

FARON

ANNUAL  
REPORT  
2018

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Pushing boundaries to save Lives

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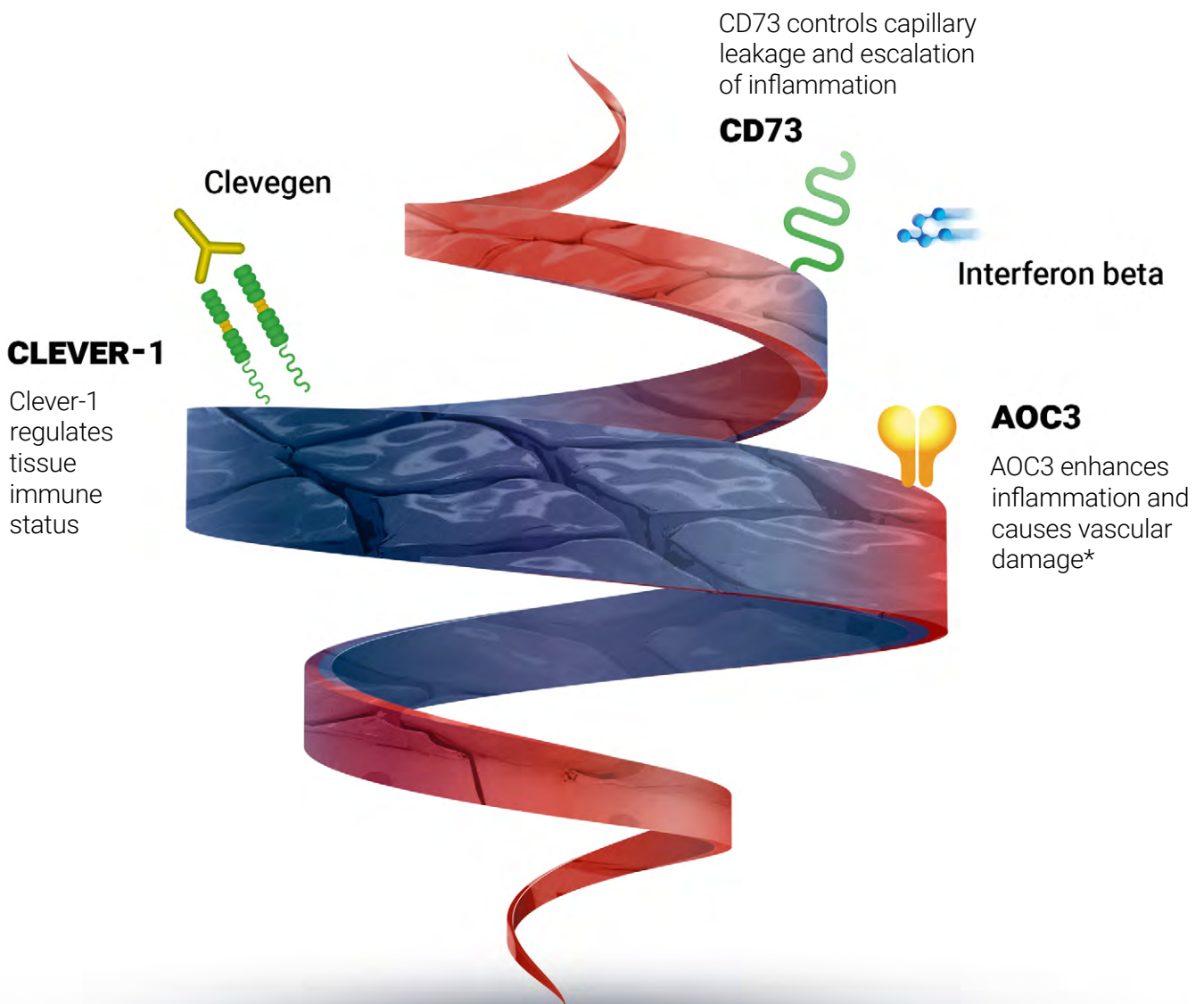
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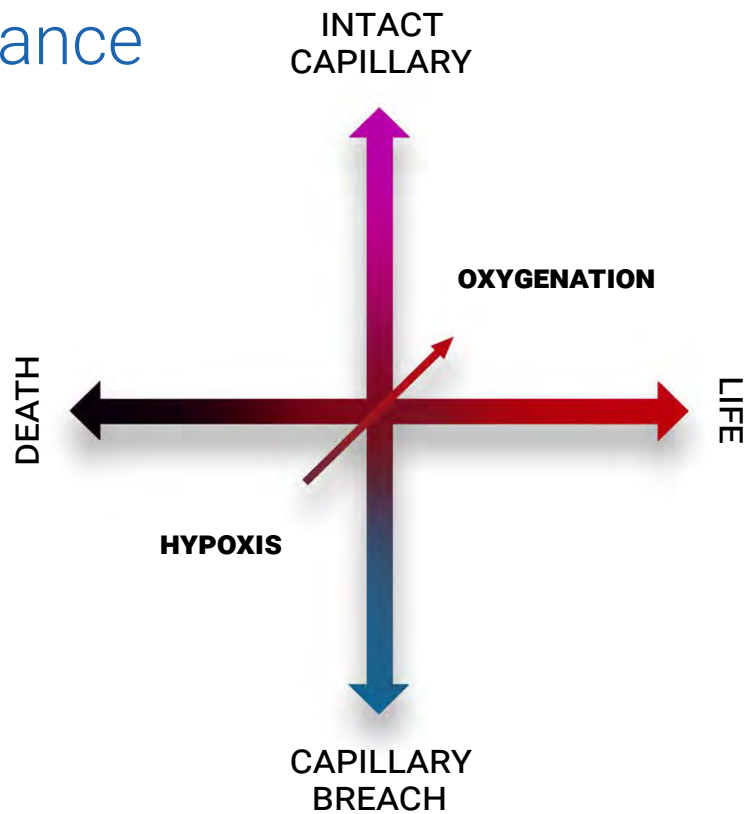
# Endothelial barrier controls fluid and cell balance between circulation and tissues

Faron’s pipeline is based on endothelial receptors involved in regulation of immune responses. Faron has mastered control of this response in both directions; slowing down immune escalation, and removal of immune suppression.



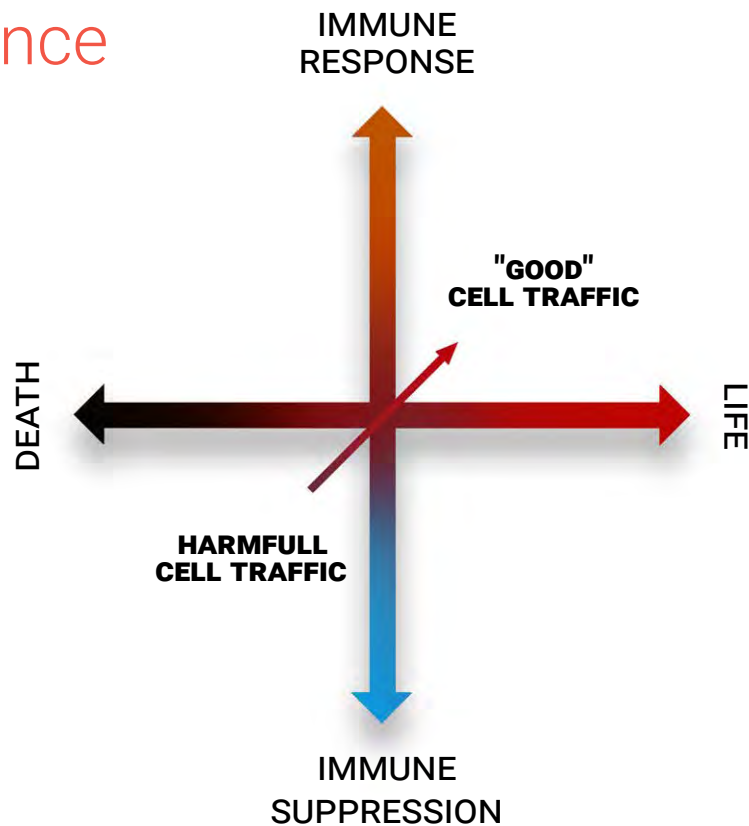
\* AOC3 inhibitor currently on hold

# Fluid Balance



Faron's two drug development programs, Traumakine and Clevegen, aim to tackle life-threatening medical conditions, such as organ damage and solid cancers. We are a group of highly committed people determined to make a difference in science, to people and ultimately to save lives.

# Cell Balance



# Drug development to save lives - We see barriers as opportunities

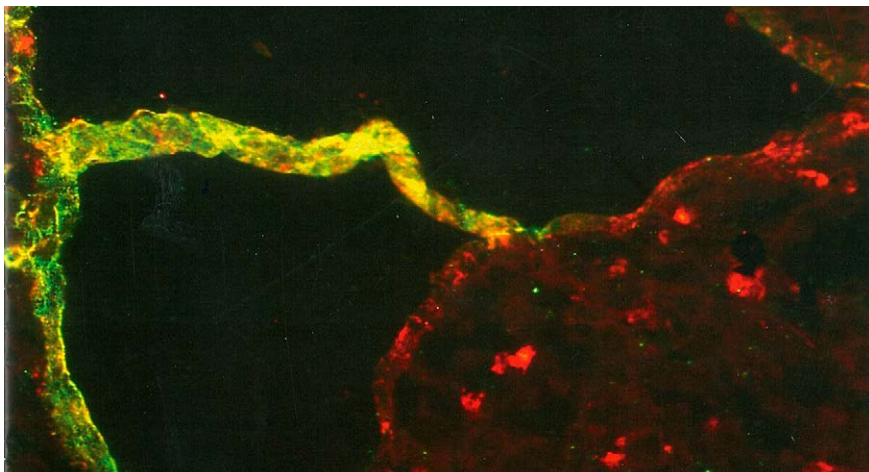


Faron (AIM:FARN) is a clinical stage biopharmaceutical company developing novel treatments for medical conditions with significant unmet needs. The Company currently has a pipeline focusing on acute organ traumas, vascular damage and cancer immunotherapy. The Company's first candidate Traumakine, to 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 early clinical 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 Turn-on-your-Immunity or Turn-It may be used alone or in combination with other immune checkpoint molecules for the treatment of cancer patients. Faron is based in Turku, Finland.

## FARON PHARMACEUTICALS

# Endothelial Barrier Is Everything



Imagine cars speeding in a dark tunnel, 100,000 kilometers long, without lights, at a speed of 700–800 km/h, navigating their way to their destinations. The situation described above applies to cells, which migrate in our vasculature system and need to move around.

This movement is part of the normal surveillance system to detect any harmful event that would put our existence at risk. This is our innate defence system, but it also provides the initial immunological reaction against any foreign material entering the body.

The “GPS” for these moving cells is a molecular recognition system consisting of special molecules on the surface of migrating cells and their counterparts on the surface of vascular endothelial cells. These “homing” molecules form an essential cellular trafficking guidance system, which we all need to

maintain our normal physiology. Unfortunately, many diseases utilise this system as well. This calls for ways to control the guidance system in order to prevent or heal diseases. Among these diseases the most harmful ones are extended inflammations and cancer spread.

Our vascular system also includes a drainage system called lymphatics. The same guidance system also operates there but the recognition molecules are unique. In both of these capillary networks the endothelial cells control the entry of migrating cells and maintain a barrier between circulation and tissues. Without this barrier, we encounter a catastrophic situation, which can lead to life-threatening conditions.

Faron is targeting several endothelial molecules involved in this guidance system and the maintenance of the endothelial barrier. We believe that the

control of these molecules provides a unique way of treating many life-threatening conditions with high unmet need. Our lead indications – acute respiratory distress syndrome (ARDS), multi-organ failure (MOF) and control of tumour immunity – are both based on the malfunction of the endothelial barrier, both of which we have learned to control (see page 3).

We hope that our 2018 Annual Report inspires you to explore our technologies, which have originated from world-class academic laboratories and developed by Faron as novel proprietary treatments for ARDS, MOF, and tumour immune suppression.

## FARON PHARMACEUTICALS

# Highlights

Operational (including post period-end)

## Traumakine®

- in development for the treatment of organ failures
- The Company continued to analyse INTEREST trial data following the finding that Traumakine treatment produced inconsistent interferon-beta (IFN-beta) bioactivity across the treatment group.
  - Data showing that concomitant use of corticosteroids and Traumakine appeared to affect both the mortality and biomarker appearance in the INTEREST study was presented at the ESICM (European Society for Intensive Care Medicine) conference.
  - Genetic testing identified a subgroup of ARDS patients for Traumakine treatment in the trial showing substantial reduction in mortality among INTEREST trial patients. Approximately 35% of Europeans carry this genetic polymorphism (C/T).
  - Interim results from the YODA study indicated that IFN-beta, regardless of the method of solubilisation, produced the expected level of bioactivity suggesting that drug formulation was not affecting the outcome of the INTEREST trial.
  - Further YODA results are expected in Q2 2019 to confirm, *in vivo*, the observed interference of corticosteroids on IFN-beta bioactivity in the INTEREST study and *ex vivo* in lung samples.
  - Top-line data from the Phase III ARDS trial with Japanese partner Maruishi Pharmaceutical Co., Ltd were, as expected, consistent with the INTEREST study results, showing that treatment with Traumakine, in a study group where there was high concomitant glucocorticoid use (77%), did not result in reduced mortality or increased number of ventilator-free survival days when compared to placebo.
- Plans announced in March 2019 for a new global phase III trial of Traumakine in the treatment of ARDS (CALIBER), subject to external funding. The Company is seeking feedback from both the FDA and EMA.
- EMA approved paediatric development plan for Traumakine in paediatric ARDS and updated orphan definition of orphan status in Europe, in which the patient population is now defined according to the Berlin classification of ARDS patients.
- Further recommendations were received from the Independent Data Monitoring Committee (IDMC) to continue the Phase II INFORAAA study for the prevention of Multi-Organ Failure (MOF) and associated mortality of surgically operated Ruptured Abdominal Aorta Aneurysm (RAAA). Advanced interim analysis is expected to take place in Q2 2019.
- Patents to use certain biomarkers to measure the severity and treatment efficacy of ARDS patients were granted in Europe, Japan and Canada. The intravenous (IV) formulation patent of IFN-beta were also approved in Europe and US, and could protect IV use of IFN-beta upto 2035-37 in various territories.



## Clevegen®

- wholly-owned novel cancer immunotherapy in development

- Completion of successful preclinical toxicity studies which showed good safety profile and potential of Clevegen to block Clever-1 on circulating monocytes.
- Following Clinical Trial Application (CTA) approval from the Finnish Medicines Agency (FIMEA), the first patient was successfully dosed in the phase I/II MATINS study in December 2018. A subsequent approval from the UK's MHRA saw the trial expand with two further sites opened in the UK.
- Encouraging early observations in the MATINS study on immunity and clinical response indicated potential early clinical benefits in dosed patients together with a switch in their immune profile towards more immune stimulatory function. No safety concerns were seen in the four subjects dosed at 0.3 and 1.0 mg/kg.
- A tumour imaging report from a patient with colorectal cancer indicated significant shrinkage of lung metastasis, classified as a partial response according to the RECIST classification. The same patient also showed a decrease in tumour load marker CEA (carcinoembryonic antigen) and an increase in circulating B-cells which could indicate an antibody-mediated response against the tumour. This patient had previously been treated with six different anti-cancer drugs, which all had failed.
- Colorectal cancer was selected as a first expansion
- *Bexmarilimab* confirmed by WHO as proposed International nonproprietary (INN) name
- New experimental data supporting the immunotherapeutic blockade of Clever-1 as an alternative to, or in combination with, PD-1 checkpoint inhibition to reactivate immunity against immunosuppressive tumours was published in *Clinical Cancer Research*, a journal of the American Association for Cancer Research.
- Patent granted by the European Patent Office for the use of Clever-1 antibodies, the mechanism behind Clevegen, for the treatment of cancer, extending the existing patent estate for Clevegen until 2030. Further protection for Clevegen epitope itself has been applied that would protect Clevegen use until 2039-40.
- Clever-1 control of B-cell mediated antibody formation *in vivo* was published by *Frontiers in Immunology*, re-enforcing the importance of the Company's program investigating the switching of immune suppression to immune activation in conditions beyond immuno-oncology.





## FINANCIAL

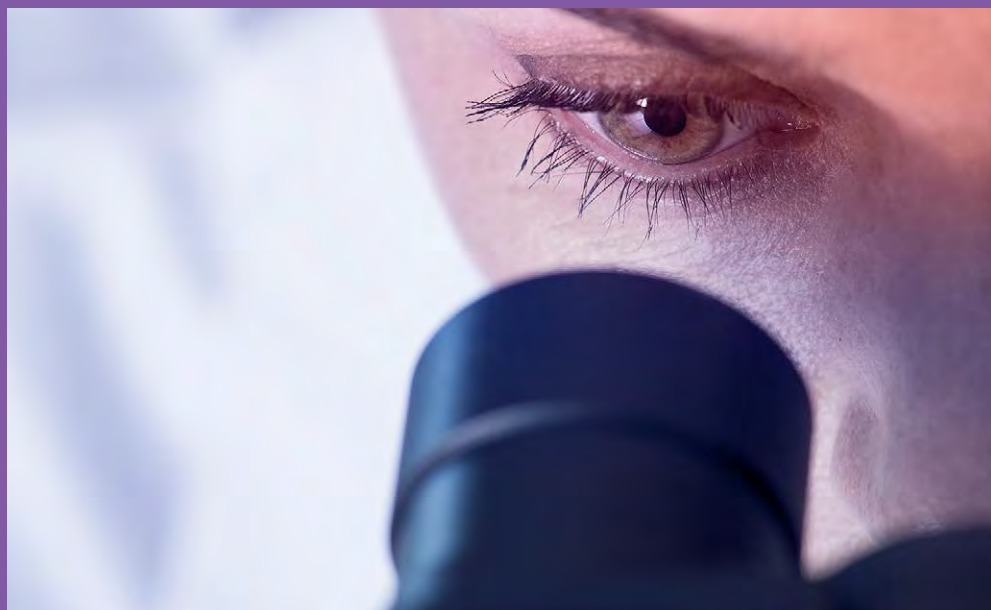
- On 31 December 2018, the Company held cash balances of €4.1 million (2017: €9.3 million).
- Loss for the period for the financial year ended 31 December 2018 was €20.1 million (2017: €21.1 million loss).
- Net assets on 31 December 2018 were €0.4 million (2017: €4.7 million). The net assets at end March 2019 were €0.7 million.
- Cash preservation program implemented to reduce cash burn and preserve existing resources in order to deliver value to shareholders.
- 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.
- Post accounting period raised net €2.9 million through placing and subscription in March 2019 by way of new shares at the issue price of 70.2 cents (60 pence) per share. The placing and subscription were supported by the participation of existing and new institutional shareholders. The proceeds will be used to further the clinical development of both Traumakine and Clevegen. The net proceeds of the fundraising are expected to provide the Company with working capital into Q3 2019. The cash position at the end of March 2019 was €4.9 million.

## CORPORATE

- Faron now has registered subsidiaries in the United States of America and in Switzerland.
- Dr Jonathan Knowles resigned from the Board to take up a position as Chair of the newly formed Clevegen Scientific Advisory Board and Dr Huaihzen Peng resigned from the Board but will continue as an invited Board Observer.

## STRATEGIC REPORT

# Addressing significant unmet medical needs



## Strategy

Faron's strategy is to maximise the potential of its pipeline of drug candidates and to progress the development of its two major programmes - Traumakine and Clevegen. Faron targets several endothelial molecules involved in the maintenance of the endothelial barrier which is a thin layer (membrane) of cells that lines blood and lymphatic vessels to separate blood content from tissue. The Company believes that the control of these molecules provides a unique way to treat many life-threatening conditions with no efficient treatment options.

