adopted standards 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 2018.

New Financial Standards Adopted

In addition to the above, IASB has issued a number of new, amended, or revised accounting standards and interpretations that have not yet come into effect. New or amended and revised standards are implemented when taking effect. The Company is assessing the impact of the following standard:

Standard	Description	Implementation	Impact
IFRS 16 "Leases" (endorsed by the EU)	IFRS 16 replaces IAS 17, and will change the accounting treatment of leases that are currently treated as operating leases. The standard requires all leases, where the Group is the lessee, regardless of type and with few exceptions, to be recognized in the balance sheet as an asset with a related liability. The lease expense will be split between a depreciation charge included in operating costs and an interest expense on lease liabilities included in financial expenses. Currently, the annual costs relating to operating leases are recognized within selling, general and administrative expenses in the income statement.	The Group will adopt the standard on the effective date, 1 January 2019. The standard will be implemented using the simplified approach, meaning that comparative information is not restated, and the lease asset will be recorded at an amount equal to the lease liability, adjusted by the amount of any prepaid or accrued lease payments relating to that lease recognized in the balance sheet immediately before the date of initial application.	The changes require capitalization of the majority of the Group's operating leases. This will increase assets and liabilities by approx. 1% of the Group's total assets, thus affecting the financial ratios related to the balance sheet. The impact on operating result will be insignificant. Cash flow from operating activities will increase as the substantial portion of lease payments will be classified as financing cash outflows.

None of the other new or revised standards or interpretations are expected to have any significant monetary effect on the statements of the Group's results, assets, liabilities or 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. In 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 in the income statement as 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.

FINANCIAL STATEMENTS

INCOME STATEMENT

Revenues

Revenues are comprised of invoiced sales for the year less any applicable discounts. Moreover, revenues include 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. Performance obligations are satisfied at one point in time, typically on delivery.

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, chargebacks, as well as rebates and discounts to government agencies, wholesalers, 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 are expensed as incurred and include costs incurred for sales campaigns, training and administration of the sales force, and marketing and promotion. Also included are salaries and other costs for the sales, supply chain 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 other direct costs are included in this line item.

Research and Development Costs

Research and development costs comprise costs by activity, and include product and manufacturing development as well as 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 based on the outstanding principal and the nominal interest rate.

Dividend from equity interests in subsidiaries is recognized in the income statement of the Parent Company in 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 be realized 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.

FINANCIAL STATEMENTS

BALANCE SHEET

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. The Company's customers are under normal payment terms, and no significant delays in payment have been noted.

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.

Non-Current Liabilities

Loan

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

Current Liabilities

Trade Payables

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

Deferred Revenue

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

Other Liabilities

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

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

Equity Interests in Subsidiaries

In the separate financial statements of the Parent Company, equity interests in subsidiaries are recognized and measured at cost and reflect amounts attributable to the Parent Company pertaining to warrants and other intercompany assets that eliminate in consolidation.

CASH FLOW STATEMENT

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

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

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

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

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

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

Segment Reporting

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

Financial Ratios

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

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

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

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

$$\textbf{Assets/Equity Ratio} = \frac{\textbf{Total Assets}}{\textbf{Equity}}$$

NOTE 2 *CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS*

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

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 judgment, as all conditions are not known at the time of sale. Accruals of sales deductions amounted to USD 0.2 – 1.6 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 periods.

