

# Final Results for the year ended 31 December 2017

Released : May 08, 2018

RNS Number : 2660N Faron Pharmaceuticals Oy 08 May 2018

> Faron Pharmaceuticals Ltd ("Faron" or the "Company")

## Final Results for the year ended 31 December 2017

**TURKU - FINLAND, 8 May 2018** Faron Pharmaceuticals Ltd ("Faron") (AIM: FARN), the clinical stage biopharmaceutical company, today reports its full year audited results for the year ended 31 December 2017. Today, the Company also separately announced top line data from the Phase III INTEREST trial.

# HIGHLIGHTS (including post period end) OPERATIONAL:

# Traumakine®

INTEREST study did not meet the Day 28 primary composite endpoint with both Traumakine and placebo reporting similar all cause mortality rates. Further investigations are currently underway to provide additional information on the outcome of the current analysis.

Japanese partner Maruishi continued to progress their pivotal Phase III ARDS trial in Japan and has received two IDMC recommendations to continue the trial as planned. Maruishi anticipates completion of recruitment of this 120-patient study in mid 2018.

Faron received the first recommendation from the Independent Data Monitoring Committee (IDMC) in the Traumakine Phase II INFORAAA study for the treatment of Multi-Organ Failure (MOF) and mortality prevention of surgically operated Ruptured Abdominal Aorta Aneurysm (RAAA), to continue the trial as planned. Study currently on pause until INTEREST study analysis completes and Japanese Phase III ARDS trial is reported.

US Food and Drug Administration (FDA) proposed that Faron proceed directly to BLA submission for Traumakine in the US upon successful completion of the

European and Japanese Phase III trials. FDA Fast Track Designation was granted in January. Initiation of a collaboration with Syneos Health for Traumakine - a global biopharmaceutical solutions organization with end-to-end clinical development and commercialization capabilities.

Second independent manufacturing facility established for Traumakine.

Patent estate for Traumakine strengthened with a formulation patent granted in Finland and filed in the US and PCT for Faron's IV dose form of interferon-beta, in addition to allowed patents in Europe and Japan for the use of certain biomarkers to measure the severity and treatment efficacy of patients with ARDS.

# Clevegen®

- Preclinical toxicity studies completed with no sign of serious adverse events indicated.
- Successful production of technical batches of Clevegen by manufacturing partner Abzena.
  - Agreement signed with the University of Birmingham Medical School, UK, to initiate a liver cancer clinical trial program, focused on the protocol design for a Phase I/II trial, MATINS. Clinical trial application expected to be filed in H2 2018.

Filed advice package to the UK Regulatory Agency MHRA on the adaptive protocol design for the MATINS trial to include dose escalation and efficacy measures in four solid tumour cancers (liver, melanoma, pancreas and ovarian).

Patent granted by the European Patent Office for the use of Clever-1 antibodies, the mechanism behind Clevegen, for the treatment of cancer.

## FINANCIAL

- Raised £5.0 million (net €5.4 million) in March 2017 to fund preclinical and early clinical development of Clevegen. Raised £10 million (net €10.4 million) in October 2017 to support the Traumakine pre-launch activities.
  - In addition to the above the Company raised €0.4 million through the subscription of shares with warrants and options in April May 2017.
- Drew down €0.5 million of a €1.5 million R&D loan granted by Tekes in June 2017 to progress the Clevegen programme.
- On 31 December 2017, the Company held cash balances of €9.3 million (2016: €11.5 million). The cash position at end March 2018 was €18.7 million.
- Operating loss for the financial year ended 31 December 2017 was €21.1 million (2016: €10.1 million loss).
- Net assets on 31 December 2017 were €4.7 million (2016: €8.4 million)
  - Post accounting period raised £15.0 million (net €15.9 million) in February 2018 intended to support preparations for the commercialisation of Traumakine and to advance the clinical development of Clevegen in several indications.

The board will be focussing on reducing cash burn and preservation of existing resources until the full data analysis is complete and it is agreed how best to deliver value to shareholders.

## CORPORATE

- Dr Juhana Heinonen was appointed Chief Commercial Officer and Dr Juho Jalkanen was appointed Vice President of Business Development within the period.
- Board strengthened by the appointments of Dr Gregory Brown and Mr John Poulos as Non-Executive Directors in May 2017.
- During the first of quarter 2018, Faron Pharmaceuticals has registered subsidiaries in the United States of America and in Switzerland.

**Commenting on the results, Dr Markku Jalkanen, CEO of Faron, said:** "Although throughout 2017 we have made significant progress across all areas of the business, we are extremely disappointed with the Traumakine data announced today. We will now take some

time to better understand the data and plan the next steps for Traumakine in ARDS, whilst remaining focused on rapidly progressing Clevegen. We remain focused on the development of drugs for life threatening conditions, and we have strong foundations in place, and I am really proud of the strong commitment and resilience of our staff and collaborators at this challenging time."

The 2017 Annual Report and Accounts will be made available shortly, in digital form and on the Company's website together with the invitation to the Annual General Meeting (AGM).

This announcement contains inside information for the purposes of Article 7 of EU Regulation 596/2014 (MAR).

For more information please contact:

Faron Pharmaceuticals Ltd Dr Markku Jalkanen, Chief Executive Officer investor.relations@faron.com

# Consilium Strategic Communications

Mary-Jane Elliott, Philippa Gardner, Matthew Neal, Lindsey Neville Phone: +44 (0)20 3709 5700 E-mail: <u>faron@consilium-comms.com</u>

Westwicke Partners, IR (US) Chris Brinzey Phone: 01 339 970 2843 E-Mail: <u>chris.brinzey@westwicke.com</u>

## Panmure Gordon (UK) Limited, Nomad and Broker

Freddy Crossley, Emma Earl, Ryan McCarthy Phone: +44 207 886 2500

## **About Faron Pharmaceuticals Ltd**

Faron (AIM:FARN) is a clinical stage biopharmaceutical company developing novel treatments for medical conditions with significant unmet needs. The Company currently has a pipeline focusing on acute organ traumas, vascular damage and cancer immunotherapy. The Company's lead candidate Traumakine, to prevent vascular leakage and organ failures, has completed a Phase III clinical trial in Acute Respiratory Distress Syndrome ("ARDS"). An additional European Phase II Traumakine trial is underway for the Rupture of Abdominal Aorta Aneurysm ("RAAA"). Faron's second candidate Clevegen is a ground breaking preclinical anti-Clever-1 antibody. Clevegen has the ability to switch immune suppression to immune activation in various conditions, with potential across oncology, infectious disease and vaccine development. This novel macrophage-directed immuno-oncology switch called Tumour Immunity Enabling Technology ("TIET") may be used alone or in combination with other immune checkpoint molecules for the treatment of cancer patients. Faron is based in Turku, Finland. Further information is available at www.faron.com

# Chairman's Statement

During 2017 Faron continued to make progress across all areas of the business, with the highly experienced management team consistently delivering against all strategic objectives

for the year. Progress was made with both Traumakine and Clevegen and the Company built out the underlying capabilities within the organisation.

Faron's lead drug candidate, Traumakine, completed patient recruitment into the pivotal, pan-European Phase III INTEREST trial in ARDS according to schedule. We are incredibly disappointed to report that the trial has not met the primary endpoint, and we will now carefully review the data in order to plan the next steps for Traumakine in ARDS.

The Company continues to believe that Traumakine could have applications across other serious indications and in early 2017, recruited the first patient in a Phase II trial (INFORAAA) assessing Traumakine for the prevention of Multi Organ Failure (MOF) and patient mortality after surgical repair of the acute rupture of abdominal aorta (RAAA). RAAA is a medical emergency with no known treatment and an overall mortality of 30 to 50% for post-operative reperfusion injury for RAAA patients. The study is currently on pause until the INTEREST study analysis completes and the Japanese Phase III ARDS trial is reported.