Faron collaborates with its strategic partners in research, manufacturing and drug development to bring new pharmaceutical products to market in a timely and cost-effective manner and has formed a core team of leading scientists in capillary biology and diseases arising from vascular leakage. The Company has established links with leading laboratories and clinics based at University of Turku in Finland, University of Birmingham Medical School in the UK and other institutions.

To date, Faron has operated on a relatively low cost basis by employing only

key members of staff and outsourcing where possible. Typically, all development work up to the proof-of-concept stage of drug development is carried out in the innovators' laboratories. The Company outsources all of its manufacturing activities in relation to its products to third parties and collaborates with Contract Research Organisations (CROs) to carry out the clinical development programmes. Faron monitors and evaluates potential commercial opportunities for its established drug candidates, such as Traumakine and Clevegen and its technologies as and when they arise, and will consider how best to crystallise as much value as possible for shareholders, which may include holding rights in main territories for as long as it is feasible or, in certain circumstances, up to the marketing stage. The Company plan to discuss with the FDA and the EMA on the next steps for Traumakine, including feedback on design of a phase III trial, and is also advancing partnering discussions in respect of both Traumakine and Clevegen.

## STRATEGIC REPORT

## Chairman's statement

2018 was a year of challenge for Faron but also one of significant progress, as the Company executed its strategy to progress the delivery of its novel pipeline. The Company continued to make rapid progress on its Clevegen cancer immunotherapy programme and established a path forward for Traumakine in ARDS after better understanding the disappointing INTEREST trial results.

Faron's wholly-owned novel precision cancer immunotherapy candidate, Clevegen, successfully completed preclinical studies and, in agreement with regulatory authorities and according to an ambitious schedule, advanced into the clinic by year end. This was a significant milestone for the Company and I am delighted that we are making such rapid progress with the development programme.

Immuno-oncology therapies have transformed cancer treatment in recent years. Antibody-based immunotherapies are now well established as effective therapeutic options and Clevegen has a novel mechanism for removing immune suppression from the tumour environment by switching immune-suppressive (M2) macrophages to immune-active (M1) macrophages.

The MATINS clinical study of Clevegen is designed to determine the potential of this novel immunotherapy and we are encouraged by initial data from the

study, showing potential early clinical benefits in dosed patients. Clevegen, may ultimately be used as a standalone therapy or in combination with other immunotherapies like PD-1/PD-L1 inhibitors and offers a potential new treatment option for patients with cancer.

We were obviously very disappointed with the surprising results from the Traumakine INTEREST trial in 2018. Throughout the remainder of the year the Company worked hard, alongside the investigators, to undertake further analyses that would help us to better understand the results and determine a path forward.

As a consequence of the INTEREST results, management took swift action, executing a significant savings programme throughout the Company, including management and Board members. This is never easy, and we regret that a number of talented colleagues had to leave the Company. I am proud of how every member of the organisation responded with professionalism and continued commitment to the development of our products and future of our business.

Following a detailed interrogation of INTEREST we have now determined the factors which led to the study's mixed results, including a higher than anticipated placebo response due to high pneumonia cases, interference of corti-

costeroids on IFN-beta bioactivity and the impact of a subgroup of patients' single nucleotide polymorphism C/T mutation in their interferon alpha and beta receptor gene. Patients with this genetic profile showed the greatest reduction in mortality when treated with Traumakine.

The conclusions from the review of the INTEREST data have allowed us to plan a new phase III trial of Traumakine in ARDS patients – CALIBER – and we are seeking guidance from regulatory authorities in the EU and US in 2019 on its design and preparations for its start.

During the year we continued to benefit from our Board's wealth of experience. As part of the Company's re-focus following INTEREST, Dr Jonathan Knowles resigned from the Board to take up a position as Chair of the newly formed Clevegen Scientific Advisory Board and Dr Huaiheng Peng resigned from the Board but continues to support Faron as an invited Board Observer. Both Jonathan and Huaizheng have been invaluable to Faron and I would like to recognise them for their time and commitment to the Company. I am pleased that we continue to benefit

from their expertise in their current advisory roles.

The Company's key priority for 2019 is to advance, expand and accelerate the clinical development of Clevegen and Traumakine. The Board was pleased to receive the support from new and existing shareholders, employees and Company directors during the successful share placing and subscription in March 2019. This allows us to further the clinical programmes for these two medicines which offer significant potential.

The Company will continue to pursue financing, co-development and future commercialisation models to secure the long-term capabilities of the Company, to give the pipeline its greatest chances of success and to best deliver value to shareholders.

On behalf of the Board I would like to thank the management team and staff for their hard work and resilience in 2018; our partners and steering committee members who have provided support and expertise to our programmes; and the investigators and patients who are part of our clinical studies.



**Dr Frank Armstrong**  
Chairman  
May 3, 2019

## STRATEGIC REPORT

# 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. All our development work is based on scientific understanding of those life-threatening conditions at the molecular level, to most effectively influence their underlying causes.

Our focus for 2018 has been two-fold: further analysing and understanding data from the phase III INTEREST trial



**Dr Markku Jalkanen**  
**Chief Executive Officer**  
 May 3, 2019

with Traumakine in ARDS, and also progressing our wholly-owned novel precision cancer immunotherapy candidate, Clevegen, into first in-human trials.

## Traumakine Development

Following the announcement in May 2018 that the INTEREST trial did not meet the primary endpoint in ARDS we have been conducting investigations to further understand the outcome and determine a way forward for the treatment's continued development.

Soon after the initial announcement, the Company conducted analysis of certain biomarker indicators which showed that the treatment did not produce the expected interferon-beta (IFN-beta) bioactivity in Traumakine treated patients that was previously seen in Faron's Phase I/II trial. Further detailed analysis carried out by the trial investigators and presented at the ESICM (European Society for Intensive Care Medicine) conference in October 2018, determined that unexpectedly high corticosteroid use in the INTEREST trial may have masked the treatment benefit of Traumakine in ARDS patients, affecting both the mortality and biomarker appearance in the INTEREST study patients.

Results from the phase III Japanese Traumakine study undertaken by our partner Maruishi also supported

this finding, showing that in a study group where there was high concomitant glucocorticoid use (77%), treatment with Traumakine did not result in reduced mortality or increased number of ventilator-free survival days when compared to placebo.

The concomitant administration of corticosteroids to ARDS patients is a controversial topic and there is an ongoing debate as to whether corticosteroids have any beneficial role, early, late or for more severe un-resolving cases. These findings from the INTEREST study, in which some patients were also given corticosteroids as part of their treatment, suggest that we should consider controlling or excluding corticosteroids from future clinical research in ARDS patients. They also present wider implications for the medical community and how ARDS patients are currently treated. IFN-beta secretion by our own defence system is a key element to control viral infections such as lung pneumonia and so corticosteroid use could be detrimental in ARDS patients as physicians try to limit viral expansion and organ damage.

To understand still further the reduced biomarker response seen in the INTEREST study, we initiated a new pharmacokinetic/dynamic study, YODA, to examine various formulations of IFN-beta in around 50 healthy volunteers. We announced interim results from the first 30 subjects in December

2018, which indicated that IFN-beta, regardless of the method of solubilisation, produced the expected level of bioactivity, confirming that drug formulation was not a factor in the lowered bioactivity seen during the INTEREST trial. This study remains ongoing and is examining concomitant administration of prednisolone and Traumakine in order to confirm, *in vivo*, the observed interference of corticosteroids on IFN-beta bioactivity in the INTEREST study and *ex vivo* lung samples. These YODA results are expected during Q2 2019. However, we already know from *ex vivo* human lung studies that, in those settings, cortisone blocks completely INF-beta signalling pathways – an effect also seen in human primary lung endothelial cells.

Further interrogation of the INTEREST data continued through 2018 and in December we announced the results of genetic testing which had identified an optimal subgroup of ARDS patients for Traumakine treatment. The data indicated that patients carrying the single nucleotide polymorphism rs9984273 (C/T) in subunit 2 of the interferon alpha and beta receptor (INFAR2) showed a substantial reduction in mortality during the INTEREST trial, suggesting that this C/T mutation and Traumakine treatment is the most favourable combination for patient outcome and interferon treatment efficacy. Around one third of

the Caucasian population carries this single nucleotide polymorphism.

As a result of these analyses, we believe we can now confidently make a number of assumptions:

- The drug product used in the INTEREST study was safe, robust and effective
- Corticosteroids could interfere with IFN-beta action and mask the treatment benefit of Traumakine for ARDS patients
- There is an optimal subgroup of ARDS patients for Traumakine treatment

This increased understanding led us to announce plans for a new phase III trial of Traumakine in the treatment of ARDS. The CALIBER study will allow corticosteroid use within the standard of care (SOC) arm, but not if the ARDS patient is on Traumakine. This double dummy structure will allow physicians to choose their preference while creating a blinded readout between Traumakine and SOC patients. We are seeking guidance from both FDA and EMA on trial design and anticipate receiving feedback during Q3 2019. CALIBER will be a global trial, supported by one of the Company's partnering candidates currently engaged in negotiations.

## Phase II INFORAAA

Beyond ARDS, we continue to believe that Traumakine has the potential for application in additional disease areas and, as such, have been conducting the INFORAAA trial with Traumakine for the prevention of multi-organ failure (MOF) and death after the surgical repair of a ruptured abdominal aortic 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 MOF 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.

In July 2018, the Company received a second recommendation from the Independent Monitoring Committee (IDMC) to continue the INFORAAA trial and we are taking the study to the advanced interim analysis point expected to take place in Q2 2019.

## Clevegen Development

2018 was a year of significant progress for Faron's second product, Clevegen, as it advanced into the clinic. Clevegen is our wholly-owned novel precision cancer immunotherapy candidate, which 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. 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. We believe it has the potential to function as a novel macrophage checkpoint immunotherapy either as a monotherapy or in combination.

In June 2018 we announced successful preclinical toxicity studies which showed, not only a good safety profile, but also the potential of Clevegen to block Clever-1 on circulating monocytes. Based on these data, we filed a Clinical Trial Application (CTA) in September 2018 which was subsequently approved by the Finnish Medicines Agency (FIMEA) to initiate the MATINS (Macrophage Antibody To INhibit immune Suppression) trial, in December 2018.

## Progress into the clinic

The MATINS study is a first-in-human open label phase I/II clinical trial to investigate the safety and efficacy of Clevegen in selected metastatic or inoperable solid tumours. In December 2018, we announced that the first patient had been successfully dosed, on schedule with previous guidance, at Helsinki and Oulu University Hospitals in Finland. The trial quickly expanded with two further sites opening in the UK at the Royal Marsden Hospital in London and the Queen Elizabeth Hospital in Birmingham. We were very encouraged by early observations which showed substantial immune activation in patients post Clevegen administration and in February 2019 announced that dosing had moved to the second level with no signs of toxicity. Subsequent tumour imaging of a trial participant with colorectal cancer, indicating a partial response, reaffirmed our belief in the potential clinical benefit Clevegen may provide to late stage cancer patients. This patient had previously been treated with six different anti-cancer drugs, which had all failed.

Based on these early data, in April we announced that late-stage colorectal cancer has been chosen for the first expansion cohort for the second part of the trial, which is expected to begin as soon as the optimal dose has been determined.

We are also continuing to seek pre-IND advice from the FDA to open sites in the US prior to entering the cohort expansion part of the trial.

Due to high interest in the potential for new combination therapies in the immuno-oncology field, we are currently engaged in partnering discussions with several parties and hope for a positive outcome from these negotiations during 2019.

## Corporate

In February 2018 I was very proud to host the Company's R&D Day in London to discuss our strategy and pipeline developments, with a particular focus on the potential of Clevegen. Members of the Executive Leadership and senior management teams were joined by external experts including Professor Geoff Bellingan, Medical Director, University College London Hospital, Assistant Professor Maija-Leena Hollmén, Medicity Laboratory, University of Turku and Dr. Shishir Shetty, Honorary Consultant Hepatologist, University of Birmingham. This was an exciting opportunity to profile the company's future potential.

## Financial

In March 2019, we successfully raised €3.12 million from new and existing shareholders, employees and Company directors. The proceeds will be used to advance Clevegen through the MATINS trial, further Traumakine development through the design and preparation of the global Phase III CALIBER clinical trial and advance partnering discussions in respect of both Traumakine and Clevegen.

## Outlook

Our immediate focus in 2019 will be to submit the body of data for Traumakine to the FDA and EMA in order to gain feedback on the CALIBER trial design and to accelerate Clevegen's clinical development and to explore further funding opportunities to enable the Company to realise the value in its products. The management team and I are optimistic about the year ahead and, with a future development plan now determined for Traumakine and Clevegen studies progressing well, believe we have built a strong investment case for Faron with clear opportunities for success. We look forward to updating the market on our progress throughout the year.



### Board of Directors

Huai Zheng Peng and Jonathan Knowles resigned from Board on 12 Sep 2018



## The Board anticipates the following pipeline progress and catalysts during 2019:

### Traumakine:

- Approval from the FDA and EMA on CALIBER trial design during H2 2019
- Further results from the YODA study are expected during Q2 2019
- INFORAAA first interim analysis point expected in Q2 2019

### Clevegen:

- Further dose escalation data from the MATINS trial expected in Q2 2019
- Enrolment of patients into additional UK cohort sites in the MATINS trial
- File US IND for MATINS trial post pre-IND feedback
- Prepare and execute a plan to include US study sites to MATINS trial latest in part III (cohort escalation)
- Partnering update during 2019



Management team

## STRATEGIC REPORT

# Financial Review

## Key Performance Indicator

As a clinical stage drug development company, Faron's primary interconnected KPIs are cash burn and cash position. The Company conducted a successful fundraising in February 2018, nevertheless the Company's net cash flow showed €5.3 million negative due to an increase in R&D spending. 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 2018 (2017: €nil).

The Company recorded €0.2 million (2017: €1.5 million) of other operational income. This comprised income recognised from the European Commission FP7 grant in support of the Traumakine programme.

## Research and development costs

The R&D costs decreased by €2.6 million from €19.1 million in 2017 to €16.5 million in 2018. The costs of outsourced clinical trial services were reduced by €4.1 million from €9.4 to €5.3 million as a result of rapid cost reduction after the disappointing Traumakine trial results.

The Company continued Clevegen development which in turn increased costs of R&D materials and services with €2.6 million from €4.7 million to €7.3 million costs. The part-time lay-offs of the whole R&D personnel reduced the R&D employee costs by €0.9 million from €2.7 million to €1.8 million despite the increase in R&D personnel employed.

## General and administration costs

Administrative expenses increased by €0.7 million from €3.1 million in 2017 to €3.7 million in 2018. The increase was mainly due to the €1.2 million increase in external costs related to the development of internal financial and reporting processes during 1H2018. This was partly counterweighted by a €0.3 million decrease in G&A employee costs and €0.2 million reduction in communication costs.

## Taxation

The Company's tax credit for the fiscal year 2018 can be recorded only after the Finnish tax authorities have approved the tax report and confirmed the amount of tax-deductible losses for 2018. The total amount of cumulative tax losses carried forward approved by tax authorities on 31 December 2018 was €11.2 million (2017: €25.9 million). The Company estimates that it can utilise

most of these during the years 2020 to 2028 by offsetting them against future profits. In addition, Faron has €49.1 million of R&D costs incurred in the financial years 2010 to 2018 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 €20.1 million (2017: €21.1 million). Net loss for the year was €20.1 million (2017: €21.1 million), representing a loss of €0.65 per share (2017: €0.76 per share) (adjusted for the changes in number of issued shares).

## Cash Flows

Net cash outflow was €5.3 million negative for the year ended 31 December 2018 (2017: €1.9 million negative). Cash used for operating activities increased by €2.1 million to €20.5 million for the year, compared to €18.4 million for the year ended 31 December 2017. This increase was mostly driven by an increase in R&D investments.

Net cash inflow from financing activities was €15.5 million (2017: €16.6 million) due to the successful equity placing completed in February 2018.

## Fundraising

Faron raised £15million (net €15.9 million) via an oversubscribed financing round in February 2018 by issuing 1,863,350 new ordinary shares at a price of 805 pence per share. The proceeds are being used to support preparations for the commercialization 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. Post the period end, Faron also raised net €2.9 million in March 2019 via a financing round by issuing 864,164 new ordinary shares at a price of 60.0 pence per share and 3,584,461 shares at a price of €70.2 cents per share to support preparations to expedite Clevegen's clinical program. After this round, at the end of March 2019, the total number of outstanding shares was 35,476,519.

## Financial Position

As at 31 December 2018, total cash and cash equivalents held were €4.1 million (2017: €9.3 million). This excludes the funds raised in the financing round announced on 26 March 2019. The cash at end of March 2019 was €4.9 million. The Company continues tight cost control to keep the cash burn as low as possible for preservation of existing resources.

## Going Concern

As part of their going concern review the Directors have followed the Finnish Limited Liability Companies Act, the Finnish Accounting Act and the guidelines published by the Financial Reporting Council entitled "Guidance on the Going Concern Basis of Accounting and Reporting on Solvency Risks – Guidance for directors of companies that do not apply the UK Corporate Governance Code".

The Group and Parent Company are subject to a number of risks similar to those of other development stage pharmaceutical companies. These risks include, amongst others, generation of revenues in due course from the development portfolio and risks associated with research, development, testing and obtaining related regulatory approvals of its pipeline products. Ultimately, the attainment of profitable operations is dependent on future uncertain events which include obtaining adequate financing to fulfil the Group's commercial and development activities and generating a level of revenue adequate to support the Group's cost structure.

The Group made a net loss of EUR 20.1 million during the year ended 31 December 2018. It had total equity of EUR 0.4 million including an accumulated deficit of EUR 66.8 million. As at that date, the Group had cash and cash equivalents of EUR 4.1 million. In March

2019, the Company raised net proceeds of approximately EUR 2.9 million through a directed share issue and at 31 March 2019 it had EUR 4.9 million cash and an unaudited equity of EUR 0.7 million.

The Directors have prepared detailed financial forecasts and cash flows looking beyond 12 months from the date of the approval of these financial statements. In developing these forecasts, the Directors have made assumptions based upon their view of the current and future economic conditions that are expected to prevail over the forecast period. The Directors estimate that the cash held by the Group together with known receivables will be sufficient to support the current level of activities into the third quarter of 2019. The Directors are continuing to explore sources of finance available to the Group and based upon initial discussions with a number of existing and potential investors they have a reasonable expectation that they will be able to secure sufficient cash inflows for the Group to continue its activities for not less than 12 months from the date of approval of these financial statements; they have therefore prepared the financial statements on a going concern basis.

Because the additional finance is not committed at the date of approval of these financial statements, these circumstances represent an uncertainty as to the Group's ability to continue as

a going concern. Should the Group be unable to obtain further finance such that the going concern basis of preparation were no longer appropriate, adjustments would be required including to reduce balance sheet values of assets to their recoverable amounts, to provide for further liabilities that might arise.

## Headcount

Average headcount of the Company for the year was 25 (2017: 18). The increase in headcount is attributable to the expansion of the Traumakine and Clevegen programs.

## Shares and Share Capital

Using the share authorities granted at the Annual General Meetings held on 16 May 2017 and on 5 May 2018, 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. On February 2018 the Company issued 1,863,350 new ordinary shares

at a subscription price of £805 pence per piece. Post the period end, on February 2019 the Company issued 1,863,350 new ordinary shares of which 864,164 shares at a subscription price of £60.0 pence per piece and 3,584,461 shares at a subscription price of €70.2 cents per piece. 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.

The Company has no shares in treasury, therefore at the end of 2018 the total number of voting rights was 31,027,894

## Money Raised to Date

To date, the Company has been funded with a total of approximately €64 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 €3.8 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 3, 2019

## STRATEGIC REPORT

## Risks and Uncertainties

Faron is a late clinical stage biopharmaceutical company and, in common with other companies operating in this field, is subject to a number of risks and uncertainties. The principal risks and uncertainties identified by Faron for the year ended 31 December 2018 are below.