Discounts, Sales Returns and Other Rebates

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

NOTE 3 *REVENUE*

The Group derives the following types of revenue:

	Consolidated		Parent	
(USD'000)	2018	2017	2018	2017
Sale of goods	39,494	21,917	-	-
Royalty and upfront	-	8,250	16,587	12,670
Total	**39,494**	**30,167**	**16,587**	**12,670**

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:

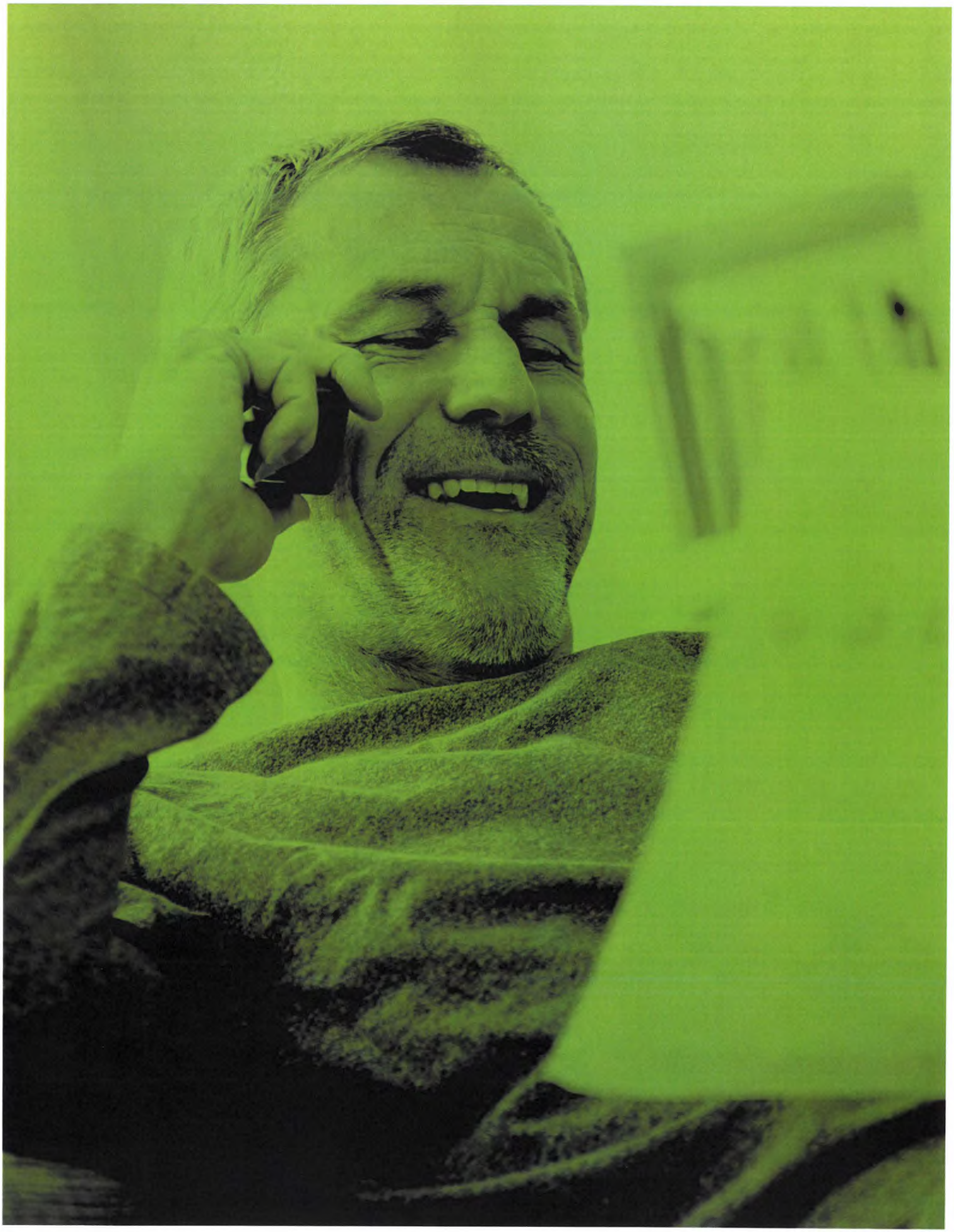
	Consolidated		Parent	
(USD'000)	2018	2017	2018	2017
Europe	5,813	4,265	-	-
United States	33,667	17,592	16,587	12,670
RoW	14	8,310	-	-
Total	**39,494**	**30,167**	**16,587**	**12,670**