Faron's second product, Clevegen, is an immunotherapy candidate that causes conversion of the immune environment around a tumour from immune suppressive to immune stimulating by reducing the number of tumour-associated macrophages (TAMs). We continue to believe that Clevegen is well differentiated from other immunotherapies and following encouraging preclinical toxicity studies, we look forward to moving Clevegen into first clinical trials in H2 2018 to study its potential in multiple solid tumours through our partnership with the University of Birmingham Medical School, UK.

The Company remains well funded, having raised £15m gross proceeds during 2017, and a further £15m gross proceeds in February 2018 which provides us with a solid financial foundation.

During the course of the year we further strengthened the Board with the appointment of Dr Gregory Brown and Mr John Poulos in May 2017. Greg and John bring a wealth of global experience in the life sciences and investment community, particularly from a US and commercial angle and I was delighted to welcome them.

The Board's key priority is to now assess the next steps for Traumakine in ARDS, once the data are fully analysed, and to progress our novel and unique immunotherapy agent Clevegen into first human trials. The board will be focussing on reducing cash burn and preservation of existing resources until the full data analysis is complete and it is agreed how best to deliver value to shareholders.

The Board would like to thank the management team, staff and key partners for continued delivery during 2017. The Board is also extremely grateful to the investigators and patients who are part of our clinical trials. We look forward to updating you on our plans in due course.

# *Dr Frank M Armstrong - Chairman* May 5, 2018

Chief Executive Officer's Review

**Overview** 

Faron is highly focused on developing novel treatments for life-threatening medical conditions with significant unmet need for both individuals and society. Whilst 2017 was a busy year for Faron in anticipation of Traumakine data, we have today reported that the trial did not meet the primary endpoint. We will now seek to analyse and understand, as quickly as possible, the implications and next steps for Traumakine in ARDS.

# **Traumakine Development**

# **INTEREST** trial

We have today reported in a separate announcement that the Traumakine INTEREST trial did not meet the primary endpoint in ARDS. This is despite many years of research suggesting a potential benefit in these very sick patients. We are conducting further investigations in order to provide additional information on the outcome of the current analysis.

Our partner Maruishi continues to progress its pivotal Phase III trial in Japan and two IDMC recommendations to continue the trial as planned have been received. Maruishi expects to complete recruitment in the second quarter of 2018.

# Phase II INFORAAA

We continue to believe that Traumakine has the potential for application in additional disease areas. In February 2017, the first patient was enrolled in the Traumakine Phase II INFORAAA trial for the treatment of Multi-Organ Failure (MOF) and mortality prevention of surgically operated Ruptured Abdominal Aorta Aneurysm (RAAA).

RAAA is a surgical emergency with an overall mortality of 70 to 80% and requires immediate surgery and aortic repair. The main cause of death for these patients is multiple organ failure following a post-operative reperfusion injury of ischemic organs including kidneys, liver, brain and intestines. We believe that Traumakine has the potential to offer significantly improved outcomes for patients following surgery for RAAA. We also believe that the clinical data from the INFORAAA trial could provide us with valuable information on the recovery of ischemic single organ injuries and are planning further trials to treat these injuries. The study is currently on pause until the INTEREST study analysis completes and the Japanese Phase III ARDS trial is reported.

The study currently has six open sites in Finland, two in Lithuania and one in Estonia. The INFORAAA study aims to treat a total of 160 post-operative RAAA patients. The study is currently on pause until the INTEREST study analysis completes and the Japanese Phase III ARDS trial is reported.

# **Clevegen Development**

Faron's second product, its preclinical immunotherapy candidate, Clevegen, causes conversion of the immune environment around a tumour from immune suppressive to immune stimulating by reducing the number and function of tumour-associated macrophages (TAMs). Recent developments in the exciting field of cancer immunotherapy have been well documented with a number of important indications of clinical success. We believe that Clevegen is differentiated from other immunotherapies through its specific targeting of M2 TAMs which facilitate tumour growth, while leaving intact the M1 TAMs that support immune activation against tumours.

Preclinical toxicity studies of Clevegen commenced as planned in 2017, following successful production of technical batches by our manufacturing partner Abzena and initial data indicate no signs of serious adverse events. In April 2017, the Company signed an agreement with the University of Birmingham Medical School, UK, to initiate a liver cancer clinical trial program, focused on the protocol design for a Phase I/II trial MATINS (<u>Macrophage Antibody To IN</u>hibit immune <u>S</u>uppression), which was also reviewed by the UK regulatory authority (MHRA) and discussed at the January 2018 meeting. Based on the MHRA positive feedback the Company anticipates filing the clinical trial application (CTA) in H2 2018.

Faron also continues a close collaboration with the MediCity unit of Turku University Medical School, where Faron has sponsored a set of Clevegen related preclinical experiments. Data reported at the international Juselius Symposium (June 2017, Helsinki, Finland) demonstrated how genetic depletion of macrophage Clever-1 resulted in tumour growth resistance and prevented the spread of Lewis lung cancer in preclinical models. Furthermore, signs of strong immune activation were observed, as evidenced by CD8 positive T-cells at the tumour site, in line with the expected effect of Clevegen. Additional data were also outlined during Faron's second R&D day in February 2018.

## Corporate

In December 2017, Faron announced the appointment of Dr Juhana Heinonen as Chief Commercial Officer. Dr Heinonen joined Faron from AstraZeneca where he served as the Global Marketing Director for AstraZeneca/Medimmune's Fasenra (benralizumab) for the treatment of asthma, the first biologic launched from the AstraZeneca respiratory unit. Dr Heinonen led the global market shaping and the patient and healthcare professional support strategy development for the new monoclonal antibody, which met the primary endpoints in two Phase III clinical trials in 2016. Prior to this, he held a variety of positions in sales and marketing at Roche between 2008 and 2015, successfully leading the launch and development of a global marketing strategy for the blockbuster treatment for rheumatoid arthritis, RoACTEMRA (tocilizumab).

Dr Juho Jalkanen was appointed as Vice President of Business Development in April 2017 and stepped down from the Board in May 2017, of which he had been a member since 2013. Dr Jalkanen has a Master's degree in Economics and Business Administration from the Turku School of Economics, a Medical Doctor's degree from the University of Turku and was a fully licensed General Practitioner and specialist in Vascular Surgery with expertise in organ protection during major cardiovascular surgery. I extend my gratitude to Juho for his contribution to the Board over the past four years and am pleased he will continue his input to the Company as a management team member.

#### Financial

The Company has adopted new and amended accounting standards and corrected certain prior period errors in accounting. The 2016 financial statements, as initially reported, have therefore been amended and restated.

# **Strengthened Board**

Dr. Gregory B. Brown and Mr John Poulos were appointed as Non-Executive Directors to the Board in May 2017. Both bring a wealth of global experience in the life sciences and investment community to strengthen our Board, particularly from a US and commercial angle.

Dr. Gregory B. Brown has more than 35 years of experience in healthcare and investment. Most recently, Greg founded HealthCare Royalty Partners, a healthcare-focused private asset management firm investing in biopharmaceutical and medical products, where he currently serves as Vice Chairman. In addition, Greg is currently a director of Caladrius Biosciences Inc (NASDAQ) and Nuron Biotech Inc and previously acted as a director of Invuity Inc (NASDAQ) between October 2014 and December 2015. Prior to this, he was a General Partner at Paul Capital Partners in New York, Co-Head of Investment Banking at Adams, Harkness & Hill, and VP of Corporate Finance at Vector Securities International.

Mr John Poulos has a wealth of expertise in global corporate life sciences, having spent 38 years working for AbbVie and Abbott. Most recently, John served as Vice President, Head of Licensing and Acquisitions for AbbVie, and Group Vice President, Head of Pharmaceutical Licensing and Acquisitions for Abbott Pharmaceuticals. During his career, John was instrumental in the negotiation of numerous acquisitions, including Knoll/BASF Pharma in 2001 for \$6.9 billion and Solvay in 2010 for \$6.2 billion.

