

"Veloxis is off to a terrific start in 2019

as sales of Envarsus® continue to accelerate through the first quarter. We are seeing increased interest from the transplant community driven largely by the approval of the de novo indication in December 2018. We are very excited about what this means for the Envarsus franchise long-term and look forward to





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PRODUCT REVENUE

for Q1 2019 was tUSD 14,261 an increase of 96% compared with the same period last year.

+96%

US REVENUE

increased 91% to tUSD 12,285.

+91%

EU REVENUE

increased 133% to tUSD 1,961.

+133%

NET RESULT

Veloxis reported net income of tUSD 111 for the first quarter of 2019 compared with a net loss of tUSD 4,030 for the same period in 2018.

+103%

TRANSPLANT CENTERS

More than 91% of US centers have used Envarsus[®] since its launch¹



¹ Symphony Health, based on Veloxis market definition, which includes total prescriptions for prescribers with a renal related specialty classification captured within the Symphony Health data set.

OUTLOOK FOR 2019

Veloxis maintains its 2019 outlook of revenues to be in the range of USD 58–68 million and operating income before accounting for stock compensation in the range of USD 4–10 million.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Veloxis's documents, including this interim 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 interim report, examples of forward-looking statements can be found under the heading Outlook for 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 interim report, reference is made to the overview of risk factors in the Risk Management section on pages 32-33 of the Company's 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 interim report whether as a result of new information, future developments or otherwise.

ENVARSUS FOR TRANSPLANTATION

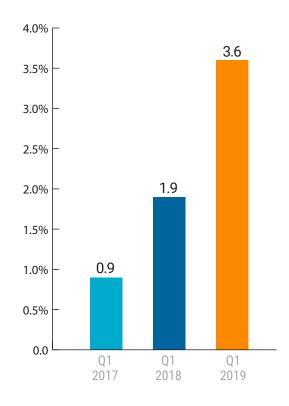
Commercial Update

An important driver of the revenue uptake in Q1 2019 was the US Food & Drug Administration's approval of Envarsus in December 2018 for the use in de novo kidney transplant patients.

In addition to the de novo indication, label enhancements allow promotion of Envarsus for use in special populations that may benefit from increased bioavailability and controlled delivery of tacrolimus. This continues to be a strong driver of revenue uptake. African-American kidney transplant patients historically experience poorer outcomes compared with other ethnic groups.² These outcomes have been associated in part due to this population's 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 upward of 30% of transplant patients regardless of race.³ Patients expressing this genotype metabolize tacrolimus rapidly and as a result typically require higher tacrolimus doses that may hinder efforts to obtain a therapeutic level and thereby may potentially increase the risk for 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.

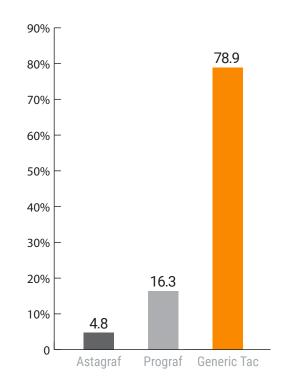
Taken together, the de novo and conversion markets have grown the Envarsus renal prescription market share in the United States to 3.6% in Q1 2019, up from 1.9% in Q1 2018. 4

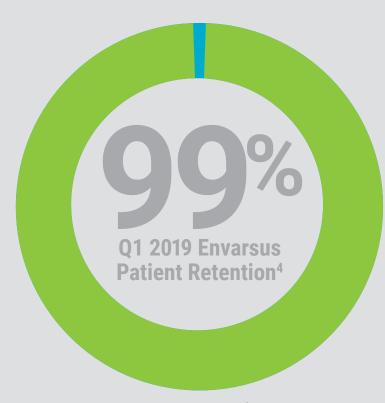




Furthermore, we continued to see a significant proportion of patients who convert to Envarsus transition from generic tacrolimus. In Q1 2019, 79% of patients who converted to Envarsus switched from generic tacrolimus. The large number of patients moving away from generic tacrolimus remains an important demonstration of the benefits Envarsus may offer over existing formulations.