Revenue, excluding RoW, is comprised from the following major customers:

	Consolidated		Parent	
(USD'000)	2018	2017	2018	2017
Customer A revenue	11,492	6,136	-	-
Customer B revenue	10,696	6,278	-	-
Customer C revenue	6,644	2,851	-	-
Customer D revenue	5,813	4,265	-	-
Customer E revenue	561	131	-	-
Other customer revenue	4,274	2,196	-	-
Total	**39,480**	**21,857**	**-**	**-**

NOTE 4 *DEPRECIATION AND AMORTIZATION*

	Consolidated		Parent	
(USD'000)	2018	2017	2018	2017
Patient rights and software	32	35	7	7
Prperty, plant and equipment	144	154	75	106
Leasehold improvements	17	16	-	-
Total	**193**	**205**	**82**	**113**
Allocated by function:				
Selling, general and administrative expenses	193	205	82	113
Research and development costs	-	-	-	-
Total	**193**	**205**	**82**	**113**



NOTE 5 *STAFF COSTS*

	Consolidated		Parent	
(USD'000)	2018	2017	2018	2017
Wages and saleries	12,858	11,494	435	360
Pension contributions	365	297	-	-
Other social security costs	1,544	1,454	9	-
Share-based payment	3,830	4,174	407	472
Total	**18,597**	**17,419**	**851**	**832**
Allocated by function:				
Selling, general and administrative expenses	18,597	17,419	851	832
Research and development costs	-	-	-	-
Total	**18,597**	**17,419**	**851**	**832**
Average number of employees (FTEs)	55	51	-	-
Remuneration of board of directors and executive management:				
Board of Directors				
Board fees	435	360	435	360
Share-based payment	398	382	398	382
	833	**742**	**833**	**742**
Executive Management				
Gross salary	1,013	837	1,013	837
Severance	168	193	168	193
Bonus	342	345	342	345
Pension contributions	27	22	27	22
Share-based payment	1,797	2,092	1,797	2,092
	3,347	**3,489**	**3,347**	**3,489**
Total	**4,180**	**4,231**	**4,180**	**4,231**

Members of the Board of Directors, except for the Chairman of the Board of Directors, receive a fixed annual fee of USD 50. The Chairman of the Board of Directors receives a fixed annual fee of USD 100. The Chairman of respectively the Audit Committee, Nominating Committee and the Compensation Committee receives a supplement of USD 20, USD 10 and USD 15, 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.

Members of Executive Management are entitled to severance payments totaling 6-12 months of annual salary if they are terminated without cause in the ordinary course of business. In the event that such termination takes place following a change of control, members of executive management are entitled to two times their ordinary severance payments totaling 12-24 months of annual salary.

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

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

Veloxis has implemented Incentive Guidelines in its Remuneration Policy, which has been adopted by the shareholders at the Annual General Meeting and are in further detailed on Veloxis´s website at http://ir.veloxis.com/general-meetings.

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

	As per 31 December 2018		As per 31 December 2017	
	Shares	Warrants	Shares	Warrants
Board of directors				
Anders Götzsche		3,702,567	-	2,808,508
Mette Kirstine Agger	1,288	3,802,567	1,288	2,958,508
Michael T. Heffernan		3,702,567	-	2,808,508
Paul K. Wotton		2,746,069	-	1,852,010
Robert S. Radie		2,746,069	-	1,852,010
Lars Kåre Viksmoen		2,746,069	-	1,852,010
Executive management				
Craig A. Collard		74,777,196	-	74,777,196
Ira Duarte		5,000,000	-	5,000,000

NOTE 6 *FINANCIAL INCOME*

	Consolidated		Parent	
(USD'000)	2018	2017	2018	2017
Interest income	347	13	2	13
Interest income from group companies	-	-	-	3,139
Exchange rate	-	186	-	220
Total	**347**	**199**	**2**	**3,372**