# Outlook

Our immediate focus in 2018 will be on determining the next steps for Traumakine in ARDS once we have completed a comprehensive review of the INTEREST Phase III data to understand why Traumakine did not have any effect over placebo in the trial. We also plan to continue to progress our immuno-oncology candidate, Clevegen, into the clinic in H2 2018.

## The Board anticipates the following pipeline progress and catalysts during 2018:

Traumakine:

- Full data analysis from the Phase III INTEREST trial
- Determine next steps for Traumakine in ARDS
- The Company currently expects to announce top-line data from the Japanese Phase III pivotal study for the treatment of ARDS with Traumakine, run by its Japanese licensing partner Maruishi Pharmaceutical Co., in 2018.

## Clevegen:

- Faron expects preclinical toxicological studies for Clevegen to be completed in Q2 2018
  - The Company expects to file the first CTA with the UK regulatory authorities (MHRA) in H2 2018 based on the preclinical safety data. The first, and primarily safety focused clinical trial is expected to be conducted with liver cancer patients at the Birmingham University Liver Cancer Centre and is expected to continue into a Phase II study via an adapted trial design for HCC patients to recognise early efficacy signals.
- The second set of clinical cancer trials will be conducted in parallel with the HCC trial in Scandinavia with melanoma, pancreas and ovarian cancer patients.
- Faron intends to expedite the expansion of its planned Clevegen clinical development program, the MATINS trial, in several solid tumours (liver, pancreas, ovarian and melanoma) in order to obtain accelerated safety and clinical data readouts.

# Dr Markku Jalkanen - Chief Executive Officer May 5, 2018

# **Financial Review**

Restatement of previously issued financial statements

Subsequent to the original issuance of the Company's financial statements for the year ended 31 December 2016, the Company has adopted new and amended accounting standards and corrected certain prior period errors in its accounting. The 2016 financial

statements, as initially reported, have therefore been amended and restated. The total impact of the restatements on the pre-tax income for periods prior to 31 December 2016 was negative EUR 2.5 million. In total the restatements reduced the 31 December 2016 equity with negative EUR 2.5 million.

Further details of the restatement are set out in Note 1 to the accounts.

## **Key Performance Indicator**

As a clinical stage drug development company, Faron's primary interconnected KPI's are cash burn and cash position. During 2017, the Company's net cash flow decreased by only €1.7 million despite a significant increase in R&D spending. This was mainly due to two successful fundraisings during the year. The Board will consider the appropriateness of monitoring additional KPIs as the Company's operations advance.

## **Revenue and Other Operating Income**

The Company's revenue was €0.0 million for the year ended 31 December 2017 (2016: €1.0 million). The revenue in 2016 included the €0.7 million licence agreement cash signing fee from Korean license partner PharmBio. The Company also recorded €1.5 million (2016: €1.0 million) of other operational income. This comprised of income recognised from the European Commission FP7 grant in support of the Traumakine programme as well as a grant component from public loans.

## **Research and development costs**

The R&D costs more than doubled by €9.9 million (107%) from €9.2 million to €19.1 million. This was a result of very strong investment in the finalisation of INTEREST trial. The trial completed recruitment in early December 2017 with results reported today. The increased activity of Clevegen development also contributed to the increase in R&D investment. In September 2017, the Company received a positive recommendation from the FDA regarding the possibility to proceed directly to BLA filing in the US upon successful completion of the European and Japanese Phase III trials without the need to conduct clinical trials for Traumakine in the US. In view of this recommendation and in anticipation of a positive INTEREST trial the Company, the Company accelerated the preparatory work for eventual Traumakine launch, including increasing production of active pharmaceutical ingredient (API), with the majority of this work to be completed 2018.

## **Share-based Compensation**

During the year, options over 500,000 ordinary shares (2016: 400,000) were awarded to Directors and key personnel. This had no cash impact on the results for the year, however, accounting standards require this share based compensation to be recognised in the Consolidated Statement of Comprehensive Income, resulting in a charge of €1.2 million (2016: €0.9 million).

#### Taxation

The Company's tax credit for the fiscal year 2017 can be recorded only after the Finnish tax authorities have approved the tax report and confirmed the amount of tax-deductible losses for 2017. The total amount of cumulative tax losses carried forward approved by tax authorities on 31 December 2017 was €23.5 million (2016: €14.2 million). The Company estimates that it can utilise €23.3 million of these during the years 2019 to 2026 by offsetting them against future profits. In addition, Faron has €2.8 million of research and development costs incurred in the financial years 2010 and 2011 that have not yet been deducted in its

taxation. This amount can be deducted over an indefinite period at the Company's discretion.

#### Losses

Loss before income tax was €21.1 million (2016: €10.1 million). Net loss for the year was €21.1 million (2016: €10.1 million), representing a loss of €0.76 per share (2016: €0.42 per share) (adjusted for the changes in number of issued shares).

## **Cash Flows**

Despite doubling its R&D expenses net cash outflow was only  $\notin 2.2$  million negative for the year ended 31 December 2017, compared to a positive net cash inflow of  $\notin 0.4$  million for the previous year. Cash used for operating activities increased by  $\notin 9.0$  million to  $\notin 18.4$  million for the year, compared to  $\notin 9.4$  million for the year ended 31 December 2016. This increase was mostly driven by a  $\notin 9.9$  million (107%) increase in R&D investment together with a  $\notin 0.6$  million (24%) increase in administrative costs.

Net cash inflow from financing activities was €16.6 million (2016: €9.3 million) due to the two successful equity placings completed during the year.

## Fundraising

Faron raised £5million (net €5.4 million) via an oversubscribed financing round in February/March 2017 by issuing 1,422,340 new ordinary shares at a price of 350 pence per share. The proceeds are being used to fund preclinical and early clinical development of Clevegen. The Company also raised £10 million (net €10.4 million) via an oversubscribed financing round in October 2017 by issuing 1,250,000 new ordinary shares at a price of 800 pence per share. The proceeds are being used to support the pre-launch activities for Traumakine and to expedite Clevegen clinical program. Post the period end, Faron also raised £15.0 million (net €15.9 million) in February 2018 via an oversubscribed financing round by issuing 1,863,350 new ordinary shares at a price of 805 pence per share to support preparations for the commercialisation of Traumakine and to advance the clinical development of Clevegen in several indications. After this round, at the end of February 2018, the total number of outstanding shares was 31,027,894.

## **Financial Position**

As at 31 December 2017, total cash and cash equivalents held were €9.3 million (2016: €11.5 million). This excludes the funds raised in the financing round announced on 21 February 2018. The cash at end of March 2018 was €18.7 million. The board will be focussing on reducing cash burn and preservation of existing resources until the full data analysis is complete and it is agreed how best to deliver value to shareholders.

## Headcount

Average headcount of the Company for the year was 17 (2016: 10). The increase in headcount is attributable to the expansion of the Traumakine and Clevegen programs, in addition to preparation for the commercialisation of Traumakine.

#### **Shares and Share Capital**

Using the share authorities granted at the Annual General Meetings held on 26 May 2016 and on 16 May 2017, in February 2017 the Company issued 1,422,340 new ordinary shares at a subscription price of £3.50 pursuant to a fundraising and in October 2017 issued 1,250,000 new ordinary shares at a price of £8.00 per share pursuant to a further fundraise. The subscription price was credited in full to the Company's reserve for invested unrestricted equity, and the share capital of the Company was not increased. Additionally during 2017, warrants over 109,800 ordinary shares in the Company were exercised at a price of  $\pounds$ 1.55 per share and further warrants over 41,600 ordinary shares in the Company were exercised at a price of  $\pounds$ 2.01 per share.

In May 2017 options over 15,000 ordinary shares in the Company were exercised at a price of  $\notin$ 3.71 per share and options over a further 14,100 ordinary shares in the Company were exercised at a price of  $\notin$ 2.90 per share.