### Research and Development

Faron's main products are in clinical development; however, they may not be successful in the clinical trials and the Company may not be able to develop approved or marketable products. Technical risk is also present at each stage of the discovery and development process of other, earlier stage products with challenges in biology (including the ability to produce candidate drugs with appropriate safety, efficacy and usability characteristics). Conversion of cutting-edge scientific research into clinical development programs of novel compounds and drugs where there is limited amount of guidance and no previous examples involves a high degree of uncertainty. This uncertainty combined with Faron's lean organisation could result in situations, where the Company needs to make rapid alterations to its development projects without full visibility to all the downstream consequences of such decisions. Additionally, drug development is a highly regulated environment which itself presents technical risk through the need for study designs and data to be accepted by regulatory agen-

cies. As part of the development risk the manufacturing of the Company's intended products would become impossible or products would be supplied in lower quantities than needed.

### Commercial products and manufacturing

Faron's industry, being biotechnology and pharmaceutical industries, is very competitive. The Company's competitors include major multinational pharmaceutical companies, biotechnology companies and research institutions. Many of its competitors have substantially greater financial, technical and other resources, such as larger research and development resources and staff. The Company's competitors may succeed in developing, acquiring or licensing drug product candidates that are more effective or less costly than any of the product candidates which the Company is currently developing or which it may develop, which may have a material adverse impact on the Company. Furthermore, there can be no guarantee that the Company will be able to, or that it will be commercially advan-

tageous for the Company to, monetize the value of its intellectual property through entering into licensing or other co-operation deals with pharmaceutical companies.

### Dependence on key personnel and scientific and clinical collaborators

The Company's success is highly dependent on the expertise and experience of the Directors and the key management. Whilst the Company has entered into employment and other agreements with each of these key personnel, the retention of such personnel cannot be guaranteed. Should key personnel leave or no longer be party to agreements or collaborations with the Company, the Company's business prospects, financial conditions and/or results of operations may be materially adversely affected. To develop new products and commercialise its current pipeline of products, the Company relies, in part, on the recruitment of appropriately qualified personnel, including personnel with a high level of scientific and technical expertise. There is

currently a shortage of such personnel in the pharmaceutical industry, meaning that the Company is likely to face significant competition in recruitment. The Company may be unable to find a sufficient number of appropriately highly trained individuals to satisfy its growth rate, which could affect its ability to develop as planned.

Further, the Company's development and prospects depend to a significant degree on the experience, performance and continued service of its senior management team including the Directors. The Company has invested in its management team at all levels. The Directors also believe that the senior management team is appropriately structured for the Company's size and is not overly dependent upon any particular individual. The Company has entered into contractual arrangements with these individuals with the aim of securing the services of each of them. Retention of these services or the identification of suitable replacements, however, cannot be guaranteed. The loss of the services of any of the Directors or other members of the senior management team and the costs of recruiting replacements may have a material adverse effect on the Company and its commercial and financial performance and reduce the value of an investment in the shares of the Company.

## Regulatory environment

The Company operates in a highly regulated environment. Whilst the Company will take every effort to ensure that the Company and its partners comply with

all applicable regulations and reporting requirements, there can be no guarantee of this. Failure to comply with applicable regulations could result in the Company being unable to successfully commercialise its products and/or result in legal action being taken against the Company, which could have a material adverse effect on the Company.

The Company will need to obtain various regulatory approvals (including from the FDA and the EMA) and comply with extensive regulations regarding safety, quality and efficacy standards in order to market its products. While efforts have been and will be made to ensure compliance with governmental standards and regulations, there is no guarantee that any product will be able to achieve the necessary regulatory approvals to promote that product in any of the targeted markets and any such regulatory approval may include significant restrictions for which the Company's products can be used. In addition, the Company may be required to incur significant costs in obtaining or maintaining its regulatory approvals. Delays or failure in obtaining regulatory approval for products would likely have a serious adverse effect on the value of the Company and have a consequent impact on its financial performance.

## Intellectual property and proprietary technology

The Company relies and will rely on intellectual property laws and third party non-disclosure agreements to protect its patents and other proprietary rights. The IPR on which the Compa-

ny's business is based is a combination of patents, patent applications, confidential business know-how and trade secrets, and trademarks. No assurance can be given that any currently pending patent applications or any future patent applications will result in patents being granted. In addition, there can be no guarantee that the patents will be granted on a timely basis, that the scope of any patent protection will exclude competitors or provide competitive advantages to the Company, that any of the Company's patents will be held valid if challenged, or that third parties will not claim rights in, or ownership of, the patents and other proprietary rights held by the Company.

Despite precautions taken by the Company to protect its products, unauthorized third parties may attempt to copy, or obtain and use the Company's IPR and other technology that is incorporated into its pharmaceutical products. In addition, alternative technological solutions similar to the Company's products may become available to competitors or prospective competitors of the Company. It should be noted that once granted, a patent could be challenged both in the relevant patent office and in the courts by third parties. Third parties can bring material and arguments, which the patent office granting the patent may not have seen at the time of granting the patent. Therefore, whilst a patent may be granted to the Company it could in the future be found by a court of law or by the patent office to be invalid or unenforceable or in need of further restriction. Should the Company be required to assert its

IPR, including any patents, against third parties it is likely to use a significant amount of the Company's resources as patent litigation can be both costly and time consuming. No assurance can be given that the Company will be in a position to devote sufficient resources to pursue such litigation. Any unfavourable outcomes in respect of patent litigation could limit the Company's IPR and activities moving forward.

The Directors do not believe that its lead pharmaceutical drug candidates, future drug candidates in development, and proprietary processes for generating those candidate compounds infringe the IPR of any third parties. However, it is impossible to be aware of all third party intellectual property. The Company's research has included searching and reviewing certain publicly available resources, which are examined by senior levels of management in order to keep abreast of developments in the field.

## Financial

The Company has incurred significant losses since its inception and does not have any approved or revenue-generating products. The Company expects to incur losses for the foreseeable future, and there is no certainty that the business will generate a profit. The Company is highly dependent on equity and public grant financing. The Company may not be able to raise additional funds that will be needed to support its product development programs or commercialisation efforts, and any additional funds that are raised could cause dilution to existing investors. The Company operates internationally, and it thus exposed in various currencies and fluctuation in their relative values. Even though the Company seeks to hedge currency positions there is no guarantee that it will be successful.

## Other risks related to operations

While operating with multiple vendors and other external suppliers, the Company regularly delivers and receives information and data through multiple channels. Some of these are trade secrets or of confidential nature. Even though the Company uses all reasonably available means to secure the data and the channels used, there is no certainty that full data security can be obtained.

The Company is publicly listed and as such subject to various securities laws in multiple jurisdictions. The Company uses significant amount of both internal and external resources to secure that all its operations and external communication is conducted in accordance to these regulations. Whilst the Company will take every effort to ensure that the Company and its partners comply with all applicable securities laws and requirements, there can be no guarantee of this.

This report was approved by the Board on 3 May 2019 and signed on its behalf.

**PIPELINE**

# Revolutionising the treatment of ARDS and breaking tumor immunity

Faron has identified several molecular mechanisms involved in the control of endothelial functions as a source of innovation. The company currently has a pipeline focusing on acute organ traumas, cancer immunotherapy and vascular damage.

The fast evolving Faron pipeline consists of drug candidates (FP-1201-lyo and FP-1305) from two major Faron programmes – Traumakine® and Clevegen®, respectively. The lead indication of the Traumakine programme is Acute Respiratory Distress Syndrome (ARDS). This and the other indications (Rupture of Abdominal Aortic Aneurysm RAAA) are all based on the same Chemistry and Manufacturing Controls (CMC) dossier sections, allowing fast protocol adjusted filing for indication expansion. Similarly, Clevegen indications utilise one common dossier with a protocol adapted to each indication.

## Therapeutic areas

“Endothelial barrier is everything” - The endothelial surface of exhaustive capillary networks of central organs controls the fluid and cell balance between circulation and tissues. The endothelium is also a critical factor in many devastating diseases, such as organ failure and cancer metastasis. Faron’s pipeline is based on endothelial receptors involved in the regulation of immune responses and cell signalling.

Faron develops novel treatments for life-threatening medical conditions with significant unmet needs. Faron’s core therapeutic areas are Acute Respiratory Syndrome (ARDS), organ protection and modulation of the immune system.





**Clevegen®**

Switches immune suppressive M2 macrophages to immune stimulating M1 macrophages



Program	Program indication	Research	Preclinical development	Phase I/II	Phase III	MAA/BLA	LAUNCH	Partnered
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**Immuno-oncology**



FP-1305 Antibody	Clever-1 Hepatobiliary cancers	[Progress bar]						
FP-1305 Antibody	Clever-1 Pancreatic cancer	[Progress bar]						
FP-1305 Antibody	Clever-1 Ovarian cancer	[Progress bar]						
FP-1305 Antibody	Clever-1 Colorectal cancer	[Progress bar]						
FP-1305 Antibody	Clever-1 Metastatic melanoma	[Progress bar]						
FP-1305 Antibody	Clever-1 Glioblastoma	[Progress bar]						
FP-1305 Antibody	Clever-1 Anti-CD20 resistant lymphomas	[Progress bar]						
FP-1305 Antibody	Clever-1 TAM-positive Hodgkin's lymphomas	[Progress bar]						

**Chronic infections**

FP-1305 Antibody	Clever-1 Tuberculosis	[Progress bar]						
FP-1305 Antibody	Clever-1 Opportunistic infections	[Progress bar]						

**Vaccination**

FP-1305 Antibody	Clever-1 Tuberculosis	[Progress bar]						
FP-1305 Antibody	Clever-1 Pertussis	[Progress bar]						
FP-1305- Antibody	Clever-1 Other 'hard to vaccinate' diseases	[Progress bar]						

# Acute Respiratory Distress Syndrome (ARDS)

C/T

C/T

C/T

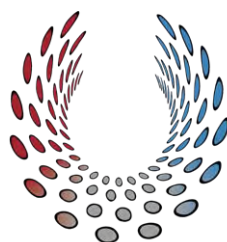
C/T

C/T

C/T

C/T

C/T



**TRAUMAKINE**

Approximately 35% of us carry a genetic polymorphism (C/T) that make us responsive to Traumakine treatment and, can resist the detrimental effect that steroids have on our interferon response

## PIPELINE: TRAUMAKINE®

Faron's first candidate, Traumakine, addresses the treatment of Acute Respiratory Distress Syndrome (ARDS), a severe, orphan lung disease. Currently there is no pharmaceutical treatment for this condition with a reported mortality rate of 30 to 45%. The scientific rationale for Traumakine treatment is based on the use of interferon-beta for the restoration of the endothelial barrier function in ARDS patients.

ARDS is a life-threatening medical condition characterised by widespread inflammation in the lungs and sudden failure of the respiratory system. ARDS causes inflammation of the alveoli in the lungs which become unable to perform the normal oxygenation of blood. It is characterized by rapid breathing, difficulty getting enough air into the lungs and low blood oxygen levels. Common causes of ARDS include sepsis, pneumonia, aspiration of fumes, food or stomach contents going into the lung or significant trauma. The condition was first described in 1967 and gained wide attention during the Vietnam War when it was nicknamed "white lung" as X-rays presented the lungs of the patients as white.

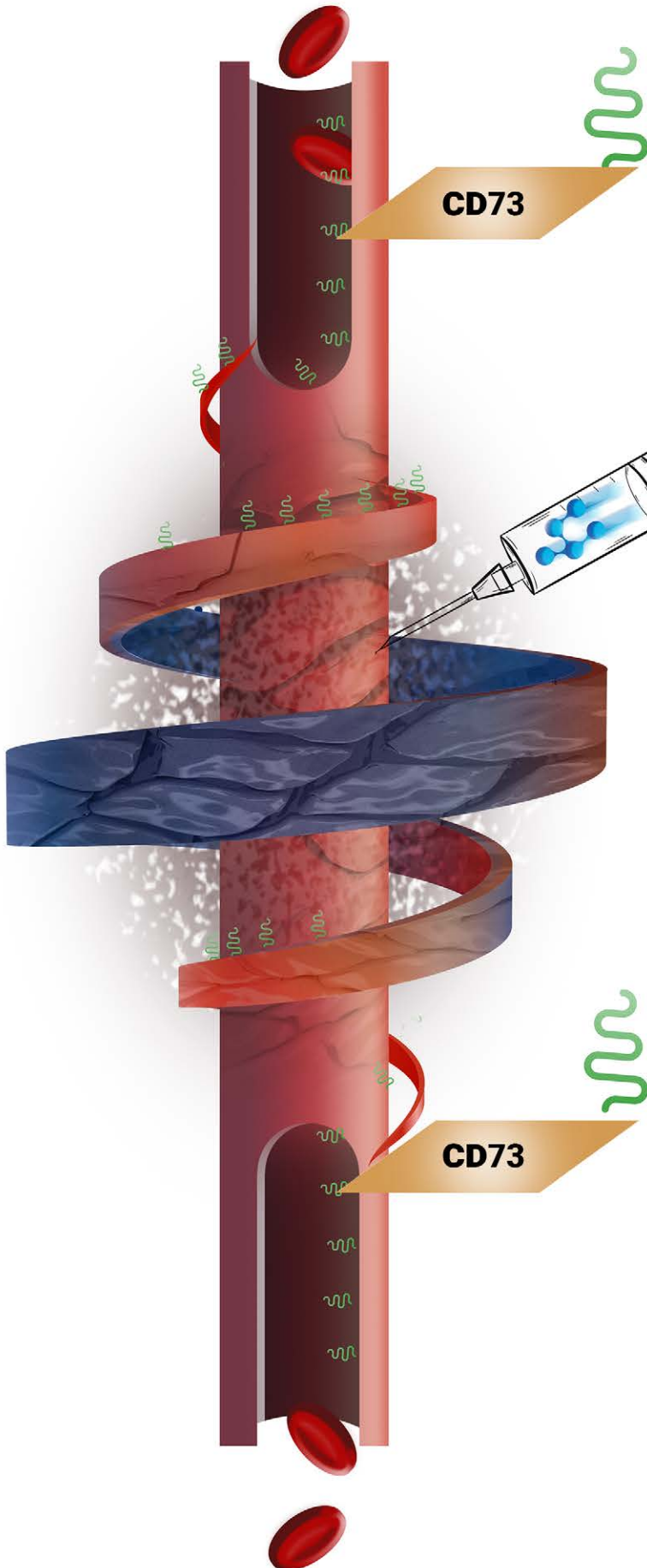
ARDS is the leading cause of respiratory failure in intensive care unit patients requiring mechanical ventilation. Despite progress in critical care medicine, ARDS is currently associated with a mortality rate of 30 to 45% depending on the severity of the condition. Although ARDS mortality has decreased in the

last decade due to improvements in supportive care and in the treatment of the underlying conditions, it still remains high. Currently, patients suffering from ARDS are generally treated with lung-protective mechanical ventilation. This treatment is accompanied by ancillary support such as positioning, fluid management and food restrictions. Extra corporeal support may also be provided depending on the severity of the condition. Complications which can also arise whilst a patient is being treated for ARDS include the development of infections, pneumothorax, lung scarring and blood clots which can develop into a pulmonary embolism. Patients who recover from ARDS often suffer other consequences of the condition after being discharged from the intensive care unit. A recovering patient's quality of life may be adversely affected by permanent damage to the lungs, respiratory problems, scar tissue, muscle weakness, depression and post-traumatic distress syndrome, all of which can have an adverse effect on the patient's quality of life.

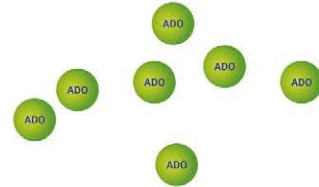
**"ARDS is the leading cause of respiratory failure in intensive care unit patients requiring mechanical ventilation."**

### ARDS

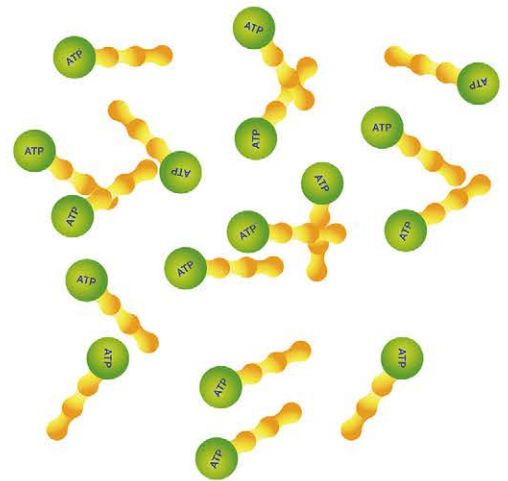
- A severe, life-threatening medical condition, most often as a result of sepsis, pneumonia or significant trauma
- Orphan lung disease with no available drug treatment
- The leading cause of respiratory failure in intensive care unit patients who require mechanical ventilation
- Annual ARDS incidence in Europe is c. 125,000 and in the US c. 200,000 patients
- High mortality rate of 30 to 45% and survivors suffer long-term mental and physical problems



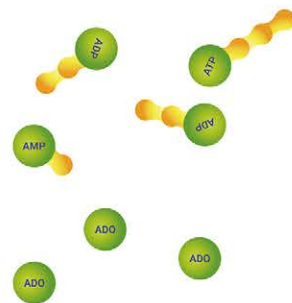
CD73 ectoenzyme produces local anti-inflammatory adenosine



Interferon-beta upregulates expression CD73

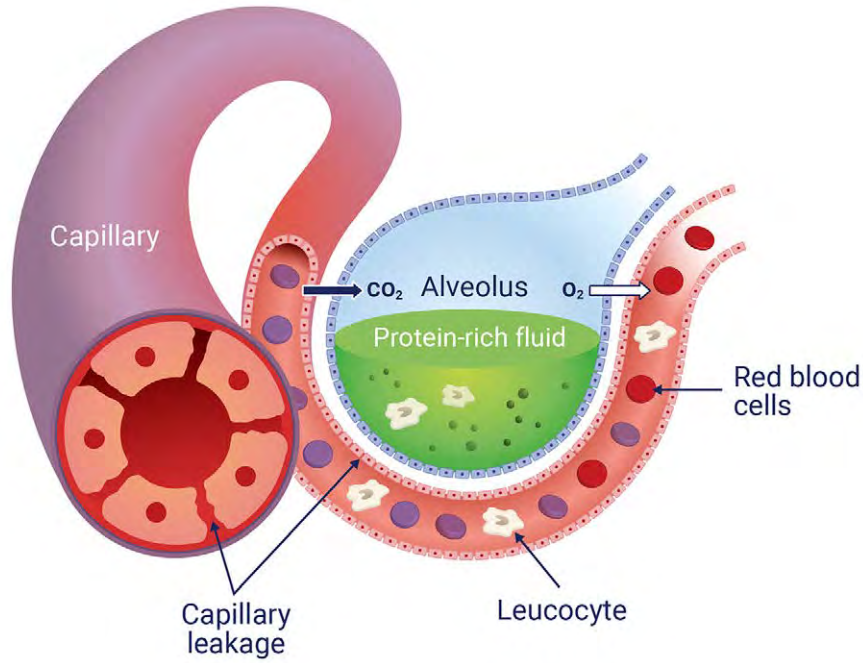


Loss of CD73 results in high amounts of proinflammatory ATP



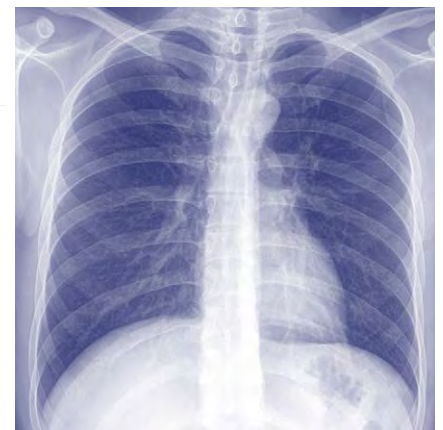
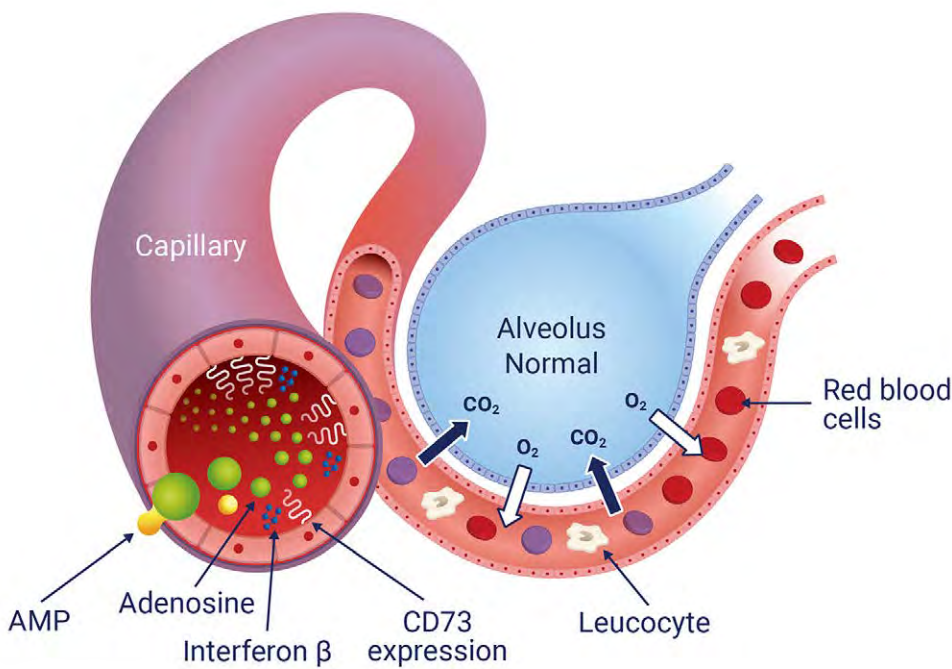
Inflammation reduces CD73 amounts and its adenosine production

ARDS lung



Widely used X-ray pictures can reveal lungs filled with blood material. This shows up as white dense material in lung air space and for this reason the lungs of these patients are often called "white lungs". Typically this picture confirms that the patient has a condition called Acute Respiratory Distress Syndrome (ARDS) and has a life-threatening disease.