NOTE 7 *FINANCIAL EXPENSES*

	Consolidated		Parent	
(USD'000)	2018	2017	2018	2017
Interest expenses	6,304	2,289	451	2,269
Exchange rate, net	59	-	66	-
Total	**6,363**	**2,289**	**517**	**2,269**

NOTE 8 *TAX AND DEFERRED TAX*

	Consolidated		Parent	
(USD'000)	**2018**	**2017**	**2018**	**2017**
Actual Corporate tax	(447)	(602)	(447)	(161)
Change in deferred tax	7,014	1,509	7,014	1,509
Tax for the year	**6,567**	**907**	**6,567**	**1,348**
Tax for the year can be explained as follows:				
Income / (loss) for the year before tax	(11,852)	(10,246)	12,938	10,964
Tax rate	**22.0%**	**22.0%**	**22.0%**	**22.0%**
Computed tax on income / (loss) for the year	2,608	2,254	(2,846)	(2,412)
Deferred tax asset not recognized	(5,681)	(2,189)	-	-
Reversal of writedown in previous years	9,327	3,670	9,327	3,671
Foreign tax withholding	-	(480)	-	-
Permanent differences	(5)	47	86	89
Deviation in foreign subsidiary tax rate	318	(2,395)	-	-
Tax for the year	**6,567**	**907**	**6,567**	**1,348**
Calculated deferred tax asset, beginning	76,193	68,169	64,560	58,724
Exchange rate adjustment	(3,084)	8,148	(3,084)	8,149
Change in deferred tax assets	3,541	(124)	(2,140)	(2,313)
Calculated deferred tax asset, ending	**76,650**	**76,193**	**59,336**	**64,560**
Write down to assesses value	(49,449)	(56,006)	(32,135)	(44,373)
Carrying amount	**27,201**	**20,187**	**27,201**	**20,187**

The remaining unrecognized tax loss carry-forward and temporary differences amounts to USD 216,636 (2017 USD 247,873) on a consolidated basis, and USD 146,085 (2017 USD 201,697) for the Parent on a stand-alone basis.

NOTE 9 *INTANGIBLE & TANGIBLE FIXED ASSETS*

Consolidated	Patent Rights & Software		Property, Plant & Equipment		Leasehold Improvements	
(USD'000)	2018	2017	2018	2017	2018	2017
Cost at 1 January	304	304	6,536	6,019	171	125
Additions	-	-	251	517	-	46
Cost at 31 December	**304**	**304**	**6,787**	**6,536**	**171**	**171**
Amortization/Depreciation/Impairment loss at 1 January	(224)	(190)	(5,738)	(5,584)	(94)	(78)
Amortization/Depreciation	(32)	(34)	(144)	(154)	(17)	(16)
Amortization/Depreciation/Impairment loss at 31 December	**(256)**	**(224)**	**(5,882)**	**(5,738)**	**(111)**	**(94)**
Net book value at 31 December	**48**	**80**	**905**	**798**	**60**	**77**

Parent	Patent Rights & Software		Property, Plant & Equipment	
(USD'000)	2018	2017	2018	2017
Cost at 1 January	182	182	5,794	5,799
Exchange adjustment	-	-	-	(5)
Cost at 31 December	**182**	**182**	**5,794**	**5,794**
Amortization/Depreciation/Impairment loss at 1 January	(149)	(142)	(5,592)	(5,491)
Amortization/Depreciation	(7)	(7)	(75)	(106)
Exchange adjustment	-	-	-	5
Write-down	-	-	-	-
Amortization/Depreciation/Impairment loss at 31 December	**(156)**	**(149)**	**(5,667)**	**(5,592)**
Net book value at 31 December	**26**	**33**	**127**	**202**

NOTE 10 *INVESTMENT IN SUBSIDIARY*

	Parent	
(USD'000)	2018	2017
Cost at 1 January	4,070	368
Addition	42,539	3,702
Total	**46,609**	**4,070**

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*

	Consolidated		Parent	
(USD'000)	2018	2017	2018	2017
Raw materials	3,566	3,837	-	-
Work in Process	992	2,212	-	-
Finished goods	3,817	732	-	-
Total	**8,375**	**6,781**	**-**	**-**

Total production costs for 2018 were USD 7,918 (2017: USD 5,202), which primarily consist of consumption of materials of USD 7,005 (2017: USD 4,274).