The Company has no shares in treasury; therefore at the end of 2017 the total number of voting rights was 29,164,544.

# Money Raised to Date

To date, the Company has been funded with a total of approximately €61 million, made up of a combination of equity, debt and grant funding, which has been used to develop the Company's products and intellectual property. The Company has also generated cash revenues of €4.5 million to date through the receipt of milestone payments pursuant to certain of its licensing arrangements and the sale of surplus raw materials.

## Yrjö E K Wichmann - Chief Financial Officer

May 5, 2017

# Statement of comprehensive income

2017 2016 €'000 (Restated) Revenue 952 Other operating income 1,495 1,025 **Research and development expenses** (19, 100)(9,223) General and administrative expenses (3,054)(2, 457)**Operating loss** (20,659) (9,703)**Financial expense** (408)(360)**Financial income** 7 Loss before tax (21,060) (10,063)Tax expense (75) (1) (21,061)(10, 138)Loss for the period Comprehensive loss for the period attributable to the equity holders of the Company (21,061) (10, 138)Loss per ordinary share Basic and diluted loss per share, EUR (0.76) (0.42)**Balance sheet** As at 31 December As at 1 January 2017 2016 2016 €'000 (Restated) (Restated) Assets

For the year ended 31 December

Non-current assets

Machinery and equipment	22	21	28
Intangible assets	325	304	283
Prepayments and other receivables	1,310	1,475	1,885
Total non-current assets	1,657	1,800	2,196
Current assets			
Prepayments and other receivables	3,920	2,469	489
Cash and cash equivalents	9,310	11,478	11,068
Total current assets	13,230	13,947	11,557
Total assets	14,887	15,747	13,753
Equity and liabilities			
Capital and reserves attributable to the equity holders			
of the Company			
Share capital	2,691	2,691	2,691
Reserve for invested unrestricted equity	48,576	32,362	23,843
Accumulated deficit	(46,524)	(26,652)	(17,450)
Total equity	4,743	8,401	9,084
Non-current liabilities			
Borrowings	2,088	2,083	1,446
Other liabilities		614	241
Total non-current liabilities	2,088	2,697	1,687
Current liabilities			
Borrowings	338	93	245
Trade payables	3,196	2,021	620
Other current liabilities	4,522	2,535	2,117
Total current liabilities	8,056	4,649	2,982
Total liabilities	10,144	7,346	4,669
Total equity and liabilities	14,887	15,747	13,753

Statement of changes in equity		Reserve for invested		
2/2.2.2			Accumulated	Total
€'000	capital	equity	deficit	equity
Balance as at 1 January				
2016	2,691	24,533	(16,046)	11,178
Impact of restatements				
(net of tax)1.1. 2016		(690)	(1,404)	(2,094)
Balance as at 1 January				
2016, restated	2,691	23,843	(17,450)	9,084
Comprehensive loss for the				
period			(10,138)	(10,138)
Transactions with				
equity holders of the				
Company				
Issue of ordinary shares,	-	8,519	-	8,519
net of transaction cost FUR		0,010		0,010

811 thousand				
Share-based compensation	-	-	936	936
	_	8,519	936	9,455
Balance as at 31				
December 2016	2,691	32,362	(26,652)	8,401
Comprehensive loss for the				
period	-	-	(21,061)	(21,061)
Transactions with				
equity holders of the				
Company				
Issue of ordinary shares,				
net of transaction costs				
EUR 1,149 thousand	-	15,863	-	15,863
Share options exercised	-	97	-	97
Warrants exercised	-	254	-	254
Share-based compensation	-	-	1,189	1,189
	•	16,214	1,189	17,403
Balance as at 31				
December 2017	2,691	48,576	(46,524)	4,743

Statement of cash flows	For the year en December	ded 31
	2017	2016
€'000		(Restated)
Cash flow from operating activities		
Loss before tax	(21,060)	(10,063)
Adjustments for:		
Depreciation and amortisation	76	78
Interest expense	75	24
Unrealised foreign exchange loss (gain), net	290	(627)
Share-based compensation	1,189	936
Adjusted loss from operations before changes in		
working capital	(19,430)	(9,652)
Change in net working capital:		
Prepayments and other receivables	(1,286)	(1,570)
Trade payables	1,175	1,402
Other liabilities	1,189	480
Cash used in operations	(18,352)	(9,340)
Taxes paid	(1)	(75)
Interest paid	(10)	(4)
Net cash used in operating activities	(18,363)	(9,419)
Cash flow from investing activities		
Payments for intangible assets	(90)	(92)
Payments for equipment	(8)	-
Net cash used in investing activities	(98)	(92)
Cash flow from financing activities		
Proceeds from issue of shares	17,362	9,330
Share issue transaction cost	(1,148)	(811)
Proceeds from borrowings	453	775
Repayment of borrowings	(84)	_

Net cash from financing activities	16,583	9,294
Net increase (+) / decrease (-) in cash and		
cash equivalents	(1,878)	(217)
Effect of exchange rate changes on cash and cash		
equivalents	(290)	627
Cash and cash equivalents at 1 January	11,478	11,068
Cash and cash equivalents at 31 December	9,310	11,478

# Note 1 Basis of preparation

The financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS) of the International Accounting Standards Board (IASB) and the interpretations of the International Financial Reporting Standards Interpretations Committee (IFRS IC). The financial statements have been prepared on a historical cost basis, unless otherwise stated.

The financial statements have been prepared on the basis of a full retrospective application of IFRS 15, Revenue from Contracts with Customers, with the adoption date as of 1 January 2017.

The principal accounting policies applied in the preparation of these financial statements are set out below. The Company has consistently applied these policies to all the periods presented, unless otherwise stated.

All amounts are presented in thousands of euros, unless otherwise indicated, rounded to the nearest euro thousand.

## Restatements of previously issued financial statements

Subsequent to the original issuance of the Company's financial statements for the year ended 31 December 2016, the Company has adopted new and amended accounting standards and corrected certain prior period errors in its accounting. The 2016 financial statements, as initially reported, have therefore been amended and restated as follows:

- 1) In the process of adopting IFRS 15 *Revenue from contracts with customers* the Company identified errors in the application of IAS 18, which resulted in corrections to the previously issued 2016 financial statements.
- 2) The Company has corrected amounts in its previous years' accounting for government grants received in the form of direct funding from the European Commission and in the form of indirect government assistance through the below-market rate government loans.
- 3) The Company has incorrectly capitalised in-process research and development expenditures which had not met the capitalisation criteria in IAS 38.
- 4) In the balance sheet, prepayments to a third party Contract Research Organisations and rental deposits have been reclassified from current prepayments and other receivables to non-current prepayments and receivables as at 1 January 2016 due to the long-term nature of the items.
- 5) The Company has revised its previous balance sheet classification of inventories and reclassified the balances previously presented as inventory prepayments and finished goods to prepayments and other receivables as such goods are not held for sale in the Company's ordinary course of business, but will be used in the Company's research and development activities.
- 6) The Company has corrected the effects of certain prior period cut-off errors related to charges by vendors and their sub-contractors in its restated financial statements.
- 7) The Company's expense for the effects of the Option Plan 2015, accounted for as an equity-settled plan, has been misstated. The misstatements relate to the valuation to the Option Plan and to errors in accruing for the share-based compensation expense and determination of the grant and service inception date.
- 8) The Company has corrected the proceeds from borrowings in the statement of cash flow for the financial year ended 31 December 2016 to reflect gross proceeds received. The cash flows for the withdrawal of the borrowings in the form of R&D loans were previously presented net of grant benefit. In addition, the Company has revised the presentation of

the statement of cash flows for the financial year ended 31 December 2016 relating to unrealised foreign exchange gains, interest expense and the interest paid, previously presented on a combined basis as financial items.

The total impact of the restatements on the pre-tax income for periods prior to 31 December 2016 was negative EUR 2.5 million. In total the restatements reduced the 31 December 2016 equity with negative EUR 2.5 million.