Normal lung



Normally functioning lung X-ray shows no "white" material, indicating that lung air space is free of blood material, in contrast to the ARDS lungs above. Long term exposure to a respiratory syndrome like ARDS, can also cause permanent loss of lung capacity due to a fibrotic process that replaces lung alveoli with scar tissue. This serious side effect of ARDS results in permanently reduced respiratory capacity.

## Treating ARDS

Supply of oxygen and nutrients to individual cells of various organs are maintained by vasculature and especially by the long and thin blood vessels called capillaries. Their integrity is sustained by endothelial cells covering the inner surfaces of these vessels forming a barrier between circulation and tissues. The breakdown of this barrier results in leakage of blood content to tissues. If this happens in lungs, the lung air space is filled with protein rich fluid and blood cells preventing normal gas exchange.

The key molecule involved in maintaining endothelial barrier and lung function is CD73, an endothelial ectoenzyme, which can produce local adenosine. Traumakine's active pharmaceutical ingredient, interferon-beta, increases CD73 expression resulting in increased local adenosine. Subsequently, high local adenosine levels reduce capillary leakage and increase lung function by allowing normal gas exchange to return.

## Mechanism of Action

The scientific rationale for Traumakine treatment is based on the use of interferon beta for the restoration of the endothelial barrier function in ARDS patients. Traumakine (FP-1201-lyo) is based on a patent-protected use of interferon-beta to prevent leakage of

vascular beds in acute lung injuries. The active pharmaceutical ingredient in Traumakine is recombinant human IFN beta-1a.

The mechanism behind Traumakine's action was invented by scientists at Turku University during the period 1995 to 2003. Through extensive research and ex vivo studies, it was identified that a molecule called CD73 is essential in maintaining the endothelial barrier function. CD73 is an ectoenzyme capable of breaking down extracellular AMP to produce locally active adenosine. Adenosine maintains the endothelial barrier and downregulates inflammation escalation, preventing both early vascular leakage and escalation of inflammation, which are the two early patho-physiological events leading to ARDS. One of the key findings that led to the development of Traumakine, was a discovery that interferon-beta could enhance CD73 expression and could therefore, be used to treat a range of vascular leakage conditions including ARDS. Traumakine works by enhancing CD73 expression in the lungs and increasing production of anti-inflammatory adenosine such that vascular leaking and escalation of inflammation are reduced.

The mode of action of FP-1201-lyo is described in a video found on Faron's website: [www.faron.com](http://www.faron.com)

**"Traumakine (FP-1201-lyo) is based on a patent-protected use of interferon-beta to prevent leakage of vascular beds in acute lung injuries."**



#### PIPELINE: TRAUMAKINE®

## Traumakine® Clinical Programme

The first indication that Traumakine addresses is the treatment of ARDS.

The first clinical trial in the Traumakine programme was a phase I/II open-label study to assess the safety, tolerability and preliminary efficacy of interferon beta in the treatment of patients with ARDS. Interferon beta was found to be safe and well tolerated in ARDS patients and the optimal tolerated dose was established. The selected pharmacodynamic marker for interferon beta bioactivity showed clear dose response and the treatment target molecule (CD73) levels were induced during the dosing period. Most importantly, interferon beta treatment significantly reduced the all-cause mortality at day 28, the primary end point of the study, compared to the control cohort<sup>1</sup>. Traumakine was associated with an 81% reduction in odds of 28-day mortality.

### The INTEREST Study

The INTEREST Study (protocol FPCLI002) was a double-blinded and randomised Phase III clinical study to investigate efficacy and safety of FP-1201-lyo (recombinant human interferon- beta-1a) compared to placebo in patients with moderate or severe ARDS. The study, which recruited 300 patients, was conducted in 64 hospital intensive care units (ICU) in Belgium, the Czech Republic, Finland, France, Germany, Italy, Spain and the UK. Patients were treated daily with either FP-1201-lyo 10 µg or placebo for 6 days and underwent daily assessments while in the ICU for a maximum of 28 days. The patients were followed up at 3, 6 and 12 months after enrolment. Information on the need for



ventilator support, as well as the need for hospital and ICU care was collected during this follow-up period. Other collected data included e.g. respiratory and neurological functions and quality of life.

Top line data showed that the study did not meet the Day 28 primary efficacy composite endpoint of ventilator free days and survival with Traumakine treatment.

Biomarker analysis confirmed that Traumakine treatment did not produce consistent interferon-beta bioactivity across the treatment group. A retrospective stratification of Traumakine treated patients was conducted, based on subjects in the INTEREST trial who demonstrated a defined biomarker response. These were defined as patients with a 2-fold increase in CD73 serum levels during the first seven days of treatment and 3-fold MxA activation (during the first four days of treatment) in peripheral blood cells.

This sub-group of patients (n=48) demonstrated a reduced D28 all-cause mortality, with a mortality rate of 14.6% compared to 32.3% in the remaining patients (n=96) in the Traumakine treatment arm (p=0.02). In addition, this sub-group of patients demonstrated a trend toward an increase in ventilator free days at D28, with 16 ventilator free days (VFDs) compared to 6.5 days (p=0.06).

## Further Analysis

To better understand the INTEREST data, Faron has conducted further analysis, particularly with regard to the administration of corticosteroids used in parallel to Traumakine treatment and their effect on Traumakine efficacy.

### Key findings showed that:

- Corticosteroid use was high among INTEREST trial patients (176/296, 59.5%)
- Concomitant corticosteroid treatment had a significant impact on mortality in the Traumakine treatment group. Mortality was 10.6% (7/66) for those receiving Traumakine and not on corticosteroids, versus 39.7% (31/78) for those receiving Traumakine and on concomitant corticosteroids. This outcome is highly statistically significant (p<0.0001) and was a similar mortality to the treatment group in the phase I/II study
- Concomitant corticosteroid use with Traumakine was also associated with worse outcomes measured by ventilator free days (VFD) compared to non-users (median 6 VFDs vs. 14 VFDs, p=0.03)
- IFN-beta had previously been demonstrated to increase CD73 expression in lung capillaries which was associated with reduced mortality in ARDS patients in the phase I/II trial. However, concomitant exposure of human lung tissue samples to hydrocortisone in *ex vivo* culture conditions prevented Traumakine induced CD73 expression in lung capillaries

Of note, we also observed that the use of corticosteroids in the placebo group was associated with an increased mortality of 27.6% compared to no use of corticosteroids of 14.8% (p=0.075). In the group receiving corticosteroids there was a significantly higher APACHE II (acute physiology and chronic health evaluation) score (23.4 versus 20.4, p=0.0007) and SOFA (sequential organ failure assessment) score (10.4 vs 9.5, p=0.0428) but this difference did not explain the scale of mortality difference associated with corticosteroid use versus non-use.

The Company believed that the inconsistent FP-1201-lyo bioactivity observed in the INTEREST trial may well, in part, have been due to corticosteroid interference of IFN-beta action. Therefore, further *in vitro* and *ex vivo* experiments with human endothelial HUVEC cells and human lung tissue samples were conducted. Based on these results, no issues were detected in the formulation of FP-1201-lyo used in the INTEREST trial and the formulation was as active as the formulation used in the phase I/II trial. In lung tissue samples, the concomitant corticosteroids prevented the CD73 induction by Traumakine, which indicated similar interference of corticosteroids on IFN-beta bioactivity as observed in the INTEREST study.

To understand the reduced biomarker response to Traumakine administration, even where corticosteroids were not administered in the INTEREST study, a new FP-1201-lyo pharmacokinetic/dynamic study, YODA, is being conducted in approximately 50 healthy volunteers to determine the optimum mechanism of administration to achieve a full biomarker response.

Interim results from the first 30 subjects indicated that IFN-beta, regardless of the method of solubilisation, produced the expected level of bioactivity suggesting that drug formulation was not a factor in the outcome of the INTEREST trial. The YODA study

is continuing and is now examining concomitant administration of prednisolone and Traumakine in order to confirm, *in vivo*, the observed interference of corticosteroids on IFN-beta bioactivity in the INTEREST study and *ex vivo* lung samples.

Additionally, by genetic testing, Faron has identified an optimal subgroup of ARDS patients for Traumakine treatment who showed a substantial reduction in mortality during the INTEREST trial.

Multivariate regression analyses that adjust for disease severity indicated that patients receiving interferon beta-1a treatment (Traumakine) and carrying the single nucleotide polymorphism rs9984273 (C/T) in subunit 2 of the interferon alpha and beta receptor (INFAR2) (n=46) had 5.7 times greater likelihood of survival at Day 28 ( $p=0.0057$ ) than patients without this mutation (n=58). No similar survival effect was seen for the C/T polymorphism in the placebo group.

This suggests that together the C/T mutation and Traumakine treatment is the most favorable combination for patient outcome and interferon treatment efficacy. The D28 overall mortality of this group was 11.1% despite receiving, or not receiving, concurrent steroids. In patients with the C/T polymorphism who received Traumakine but not concurrent steroid treatment, mortality was only 4.2% (n=25).

## CALIBER

Based on these findings, the Company has designed a new phase III trial with Traumakine for the treatment of ARDS. The CALIBER study will allow corticosteroid use within the standard of care (SOC) arm, but not if the ARDS patient is on Traumakine. This double dummy structure will allow physicians to choose their preference whilst creating a blinded readout between Traumakine and SOC patients. We are seeking guidance from both the FDA and the EMA on the trial design and anticipate feedback during

Q3 2019. CALIBER will be a global trial. The company is seeking support for the trial from a licensing partner and is currently engaged in discussions with potential partners.

## INFORAAA trial

Ruptured Abdominal Aortic Aneurysm (RAAA) is a surgical emergency with an overall mortality of up to 80%. It requires immediate surgery and aortic repair. Approximately half of the deaths of RAAA patients are due to not reaching the hospital in time, and, despite immediate surgery and intensive care treatment, the second half die in hospital within 30 days post-operatively, mostly due to multi-organ failure. The cause of high post-operative mortality is mainly due to prolonged hypotension/hypoxia from the ruptured aorta and the aftermath of restoring blood flow: reperfusion, vascular leakage and failure of vital organs. Currently, there are an estimated 20,000 US and European patients per annum eligible for treatment.

The high mortality rate of RAAA, which accounts for 4-5 deaths per 100,000 population<sup>2</sup>, requires new treatments to prevent post-operative reperfusion injury leading to the death of RAAA patients, which exhibits a 30-50% mortality rate post-operatively. RAAA accounts for 13-14/100,000 hospital admissions annually<sup>3</sup>, and is the second indication for Traumakine targeted by Faron.

Open surgical aortic repair to treat RAAA patients is associated with a Systemic Inflammatory Response Syndrome (SIRS) affecting vital organs, especially the heart, lungs, kidneys, and intestines. The death of approximately 80% of the operated RAAA patients is caused by MOF, similar to patients with ARDS. The Directors consider that data seen to date supports the rationale for extending the use of Traumakine in similar conditions to potentially treat single, and multiple, organ failures. For

example, during the Traumakine phase I/II study, there was a reduced need for haemodialysis (an indication of improved kidney function) among the ARDS patients Traumakine.

The INFORAAA trial is a European Phase II multi-center double blinded placebo-controlled trial with Traumakine underway for the prevention of MOF and death after the surgical repair of a RAAA. The study aims to recruit 160 patients and currently has open sites in Finland, Lithuania and Estonia and sites in the UK are planned to open. In July 2018, the Company received a second recommendation from the IDMC to continue the INFORAAA trial and will take the study to the first interim point.

## INTEREST Study Analysis

- The drug product used in the INTEREST study was safe, robust and effective.
- Corticosteroids could interfere with IFN-beta action and mask the treatment benefit of Traumakine for ARDS patients
- There is an optimal subgroup of ARDS patients for Traumakine treatment

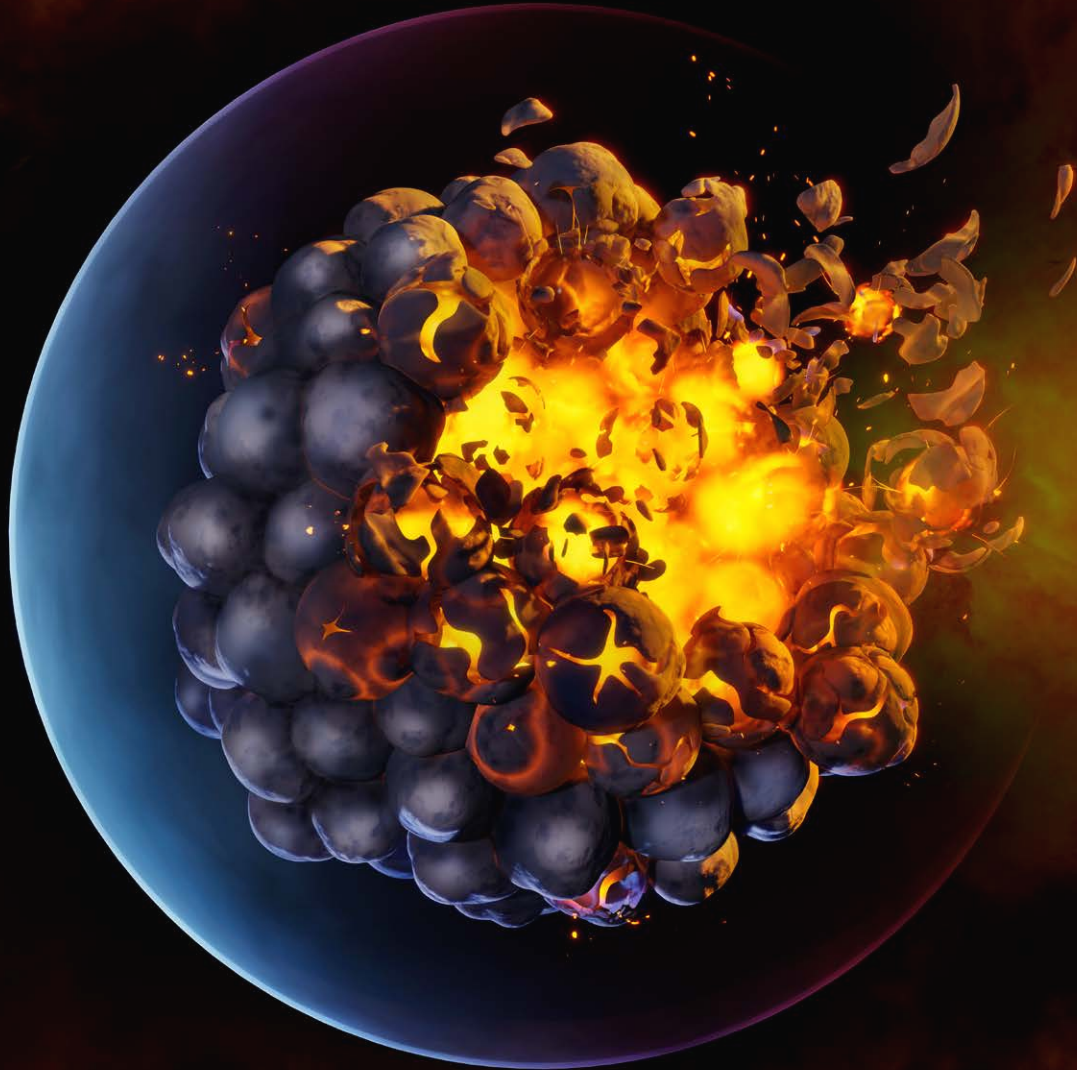


<sup>1</sup> Bellingan et al., 2014

<sup>2</sup> Karthikesalingam et al., 2014

<sup>3</sup> Anjum et al., 2012

**Clevegen can switch  
immune suppression to  
immune activation**



## PIPELINE: CLEVEGEN®

One of Faron's key areas of focus is to develop a cancer treatment which supports the hosts' immune defences against tumours, as these are often suppressed in cancer patients. Our second most advanced drug development project, Clevegen, revolves around a common lymphatic endothelial and vascular endothelial receptor-1 (CLEVER-1).

## Clever-1: an immuno switch molecule

CLEVER-1, also known as Stabilin-1, is a large glycoprotein, which originally was described to function as a scavenging receptor and an adhesion molecule. Its intracellular part regulates the recycling of the receptor between the cell surface and intracellular compartments. CLEVER-1 is present on lymphatic vessels and is induced on a subpopulation of type 2 (immunosuppressive) macrophages during their polarization. It is induced on cancer vasculature. Moreover, its expression on tumour-associated macrophages is a sign of poor prognosis in colorectal cancers of advanced stage. More recently, it has become very clear that CLEVER-1 maintains the immunosuppressive phenotype of tumour associated macrophages (TAMs). Blocking or silencing of CLEVER-1 on human macrophages induces MHC expression and promotes IFN- $\gamma$  leukocyte cultures. Genetic disruption or pharmaceutical inhibition of CLEVER-1 attenuates tumour progression in mice. The active pharmaceutical ingredient of Clevegen is a humanised anti-Clever-1 antibody, which modulate Clever-1 function to switch the immunosuppressive M2 macrophages to immune stimulating M1 macrophages.