Production costs also include an inventory write down of USD 231. (2017: USD 305).

NOTE 12 *SHARE CAPITAL*

On 31 December 2018 the total number of outstanding shares was 1,718,195,348. Each share has a nominal value of DKK 0.1 and one vote. The shares do not have any restrictions as to their transferability. The Board of Directors is authorized until 13 April 2023 to issue an additional 171,263,853 shares. Any new shares issued shall carry the same rights and other characteristics as the Company's existing shares.

Changes in Share Capital from 2014 to 2018

The table below sets forth the changes in our issued share capital since 2014:

					Share price in DKK	
Year	Transaction	Share Capital	Share classes after captial increase		pre bonus shares	post bonus shares range
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
2018	Cash contribution	5,756,817	1,718,195,348	shares	-	0.35 - 1.01

NOTE 13 *NON-CURRENT DEBT*

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. The loan and security agreement carries with it several covenants regarding cash coverage and revenue amounts. Management monitors compliance with these covenants quarterly.

Non-current debt in 2017 related to the 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 had the ability to be utilized in tranches and repaid without penalty. It carried 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 was payable annually in arrears and no principal payments were required until the maturity of 8 March, 2021. The amended and restated agreement also provided 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 carried with it several covenants regarding cash coverage and financial ratios as compared with the Company's latest consolidated budget.

Liabilities Arising from Financing Activities

	Consolidated	Parent
(USD'000)	2018	2018
Long-term debt at 1 January	**26,000**	**26,000**
Cash Flows	34,000	(26,000)
Long-term borrowings	**60,000**	**-**
Long-term debt at 31 December	**60,000**	**-**

Total Non-Current Debt Payments Fall Due

	Consolidated		Parent	
(USD'000)	2018	2017	2018	2017
Within 1 year	6,540	2,570	-	2,570
From 1 to 5 years	80,168	31,783	-	31,783
After 5 years	-	-	-	-
Total	**86,708**	**34,353**	**-**	**34,353**

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.

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 regard to cash deposits, the Company's two major banks have credit ratings of A1 and Aa1 according to Moody's. The credit risk attributable 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:

	Consolidated		Parent	
(USD'000)	2018	2017	2018	2017
EUR'000	1,607	858	555	858
DKK'000	974	1,050	974	1,050

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 2018, a 10% change in the USD/EUR rate will impact result and equity with approximately USD 138.

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 2017	**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**
Granted in the year	35,384,739	-	5,364,356	40,749,095	1.09
Exercised in the year	(5,756,817)	-	-	(5,756,817)	0.86
Cancelled in the year	(24,728,994)	-	-	(24,728,994)	1.32
Expired in the year	(388,466)	-	(50,000)	(438,466)	1.18
Change between categories	(5,000,000)	5,000,000	-	-	-
Outstanding as of 31 December 2018	**91,054,202**	**79,777,196**	**19,445,910**	**190,277,308**	**1.14**
Weighted average exercise price DKK	**1.05**	**1.27**	**1.06**	**1.14**	

As at 31 December 2018, a total of 190,277,308 warrants were outstanding with a weighted average exercise price of DKK 1.14. 117,013,609 of these warrants had vested and are exercisable as at 31 December 2018 with a weighted average exercise price of DKK 1.20. For comparison, as at 31 December 2017, a total of 180,452,490 warrants were outstanding with a weighted average exercise price of DKK 1.17.