An equally important measurement of Envarsus's potential benefits is the patient's ability to stay on the drug after switching from another formulation. Since it's launch, 99% of patients who convert to Envarsus stay on it after conversion.⁴

Other key performance indicators in the US market also demonstrated successful adoption of Envarsus within transplant centers. Renal prescriptions of Envarsus grew from 8,225 in Q1 2018 to 16,151 in Q1 2019, representing a growth of 96% over the same time period last year.⁴ Renal prescribers also showed strong growth from 688 in Q1 2018 to 1,219 in Q1 2019.⁴ The significant increase in prescriptions and prescribers demonstrates the broad adoption of Envarsus by the transplant community.

² Taber DJ, Gebregziabher MG, Srinivas TR, et al. African-American race modifies the influence of tacrolimus concentrations on acute rejection and toxicity in kidney transplant recipients. Pharmacotherapy. 2015;35(6):569-77.

³ Trofe-Clark J, Brennan DC, West-Thielke P, et al. Results of ASERTAA, a Randomized Prospective Crossover Pharmacogenetic Study of Immediate-Release Versus Extended-Release Tacrolimus in African American Kidney Transplant Recipients. Am J Kidney Dis. 2018;71(3):315-326.

⁴ Symphony Health, based on Veloxis market definition, which includes total prescriptions for prescribers with a renal related specialty classification captured within the Symphony Health data set.

ENVARSUS FOR TRANSPLANTATION

About Envarsus

Envarsus is a novel formulation of tacrolimus designed using advanced technology that allows for increased bioavailability and a controlled, smooth delivery, resulting in once-daily dosing, a lower total daily dose requirement, and lower peak concentrations with less fluctuation.

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

About Veloxis Pharmaceuticals

Veloxis Pharmaceuticals A/S is a commercial-stage, specialty pharmaceutical company committed to improving the lives of transplant patients. A Danish company, Veloxis Pharmaceuticals A/S operates in the United States through Veloxis Pharmaceuticals, Inc., a wholly owned subsidiary headquartered in Cary, North Carolina. Veloxis has successfully developed Envarsus based on the Company's unique and patented delivery technology, MeltDose®, which is designed to enhance the absorption and bioavailability of select orally administered drugs. The Company is focused on the direct commercialization of Envarsus in the United States, expansion of partnerships for markets around the world, and acquisition of assets used in transplant patients and by adjacent medical specialties. Veloxis is listed on the NASDAQ OMX Copenhagen under the trading symbol OMX: VELO.

For further information, please visit: www.veloxis.com.

Conference Call

A conference call will be held 7 May 2019 at 4:00 PM CET (Denmark); 10:00 AM EST (New York).

To access the live conference call, please dial one of the following numbers:

Confirmation Code: 7877813

US: +1 917 720 0178

DK: +45 32 72 75 18

UK: +44 (0) 203 009 5710

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







Financial Highlights

	Q1	Q1	Year
	2019	2018	2018
	USD'000	USD'000	USD'000
Income Statement			
Revenue	14,261	7,265	39,494
Production costs	(2,747)	(1,342)	(7,918)
Gross profit	11,514	5,923	31,576
Selling, general and administrative costs	(10,409)	(9,111)	(35,611)
Research and development costs	(597)	(180)	(1,801)
Operating result	508	(3,368)	(5,836)
Net financial income/(expenses)	(1,582)	(1,188)	(6,016)
Result before tax	(1,074)	(4,556)	(11,852)
Tax for the period	1,185	526	6,567
Net result for the period	111	(4,030)	(5,285)
			_
Balance Sheet			
Cash and cash equivalents	28,394	35,587	30,520
Total assets	78,802	70,357	77,117
Total equity	6,264	2,406	4,614
Investment in property, plant and equipment	76	150	251
Cash Flow Statement			
Cash flow from operating activities	(2,897)	(5,723)	(11,265)
Cash flow from investing activities	(76)	(150)	(251)
Cash flow from financing activities	900	33,631	34,371
Cash and cash equivalents at period end	28,394	35,587	30,520
			_
Financial Ratios			
Weighted average number of shares	1,718,977,836	1,712,474,087	1,713,188,778
Average number of employees (FTEs)	58	53	55
Assets/equity	12.58	29.25	16.71
Share price DKK	2.31	0.94	2.19