### Mechanism of Action

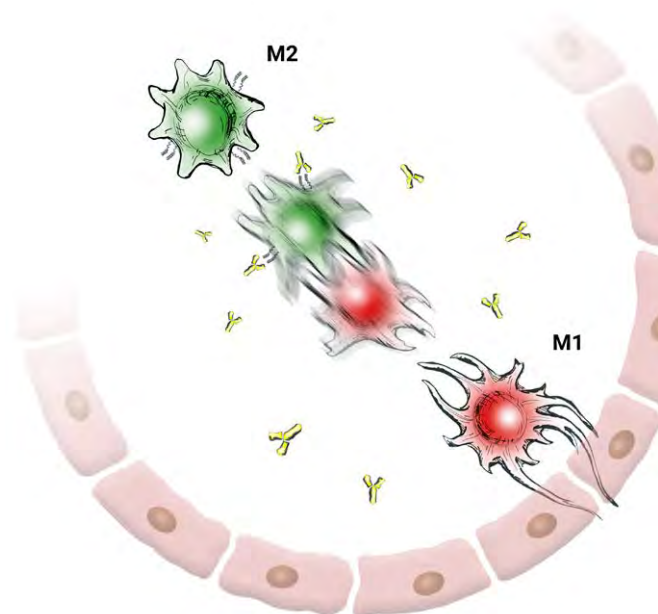
All tumours are infiltrated by immune cells, for example macrophages, neutrophils, T cells, dendritic cells, mast cells, myeloid derived suppressor cells and natural killer cells. Depending on the immune cell content and the activation status of the immune cells, they can either protect the host through suppression of tumour growth and elimination of tumour or harm the host by promoting tumour growth, invasion,

metastasis and angiogenesis. Tumour associated macrophages (TAMs) have emerged as an essential constituent of the tumour environment. TAMs can promote tumour progression directly by inducing cancer cell proliferation and survival as well as indirectly via the surrounding elements by stimulating angiogenesis or help in escaping from antitumour specific immunity. When TAMs populate a tumour, one of the very significant influences they exert over it is a strong increase in immuno

*Clever-1-positive TAMs represent one major macrophage population involved in the elimination of host immune activity against the tumour cells.*



*Clevegen switches immune suppressive type 2 (M2) macrophages to immune stimulating (M1) macrophages and provides new ways to stimulate host immune system to fight cancer.*



suppression. Clever-1-positive TAMs represent a major macrophage population involved in the elimination of host immune activity against the tumour cells. Clevegen is an anti-Clever-1 antibody which targets Clever-1-positive TAMs in cancer patients and converts these highly immunosuppressive type 2 “healing” macrophages (M2) to type 1 “pro-inflammatory” macrophages (M1).

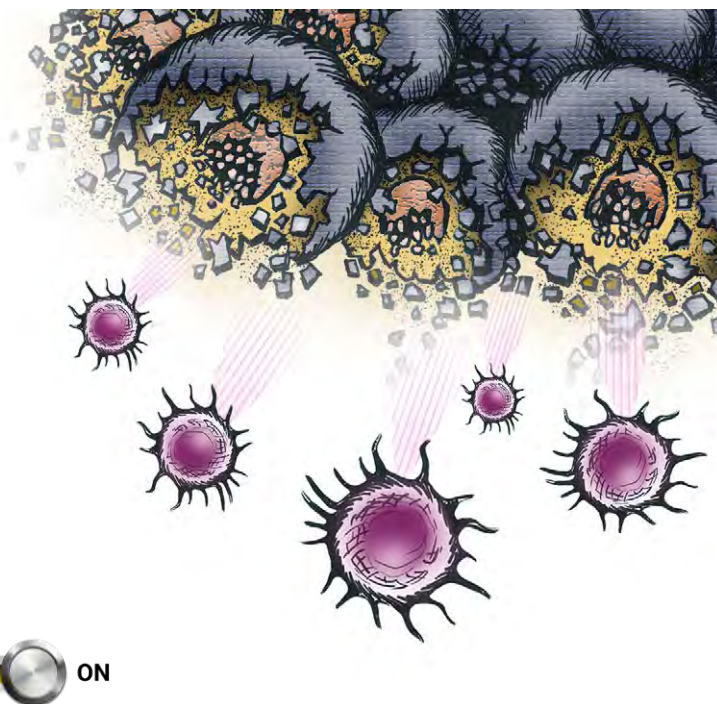
Clevegen also prevents TAM infiltration into a tumour and therefore blocks their accumulation at tumour sites and can, therefore, also control the tumour content of regulatory T-cells, which are dependent on M2 macrophage support. Inhibition of CLEVER-1 alters IFN-gamma production in immune cells and reduces the number of regulatory T-cells within the tumour. Expansion of Clevegen’s use, to include removal of local immune suppression in chronic infections and vaccination sites, are also being explored alongside tumours. These platforms are called CIRT, VRET and TIET, respectively and are all based on the same anti- Clever-1 antibody.

### Blocking TAM infiltration into a Tumour

Tumour endothelial cells are Clever-1 positive and when anti-Clever-1 antibodies bind to the Clever-1 receptor, the infiltration of TAMs is prevented. Through blocking the infiltration of TAMs into the tumour, the ability of the tumour to suppress the hosts’ immune system is reduced.

### Change in Tumour Immunity

Anti-Clever-1 antibodies change the tumour immunity by lowering the presence of tumour supportive TAMs in the tumour. This will allow other immune cells to attack tumour cells and drive them to programmed cell death (apoptosis). In some tumours up to 50% of the tumour mass may contain immunosuppressive TAMs and the only way to eliminate this dominance is remove



*Anti-Clever-1 antibodies switch innate immune system to adaptive one and allow other immune cells to attack tumour cells and drive them to programmed cell death (apoptosis).*

them from tumours and/or convert them to stimulate other cells of the immune system. It is these highly immunosuppressive CLEVER-1 positive TAM cells that are the main target of the Clevegen programme.

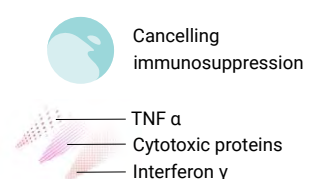
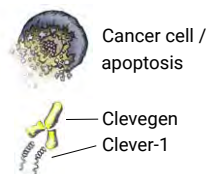
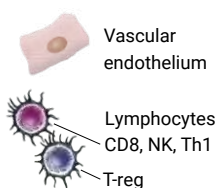
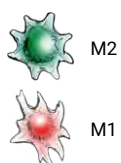
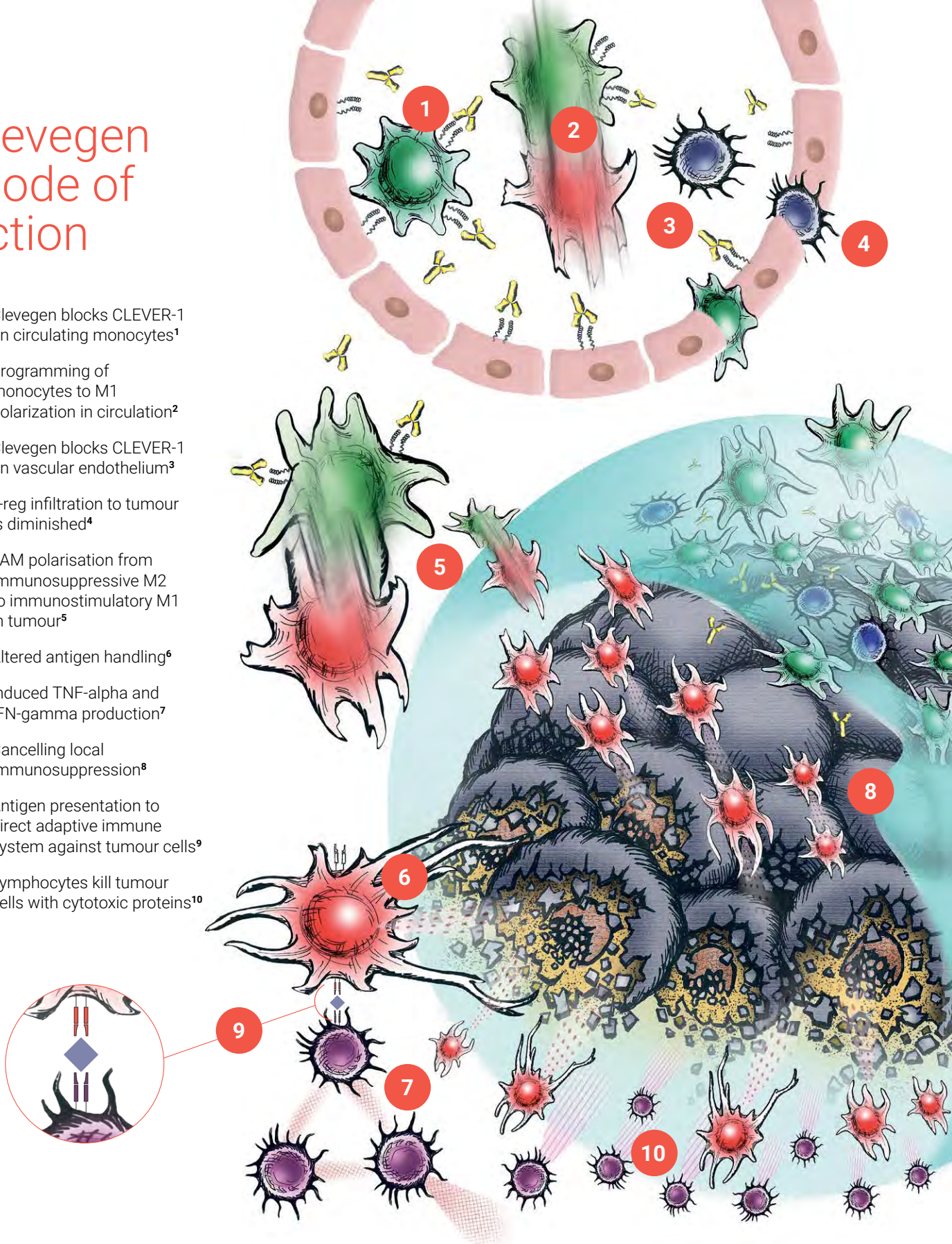
### About Tumor Immunity Enabling Technology (TIET)

The TIET technology is built around the humanised anti-Clever-1 antibody FP-1305, which binds to a specific Clever-1 proprietary epitope. Clevegen binds to this epitope, activating conversion of type 2 tumour associated macrophages to type 1 macrophages, resulting in the transformation of the tumour environment from immunosuppression to activation of the immune system. As the TIET technology is based on a humanized antibody, the Faron Directors believe it can be combined with a number of other immunotherapies without a significant risk of increased adverse events. The TIET

technology could provide a significant boost for the efficacy of other immune checkpoint molecules, as its target is unique and represents a completely separate control of immunity.

# Clevegen mode of action

- 1 Clevegen blocks CLEVER-1 on circulating monocytes<sup>1</sup>
- 2 Programming of monocytes to M1 polarization in circulation<sup>2</sup>
- 3 Clevegen blocks CLEVER-1 on vascular endothelium<sup>3</sup>
- 4 T-reg infiltration to tumour is diminished<sup>4</sup>
- 5 TAM polarisation from immunosuppressive M2 to immunostimulatory M1 in tumour<sup>5</sup>
- 6 Altered antigen handling<sup>6</sup>
- 7 Induced TNF-alpha and IFN-gamma production<sup>7</sup>
- 8 Cancelling local immunosuppression<sup>8</sup>
- 9 Antigen presentation to direct adaptive immune system against tumour cells<sup>9</sup>
- 10 Lymphocytes kill tumour cells with cytotoxic proteins<sup>10</sup>



**References:** 1. Clevegen blocks CLEVER-1 on circulating monocytes (Palani et al. 2016). 2. Programming of monocytes to M1 polarization in circulation (Palani et al. 2016). 3. Clevegen blocks CLEVER-1 on vascular endothelium (Irijala et al 2003; Shetty et al 2011). 4. T-reg infiltration to tumour is diminished (Shetty et al 2011; Karikoski et al 2014). 5. TAM polarisation from immunosuppressive M2 to immunostimulatory M1 in tumour (Karikoski et al 2014; Palani et al 2016). 6. Altered antigen handling (Palani et al 2016). 7. Induced TNF-alpha and IFN-gamma production (Palani et al 2016). 8. Cancelling local immunosuppression (Karikoski et al 2014; Palani et al 2016). 9. Antigen presentation to direct adaptive immune system against tumour cells (Karikoski et al 2014; Palani et al 2016). 10. Lymphocytes kill tumour cells with cytotoxic proteins (Karikoski et al 2014).



Full control of immune mechanisms may help us to convert lethal cancers to treatable conditions. Removal of immunosuppressive elements like type 2 macrophages help to conquer this aim.

Successful preclinical toxicity studies, designed to fulfil regulatory requirements for 3-week interval intravenous administration of Clevegen, showed no toxicologically relevant changes in any subject and no major changes after treatment with FP-1305 in T lymphocytes subsets. The binding of Clevegen to its receptor on circulating CD14+ monocytes was confirmed by investigating the receptor occupancy, the recovery of which occurred between 3 to 20 days after dosing in a dose-dependent manner. No relevant changes were present in cytokines and no anti-drug antibodies (ADA) were detected in any subject. Therefore, the highest dose of 100 mg/kg was considered the no-observed-adverse-effect-level (NOAEL).

## MATINS Study

The MATINS study is Faron's first-in-human open label Phase I/II adaptive clinical trial in selected metastatic or inoperable solid tumours to investigate the safety and efficacy of Clevegen (FP-1305). The selected tumours are cutaneous melanoma, hepatobiliary, pancreatic, ovarian or colorectal cancer, which are all known to contain high amounts of Clever-1 positive TAMs. The trial is being run in three parts. Part I, to determine the safe and tolerable dose of Clevegen, which will then be used in Part II to expand the cohorts of individual tumour types. Part III of the trial aims to confirm the efficacy of Clevegen with the cohorts selected based on Part II.

The Company filed a Clinical Trial Application (CTA) in September 2018 which was subsequently approved by the Finnish Medicines Agency (FIMEA). The first patient was dosed in December 2018 at Helsinki and Oulu University Hospitals in Finland.

## MATINS update

Early data from MATINS have been encouraging with all dosed patients, thus far, showing a switch in their immune profile towards more immune activation, observed as an increase in CD8+ cells, an increased CD8/CD4 ratio, decreased regulatory T-cells (T-regs) and a high appearance of mobile NK cells in the blood.

Late-stage colorectal cancer has been selected as the first cohort expansion phase (Part 2), which will commence once the optimal dosing has been determined.

Faron has also received a tumour imaging report on a patient with colorectal cancer, which indicates significant shrinkage of lung metastasis (classified as a partial response). Positively, the patient has also shown a decrease in the tumour load marker CEA (carcinoembryonic antigen) and an increase in circulating B-cells, which could indicate an antibody-mediated response against the tumour. This patient, whose tumour has been classified as MSI-low (microsatellite instability) had previously been treated with six different anti-cancer drugs, which had all failed.

The Company believes these findings are encouraging and is confident it has identified a group of patients who are thought to be most likely to respond to treatment.

Furthermore, the Company has expanded the trial to two sites in the UK (London, Birmingham) following CTA approval by the UK regulator, the Medicines & Healthcare products Regulatory Agency (MHRA). The Company also intends to seek pre-IND advice from the US Food and Drug Administration (FDA) to open sites in USA prior to entering the cohort expansion part of the trial.

Due to high interest in potential new therapies in the immuno-oncology field, either as monotherapy or in combination, the Company is currently engaged in partnering discussions with several parties and hopes for a positive outcome from these negotiations during 2019.

## CORPORATE GOVERNANCE

# Corporate Governance

## Chairman's Introduction to Governance

The Board of Faron emphasises the importance of good corporate governance and is aware of its responsibility for overall corporate governance and for supervising the general affairs and business of the Company.

As the Chairman of the Board, I oversee the adoption, delivery and communication of Faron's corporate governance model. In this role I endeavour to foster a positive governance culture throughout the Company, seeing that ultimate responsibility for the quality of, and Faron's approach to, corporate governance lies with me.

Faron is not required to comply with the UK Corporate Governance Code by virtue of being an AIM quoted company. The Board does, however, seek to apply the QCA Corporate Governance Code (as devised by the Quoted Companies Alliance in consultation with a number of significant institutional small company investors).

In 2018, the Board of Faron confirmed the Company's continued commitment to the QCA Code in its updated form, and the terms of reference of the Board committees were reviewed and revised accordingly. As part of the Company's re-focus, Dr Jonathan Knowles resigned from the Board to take up a position as Chair of the newly formed Clevegen Scientific Advisory Board and Dr Huaizheng Peng resigned from the Board but will continue as an invited observer. Otherwise, no significant changes in governance arrangements occurred during the year.

As described below, the Board continues to promote a healthy corporate culture that is based on ethical values and behaviours and consistent with the Company's objectives, strategy and business model described in the strategic report and with the description of principal risks and uncertainties. As good corporate governance is fundamentally about culture, rather than procedure, the state of Faron's corporate culture is monitored on a regular basis, and appropriate action is taken if and to the extent deemed necessary.



## CORPORATE GOVERNANCE

# Compliance with the Principles of the QCA Code

The Principles of the QCA Code	Comply/ Explain	Disclosure in the 2018 Report
1. Establish a strategy and business model which promote long-term value for shareholders	Comply	Pages 2 to 6 and 10
2. Seek to understand and meet shareholder needs and expectations	Comply	Page 55
3. Take into account wider stakeholder and social responsibilities and their implications for long-term success	Comply	Page 56
4. Embed effective risk management, considering both opportunities and threats, throughout the organisation	Comply	Pages 21 to 23 and 55
5. Maintain the board as a well-functioning, balanced team led by the chair	Comply	Pages 47 to 48 and 58 to 59
6. Ensure that between them the directors have the necessary up-to-date experience, skills and capabilities	Comply	Pages 42 to 47
7. Evaluate board performance based on clear and relevant objectives, seeking continuous improvement	Comply	Page 47
8. Promote a corporate culture that is based on ethical values and behaviours	Comply	Page 40
9. Maintain governance structures and processes that are fit for purpose and support good decision-making by the board	Comply	Pages 40 and 42
10. Communicate how the company is governed and is performing by maintaining a dialogue with shareholders and other relevant stakeholders	Comply	Pages 47 and 49 to 54

## CORPORATE GOVERNANCE

## Board of Directors

On 31 May 2018, Frank Armstrong, Markku Jalkanen, Jonathan Knowles, Matti Manner, Huaizheng Peng, Yrjö Wichmann, Leopoldo Zambelletti, Gregory Brown and John Poulos were elected to the Board for a term that ends at the end of the next Annual General Meeting. The elected Board comprised seven Non-Executive Directors and two Executive Directors. At the meeting of the Board held following the AGM held in 31 May 2018, Frank Armstrong was re-elected Chairman of the Board and Matti Manner was re-elected Deputy Chairman of the Board. During 2018, the Board held 15 meetings.

As part of the Company's re-focus, Faron announced on 13 September 2018 that Dr Jonathan Knowles had resigned from the Board to take up a position as Chair of the newly formed Clevegen Scientific Advisory Board and Dr Huaizheng Peng resigned from the Board but will continue as an invited Board Observer. Brief biographical details for the remaining Directors can be found on pages 43 to 46.

The Board is responsible to the shareholders for the proper management of the Company and meets regularly to set the overall direction and strategy of the Company, to review scientific, operational and financial performance, to review the strategy and activities of the business, and to advise on management appointments. The Board sees to the administration of the Company and the appropriate organisation of its operations, being responsible for the appropriate arrangement of the control of the Company accounts and finances. Faron's strategy is explained fully within its Strategic Report section on page 10.

All key operational and investment decisions are subject to full Board approval. The management of the Company prepares a monthly management and financial accounts pack, which is distributed to the Board every month and in advance of Board meetings. In individual cases the Board may decide

in a matter falling within the general competence of the Chief Executive Officer.

The roles of Chief Executive Officer and Non-Executive Chairman are well defined and clearly separated. The Chairman oversees the Board's work, ensures that the Board's decision-making is balanced and that the Non-Executive Directors have all relevant information on matters to be decided. The Chairman sees to it that the Board meets when necessary.

The Chief Executive Officer is responsible for implementing the strategy of the Board and managing the day-to-day business activities of the Company. The Chief Executive Officer, reviewing the operating results regularly to make decisions about the allocation of resources and to assess overall performance, is the chief operating decision-maker.

The Board considers there to be sufficient independence of the Board and that all the Non-Executive Directors are of sufficient competence and calibre to add strength and objectivity to the Board, and to bring considerable experience in terms of their knowledge of the scientific, operational and financial development of biopharmaceutical products and companies. Where necessary, the Company facilitates that Non-Executive Directors obtain specialist external advice from appropriate advisers.