Accordingly, these restated financial statements as of 31 December 2017 and for the year ended 31 December 2016 have been approved and authorized for issue by the Company's Board of Directors on [5] May, 2018. The Company's previously issued financial statements were approved and authorized for issue by the Board of Directors on 28 March 2017.

## Going concern

The Company has incurred net losses since its inception and for the years ended 31 December 2017 and 2016, the Company reported losses of EUR 21,061 thousand and EUR 10,138 thousand, respectively.

The Company has primarily relied upon financing its development operations with funds that the Company has raised from share issues. In September 2016, the Company raised a total of EUR 8,519 thousand and during 2017, the Company had two separate issues raising a total of EUR 16,214 thousand. In addition to equity financing, the Company has obtained funding from license agreements and public R&D loans and grants.

The financial information in these financial statements has been prepared on a going concern basis, which assumes that the Company will continue in operational existence for the foreseeable future. After review of the future operating costs of the Company in conjunction with the cash held at 31 December 2017 and the net proceeds of approximately EUR 15,863 thousand received following the completion of a fundraising in February 2018, management believes the Company has sufficient funds to continue as a going concern for the foreseeable future.

# Critical accounting estimates and significant management judgements in applying accounting policies

#### Revenue recognition

The Company early adopted IFRS 15 on 1 January 2017 with full retrospective application. In determining the amounts to be recognised as revenue, the Company uses its judgement in the following main issues:

- Identifying the performance obligations in the license agreements and determining whether the license provided is distinct - based on the Company's analysis, the license is distinct as the licensee is able to benefit from the license on its own at its current stage and the licensee has the responsibility for the development in that territory. The management has determined that the provision of data and information generated by the Company in connection with its own development activities to facilitate the licensees' territory-specific development efforts is immaterial (perfunctory) to the grant of the license to the IP and does not constitute a separate performance obligation.
- Management has concluded that the license meets the criteria to be classified as a right to use, as the license granted provides at the outset of the contract all necessary documents and knowhow to utilize the license. The contract does not define activities that would significantly affect the intellectual property to which the licensee has rights after the date of granting.

## Share-based compensation

The Company recognises expenses for share-based compensation. For share options and warrants management estimates certain factors used in the option pricing model, including volatility, vesting date of options and number of options and warrants likely to vest. If these estimates vary from actual occurrence, this will impact the value of the share-based compensation.

## Clinical trial accruals

Quantification of the accruals related the clinical trials require significant management judgement. The services invoiced by Contract Research Organisations consist of contributions of various independent subcontractors and the actual tasks completed may be reported with significant delays. Also the clinical study sites, which are mainly public sector hospitals, may invoice their costs with long delays. These factors combined result in a complicated task of defining on which period the cost belongs to and requires management to make assumptions when defining the right timing of the delivered services.

## Foreign currency transactions and balance

## Functional and presentation currency

The financial statements are presented in euro, which is the Company's functional and presentation currency.

## Transaction currency

Transactions in foreign currencies are translated at the exchange rates ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are translated at the exchange rates ruling at the reporting date. Foreign exchange differences arising on translation are recognised in the statement of comprehensive income, within financial income and expenses. Non-monetary assets and liabilities denominated in foreign currencies are translated at the foreign exchange rate ruling at the date of the transaction.

## Revenue recognition

The Company's revenue for the periods presented in these financial statements consists mainly of upfront payments from a license agreement with Pharmbio. The Company adopted IFRS 15 Revenue from Contracts with Customers effective 1 January 2017 and has applied the single, principles based five-step model to all contracts with customers provided by IFRS 15 as follows:

- 1. Identify the contract with a customer
- 2. Identify the performance obligations in the contract
- 3. Determine the transaction price
- 4. Allocate the transaction price to the performance obligations in the contract
- 5. Recognise revenue when (or as) the entity satisfies a performance obligation (over time or at a point in time).

### Revenue from licensing agreements

According to IFRS 15, performance obligation is a promise to provide a distinct good or service or a series of distinct goods or services. Goods and services that are not distinct are bundled with other goods or services in the contract until a bundle of goods or services that is distinct is created. A good or service promised to a customer is distinct if the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract.

The Company's existing license agreements with Maruishi in Japan, with A&B in Greater China and with Pharmbio in Republic of Korea each include only one performance obligation, which is the grant of the license to use of its intellectual property ("IP"). After the Company has granted the license, it does not have an obligation to participate or provide additional services to its customers. The transaction price for the grant of the license to use the Company's IP comprises of fixed and variable payment streams and the grant of the license is considered to be a right to use IP. Upfront fees earned, are recognised as revenue at a point in time, upon transfer of control over the license to the licensee. Revenue from variable consideration, which are contingent on achievements of future milestones or future sales of the products by the licensees, are recognised as revenue when it is highly probable the revenue will not reverse, that is when the underlying contingencies have been resolved. For future royalty payments, the Company applies exception for sales-based royalties and recognises the revenue only when the subsequent sale occurs.

In addition, there is a potential performance obligation regarding future manufacturing. The Company has tentatively agreed on supply and manufacture of the drug product to its licensees. The terms including quantities and commercial terms for the future supply will be subject to separate negotiations.

## **Recognition of government grants**

The direct government grants are recognised as other operating income at the same time as the underlying expenditure is incurred, provided that there is reasonable assurance that the Company will receive the grant and complies with the conditions of such grant. Direct grant payments received in advance of the incurrence of the expenditure that the grant is intended to compensate are deferred at the reporting date and presented under advances received on the balance sheet.

The indirect government assistance in the form of below-market interest government loans is recognised as grant income and recorded as other operating income in the same period in which the company recognises the expenses for which the benefit is intended to compensate. Grant income is measured as the difference between the initial carrying value of the loan and the proceeds received.

€'000	2017	2016 (Restated)
Grants from the European Union	1,063	873
Grant component of government loans	432	148
Other income	-	4
Total operating income	1,495	1,025

Grants from the European Union comprise of direct funding from the European Commission under the Seventh Framework Programme for Research and Technological Development to support the Traumakine clinical program. The grant component of government loans comprises of indirect financial benefit from the below-market interest of a loan from the Finnish Funding Agency for Technology and Innovation ("Tekes", currently "Business Finland"), which has been granted to finance the Clevegen clinical development program.

# Note 3 Research and development expenses

Research and development costs are expensed as incurred and presented under research and development expenses in the statement of comprehensive income. Research and development expenses include costs for outsourced clinical trial services, materials and services, employee benefits and other expenditure directly attributable to the Company's research and development activities. The Company's research and development expenses are directly related to the Company's development projects and may therefore fluctuate strongly from year to year.

Capitalization of expenditure on the development of the Company's products commences from the point at which technical and commercial feasibility of the product can be demonstrated and it is probable that future economic benefits will result from the product once completed. As at 31 December 2017, considering the development stage of the Company's drug candidates, no internally developed assets related to Company's development activities had met these criteria and had therefore not been recognised.

	Year ended 3	1 December
€'000	2017	2016
		(Restated)
Outsourced clinical trials services	(9,392)	(5,218)
Materials and services	(4,727)	(1,594)
Employee benefits	(2,704)	(1,475)
Other R&D costs	(1,315)	(865)
Inventory write-down	(893)	-
Depreciation and amortization	(69)	(71)
Total research and development expenses	(19,100)	(9,223)

# Note 4 Share-based compensation

The options and warrants granted under share-based incentive programs are measured at fair value at earlier of the grant date or the service commencement date, using the Black-Scholes valuation model. The options, for which the option exercise price is determined later, right before the vesting, an estimate is used to determine the fair value at service commencement date and the estimate is subsequently revised until the options become granted.

The share-based compensation expense is recognised on a straight-line basis over the vesting period together with a corresponding increase in equity, based on the Company's estimate of equity instruments that will eventually vest. At each reporting date, the Company revises its estimate of the number of equity instruments that are expected to vest and its estimate of the grant date fair value for the options with earlier service commencement date. The exercise price paid by the option or warrant holder to subscribe the Company's shares is recognised in the reserve for invested unrestricted equity.