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 50% 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 2018, a total of USD 3,830 was recognized as share-based compensation compared with USD 4,174 in 2017.

The entire warrant compensation costs for 2018 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 17 April 2018	Granted 13 July 2018	Granted 31 December 2018
Share price at grant (DKK)	1.01	0.91	2.19
Volatility (%)	52%	52%	50%
Exercise price (DKK)	1.01	0.91	2.19
Risk-free interest rate for options (%)	0.53%	0.32%	0.26%
Annual dividend per share (DKK)	-	-	-
Years to expiry	7	7	7
Exercise period	2025	2025	2025
Market value at grant (USD'000)	2,360	218	435

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)
2011	4,665,291	-	1.15	0.00	1.00 - 1.23
2012	59,047,200	4,406,700	0.35	10.45	0.35
2013	20,930,000	100,000	0.58	19.69	0.36 - 0.63
2014	26,046,891	5,355,550	1.05	27.15	0.95 - 1.86
2015	34,438,935	10,417,843	0.92	38.71	0.86 - 1.06
2016	91,890,178	72,998,207	1.40	51.81	0.95 - 1.43
2017	64,381,974	59,831,974	0.96	68.22	0.84 - 1.12
2018	40,707,033	37,167,034	1.10	76.61	0.91 - 2.19
31 December 2018	**342,107,502**	**190,277,308**	**1.14**	**59.43**	**0.35 - 2.19**

NOTE 16 *OTHER COMMITMENTS*

	Consolidated		Parent	
(USD'000)	2018	2017	2018	2017
Operating lease commitments regarding offices	938	1,204	-	-
Operating lease commitments regarding property, plant and equipment	184	257	-	3
Total operating lease commitments	**1,122**	**1,461**	**-**	**3**
Total operating lease payments fall due:				
Within 1 year	430	335	-	3
From 1 to 5 years	692	1,126	-	-
After 5 years	-	-	-	-
Total	**1,122**	**1,461**	**-**	**3**
Expensed operating lease payments	339	330	10	12

Veloxis has one lease commitment regarding offices related to its Corporate office in North Carolina, which includes escalating rent payments that are recorded on a straight-line basis. All other lease commitments regarding property, plant and equipment include smaller leases pertaining to copiers, internet, cloud storage, and other IT-related leases.

NOTE 17 *RELATED PARTIES*

Shareholders with Significant Influence

- Lundbeckfond Invest A/S 41.2% (100% owned by the Lundbeck Foundation), Denmark, municipality of Copenhagen
- Novo Holdings A/S 41.2% (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, which was repaid in 2018 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 2018, 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 both 2018 and 2017. In addition, the subsidiary incurred interest expenses of USD 3,139 for the period 1 January to 31 December 2017 due to outstanding intercompany balances between the two companies.

At 31 December 2018, the Parent Company had a net receivable from Veloxis Pharmaceuticals, Inc., totaling USD 0 (2017: USD 48,026). The previous receivable was settled through a non-cash equity contribution during the current year as disclosed in the statement of cash flows.

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*

	Consolidated		Parent	
(USD'000)	2018	2017	2018	2017
Trade receivables	(2,549)	(2,142)	-	-
Other receivables	(3)	41	(6)	7
Prepayments	(1,222)	(1,021)	15	43
Inventories	(1,593)	(2,640)	-	-
Trade payables	(432)	1,471	(64)	(11)
Other payables	3,931	1,574	14	3,328
Exchange gains/(losses)	(59)	200	(66)	-
Total	**(1,927)**	**(2,517)**	**(107)**	**3,367**

NOTE 19 *FEES TO AUDITORS APPOINTED BY THE ANNUAL GENERAL MEETING*

	Consolidated		Parent	
(USD'000)	2018	2017	2018	2017
PricewaterhouseCoopers				
Audit	94	89	94	89
Tax Services	82	81	82	81
Other assurance engagements	-	-	-	-
Other services	29	28	29	28
Total	**205**	**198**	**205**	**198**