The term of office of each Director expires on the closing of the AGM immediately following his/her appointment to the Board. Under the Finnish Limited Liability Companies Act and the Company's Articles of Association, the Directors are elected by the shareholders at General Meetings annually. Under the Act, Directors may be removed from office at any time, with or without cause, by a majority of votes cast at a General Meeting. Vacancies on the Board may only be filled by a majority of shareholder votes cast at a General Meeting.



Dr Frank Armstrong  
Non-Executive Chairman



Matti Manner  
Non-Executive Vice-Chairman

Dr Armstrong has held Chief Executive roles with five biotechnology companies (both public and private) including FulcrumPharma PLC (AIM). He led Medical Science and Innovation at Merck Serono and was previously Executive Vice President of Product Development at Bayer and Senior Vice President of Medical Research and Communications at Zeneca. Dr Armstrong is currently the Chairman of Summit Therapeutics (AIM and NASDAQ) and Caldan Therapeutics and a Non-Executive Director of and Mereo BioPharma (AIM). He is a member of the Senior Advisory Board at Healthcare Royalty Partners and an SAB Member at Epidarex Capital. Dr Armstrong is a Member of the Court of the University of Edinburgh. Dr Armstrong is a physician and a Fellow of the Royal College of Physicians (Edinburgh).

He was appointed as a Non-Executive Director of the Company in September 2015.

Mr Matti Manner was appointed as a partner of Brander & Manner Attorneys Ltd in 1980 having previously sat as a judge at Turku Appeal Courts. He has significant experience in national and international business deals, corporate law and mergers and acquisitions having held a number of board memberships throughout his career. Mr Manner joined the Board of the Company as Chairman in 2007, Vice-Chairman since October 2015, having previously been the Chairman of Faron Ventures Oy from 2002.

He is currently Chairman of Turun Osuuskauppa and Ruisalo Foundation and a member of the board of Marva Media Ltd, Satatuote Ltd, YH VS-Rakennuttajat Ltd, Kauppakeskus Mylly Ltd and Nurmi-Yhtiöt Oy. Mr Manner has experience of several trustee posts including the Presidency of the Finnish Bar (Lawyers) Association during the period of 1998 to 2004. Mr Manner obtained a Master of Laws from the University of Turku. He became an honorary Chief Justice in Finland in 2013.



**Dr Markku Jalkanen**  
**Chief Executive Officer**

Dr Jalkanen has more than 25 years of experience within biomedical research, biotech development and the biopharmaceutical industry. He was a founding member of the Company and is the Company's CEO. In addition to his role as CEO of the Company, Dr Jalkanen is an advisor for the only active Finnish life sciences fund – Inveni Capital. Between 1996 and 2002, Dr Jalkanen was the founding CEO and President of BioTie Therapies Corp which has since become the first publicly traded Finnish biotech company to have listed on NASDAQ. Dr Jalkanen has published over 130 peer reviewed scientific publications in various highly ranked international journals and has held several board memberships for both public and private companies.

Dr Jalkanen obtained a Masters in Medical Biochemistry from the University of Kuopio and subsequently received a PhD in Medical Biochemistry from the University of Turku. He completed a side-laudatur examination in Molecular Biology from the University of Turku and completed his post-doctoral training at Stanford University, California between 1983 and 1986.

Dr Jalkanen obtained the position of docent in Biochemistry from University of Helsinki and the same qualification in Molecular and Cell Biology from the University of Turku. He became a Professor at the University of Turku in 1992 as well as Head of Turku Centre for Biotechnology.



**Dr Gregory B. Brown**  
**Non-Executive Director**

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), Cambrex Corporation (NYSE) and Aquestive Therapeutics (NASDAQ) and previously acted as a director of Invuity Inc (NASDAQ) between October 2014 and December 2015. Prior to this, he was a Managing Director 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.

He was appointed as a Non-Executive Director of the Company in May 2017.



**John Poulos**  
Non-Executive Director



**Leopoldo Zambelletti**  
Non-Executive Director

Mr. John Poulos has a wealth of expertise in global corporate life sciences, having spent 38 years working for AbbVie and Abbott. Mr. Poulos served as Vice President, Head of Business Development and Acquisitions for AbbVie from 2013 until 2016. John was also Group Vice President, Head of Pharmaceutical Licensing and Acquisitions for Abbott from 2005 until 2012. During his career with AbbVie and Abbott, John was instrumental in the negotiation of numerous acquisitions, including Knoll/BASF Pharma in 2001 for \$6.9 billion, Kos Pharmaceuticals in 2006 for \$3.7 billion, Solvay in 2010 for \$6.2 billion and Pharmacyclics in 2015 for \$21 billion.

Mr. Poulos is currently an Operating Partner with Linden Capital Partners, a private equity firm focused exclusively on healthcare.

He was appointed as a Non-Executive Director of the Company in May 2017.

During a 19-year career as an investment banker, Mr Zambelletti led the European Healthcare Investment Banking team at JP Morgan for eight years before taking up the same position at Credit Suisse for a further five years. Since 2013 he has been an independent strategic advisor to life science companies on merger and acquisitions, out-licencing deals and financing strategy.

He is a Non-Executive Director of Philogen, Qardio Inc., Summit Therapeutics PLC (NASDAQ and AIM), Nogra Pharma and Tiziana Life Sciences (Nasdaq and AIM), OKYO (AIM). Mr Zambelletti started his career at KPMG as an auditor.

Mr Zambelletti received a BA in Business from Bocconi University in Milan, Italy. Mr Zambelletti was appointed as a Non-Executive Director of the Company in September 2015.



Yrjö E K Wichmann  
Chief Financial Officer

Mr Wichmann has a career spanning close to 25 years in financing and investment banking. He was appointed as a Chief Financial Officer of the Company in 2014. Prior to his appointment at the Company, Mr Wichmann held a number of senior positions within the life sciences and biotechnology sector, most recently at IP Finland Oy, Biohit Oyj (NASDAQ OMX Helsinki), Capman Oyj, FibroGen Europe Oyj (NASDAQ) and D. Carnegie & Co AB. Whilst carrying out these roles Mr Wichmann has participated in healthcare IPOs on the London, Stockholm and Helsinki stock exchanges as both an investment banker and as a member of the board. Mr Wichmann is a member of the Investment Committee at Dasos Timberland Fund I and II.

Mr Wichmann obtained a Masters in Economics from Helsinki University.

He was appointed as an Executive Director of the Company in 2015.

## Performance Evaluation

The Board has a process for evaluation of its own performance and that of its committees and individual Directors, including the Chairman. These evaluations are carried out at least annually.

In the Board performance evaluation process adopted by the Company, Board, Committee and individual effectiveness is considered against the criteria of creating and running an effective Board, professional development, strategic foresight, stewardship, managing management, value creation and corporate culture.

In the most recent Board assessment, succession planning, setting clear collective objectives for the Board, opportunities for Board members to engage in professional development and greater use of scenario planning in the evaluation of strategic risks were identified as areas meriting further discussion by the Board.

As a result of the evaluation process, the following practical changes have been implemented to increase the effectiveness of the Board: sending Board meeting material earlier so that all Board members have a chance to familiarise themselves with the material prior to the meeting, maximising physical participation in Board meetings and setting aside time in Board meetings to discuss emerging issues that could affect the organisation in the future.

## Board Committees

In conjunction with being admitted to trading on AIM, the Company has established audit, nomination and remuneration committees of the Board with formally delegated duties and responsibilities.

Generally speaking, Board committees do not have a formal legal status or independent decision-making powers under the Finnish Limited Liability Companies Act; rather, their role is to provide support in the preparation of the decision-making. The responsibility for the decisions remains with the Board even if the preparation of a matter has been delegated to a Committee.

At the meeting of the Board held following the Annual General Meeting of 31 May 2018, the Board of Directors re-elected the Chairmen and other members to the Board committees.

## Remuneration Committee

The Remuneration Committee comprises Frank Armstrong as Chairman together with John Poulos since 13 September 2018. The Remuneration Committee has the task of advising on and making recommendations to the Board in relation to the remuneration paid to the Directors and supervising the development of any other remuneration or reward systems of the Company. During 2018, the Remuneration Committee held two meetings.

## Audit Committee

The Audit Committee, which comprises Leopoldo Zambelletti as Chairman together with Matti Manner and Gregory Brown, meets not less than twice a year. The Audit Committee has the task of supervising and developing the internal audit of the Company and advising and making recommendations to the Board of Directors on issues related to the same. During 2018, the Audit Committee held four meetings.

## Nomination Committee

The Nomination Committee comprises Matti Manner as Chairman together with Frank Armstrong since 13 September 2018. The Nomination Committee has the task, in co-operation with the Board, of advising on and making recommendations to the Board on issues relating to the composition and nomination of the Board. During 2018, the Nomination Committee held one meeting.

The Nomination Committee considers succession planning for Directors and other senior executives in the course of its work, bearing in mind the challenges and opportunities facing the Company and the skills and expertise needed on the Board in the future, and makes recommendations to the Board concerning formulating plans for succession for both Executive and Non-Executive Directors and in particular for the key roles of Chairman and Chief Executive Officer.

## Attendance at Board meetings

During 2018 the Board held 15 meetings. The table below lists the Directors' attendance to the Board and Committee meetings during the year:

### The Directors' attendance during the year ended 31 December 2018

	Board	Audit Committee	Remuneration Committee	Nomination Committee
<b>Executive directors</b>				
Jalkanen Markku	15			
Wichmann Yrjö	15			
<b>Non-executive directors</b>				
Armstrong Frank	15		2(2)	1(1)
Manner Matti	14	3(4)		1(1)
Brown Gregory B	13	4(4)		
Knowles Jonathan*	7(12)		0(1)	
Peng Huaizheng*	10(12)			1(1)
Poulos John	14		2(2)	
Zambeletti Leopoldo	12	4(4)		

\* Resigned from Board on 12 September 2018



## CORPORATE GOVERNANCE

# Remuneration Report

## ***Audited Information***

### Remuneration policy for Directors

The Remuneration Committee sets the remuneration policy that aims to align Director remuneration with shareholders' interests and attract and retain the best talent for the benefit of the Company.

The remuneration of the Directors during the year ended 31 December 2018 is set out below:

This report sets out Faron's remuneration policy for the Executive and Non-Executive Directors. No Director is involved in discussions relating to their own remuneration.

#### **Basic salary**

Basic salaries are reviewed annually. The review process is managed by the Remuneration Committee with reference to market salary data, the Executive Director's performance and contribution to the Company during the year.

#### **Bonuses**

Annual bonuses are based on the achievement of Company strategic and financial targets and personal performance objectives. The Non-Executive Directors believe that bonuses are an incentive to achieve the targets and objectives, and represent an important element of the total compensation of the Executive Directors; they have established that the annual bonus potential will be up to 50% for the Executive Directors.

On 20 February 2018 the Chief Executive Officer was awarded a bonus representing 50% of their 2017 gross basic salaries.

#### **Longer term incentives**

In order to further incentivise the Executive Directors and employees, and align their interests with Shareholders, the Extraordinary General Meeting of the Company on 15 September 2015 approved a share option plan and granted share options to the members of the Board under this option plan. Details of the option plan are on a page 51. The Company's policy is to maintain an incentive policy also in the future.

#### **Pension**

Faron has a law-defined contribution plan under which it pays fixed contributions into a separate entity. The plan covers all the employees of Faron including the Executive Directors. Faron has no legal or constructive obligations to pay further contributions if the fund does not hold sufficient assets to pay all employees the benefits relating to employee service in the current and prior periods.

#### **Other benefits**

Some employees have the possibility to take a company car allowance, which is part of their gross salary. All employees have a company mobile phone that constitutes a company mobile phone allowance.

## Executive Directors' service contracts and termination provisions

The service contracts of Executive Directors are approved by the Board and are concluded for an indefinite period of time.

The details of the Executive Directors' contracts are summarised below:

		Date of contract	Notice period
Markku Jalkanen	CEO	16.09.2015	6 months
Yrjö E K Wichmann	CFO	16.09.2015	6 months

## Non-Executive Directors' service contracts and remuneration

The remuneration and compensation payable to the members of the Board including the Non-Executive Directors shall be approved by the Shareholders at the AGM. Any Non-Executive Director who, by request, goes or resides abroad for any purposes of the Company or who performs services which in the opinion of the Board go beyond the ordinary duties of a Director may be paid extra remuneration or may receive such other benefits as the remuneration Committee may approve. Non-Executive Directors are entitled to be reimbursed in respect of their reasonably and properly incurred travelling, accommodation and incidental expenses for attending and returning from meetings of the Board, Committee meetings or the general meetings of Shareholders.

The Non-Executive Directors do not receive any pension, bonus or benefit from the Company. The contracts of the Non-Executive Directors, excluding remuneration and compensation, are reviewed by the Board annually.

Current contracts are summarised below:

Non-Executive Directors' Contracts	Independence	Contract	Date of Contract
Frank Armstrong	Independent	Chairman	16.09.2015
Matti Manner	Non-independent	Vice-chairman	16.09.2015
Gregory Brown	Independent	Member	16.05.2017
John Poulos	Independent	Member	16.05.2017
Leopoldo Zambelletti	Independent	Member	16.09.2015

The appointments of Non-Executive Directors are terminable with immediate effect in accordance with the Articles of Association and pursuant to the Finnish Companies Act, through a resolution of Shareholders at a General Meeting on any grounds. The Non-Executive Directors may resign as a director by delivering three months' notice to the Registered Office of the Company or through tendering such resignation at a meeting of the Board.

The Directors received the following remuneration during the year:

€	Salaries and fees	Bonus 2018	Taxable benefits	Total
<b>Executive</b>				
Markku Jalkanen	221,078.73	123,641.00	15,900.00	360,619.73
Yrjö E K Wichmann	163,588.26	52,322.40	1,018.10	216,928.76
<b>Non-Executive</b>				
Frank Armstrong	77,790.36			77,790.36
Matti Manner	44,421.57			44,421.57
Jonathan Knowles*	33,691.22			33,691.22
Huaizheng Peng*	36,198.04			36,198.38
Leopoldo Zambelletti	43,139.38			43,139.38
Gregory Brown	46,695.81			46,695.81
John Poulos	48,213.62			48,213.62

\*Resigned from Board on 12 September 2018

## Directors' share options

Aggregate remunerations disclosed above do not include any amounts for the value of options to acquire Ordinary Shares in the Company granted to or held by the Directors. A share option plan was adopted by the Company at the Extraordinary General Meeting held on 15 September 2015 and amended in Annual shareholders Meeting on 16 May 2017. The option plan allows the Company to offer options for subscription free of charge to members of the Board, and to such officers and employees of the Company as the Board sees fit. Each option will entitle the holder of the option to subscribe for one Ordinary Share. Under the terms of the option plan, an aggregate maximum number of 1,800,000 options may be granted, such aggregate being made up of a maximum of 400,000 "A" options, the subscription period for which ended on 9 June 2016 (such options exercisable between 2 November 2015 and 30 September 2021), a maximum of 400,000 "B" options to be subscribed for between 8 October 2016 and 30 September 2019 (exercisable between 8 October 2016 and 30 September 2021), a maximum of 500,000 "C" options to be subscribed for between 8 October 2017 and 30 September 2019 (exercisable between 8 October 2017 and 30 September 2021), and a maximum of 500,000 "D" options to be subscribed for between 8 October 2018 and 30 September 2019 (exercisable between 8 October 2018 and 30 September 2021).

The exercise price for Ordinary Shares based on "A" options shall be €3.71. The exercise price for Ordinary Shares based on "B" options shall be €2.90. The exercise price for Ordinary Shares based on "C" options shall be €8.39. The exercise price for Ordinary Shares based on "D" options shall be €1.09.

Details of these options are as follows:

2015A Options	Date of grant of A options <sup>1)</sup>	At 1 January 2018	Granted during the period	Cancelled during the period	At 31 December 2018	Subscription price per share, €	Date from which exercisable	Expiry date of A options
Markku Jalkanen	16.09.2015	80,000	0	0	80,000	3.71	02.11.2015	30.09.2021
Yrjö E K Wichmann	16.09.2015	30,000	0	0	30,000	3.71	02.11.2015	30.09.2021
Frank Armstrong	16.09.2015	40,000	0	0	40,000	3.71	02.11.2015	30.09.2021
Matti Manner	16.09.2015	20,000	0	0	20,000	3.71	02.11.2015	30.09.2021
Jonathan Knowles	16.09.2015	20,000	0	0	20,000	3.71	02.11.2015	30.09.2021
Huaizheng Peng	16.09.2015	20,000	0	0	20,000	3.71	02.11.2015	30.09.2021
Leopoldo Zambelletti	16.09.2015	20,000	0	0	20,000	3.71	02.11.2015	30.09.2021
Gregory Brown	-	0	0	0	0	-	-	-
John Poulos	-	0	0	0	0	-	-	-
		230,000			230,000			

2015B Options	Date of grant of B options <sup>1)</sup>	At 1 January 2018	Granted during the period	Cancelled during the period	At 31 December 2018	Subscription price per share, €	Date from which exercisable	Expiry date of B options
Markku Jalkanen	18.11.2016	80,000	0	0	80,000	2.90	08.10.2016	30.09.2021
Yrjö E K Wichmann	18.11.2016	30,000	0	0	30,000	2.90	08.10.2016	30.09.2021
Frank Armstrong	18.11.2016	40,000	0	0	40,000	2.90	08.10.2016	30.09.2021
Matti Manner	18.11.2016	20,000	0	0	20,000	2.90	08.10.2016	30.09.2021
Jonathan Knowles	18.11.2016	20,000	0	0	20,000	2.90	08.10.2016	30.09.2021
Huaizheng Peng	18.11.2016	20,000	0	0	20,000	2.90	08.10.2016	30.09.2021
Leopoldo Zambelletti	18.11.2016	20,000	0	0	20,000	2.90	08.10.2016	30.09.2021
Gregory Brown	-	0	0	0	0	-	-	-
John Poulos	-	0	0	0	0	-	-	-
		230,000	0	0	230,000			

2015C Options	Date of grant of C options <sup>1)</sup>	At 1 January 2018	Granted during the period	Cancelled during the period	At 31 December 2018	Subscription price per share, €	Date from which exercisable	Expiry date of C options
Markku Jalkanen	4.10.2017	80,000	0	0	80,000	8.39	08.10.2017	30.09.2021
Yrjö E K Wichmann	4.10.2017	30,000	0	0	30,000	8.39	08.10.2017	30.09.2021
Frank Armstrong	4.10.2017	40,000	0	0	40,000	8.39	08.10.2017	30.09.2021
Matti Manner	4.10.2017	20,000	0	0	20,000	8.39	08.10.2017	30.09.2021
Jonathan Knowles	20.10.2017	20,000	0	0	20,000	8.39	08.10.2017	30.09.2021
Huaizheng Peng	8.11.2017	20,000	0	0	20,000	8.39	08.10.2017	30.09.2021
Leopoldo Zambeletti	14.11.2017	20,000	0	0	20,000	8.39	08.10.2017	30.09.2021
Gregory Brown	13.10.2017	20,000	0	0	20,000	8.39	08.10.2017	30.09.2021
John Poulos	4.10.2017	20,000	0	0	20,000	8.39	08.10.2017	30.09.2021
		270,000	0	0	270,000			

Total Options	At 1 January 2018	Granted during the period	Cancelled during the period	At 31 December 2018	Average subs. price per shares, €
Markku Jalkanen	240,000	0	0	240,000	5.00
Yrjö E K Wichmann	90,000	0	0	90,000	5.00
Frank Armstrong	120,000	0	0	120,000	5.00
Matti Manner	60,000	0	0	60,000	5.00
Jonathan Knowles	60,000	0	0	60,000	5.00
Huaizheng Peng	60,000	0	0	60,000	5.00
Leopoldo Zambeletti	60,000	0	0	60,000	5.00
Gregory Brown	20,000	0	0	20,000	8.39
John Poulos	20,000	0	0	20,000	8.39
	730,000	0	0	730,000	

## At 31 December

2018 Executive	Issued Share Capital		Share Options	
	Ordinary shares	Percentage held	Ordinary shares	Average exercise price, € cent
Markku Jalkanen <sup>1)</sup>	2,909,390	9.4%	240,000	5.00
Matti Manner <sup>2)</sup>	508,300	1.6%	60,000	5.00
Jonathan Knowles*	119,212	0.4%	60,000	5.00
Yrjö Wichmann	74,640	0.2%	90,000	5.00
Leopoldo Zambeletti	17,461	0.1%	60,000	5.00
Frank Armstrong	22,396	0.1%	120,000	5.00
Huaizheng Peng*	4,000	0.0%	60,000	5.00
Gregory Brown	18,000	0.1%	20,000	8.39
John Poulos	0	0.0%	20,000	8.39
	<b>3,649,399</b>	<b>11.8%</b>	<b>730,000</b>	<b>8.39</b>

\*Resigned from Board on 12 September 2018

<sup>1)</sup> of which, 1,794,890 are held by Markku Jalkanen directly, and 1,078,500 are held by Markku Jalkanen's wife being Sirpa Jalkanen and her related party.