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





Revenue

In the first quarter of 2019, Veloxis reached revenue of USD 14,261, an increase of 96% compared to revenue of USD 7,265 for the same period of 2018. The increase is driven by growth in commercial sales of Envarsus in the U.S. which increased by 91% to USD 12,285 compared to USD 6,418 for the first quarter of 2018. Sales to Chiesi Farmaceutici S.p.A ("Chiesi") in Europe were USD 1,961, an increase of 133% compared to USD 841 for the same period in 2018.

See Revenue Note 2 for more detail.

Selling, General and Administrative Costs

For the first quarter of 2019, Veloxis's selling, general and administrative costs amounted to USD 10,409 compared to USD 9,111 during the same period in 2018. The increase reflects additional spends in our sales, marketing, and medical affairs department in our continued effort to maximize the growth of Envarsus.

Research & Development Costs

For the first quarter of 2019, Veloxis's research and development costs amounted to USD 597 compared to USD 180 during the same period in 2018.

Compensation Costs

For the first quarter of 2019, a total of USD 639 was recognized as share-based compensation. The cost is included in selling, general and administrative. The comparable cost for 2018 was USD 1,108.

In the first quarter of 2019, a total of 12,547,617 warrants were cancelled, zero expired, and a total of 6,402,175 warrants were exercised. The subscription price for the exercised shares was DKK 0.35 per share of nominal DKK 0.10 (with regard to 452,414 shares), DKK 0.94 per share of nominal DKK 0.10 (with regard to 137,197 shares), DKK 0.95 per share of nominal DKK 0.10 (with regard to 2,872,534 shares), and DKK 1.01 per share of nominal DKK 0.10 (with regard to 2,940,030 shares).

On 31 March 2019, there were a total of 171,327,516 warrants outstanding at an average strike price of DKK 1.16. Members of the Board of Directors held 19,445,908 warrants at an average strike price of DKK 1.06. Members of the Executive Management held 79,777,196 warrants at an average strike price of DKK 1.27, while other current and former employees held 72,104,412 warrants at an average strike price of DKK 1.07.

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

Operating Income

Veloxis's operating income for the first quarter of 2019 was USD 508 compared to a loss of USD 3,368 in the corresponding period of 2018.

Financial Income

During the first quarter of 2019, the Company recognized net financial expense of USD 1,582 compared to net financial expense of USD 1,188 in the corresponding period of 2018.

Tax for the Period

Tax for the first quarter of 2019 was a benefit of USD 1,185 primarily related to the revaluation and recognition of further deferred tax assets. As of 31 March 2019, the deferred tax asset was USD 28,717 compared to USD 27,201 at the end of 2018.

Net Result

Veloxis's net result for the first quarter of 2019 was income of USD 111 compared to a net loss of USD 4,030 in the corresponding period of 2018.

Cash Flow

As of 31 March 2019, the balance sheet reflects cash and cash equivalents of USD 28,394 compared to USD 30,520 on 31 December 2018.

Balance Sheet

As of 31 March 2019, total assets were USD 78,802 compared to USD 77,117 at the end of 2018.

Shareholders' equity equaled USD 6,264 as of 31 March 2019, compared to USD 4,614 at the end of 2018.

Significant Risks and Uncertainties

Veloxis faces a number of risks and uncertainties related to operations, research and development, commercial and financial activities. For further information about risks and uncertainties, we refer to the Annual Report for 2018. As of the date of this Interim Report, there have been no significant changes to Veloxis's overall risk profile since the disclosures made in the Risk Management section on pages 32-33 of the Company's 2018 Annual Report.

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

The Executive Management and the Board of Directors have considered and adopted the Interim Report for the three months ended 31 March 2019 of Veloxis Pharmaceuticals A/S.