## Option Plan 2015

The Option Plan 2015 was approved at the Company's extraordinary shareholders' meeting on 15 September 2015 as part of the Company's incentive scheme determined by the Board of Directors. The share options are granted to the members of the Board of Directors and the management team and other management and employees for no consideration. The annual general meeting on 10 May 2017 resolved to amend, due to the increase in the number of employees in the Company and the increase in the number of members of the Board of Directors, the Option Plan so that a maximum total of 500,000 C options and a maximum total of 500,000 D options may be offered under initial Option Plan terms and conditions. The share options have a service condition and are forfeited in case the employee leaves the Company before the share options vest, unless the Board of Directors approves otherwise. After the beginning of the share subscription period, the vested options may be freely transferred or exercised. The fair value of the options was determined at the grant date or estimated at earlier service commencement date by using the Black & Scholes option valuation model and expensed over the vesting period. Grant dates for the share options may vary depending on the date when the Company and the employees agree to the key terms and conditions of the Option Plan. The maximum number of share options that can be awarded under the Option Plan is 1.800.000 in four different tranches designated as A options, B options, C options and D options. Each share option entitles the holder of the option to subscribe for one ordinary share in the Company.

The exercise price for ordinary shares based on A options is euro equivalent of the Company's share subscription price in the Company's initial public offering on the AIM market place of the London Stock Exchange on 17 November 2015. The exercise price for ordinary shares based on B options, C options and D options is euro equivalent of the exercise price determined based on the Company's average share price on the AIM market place during 1 July - 30 September 2016, 2017 and 2018, respectively.

Key characteristics and terms of the option plan are listed in the table below.

2015 Option Plan	A options	B options	C options	D options	
Maximum number of					
share options	400,000	400,000	500,000	500,000	
Exercise price, EUR	3.71	2.90	8.39	(*)	
Dividend adjustment	No	No	No	No	
Beginning of subscription	2 November				
period	2015	8 October 2016	8 October 2017	8 October 2018	
End of subscription	20 September	20 September	20 September	20 September	
period	2021	2021	2021	2021	
Vesting conditions	Service until the beginning of the subscription period				

(\*) Exercise price will be determined based on euro equivalent of the Company's average share price on the AIM market place during 1 July - 30 September 2018. For the year ended 31 December For the year ended 31 December

	2017		i or the	20	16			
		2015 Op	tion Plan			2015 Opt	tion Plan	
Number of share								
options	Α	В	С	D	Α	В	С	D
Outstanding at 1								
January	400,000	400,000	250,000	250,000	250,000	250,000	250,000	250,000
Granted			250,000	20,000	150,000	150,000	-	-
Forfeited	-	-	-	-	-	-	-	-
Exercised	(15,000)	(14,100)	-	-	-	-	-	-
Outstanding at 31								
December	385,000	385,900	500,000	270,000	400,000	400,000	250,000	250,000
Exercisable at 31								
December	385,000	385,900	500,000	-	400,000	400,000	-	-
The weighted average								
fair value of the share								
options granted, EUR	-	-	3.23	0.53	1.27	1.43	-	-
The weighted average								
share price at the date	0.00	0.00						
of exercise, EUR	8.83	8.83	-	-	-	-	-	-

С

Share price at grant date, EUR	4.51-9.39	9.21	2.69-3.38	2.96-4.10
Subscription price, EUR	4.51-8.39	9.21	3.71	2.90-4.10
Volatility, % (*)	42.59-52.57	42.59	50.03-52.57	50.03-52.57
Interest free rate, %	0.01	0.01	0.01	0.01
Expected dividends yield, %	0	0	0	0
Option fair value, EUR	1.42-4.01	2.87	1.00-1.54	1.32-1.57
Effect on earnings 2016, EUR thousand (*	*) 43	-	191	188
Effect on earnings 2017, EUR thousand (*	*) 758	25	-	-

(\*) Expected volatility was determined as the average volatility of a peer group consisting of ten comparable

biotechnology companies listed on London Stock Exchange AIM list.

(\*\*) Effect of share options granted on earnings is calculated based on earlier of the grant date or the service commencement date.

The share-based compensation expense for the Option Plan 2015, was EUR 1,189 thousand in 2017 (EUR 936 thousand in 2016).

## Warrants

Based on authorization given by the Company's extraordinary shareholders' meeting on September 15, 2015, the Board of Directors approved on 16 September 2015, the issuance of 151,400 warrants that entitled the holder to subscribe for a maximum number of 151,400 ordinary shares in the Company. The warrants were issued in exchange for services received from a Company's external advisor. The warrants were granted in two tranches designated as Warrants A and Warrants B and each warrant entitles the holder of the warrant to subscribe for one ordinary share in the Company. After the beginning of the share subscription period, the vested warrants may be freely transferred or exercised. The fair value of the warrants was determined at the grant date or by using the Black & Scholes valuation model and expensed over the vesting period during 2015.

Tranche	Number of warrants	Share subscription period	Exercise price, EUR
Warrants A	109,800	2 November 2015 - 7 May 2018	1.55
Warrants B	41,600	2 November 2015 - 28 February 2018	2.01

	2017		2016	
Number of warrants	Warrants A	Warrants B	Warrants A	Warrants B
Outstanding at 1 January	109,800	41,600	109,800	41,600
Granted	0	0	0	0
Forfeited	0	0	0	0
Exercised	(109,800)	(41,600)	0	0
Outstanding at 31 December	0	0	109,800	41,600
Exercisable at 31 December	0	0	109,800	41,600
The weighted average share price at the date of exercise, EUR	8.72	8.72	-	

All of the warrants the Company had issued in 2015, were exercised during 2017.

Note 5	Financial income and expenses
--------	-------------------------------

	Year ended 31 December	
€'000	2017	2016
Financial income		
Interest income	-	0
Gains from foreign exchange	7	0
Total financial income	7	0
Financial expenses		
Interest expenses	(75)	(24)
Losses from foreign exchange	(332)	(333)
Other financial expenses	(1)	(3)
Total financial expenses	(408)	(360)
Total financial income and expenses, net	(401)	(360)

Interest expenses consist of paid and accrued interest expenses. The accrued interest expense relates mainly to the government loans.

The foreign exchange losses relate to euro value changes of cash balances nominated in Pound Sterling.

Unrealised foreign exchange loss is EUR 290 thousand and gain is EUR 627 thousand for the years ended 31 December 2017 and 2016, respectively.

## Note 6 Tax expense

Income tax expense for the period consists of current and deferred taxes. Tax is recognised in the statement of comprehensive income, except for the income tax effects of items recognised in other comprehensive income or directly in equity, which is similarly recognised in other comprehensive income or equity.

Deferred taxes are recognised using the liability method on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the financial statements. Deferred taxes are determined using tax rates enacted or substantively enacted by the balance sheet date in the respective countries and are expected to apply when the related deferred tax asset is realised or the deferred tax liability is settled.

Deferred income tax assets are recognised only to the extent that it is probable that future taxable income will be available against which the temporary differences can be utilized.

	Year ended 31	December
€'000	2017	2016
Tax expense	(1)	(75)
Total tax expense	(1)	(75)
During the financial year ended 31 December 2016, income tax	x consists of forei	gn

withholding tax on upfront fee received.