<sup>2)</sup> of which 500,400 are held by Matti Manner directly and 7,900 are held by his spouse.

## CORPORATE GOVERNANCE

# Corporate governance statement

For the year ended 31 December 2018.

## Communicating with Shareholders

The Company acknowledges that effective communication with shareholders on strategy and governance is an important part of its responsibilities. Interim and final results are communicated via formal meetings with roadshows, participation in conferences and additional dialogue with key investor representatives held in the intervening periods. Faron recognises the Annual General Meeting as an opportunity to meet shareholders.

As an AIM company, Faron complies with the AIM Rules for Companies, the Market Abuse Regulation and other relevant legislation in all its corporate communications issues. The Company announcements are published via Regulatory Information Service providers.

The Company speaks to the financial community and shareholders only through authorised representatives. The Chief Executive Officer is the designated person to make public statements. The Chief Executive Officer may delegate this authority to other members of the management team.

### The contact details are below:

Faron  
email: investor.relations@faron.com

### Media and investor relations:

Consilium Strategic Communications  
email: faron@consilium-comms.com

## Share Dealing

The Company has established a share dealing code appropriate to an AIM-listed company, and all the Directors of the Company understand the importance of compliance to that code.

## Ethical Values and Corporate Culture

Faron is strongly committed to conducting its business affairs with honesty and integrity and in full compliance with all applicable laws, rules and regulations. The Company requires that all employees and Directors comply with all laws, rules and regulations applicable to the Company wherever it does business.

Employees and Directors should endeavour to deal honestly, ethically and fairly with the Company's collaborators, licensors, licensees, business partners, suppliers, customers, competitors and employees. Statements regarding the Company's therapies and services must not be untrue, misleading, deceptive or fraudulent.

Employees and Directors act in the best interests of the Company and use the Company's assets and services solely for legitimate business purposes of the Company and not for any personal benefit or the personal benefit of anyone else.

## Risk management and Internal control

The principal risks and uncertainties identified by the Board are set out on pages 21 to 23 of the 2018 Annual Report. The Board has put in place internal controls and systems which are designed to manage rather than eliminate risk and provide reasonable but not absolute assurance against material misstatement or loss. A key element of delivering the Company's strategy and managing the risks facing the Company is the employment of a skilled workforce and use of appropriate third parties. The Board reviews the risks and uncertainties facing the Company and the effectiveness of its systems annually.

At present the Company does not consider it necessary to have an internal audit function due to the small size of the administrative function and the frequent interaction with the auditors and the supervision of the audit Committee. The Board is, however, following closely both regulatory and operational developments in this realm and plans to react appropriately if and to the extent considered necessary.

There is a monthly review and authorisation of transactions by the Chief Financial Officer and Chief Executive Officer. A comprehensive budgeting process is completed once a year and is reviewed and approved by the Board. The Company's results, compared with the budget, are reported to the Board on regular basis and discussed in detail.

The Company maintains appropriate insurance cover in respect of actions taken against the Directors because of their roles, as well as against material loss or claims against the Company. The insured values and type of cover are comprehensively reviewed on a periodic basis.

## Corporate Social Responsibility

Faron acknowledges that running its business has an effect on society. In particular, the Company has a responsibility to the patients, our employees and contractors as well as the broader community in which we operate.

We are committed to taking responsibility for our actions and encourage a positive contribution towards improving standards for patients and our employees, minimising our impact on the environment and improving the quality of the local community.

We are committed to maintaining and promoting high standards of business integrity. Company values, which incorporate the principles of corporate social responsibility and sustainability, guide our relationships with clients, employees and the communities and environment in which we operate. Faron's approach to sustainability addresses both our environmental and social impacts, supporting our vision to remain an employer of choice, while meeting client demands for socially responsible partners. We respect local laws and customs while supporting international laws and regulations.

By putting CSR into practice, we are committed, wherever possible, to:

- developing treatments for medical conditions with significant unmet needs
- conducting ourselves responsibly and in an ethical manner
- creating a positive and supportive working environment
- acting fairly in our dealings with suppliers and other third parties
- minimising the impact on our environment

## Our CSR principles

### Conduct

We aim to adopt the highest professional standards and not to act in such a way as to compromise Faron's integrity. We actively promote respect between our staff members in their dealings with each other and with suppliers and other third parties.

### Working environment

We recognise that our staff are our most important resource. We actively seek to offer our staff a positive and healthy working environment and ensure that they have rewarding careers and job satisfaction.

We seek to ensure that all staff have access to the training they need both for their own development and to enable them to deliver a high-quality work contribution.

We consider all staff members to be equal and we aim to create a working environment which is free of unlawful discrimination. In this regard, we maintain an internal code of conduct based on professionalism and respect.

### Suppliers

We are committed to eliminating unlawful discrimination and to promoting equality and diversity in our professional dealings with suppliers and other third parties. We endeavour to enter into clear and fair contracts with our suppliers.

### Environment

We are committed to behaving responsibly and to minimising our impact on the environment. In considering the environment, we have resolved to include environmental considerations in our business travel and to minimise our consumption of natural resources and manage waste through responsible disposal and reuse and recycling, including paper and ink cartridges.

### Responsibility and review

The Board has overall responsibility for our CSR strategy and for implementing our CSR principles. They have a key role in ensuring the systems and controls we have in place are effective. All members of staff have a role to play in complying with our CSR objectives and are encouraged to make further suggestions in relation to initiatives we could undertake.

We are fully committed to the highest possible standards of openness, honesty and accountability. In line with that commitment, we actively encourage all staff members who have serious concerns about any real or perceived departure from the high ethical standard that we set to voice those concerns openly.



## Statement of Responsibilities

Under the Finnish Limited Liability Companies Act and the Finnish Accounting Act the Company must prepare an Annual Report and financial statements in accordance with applicable law and regulations.

The Board of Directors and the CEO are responsible for the preparation of financial statements that give a true and fair view in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU, as well as for the preparation of financial statements and the report of the Board of Directors that give a true and fair view in accordance with the laws and regulations governing the preparation of the financial statements and the report of the Board of Directors in Finland. The Board of Directors is responsible for the appropriate arrangement of the control of the Company's accounts and finances, and the CEO shall see to it that the accounts of the Company are in compliance with the law and that its financial affairs have been arranged in a reliable manner. In accordance with the rules of the London Stock Exchange for companies trading securities on the Alternative Investment Market, the Company is also required to prepare annual accounts and financial statements under IFRS.

In preparing these financial statements, the Board of Directors is required to:

- select suitable accounting policies and then apply them consistently;
- make judgements and accounting estimates that are reasonable and prudent;
- state whether they have been prepared in accordance with IFRS as adopted by the European Union, subject to any material departures disclosed and explained in the financial statements;
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Company will continue in business.

The Board of Directors and the CEO are responsible for keeping adequate accounting records that are sufficient to show and explain the Company's transactions and disclose with reasonable accuracy at any time the financial position of the Company and enable them to ensure that the financial statement comply with the requirements of the Finnish Accounting Act. They are also responsible for safeguarding the assets of the Company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

## Website publication

The Directors are responsible for ensuring that the annual report and the financial statements are made available on a website. Financial statements are published on the Company's website in accordance with the AIM rule 26 and the recommendations of the QCA's Corporate Governance Code for Small and Medium Sized Companies.

On behalf of the Board



**Frank Armstrong**

Chairman

3 May 2019

## CORPORATE GOVERNANCE

# Directors' Report

For the year ended 31 December 2018.

The Directors present their report together with the audited financial statements for the year ended 31 December 2018.

## Directors

During the year ended 31 December 2018 following persons have been members of Board of Directors of the Company:

### Executive

Dr Markku Jalkanen, PhD, Chief Executive Officer

Mr Yrjö Wichmann, MSc, Chief Financial Officer

### Non-Executive

Dr Frank Armstrong, FRCPE, FFPM, Chairman

Mr Matti Manner, LL.M, Vice-chairman

Dr Jonathan Knowles, PhD, Non-Executive Director\*

Dr Huaizheng Peng, MD, PhD, Non-Executive Director\*

Mr Leopoldo Zambelletti, Non-Executive Director

Mr John Poulos, Non-Executive Director

Dr Gregory B. Brown, Non-Executive Director

\*resigned from Board on 12 September 2018

## Principal risks and uncertainties

For a discussion of the principal risks and uncertainties which face Faron please see pages 21 to 23 Risks and uncertainties.

## Results and dividends

The Consolidated Statement of Comprehensive Income for the year is set out on here.

The Company's loss of the financial year after taxation and other comprehensive losses was € 20.1 million (2017: € 21.1 million).

The Company has no distributable equity and thus the Directors do not recommend the payment of a dividend (2017: nil).

## Financial information

The Company produces budgets and cash flow projections on an annual basis for approval by the Board. These are reviewed during the year and updated if needed to reflect any changes in the business. Detailed management accounts are produced on a monthly basis, with all significant variances investigated promptly. The management accounts are reviewed and commented on by the Board at Board meetings and are reviewed and reported to the Directors on a monthly basis by the management team.

## Financial Key Performance Indicators (KPIs)

For a review of the Group's KPIs please see page 18 Financial Review.

## Research and development

Details of Company's key research and development programs can be found in the Strategic Report and the detailed program sections. See also notes 2.8 and 6. Further information is also available on the Company website, [www.faron.com](http://www.faron.com).

## Post balance sheet events

In January 2019, the Company received the fourth and last instalment of the Clevegen Tekes R&D loan of € 307 thousand.

In March 2019, the Company raised net proceeds of approximately € 2,900 thousand through a directed share issue and at 31 March 2019 it had € 4,877 thousand cash and equity of € 731 thousand.

## Financial instruments and management of liquid resources

The Company's principal financial instrument comprises cash, and this is used to finance Company's operations. The Company has also other financial instruments such as leasing facilities that arise directly from its operations.

The Company has a policy, which has been consistently followed, of not trading in financial instruments and to minimize currency exposure by actively matching currency expenses and income to the extent possible. The Company's cash is held on bank accounts in reputable bank in Finland. The Group's treasury policy is reviewed annually. See note 2.16 'Financial assets', note 19 'Financial assets and liabilities' and note 20, 'Financial risk management' in the notes to the Financial Statements for IFRS disclosure regarding financial instruments.

## Substantial shareholdings

On 31 December 2018 the Company had been notified of the following holdings of more than 3% or more of the issued share capital of the Company.

A&B (HK) Company Limited	3,408,409	10.98%
Marko Salmi	3,093,439	9.97%
Markku Jalkanen*	2,909,390	9.38%
Tom-Erik Lind	2,813,835	9.07%
Hargreaves Lansdown Asset Mgt	1,860,876	6.00%
Timo Syrjälä**	1,460,830	4.71%
Aviva Investors	1,339,008	4.32%
Juho Jalkanen***	1,094,570	3.53%

\* of which, 1,806,890 are held by Markku Jalkanen directly, and 1,078,500 are held by Markku Jalkanen's wife being Sirpa Jalkanen and her related party.

\*\* of which, 550,830 are held directly by Timo Syrjälä and 910,000 are held by Acme Investments SPF S.à.r.l., an entity which is wholly owned by Timo Syrjälä.

\*\*\* Held by Juho Jalkanen and related parties.

## Annual General Meeting

The AGM will be held in 28 May 2019 and further details will be provided to shareholders in advance of the meeting.

## Independent auditors

PricewaterhouseCoopers have expressed their willingness to continue in office as auditors for the year. A resolution to reappoint them will be proposed at the forthcoming AGM.

## Disclosure and information to auditors

Each of the current Directors hereby confirms that:

- So far as he is aware, there is no relevant audit information of which the auditors are unaware; and
- He has taken all reasonable steps to ascertain any relevant audit information and to ensure that the auditors are aware of such information

On behalf of the Board



**Frank M Armstrong**  
Chairman  
3 May 2019

## FINANCIAL STATEMENTS

## Statement of comprehensive income

For the year ended 31 December

€'000	Note	Group		Parent	
		2018	2017	2018	2017
<b>Revenue</b>	3, 4	19	-	19	-
Other operating income	5	205	1,495	205	1,495
Research and development expenses	6, 7, 8	(16,463)	(19,100)	(16,463)	(19,100)
General and administrative expenses	7, 8	(3,750)	(3,054)	(3,740)	(3,054)
<b>Operating loss</b>		<b>(19,989)</b>	<b>(20,659)</b>	<b>(19,979)</b>	<b>(20,659)</b>
Financial expense	9	(397)	(408)	(397)	(408)
Financial income	9	302	7	302	7
<b>Loss before tax</b>		<b>(20,084)</b>	<b>(21,060)</b>	<b>(20,074)</b>	<b>(20,074)</b>
Tax expense	10	(2)	(1)	(2)	(1)
<b>Loss for the period</b>		<b>(20,086)</b>	<b>(21,061)</b>	<b>(20,076)</b>	<b>(21,061)</b>
Other comprehensive income		-	-	-	-
<b>Total comprehensive loss for the period</b>		<b>(20,086)</b>	<b>(21,061)</b>	<b>(19,409)</b>	<b>(20,076)</b>
<b>Loss per ordinary share</b>					
Basic and diluted loss per share, EUR	11	(0.65)	(0.76)	(0.65)	(0.76)

## FINANCIAL STATEMENTS

## Balance sheet

As at 31 December

€'000	Note	Group		Parent	
		2018	2017	2018	2017
<b>Assets</b>					
<b>Non-current assets</b>					
Machinery and equipment	12	17	22	17	22
Subsidiary shares	1,23	-	-	18	-
Intangible assets	12	525	325	525	325
Prepayments and other receivables	13	636	1,310	636	1,310
<b>Total non-current assets</b>		<b>1,177</b>	<b>1,657</b>	<b>1,195</b>	<b>1,657</b>
<b>Current assets</b>					
Prepayments and other receivables	15	2,759	3,920	2,759	3,920
Cash and cash equivalents	16	4,067	9,310	4,058	9,310
<b>Total current assets</b>		<b>6,825</b>	<b>13,230</b>	<b>6,817</b>	<b>13,230</b>
<b>Total assets</b>		<b>8,002</b>	<b>14,887</b>	<b>8,012</b>	<b>14,887</b>
<b>Equity and liabilities</b>					
<b>Capital and reserves attributable to the equity holders of the Company</b>					
Share capital		2,691	2,691	2,691	2,691
Reserve for invested unrestricted equity		64,464	48,576	64,464	48,576
Accumulated deficit		(66,786)	(46,524)	(66,775)	(46,524)
Translation difference		-	-	-	-
<b>Total equity</b>	17, 18	<b>369</b>	<b>4,743</b>	<b>380</b>	<b>4,743</b>
<b>Non-current liabilities</b>					
Borrowings	19	1,887	2,088	1,887	2,088
<b>Total non-current liabilities</b>		<b>1,887</b>	<b>2,088</b>	<b>1,887</b>	<b>2,088</b>
<b>Current liabilities</b>					
Borrowings	19	245	338	245	338
Trade payables	21	3,534	3,196	3,533	3,196
Other current liabilities	21	1,967	4,522	1,967	4,522
<b>Total current liabilities</b>		<b>5,745</b>	<b>8,056</b>	<b>5,744</b>	<b>8,056</b>
<b>Total liabilities</b>		<b>7,633</b>	<b>10,144</b>	<b>7,631</b>	<b>10,144</b>
<b>Total equity and liabilities</b>		<b>8,002</b>	<b>14,887</b>	<b>8,012</b>	<b>14,887</b>

## FINANCIAL STATEMENTS

## Parent Company Statement of changes in equity

€'000	Note	Share capital	Reserve for invested unrestricted equity	Accumulated deficit	Total equity
<b>Balance as at 31 December 2016</b>		<b>2,691</b>	<b>32,362</b>	<b>(26,652)</b>	<b>8,401</b>
Comprehensive loss for the period		-	-	(21,061)	(21,061)
<b>Transactions with equity holders of the Company</b>					
Issue of ordinary shares, net of transaction costs EUR 1,149 thousand	17	-	15,863	-	15,863
Share options exercised	17,18	-	97	-	97
Warrants exercised	17,18	-	254	-	254
Share-based compensation	7,18	-	-	1,189	1,189
		-	<b>16,214</b>	<b>1,189</b>	<b>17,403</b>
<b>Balance as at 31 December 2017</b>		<b>2,691</b>	<b>48,576</b>	<b>(46,524)</b>	<b>4,743</b>
Comprehensive loss for the period		-	-	(20,076)	(20,076)
<b>Transactions with equity holders of the Company</b>					
Issue of ordinary shares, net of transaction costs EUR 1,149 thousand	17	-	15,888	-	15,888
Share-based compensation	7,18	-	-	(176)	(176)
		-	<b>15,888</b>	<b>(176)</b>	<b>15,712</b>
<b>Balance as at 31 December 2018</b>		<b>2,691</b>	<b>64,464</b>	<b>(66,775)</b>	<b>380</b>

## FINANCIAL STATEMENTS

## Group Statement of changes in equity

€'000	Note	Share capital	Reserve for invested unrestricted equity	Translation difference	Accumulated deficit	Total equity
<b>Balance as at 31 December 2016</b>		<b>2,691</b>	<b>32,362</b>	-	<b>(26,652)</b>	<b>8,401</b>
Comprehensive loss for the period		-	-	-	(21,061)	(21,061)
<b>Transactions with equity holders of the Company</b>						
Issue of ordinary shares, net of transaction costs EUR 1,149 thousand	17	-	15,863	-	-	15,863
Share options exercised	17,18	-	97	-	-	97
Warrants exercised	17,18	-	254	-	-	254
Share-based compensation	17,18	-	-	-	1,189	1,189
		-	<b>16,214</b>	-	<b>1,189</b>	<b>17,403</b>
<b>Balance as at 31 December 2017</b>		<b>2,691</b>	<b>48,576</b>	-	<b>(46,524)</b>	<b>4,743</b>
Comprehensive loss for the period		-	-	-	(20,086)	(20,086)
<b>Transactions with equity holders of the Company</b>						
Issue of ordinary shares, net of transaction costs EUR 1,149 thousand	17	-	15,888	-	-	15,888
Share-based compensation	17,18	-	-	-	(176)	(176)
		-	<b>15,888</b>	-	<b>(176)</b>	<b>15,712</b>
<b>Balance as at 31 December 2018</b>		<b>2,691</b>	<b>64,464</b>	-	<b>(66,786)</b>	<b>369</b>

## FINANCIAL STATEMENTS

## Statement of cash flows

As at 31 December

€'000	Note	Group		Parent	
		2018	2017	2018	2017
<b>Cash flow from operating activities</b>					
Loss before tax		(20,084)	(21,060)	(20,074)	(21,060)
Adjustments for:					
Depreciation and amortisation	8	100	76	100	76
Interest expense	9	121	75	121	75
Unrealised foreign exchange loss (gain), net	9	(36)	290	(36)	290
Share-based compensation	18	(176)	1,189	(176)	1,189
Adjusted loss from operations before changes in working capital		(20,075)	(19,430)	(20,065)	(19,430)
Change in net working capital:					
Prepayments and other receivables		1,836	(1,286)	1,836	(1,286)
Trade payables		338	1,175	337	1,175
Other liabilities		(2,595)	1,189	(2,595)	1,189
Cash used in operations		(20,496)	(18,352)	(20,487)	(18,352)
Taxes paid	10	(2)	(1)	(2)	(1)
Interest paid	9	(27)	(10)	(27)	(10)
<b>Net cash used in operating activities</b>		<b>(20,525)</b>	<b>(18,363)</b>	<b>(20,516)</b>	<b>(18,363)</b>
<b>Cash flow from investing activities</b>					
Payments for acquisition of shares in subsidiaries	1,23	-	-	(18)	-
Payments for intangible assets	12	(293)	(90)	(293)	(90)
Payments for equipment	12	(2)	(8)	(2)	(8)
<b>Net cash used in investing activities</b>		<b>(295)</b>	<b>(98)</b>	<b>(313)</b>	<b>(98)</b>
<b>Cash flow from financing activities</b>					
Proceeds from issue of shares	17	17,023	17,362	17,023	17,362
Share issue transaction cost	17	(1,135)	(1,148)	(1,135)	(1,148)
Proceeds from borrowings		-	453	-	453
Repayment of borrowings	20	(347)	(84)	(347)	(84)
<b>Net cash from financing activities</b>		<b>15,541</b>	<b>16,583</b>	<b>15,541</b>	<b>16,583</b>
<b>Net increase (+) / decrease (-) in cash and cash equivalents</b>		<b>(5,279)</b>	<b>(1,878)</b>	<b>(5,288)</b>	<b>(1,878)</b>
Effect of exchange rate changes on cash and cash equivalents		36	(290)	36	(290)
Cash and cash equivalents at 1 January	16	9,310	11,478	9,310	11,478
<b>Cash and cash equivalents at 31 December</b>	<b>16</b>	<b>4,067</b>	<b>9,310</b>	<b>4,058</b>	<b>9,310</b>



## FINANCIAL STATEMENTS

# Notes to the financial statements

## 1. Corporate information

Faron Pharmaceuticals Ltd. (the "Company") is a clinical stage biopharmaceutical company incorporated and domiciled in Finland, with its headquarters at Joukahaisenkatu 6 B, 20520 Turku, Finland. The Company has two major drug development projects focusing on acute trauma, cancer growth and spread and inflammatory diseases. During the first quarter 2018, Faron Pharmaceuticals Ltd has registered subsidiaries in the United States of America and in Switzerland.