The Interim Report is prepared in accordance with International Accounting Standard No. 34 (IAS 34), "Interim Financial Reporting" and additional Danish disclosure requirements for financial reporting of listed companies.

We consider the applied accounting policies to be appropriate and, in our opinion, the Interim Report gives a true and fair view of the assets and liabilities, financial position, results of the operation and cash flow of the group for the period under review. Furthermore, in our opinion Executive Management's review includes a fair review of the development and performance of the business and the financial position of the group, together with a description of the material risks and uncertainties the group faces.

Copenhagen, 6 May 2019

Executive Management

Craig A. Collar

President & CEO

Ira Duarte

Board of Directors

Michael T. Heffernan Chairman

AS Padie Robert S. Radie Member

It Lash Argre

Mette Kirstine Agger Deputy Chairman

Paul K. Wotton

Member

Anders Götzsche Member

Lars Kåre Viksmoen Member

FINANCIAL STATEMENTS

Financial Highlights - Quarterly

	Q1	Q4	Q3	Q2	Q1
	2019	2018	2018	2018	2018
	USD'000	USD'000	USD'000	USD'000	USD'000
Income Statement					
Revenue	14,261	11,741	10,592	9,896	7,265
Production costs	(2,747)	(2,647)	(1,869)	(2,061)	(1,342)
Gross profit	11,514	9,095	8,723	7,835	5,923
Selling, general and administrative costs	(10,409)	(8,957)	(8,381)	(9,163)	(9,111)
Research and development costs	(597)	(1,301)	(130)	(190)	(180)
Operating result	508	(1,162)	212	(1,518)	(3,368)
Net financial income/(expenses)	(1,582)	(1,611)	(1,528)	(1,689)	(1,188)
Result before tax	(1,074)	(2,772)	(1,316)	(3,207)	(4,556)
Tax for the period	1,185	1,624	2,843	1,574	526
Net result for the period	111	(1,149)	1,527	(1,633)	(4,030)
Balance Sheet					
Cash and cash equivalents	28,394	30,520	30,564	30,783	35,587
Total assets	78,802	77,117	76,104	70,525	70,357
Share capital	24,495	24,399	24,317	24,314	24,314
Total equity	6,264	4,614	4,307	2,121	2,406
Investment in property, plant and equipment	76	101	-	-	150
Cash Flow Statement					
Cash flow from operating activities	(2,897)	(644)	(223)	(4,675)	(5,723)
Cash flow from investing activities	(76)	(101)	-	-	(150)
Cash flow from financing activities	900	730	10	_	33,631
Cash and cash equivalents at period end	28,394	30,520	30,564	30,783	35,587
Financial Ratios					
Basic EPS	0.00	(0.00)	0.00	(0.00)	(0.00)
Diluted EPS (DEPS)	0.00	(0.00)	0.00	(0.00)	(0.00)
Weighted average number of shares EPS	1,718,977,836	1,714,897,661	1,712,723,314	1,712,638,531	1,712,474,087
Weighted average number of shares DEPS	1,778,776,362	1,714,897,661	1,721,539,307	1,712,638,531	1,712,474,087
Average number of employees (FTEs)	58	56	55	54	53
Assets/equity	12.58	16.71	17.67	33.25	29.25

Income Statement and Statement of Comprehensive Income

Income Statement	Consolidated			
(USD'000)	Q1 2019	Q1 2018	Year 2018	
Revenue	14,261	7,265	39,494	
Production costs	(2,747)	(1,342)	(7,918)	
Gross profit	11,514	5,923	31,576	
dioss pione	11,314	3,323	31,370	
Selling, general and administrative costs	(10,409)	(9,111)	(35,611)	
Research and development costs	(597)	(180)	(1,801)	
Operating result	508	(3,368)	(5,836)	
		(-)	(-,,	
Financial income	104	109	347	
Financial expenses	(1,686)	(1,297)	(6,363)	
Result before tax	(1,074)	(4,556)	(11,852)	
Tax for the period	1,185	526	6,567	
Net result for the period	111	(4,030)	(5,285)	
The second secon		(1,000)	(5)=55)	
Basic EPS	0.00	(0.00)	(0.00)	
Diluted EPS	0.00	(0.00)	(0.00)	
Weighted average number of shares EPS	1,718,977,836	1,712,474,087	1,713,188,778	
Weighted average number of shares DEPS	1,778,776,362	1,712,474,087	1,713,188,778	