The difference between income taxes at the statutory tax rate in Finland (20%) and income taxes recognised in the statement of comprehensive income is reconciled as follows:

	Year ended 31 December	
	2017	2016
€'000		(Restated)
Loss before tax	(21,060)	(10,063)
Income tax calculated at Finnish tax rate 20%	4,212	2,013
Tax losses and temporary differences for which no deferred tax asset is recognised	(3,974)	(1,937)
Non-deductible expenses and tax exempt income	(238)	(1)
Non-credited foreign withholding taxes	(1)	(75)
Taxes in the statement of comprehensive income	(1)	(75)

Tax losses and deductible temporary differences for which no deferred assets have been recognised, are as follows:

	Year ended 31 December	
	2017	2016
€'000		(Restated)
R&D expenses not yet deducted in taxation <sup>(1)</sup>	16,893	47
Tax losses carried forward <sup>(2)</sup>	25,862	23,527
Deferred tax depreciation on fixed assets	1,628	1,012
Total	44,383	24,586

1) The Company has incurred research and development costs, mostly during the year ended 31 December 2017, that have not yet been deducted in its taxation. The amount deferred for tax purposes can be deducted over an indefinite period.

2) Tax losses carried forward expire over the period of 10 years. The tax losses will expire as follows:

€'000	2017	2016
Expiry within five years	3,164	1,565
Expiry within 6-10 years	22,698	21,962
Total	25,862	23,527

The related deferred tax assets have not been recognised in the balance sheet due to the uncertainty as to whether they can be utilized. The Company has a loss history, which is considered a significant factor in the consideration of not recognising deferred tax assets. The total tax value of unrecognised deferred tax assets is EUR 8,877 thousand (2016: EUR 4,917 thousand).

The Company does not have any other deductible or taxable temporary differences. Therefore, no deferred tax assets or liabilities have been recognised in the balance sheet

and thus the itemisation of deferred taxes is not provided.

# Note 7 Loss per share

Basic loss per share is calculated by dividing the loss for the period with the weighted average number of ordinary shares during the year.

	Year ended 31 December	
	2017	2016
Loss for the period	(21,061)	(10,138)
Weighted average number of ordinary shares in issue	27,887,901	23,979,650
Basic and dilutive loss per share (in €)	(0.76)	(0.42)

As of 31 December 2016, the Company had two potentially dilutive instruments comprising of share options and warrants.

As of 31 December 2017, the Company had only share options outstanding as the warrants were exercised during the period. Number of potentially dilutive instruments currently outstanding totalled 1,540,900 as of 31 December 2017 (31 December 2016: 1,451,500). Since the Company has reported a net loss, the share options and warrants would have an anti-dilutive effect and are therefore not taken into account in diluted loss per share - calculation. As such, there is no difference between basic and diluted loss per share.

# Note 8 Intangible assets and machinery and equipment

The Company's intangible assets comprise of capitalized patent costs arising in connection with the preparation, filing and obtaining of patents. Patent cost are amortised on a straight-line basis over the useful lives of the patents of ten years.

The Company's machinery and equipment comprise of office furniture and equipment, which is stated at historical cost less depreciation and any impairment losses. The historical cost includes expenditure that is directly attributable to the acquisition of the machinery and equipment.

Depreciation is calculated using the straight-line method over the asset's estimated useful life of four years. Depreciation is recorded to the costs of the asset function

€'000	Intangible assets	Machinery and equipment
Book value 1 January 2016 (restated)		
Acquisition cost (restated)	348	32
Accumulated depreciation/amortisation	(65)	(4)
Book value 1 January 2016 (restated)	283	28
Additions	92	0
Depreciation/amortisation (restated)	(71)	(7)
Book value 31 December 2016 (restated)	304	21
As at 31 December 2016 (restated)		
Acquisition cost	440	28
Accumulated depreciation/amortisation	(136)	(7)
Book value 31 December 2016 (restated)	304	21
Book value on 1 January 2017	304	21
Additions	90	8
Depreciation/amortisation	(69)	(7)
Book value 31 December 2017	325	22
As at 31 December 2017		
Acquisition cost	530	36
Accumulated depreciation/amortisation	(205)	(14)
Book value 31 December 2017	325	22

Note 9	Non-current prepayments and other receivables
--------	---

	As at 31 December	
	2017	2016
€'000		(Restated)
Prepayments for API	1,192	1,451
Production supplies	86	-

Other receivables	32	24
Total non-current prepayments and other	1,310	1,475
receivables		

Prepayments for API consist of payments remitted to manufacturer for API to be consumed in the Company's development activities. Other receivables consist of restricted cash in the form of security deposits for rental agreements.

# Note 10 Inventories

Inventories are stated at the lower of cost and net realizable value. The cost includes all costs of direct materials and external services associated with the process of manufacturing of the goods sellable upon obtaining the regulatory marketing approval. The cost of inventories is fully written down, with a corresponding charge recognised in research and development expenses until such approval has been obtained. When marketing approval from the relevant regulatory authority is received, the write-down is reversed to net realisable value, which may not exceed the original cost.

	As at 31 December	
	2017	2016
€'000		(Restated)
Work in process	893	-
Write-down of inventory	(893)	-
Total inventories	-	-

. . . . .

Inventories purchased prior to regulatory marketing approval are recognised as inventory but are subject to full write-down. Write-downs of inventories to net realisable value amounted to EUR 893 thousand (2016 nil). These were recognised as research and development expenses. The Company has not reversed any previous inventory writedowns.

## Note 11 Current prepayments and other receivables

	As at 31 December	
	2017	2016
€'000		(Restated)
Prepayments	1,594	1,200
Grant receivable	1,063	160
Receivable for production defects	434	-
VAT receivable	404	342
Receivable for joint purchase agreement	-	474
Other receivables	425	293
Total current prepayments and other	3,920	2,469

# receivables

The majority of prepayments consist of the Clinical Service Agreements with Contract Research Organisations, which are or were current service providers in different clinical trials. Grant receivable consist of the grant income from the European Union for which the grant payment has not been received.

## Note 12 Shareholders' equity

Movements in number of shares, share capital and reserve for invested unrestricted equity were as follows.

€'000	Total registered shares (pcs)	Share capital	Reserve for unrestricted equity
1 January 2016	23,111,704	2,691	23,843
Issue of new shares, net of transaction			
costs	3,200,000	-	8,519
31 December 2016	26,311,704	2,691	32,362
1 January 2017	26,311,704	2,691	32,362
Issue of new shares, net of transaction			
costs	2,672,340	-	15,863
Exercise of warrants	151,400	-	254
Exercise of options	29,100	-	97
31 December 2017	29,164,544	2,691	48,576

On 23 September 2016, the number of shares was increased to 26,311,704 following the issue of 3,200,000 new shares. On 1 March 2017, the number of shares was increased to 27,734,044 following the issue of 1,422,340 new shares. On 27 April 2017, the number of shares was increased to 27,787,034 following the issue of 52,990 new shares due to exercise of warrants. On 31 May 2017, the number of shares was increased to 27,914,544 following the issue of 127,510 new shares due to exercise of warrants and options and on 11 October 2017, the number of shares was increased to 29,164,544 following the issue of 1,250,000 new shares.

The Company has one class of ordinary shares. The shares have no par value. Each share entitles the holder to one vote at the Annual General Meeting and equal dividend. All shares are fully paid.

The subscription price for the shares is recorded to the share capital, unless the Board has made a resolution to record the subscription price in the reserve for invested unrestricted equity. Reserve of invested unrestricted equity includes, under the Finnish Limited Liability Companies Act, the exercise value of shareholders' investment comprising share subscription prices and exercise prices of share options and warrants.

## Note 13 Financial assets and liabilities

The Company's financial assets comprise of other receivables and cash and cash equivalents, which are all classified to the category "loans and receivables". Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are included in current assets, except for maturities greater than 12 months after the reporting date, which are classified as non-current assets.

Other receivables consist mainly of the deferred grant income from the European Union for which the grant payment has not been received, carried at the amount expected to be received according to the terms and conditions of the grant.

Cash and cash equivalents comprise cash on hand and at banks.

The Company's financial liabilities comprise of interest bearing borrowings, trade payables, other non-current and current liabilities.