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

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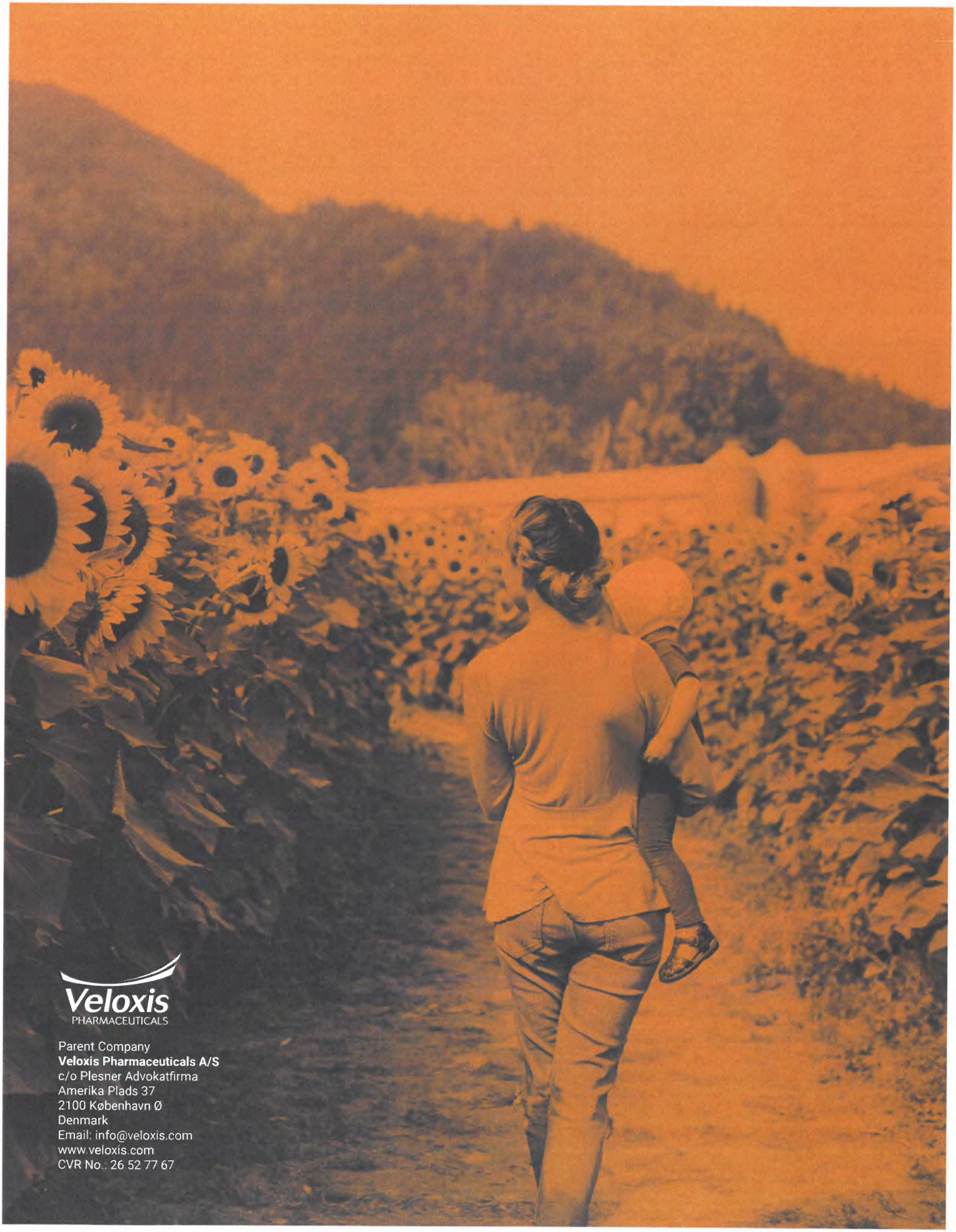

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