Statements of comprehensive income		Consolidated	
(USD'000)	Q1 2019	Q1 2018	Year 2018
Net result for the period	111	(4,030)	(5,285)
Other comprehensive income for the period	-	-	-
Total comprehensive income for the period	111	(4,030)	(5,285)

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1 FINANCIAL STATEMENTS

Balance Sheet

Assets	Consolidated			
(USD'000)	31 Mar. 2019	31 Mar. 2018	31 Dec. 2018	
Patent rights and software	40	72	48	
Intangible assets	40	72	48	
Property, plant and equipment	1,743	987	965	
Tangible fixed assets	1,743	987	965	
Deferred tax asset	28,717	20,774	27,201	
Financial assets	28,717	20,774	27,201	
Non-current assets	30,500	21,833	28,214	
Inventories	8,424	7,869	8,375	
Trade receivables Other receivables Prepayments	8,312 56 3,116	3,445 23 1,600	6,903 59 3,046	
Receivables	11,484	5,068	10,008	
Cash	28,394	35,587	30,520	
Cash and cash equivalents	28,394	35,587	30,520	
Current assets	48,302	48,524	48,903	
Assets	78,802	70,357	77,117	

Balance Sheet (Continued)

Equity & Liabilities	Consolidated			
(USD'000)	31 Mar. 2019	31 Mar. 2018	31 Dec. 2018	
Share capital	24,495	24,314	24,399	
Special reserve	-	57,804	-	
Translation reserves	(4,052)	(4,052)	(4,052)	
Retained earnings/loss	(14,179)	(75,660)	(15,733)	
Equity	6,264	2,406	4,614	
Equity	0,20 :	2,100	1,021	
Loan	59,984	59,670	59,905	
Other non-current liabilities	549	-	-	
Non-current liabilities	60,533	59,670	59,905	
Trade payables	1,168	765	1,996	
Other payables	10,837	7,516	10,602	
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Current liabilities	12,005	8,281	12,598	
Liabilities	72,538	67,951	72,503	
Equity and liabilities	78,802	70,357	77,117	



Cash Flow Statement

		Consolidated	
		_	
(USD'000)	Q1	Q1	Year
	2019	2018	2018
Operating result	508	(3,368)	(5,836)
Share-based payment	639	1,108	3,830
Depreciation and amortization	124	46	193
Changes in working capital	(2,582)	(767)	(1,927)
Changes in Working capital	(2,302)	(707)	(1,327)
Cash flow from operating activities before interest	(1,311)	(2,981)	(3,740)
Interest paid	(1,586)	(2,742)	(7,516)
Corporate tax paid	-	-	(9)
Cash flow from operating activities	(2,897)	(5,723)	(11,265)
Purchase of property, plant and equipment	(76)	(150)	(251)
Cash flow from investing activities	(76)	(150)	(251)
Cash now nom myesting activities	(70)	(130)	(231)
Proceeds from borrowings	_	60,000	60,000
Repayment of loan prinicpal	-	(26,000)	(26,000)
Cost of borrowings	-	(381)	(382)
Proceeds from issuance of shares	900	12	753
Cash flow from financing activities	900	33,631	34,371
Increase/(decrease) in cash	(2,073)	27,758	22,855
Cash at beginning of period	30,520	7,766	7,766
Exchange gains/(losses) on cash	(53)	63	(101)
Cash at end of period	28,394	35,587	30,520