Borrowings are initially recognised at fair value, less any directly attributable transaction costs. Subsequently borrowings are carried at amortised cost using the effective interest method. Borrowings are presented as current liabilities unless the Company has an unconditional right to defer settlement of the liability for at least 12 months after the end of the reporting period. Borrowings are not derecognised until the liability has ceased to exist, that is, when the obligation identified in a contract has been fulfilled or cancelled or is no longer effective.

Borrowings comprise of three government loans with a below-market rate of interest from The Finnish Funding Agency for Technology and Innovation ("Tekes", currently "Business Finland"), of which two have been fully drawn down before the Company's date to transition to IFRS. Accordingly, the Company has utilized the IFRS 1 exemption and not accounted for the below-market grant separately for these two loans, which are carried at amortised cost.

The government loan originated after the date of transition to IFRS was initially recognised and measured at fair value and subsequently at amortised cost over the loan period by using the effective interest method. The grant component of the loan, which is the benefit of the below-market interest rate, is measured as the difference between the initial fair value of the loan and the proceeds received.

Trade payables and other liabilities are classified as current liabilities, unless the Company has an unconditional right to defer settlement of the liability for at least 12 months after the end of the reporting period, in which case they are classified as non-current liabilities. The carrying amount of trade payables and other current liabilities are considered to be the same as their fair values, due to their short-term nature. Non-current liabilities are initially measured at fair value and subsequently at amortised cost.

	As at 31 December	
€'000	2017	2016 (Restated)
Loans and receivables		
Other receivables (*)	1,497	634
Cash and cash equivalents	9,310	11,478

Total loans and receivables	10,807	12,112
<b>Financial liabilities measured at amortised cost</b> Trade payables Borrowings in form of Tekes R&D loans	3,196 2.426	2,021 2.176
Total financial liabilities measured at amortised cost	5,622	4,197

\*Prepayments are excluded as they are not considered to be financial instruments.

Due to the short-term nature of the other receivables, their carrying amount is considered to equal their fair values.

## Borrowings in the form of Tekes R&D loans

Fair value for the Tekes R&D loans is calculated by discounting estimated future cash flows for the loans using appropriate interest rates at the reporting date. The discount rate considers the risk-free interest rate and estimated margin for the Company's own credit risk. Discounted future cash flows are derived from the terms containing the repayment amounts and repayment dates for the principal and the cash payments for interest. Given that some of the inputs to the valuation technique rely on unobservable market data, loan fair values are classified in Level 3.

The fair value of all the Tekes loans was EUR 2,139 thousand (2016 EUR 2,035 thousand).

Tekes R&D loans are granted to a defined product development project and cover a contractually defined portion of the underlying development projects' R&D expenses. The below-market interest rate for these loans is the base rate set by the Ministry of Finance minus three (3) percentage points, subject to a minimum rate of 1%. Repayment of these loans shall be initiated after 5 years, thereafter loan principals shall be paid back in equal instalments over a 5-year period, unless otherwise agreed with Tekes. The accrued interest on Tekes R&D loans amounted to EUR 65 thousand (2016 EUR 20 thousand). Grant payments received in advance of the incurrence of the costs the grant is intended to compensate are deferred at the reporting date and presented under advances received on the balance sheet.

Analysis of net debt and the movements in net debt (calculated as cash and cash equivalents less borrowings) for each of the periods presented.

	As at 31 December		
	2017	2016	
€'000		(Restated)	
Net debt			
Cash and cash equivalents	9,310	11,478	
Tekes R&D loans- repayable within one			
year	(338)	(93)	
Tekes R&D loans- repayable after one			
year	(2,088)	(2,083)	
Net debt	6,884	9,302	

	Cash and cash		
€'000	equivalents	Borrowings	Total
Net debt as at 1 January 2016	11,068	(1,691)	9,377
Cash flows	(217)	(775)	(992)
Foreign exchange adjustments	627	-	627
Other non-cash movements		290	290
Net debt as at 31 December 2016	11,478	(2,176)	9,302
Cash flows	(1,878)	(369)	(2,247)
Foreign exchange adjustments	(290)	-	(290)
Other non-cash movements		119	119
Net debt as at 31 December 2017	9,310	(2,426)	6,884

	As at 31 December	
	2017	2016
€'000		(Restated)
Trade payables	3,196	2,021
Clinical trial hospital fees	1,241	245
Advances received	976	1,021
Accrued payroll	969	599
Accrued milestone payment	600	600
Accrued research costs	350	-
Other accruals	84	5
Other liabilities	301	65
Total	7,718	4,556

As at 21 December

Advances received comprise mainly received grant payments from European Union for which the related grant income has not yet been recognised or which have not been forwarded to the other participants of the grant consortium.

Accrued expenses comprise mainly accrued clinical trial fees EUR 1,241 thousand (31 December 2016: EUR 245 thousand), salary accruals EUR 969 thousand (31 December 2016: EUR 599 thousand) and milestone payment EUR 600 thousand (31 December 2016: EUR 600 thousand).

# Note 15 Contingencies and commitments

Operating lease - Faron as a lessee

The future aggregate minimum lease payments under non-cancellable operating leases are as follows

	Year ended 31 December	
€'000	2017	2016
No later than 1 year	172	144
Later than 1 year and no later than 5 years	231	261
Later than 5 years	-	-

The Company's operating lease commitments comprise of rent commitments for leasehold properties and lease commitments for cars, machines and equipment with leases of 3 to 4 years. The Company's operating leases are non-cancellable and they do not include redemption or extension options.

## Contractual contingencies

In addition to the accrued milestone payment to a subcontractor of Traumakine of EUR 600 thousand, the Company has contingent milestone payments of EUR 1,400 thousand to the same party that will become payable only upon the Company achieving certain milestones it its clinical development and obtaining the regulatory approval for Traumakine.

The Company has a contingent contractual liability to a development party for pre-clinical product candidate Clevegen to pay milestone payments. First milestone payment of EUR 427 thousand is contingent to production system reaching certain material yield threshold and the remaining ones upon the Company achieving subsequent regulatory filings and approvals for Clevegen. The milestone payments related to subsequent regulatory filings and approvals for Clevegen are considered to be remote. At the date of these financial statements there is no certainty that the yield threshold will be reached

# Note 16 Related party transactions

The Company identifies the following related parties:

- A&B (HK) Company Limited, an investment company existing under the laws of Hong Kong having significant influence in Faron Pharmaceuticals Oy, given its shareholding of 11.69% and membership on the Board of Directors.
- Members of the Board of Director, and their close family members; and
- Company's Key Management team and their close family members

Faron has not had interests in other entities as at and for the years ended December 31, 2016 and 2017.

# Key management personnel

The Company's key management personnel consist of the following:

- Members of the Board of Directors
- Management team, including CEO

€'000	2017	2016
Compensation of key management personnel*		
Salaries and other short-term employee benefits	1,668	832
Post-employment benefits	220	159
Share-based payments	883	785
Total	2,551	1,617

The Management team was awarded 249,850 share options during 2017 (2016: 303,600 share options). At the end of the 2017, the number of outstanding options and share granted to the Management team amounted to 663,450 share options (at the end of 2016: 413,600 share options).

Non-executive Directors were awarded 40,000 share options during 2017 (2016: 0 share options). At the end of 2017, the number of outstanding options and share options granted to the non-executive directors amounted to 600,000 share options (at the end of 2016: 560,000 share options).

Management and Board shareholding	
Management* shareholding, 31 December 2017	
Number of shares (pcs)	4,047,740
Shareholding, percentage	13.9 %
Board** shareholding, 31 December 2017	
(excluding the shareholding of CEO and CFO)	
Number of shares (pcs)	626,169
Shareholding, percentage	2.1 %
Total number of shares outstanding at 31 December 2017 (pcs)	29,164,544
*Presented information for the Management Includes the executive directors of the Board	
**Presented information for the Board includes only non-executive directors.	

# Transactions with related parties

There are no additional related party transactions during 2017 and 2016 than already disclosed.

This information is provided by RNS

The company news service from the London Stock Exchange

END

FR FDLLBVEFFBBZ