Statement of Changes in Equity

Consolidated						
	Number of Shares	Share Capital USD'000	Special Reserves USD'000	Translation Reserves USD'000	Retained Earnings USD'000	Total USD'000
Equity as of 1 Jan. 2018	1,712,438,531	24,311	57,804	(4,052)	(72,747)	5,316
Net result for the year					(4,030)	(4,030)
Total comprehensive income				-	(4,030)	(4,030)
Warrant exercises Share-based payment	200,000	3			9 1,108	12 1,108
Other transactions	200,000	3	_	_	1,108	1,120
Equity as of 31 Mar. 2018	1,712,638,531	24,314	57,804	(4,052)	(75,660)	2,406
Net result for the year					(1,255)	(1,255)
Total comprehensive income				-	(1,255)	(1,255)
Warrant exercises Share-based payment	5,556,817	85			656 2,722	741 2,722
Transfer to retained earnings			(57,804)		57,804	
Other transactions	5,556,817	85	(57,804)	-	61,182	3,463
Equity as of 31 Dec. 2018	1,718,195,348	24,399	-	(4,052)	(15 <i>,</i> 733)	4,614
Net result for the year					111	111
Total comprehensive income				-	111	111
Warrant exercises Share-based payment	6,402,175	96			804 639	900 639
Other transactions	6,402,175	96	-	-	1,443	1,539
Equity as of 31 Mar. 2019	1,724,597,523	24,495	-	(4,052)	(14,179)	6,264



NOTE 1

Accounting Policies

The Interim Report is prepared in compliance with International Accounting Standard No. 34 (IAS 34), "Interim Financial Reporting" and in accordance with the NASDAQ OMX Copenhagen's financial reporting requirements for listed companies.

Veloxis has adopted IFRS 16 Leases (the Standard) retrospectively from 1 January 2019 but has not restated comparative reporting periods as permitted under the specific transition provisions in the standard. In accordance with the transition provisions in IFRS 16, the new rules have been adopted retrospectively with the cumulative effect of initially applying the new standard recognized on 1 January 2019.

On adoption of IFRS 16, Veloxis recognized lease liabilities in relation to leases which had previously been classified as 'operating leases' under the principles of IAS 17 Leases. These liabilities were measured at the present value of the remaining lease payments, discounted using the lessee's incremental borrowing rate as of 1 January 2019 of 10.79%.

The difference between operating lease commitments disclosed applying IAS 17 as of 31 December 2018 and the lease liabilities recognized in the statement of financial position at 1 January 2019 is reconciled as follows:

	(USD'000)
Operating lease commitments disclosed as of 31 December 2018	1,122
(Less): Discount taken for long-term leases at incremental borrowing rate	(156)
(Less): Short-term leases recognized on a straight-line basis as expense	(107)
Lease liability recognized as of 1 January 2019	859

The associated right-of-use assets were measured at the amount equal to the lease liability, adjusted by the amount of accrued lease payments relating to the leases recognized in the balance sheet as at 31 December 2018. Property, plant and equipment increased by USD 817 on 1 January 2019, and other payables decreased by USD 42. The net impact on retained earnings on 1 January 2019 was zero.

In applying IFRS 16 for the first time, Veloxis used the following practical expedients permitted by the Standard:

- the use of a single discount rate to a portfolio of leases with reasonably similar characteristics
- the accounting for operating leases with a remaining lease term of less than 12 months as of 1 January 2019 as short-term leases

- the exclusion of initial direct costs for the measurement of the right-of-use asset at the date of initial application, and
- the use of hindsight in determining the lease term where the contract contains options to extend or terminate the lease.

The Company also elected not to apply IFRS 16 to contracts that were not identified as containing a lease under IAS 17 and IFRIC 4 Determining whether an Arrangement contains a Lease.

There have been no other changes in accounting policies used for the Interim Report compared to the accounting policies used in the preparation of Veloxis Pharmaceuticals' Annual Report for 2018.

NOTE 2

Revenue

Revenue was comprised of the following:

	Q1			
(USD'000)	2019	2018		
·				
Europe	1,961	841		
United States	12,285	6,418		
RoW	15	6		
Total	14,261	7,265		