The Company is listed on the London Stock Exchange's AIM market since 17 November 2015, with a ticker FARN.

The Board of Directors of the Company approved the financial statements on 3 May 2019.

## 2. Summary of significant accounting policies

### 2.1. Basis of preparation

The financial statements have been prepared in accordance with the International Financial Reporting Standards of the International Accounting Standards Board (IASB) and as adopted by the European Union (IFRS) 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. The areas of the financial statements involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the financial statements are disclosed in note 2.21.

The Consolidated Financial Statements incorporate the parent company, Faron Pharmaceuticals Ltd, and all subsidiaries in which it holds over 50% of the voting rights. The subsidiaries established during the financial period are consolidated from the date that control was obtained by the Group.

The subsidiaries are consolidated by using the purchase method. All intragroup transactions, receivables, liabilities and unrealized gains are eliminated in the Consolidated Financial Statements. Faron Pharmaceuticals Ltd holds 100% ownership of all its subsidiaries.

The Consolidated Financial Statements are presented in euro which is the functional currency of the parent company. The statements of comprehensive income and statements of cash flows of foreign subsidiaries, whose functional currency is not euro, are translated into euro each month at the average monthly exchange rates, while the statements of financial position of such subsidiaries are translated at the exchange rate prevailing at the reporting date. Translation differences resulting from the translation of profit for the period and other items of comprehensive income in the statement of comprehensive income and statement of financial position are recognized as a separate component in equity and in other comprehensive income. Also, the translation differences arising from the application of the purchase method and from the translation of equity items cumulated subsequent to acquisition are recognized in other comprehensive income.

During the financial year 2018 the impact of subsidiaries is rather moderate and therefore all figures stated in notes are parent company figures if not else stated.

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

### 2.2. Going concern

As part of their going concern review the Directors have followed the Finnish Limited Liability Companies Act, the Finnish Accounting Act and the guidelines published by the Financial Reporting Council entitled "Guidance on the Going Concern Basis of Accounting and Reporting on Solvency Risks – Guidance for directors of companies that do not apply the UK Corporate Governance Code".

The Group and Parent Company are subject to a number of risks similar to those of other development stage pharmaceutical companies. These risks include, amongst others, generation of revenues in due course from the development portfolio and risks associated with research, development, testing and obtaining related regulatory approvals of its pipeline products. Ultimately, the attainment of profitable operations is dependent on future uncertain events which include

obtaining adequate financing to fulfil the Group's commercial and development activities and generating a level of revenue adequate to support the Group's cost structure.

The Group made a net loss of EUR 20,086 thousand during the year ended 31 December 2018. It had total equity of EUR 369 thousand including an accumulated deficit of EUR 66,786 thousand. As at that date, the Group had cash and cash equivalents of EUR 4,067 thousand. In March 2019, the Company raised net proceeds of approximately EUR 2,900 thousand through a directed share issue and at 31 March 2019 it had EUR 4,877 thousand cash and an unaudited equity of EUR 731 thousand.

The Directors have prepared detailed financial forecasts and cash flows looking beyond 12 months from the date of these financial statements. In developing these forecasts, the Directors have made assumptions based upon their view of the current and future economic conditions that are expected to prevail over the forecast period. The Directors estimate that the cash held by the Group together with known receivables will be sufficient to support the current level of activities into the third quarter of 2019. The Directors are continuing to explore sources of finance available to the Group and based upon initial discussions with a number of existing and potential investors they have a reasonable expectation that they will be able to secure sufficient cash inflows for the Group to continue its activities for not less than 12 months from the date of approval of these financial statements; they have therefore prepared the financial statements on a going concern basis.

Because the additional finance is not committed at the date of approval of these financial statements, these circumstances represent material uncertainty that may cast significant doubt on the Company's ability to continue as going concern. Should the Group be unable to obtain further finance such that the going concern basis of preparation were no longer appropriate, adjustments would be required including to reduce balance sheet values of assets to their recoverable amounts, to provide for further liabilities that might arise.

## 2.3. Foreign currency transactions and balances

### *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.

## 2.4. Segment reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision maker. The Chief Executive Officer, reviewing the operating results regularly to make decisions about the allocation of resources and to assess overall performance, is identified as the chief operating decision maker. The Chief Executive Officer manages the Company as one integrated business and hence, the Company has one operating and reportable segment.

## 2.5. Revenue recognition

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 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 associated with a license, the Company applies the IFRS 15 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.

For further information on revenue recognition, see notes 2.21 and 3.

## 2.6. 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 fair value of the loan and the proceeds received.

## 2.7. 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 2018, 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. The uncertainties inherent in developing pharmaceutical products prohibits the capitalization of internal development expenses as an intangible asset until the marketing approval has been received from the relevant regulatory agencies.

## 2.8. Employee benefits

The Company's employee benefits consist of short-term employee benefits, post-employment benefits (defined contribution pension plans) and share-based compensation. Short-term employee benefits are charged to the statement of comprehensive income in the year in which the related service is provided. Under defined contribution plans, the Company's contributions are recorded as an expense in the accounting period to which they relate and the Company does not have any further obligations once the contributions have been paid.

## 2.9. 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.

## 2.10. 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.

Since the Company has reported losses, inclusion of unexercised options and warrants would decrease the loss per share and therefore not taken into account in diluted loss per share calculation.

## 2.11. Income tax

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.

## 2.12. Machinery and equipment

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.

## 2.13. Intangible assets

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.

## 2.14. Impairment of non-financial assets

Assets that are subject to depreciation or amortisation are reviewed for impairment whenever there are indications that the carrying amount may not be recoverable.

An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. The value in use represents the discounted future net cash flows expected to be derived from the asset.

## 2.15. 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.

## 2.16. Financial assets

The Company's financial assets comprise of other receivables and cash and cash equivalents, which are all classified to the category "financial assets measured at amortised cost". These 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.

## 2.17. Financial liabilities

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.

## 2.18. Equity

The Company's equity comprises of share capital, reserve for invested unrestricted equity and accumulated deficit. The proceeds from issuance of new ordinary shares, less incremental costs directly attributable to the issue, are credited to the reserve for invested unrestricted equity, in accordance with the terms and conditions of the share issue.

The accumulated deficit comprises of the accumulated profits and losses of the Company since the inception.

## 2.19. Leases

### *The Company as lessee*

Leases of equipment, where substantially all the risks and rewards of ownership, are classified as finance leases. Assets leased under finance leases are capitalized at the inception of the lease at the lower of the fair value of the leased property and the present value of the minimum lease payments. Lease obligations are included in current and non-current financial liabilities based on their maturity, net of finance charges. The

interest element of the payments is expensed. An asset recognised under a finance lease is depreciated over its useful life. The Company has no finance leases.

Leases where a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments made under operating leases are charged to the income statement on a straight-line basis over the lease term.

In January 2016, the IASB published IFRS 16, Leases, its new leasing standard. As a result of the new standard, the Company has reviewed all of the group's leasing arrangements over the last year. The Company applies the simplified transition approach and will not restate comparative amounts for the year prior to first adoption. All lease arrangements are both short-term and low value leases. See note 2.23.

## 2.20. Provisions and contingent liabilities

Provisions are recognised when the Company has a present legal or constructive obligation as a result of past events, it is probable that an outflow of resources will be required to settle the obligation, and a reliable estimate of the amount can be made. The Company does not have provisions at the end of the reporting periods presented in these financial statements.

A contingent liability is a possible obligation that arises from past events and whose existence will be confirmed only by the occurrence of uncertain future events not wholly within the control of the entity. Such present obligation that probably does not require settlement of a payment obligation and the amount of which cannot be reliably measured is also considered to be a contingent liability. Contingent liabilities are disclosed in the notes to the financial statements.

## 2.21. 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 licensee's 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. Further details of the Company's estimation of share-based compensation are disclosed in note 18.

### 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.

## 2.22. New and amended standards and interpretations adopted by the Company

- In July 2014, the IASB published the final version of IFRS 9, *Financial Instruments*, which reflects all phases of the financial instruments project and replaces IAS 39, *Financial Instruments: Recognition and Measurement*, and all previous versions of IFRS 9, *Financial Instruments*. IFRS 9 addresses the classification, measurement and derecognition of financial assets and financial liabilities, introduces new rules for hedge accounting and a new impairment model for financial assets. IFRS 9 is effective for annual periods beginning on or after 1 January 2018, with early application permitted. The Company has applied IFRS 9 retrospectively

as required by the standard, but has not restated comparative financial information. Upon adoption on 1 January 2018, IFRS 9, *Financial Instruments* did not have an impact on the financial statements, as the most significant financial instrument the Company holds is cash and cash equivalents and the standard will not materially impact the classification or measurement of cash and cash equivalents.

- In June 2016, the IASB issued three amendments to IFRS 2, *Share-based Payment*, in relation to the classification and measurement share-based compensation transactions. The amendments clarify how to account for certain types of share-based payment transactions and provide requirements on the accounting for:
  - o The effects of vesting and non-vesting conditions on the measurement of cash-settled share-based payments;
  - o Share-based payment transactions with a net settlement feature for withholding tax obligations; and
  - o A modification to the terms and conditions of a share-based payment that changes the classification of the transaction from cash-settled to equity-settled

The adaptation of the amendments to IFRS 2, *Share-based Payment*, had no material impact on the Company's financial statements

## 2.23. New standards and interpretations issued not yet effective

- In January 2016, the IASB published IFRS 16, *Leases*, its new leasing standard, which will replace the current guidance in IAS 17, *Leases*, and related interpretations IFRIC 4, SIC-15 and SIC-27. The new standard will result in almost all leases being recognised on the balance sheet, as the distinction between operating and finance leases is removed. Under the new standard, an asset (the right to use the leased item) and a financial liability to pay rentals are recognised. The only exceptions are short-term and low-value leases. The standard applies to annual periods beginning on or after 1 January 2019, with earlier application permitted. As a result of the new standard, the Company has reviewed all of the group's leasing arrangements over the last year. The Company applies the simplified transition approach and will not restate comparative amounts for the year prior to first adoption. All lease arrangements are both short-term and low value leases.

The amendments are effective for accounting periods beginning on or after 1 January 2018. The amendments are required to be applied without restating prior periods, but retrospective application is permitted if elected for all three amendments and other criteria are met.

There are no other IFRS or IFRIC interpretations that are not effective that are expected to have a material impact on the Company.

### 3. Revenue

The Company has entered into exclusive license agreements with Maruishi in Japan, with A&B in Greater China and with Pharmbio in the Republic of Korea for the development, commercialization and supply of Traumakine and is entitled to related milestone payments. The Company retains rights to Traumakine in the rest of the world. The license partners are responsible for all regulatory activities and needed clinical activities necessary for commercialization in respective territories. Under the license agreements, the Company is also entitled to receive royalty payments based on the product sales in territories, but such royalties have not been earned or recognised to revenue during the periods presented.

#### *License agreement and supply agreement with Maruishi*

In 2011, the Company entered into a license agreement with Japanese license partner Maruishi. The Company has not recognised revenue for the Maruishi license agreement during the periods presented, but is entitled to receive additional payments upon achievement of certain development or commercial milestones.

In 2014, the Company entered into a separate supply agreement with Maruishi for the delivery of investigational medicinal products to be used in territory-specific clinical studies. In 2018 the Company recognised EUR 19 thousand revenue from deliveries based on this agreement.

#### *License agreement with Pharmbio*

In 2016, the Company entered into license agreement with Korean license partner Pharmbio and met the upfront at signing. In this connection the Company satisfied the performance obligation for the grant of the license and use of its IP and recognised revenue in the amount of EUR 750 thousand. The Company is entitled to receive additional milestone payments from Pharmbio only if certain development or commercial milestones are achieved.

### 4. Segment reporting

The Company is a late clinical stage drug discovery and development company. Its operations have been focused on the development of its main drug candidates Traumakine and Clevegen. The Company's chief operating decision maker has been identified as the Chief Executive Officer (CEO).

The CEO manages the Company as one integrated business and hence the Company has one operating and reportable segment.

The Company had EUR 19 thousand revenue in 2018 (nil in 2017).

All of the Company's non-current assets are located in Finland.

### 5. Other operating income

€'000	Year ended 31 December	
	2018	2017
Grants from the European Union	191	1,063
Other income	14	-
Grant component of government loans	-	432
<b>Total operating income</b>	<b>205</b>	<b>1,495</b>

Grants from the European Union comprise of direct funding from the European Commission under the Seventh Framework Programme (FP7) 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. The project funded with the FP7 -funding ended in 2H2018.

## 6. Breakdown of expenses by function

### Research and development expenses

€'000	Year ended 31 December	
	2018	2017
Outsourced clinical trials services	(5,250)	(9,392)
Materials and services	(7,311)	(4,727)
Employee benefits	(1,820)	(2,704)
Other R&D costs	(1,652)	(1,315)
Inventory write-down	(338)	(893)
Depreciation and amortization	(92)	(69)
<b>Total research and development expenses</b>	<b>(16,463)</b>	<b>(19,100)</b>

### General and administration expenses

€'000	Year ended 31 December	
	2018	2017
Internal financial and reporting process development	(1,358)	(165)
Employee benefits	(1,330)	(1,665)
Other G&A costs	(907)	(849)
Communication	(137)	(368)
Depreciation and amortization	(8)	(7)
<b>Total general and administrative expenses</b>	<b>(3,740)</b>	<b>(3,054)</b>

## 7. Employee benefits

€'000	Year ended 31 December	
	2018	2017
Salaries	(2,816)	(2,713)
Pension expenses – contribution-based plans	(513)	(360)
Social security contributions	3	(107)
Share-based compensation	176	(1,189)
<b>Total employee benefit expenses</b>	<b>(3,150)</b>	<b>(4,369)</b>
<b>Employee benefit expenses by function</b>		
Research and development expenses	(1,820)	(2,704)
General and administrative expenses	(1,330)	(1,665)
<b>Total employee benefit expenses</b>	<b>(3,150)</b>	<b>(4,369)</b>

The average number of personnel in 2018 was 25 (2017: 18). Share-based compensation information is included in note 18 and management remuneration information in note 23.



## 8. Depreciation and amortisation

€'000	Year ended 31 December	
	2018	2017
<b>Depreciation and amortisation by type of asset</b>		
Intangible assets - patents	(92)	(69)
Intangible assets	(1)	-
Machinery and equipment	(7)	(7)
<b>Total depreciation and amortisation</b>	<b>(100)</b>	<b>(76)</b>
<b>Depreciation and amortisation by function</b>		
Research and development expenses	(92)	(69)
General and administrative expenses	(8)	(7)
<b>Total depreciation and amortisation</b>	<b>(100)</b>	<b>(76)</b>

## 9. Financial income and expenses

€'000	Year ended 31 December	
	2018	2017
<b>Financial income</b>		
Interest income	-	-
Gains from foreign exchange	302	7
<b>Total financial income</b>	<b>302</b>	<b>7</b>
<b>Financial expenses</b>		
Interest expenses	(121)	(75)
Losses from foreign exchange	(274)	(332)
Other financial expenses	(2)	(1)
<b>Total financial expenses</b>	<b>(397)</b>	<b>(408)</b>
<b>Total financial income and expenses, net</b>	<b>(95)</b>	<b>(401)</b>

Interest expenses consist of paid and accrued interest expenses. The accrued interest expense relates mainly to the government loans (note 19).

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

Unrealised foreign exchange loss is EUR 36 thousand and gain is EUR 290 thousand for the years ended 31 December 2018 and 2017, respectively.

## 10. Tax expense

€'000	Year ended 31 December	
	2018	2017
Tax expense	(2)	(1)
<b>Total tax expense</b>	<b>(2)</b>	<b>(1)</b>

Income tax consists of foreign corporation tax.

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:

€'000	Year ended 31 December	
	2018	2017
Loss before tax	(20,074)	(21,060)
Income tax calculated at Finnish tax rate 20%	4,015	4,212
Tax losses and temporary differences for which no deferred tax asset is recognised	(4,266)	(3,974)
Non-deductible expenses and tax exempt income	(251)	(238)
Non-credited foreign withholding taxes	(2)	(1)
<b>Taxes in the statement of comprehensive income</b>	<b>(2)</b>	<b>(1)</b>

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

€'000	Year ended 31 December	
	2018	2017
R&D expenses not yet deducted in taxation <sup>(1)</sup>	49,063	16,893
Tax losses carried forward <sup>(2)</sup>	11,151	25,862
Deferred tax depreciation on fixed assets	-	1,628
<b>Total</b>	<b>60,214</b>	<b>44,383</b>

1) The Company has incurred research and development costs, 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	Year ended 31 December	
	2018	2017
Expiry within five years	1,164	3,164
Expiry within 6-10 years	9,987	22,698
<b>Total</b>	<b>11,151</b>	<b>25,862</b>

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 12,043 thousand (2017: EUR 8,877 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.

## 11. Loss per share

Loss per share is calculated by dividing the net loss by the weighted average number of ordinary shares in issue during the year.

€'000	Year ended 31 December	
	2018	2017
Loss for the period	(20,076)	(21,061)
Weighted average number of ordinary shares in issue	<b>30,749,648</b>	<b>27,887,901</b>
<b>Basic and dilutive loss per share (in €)</b>	<b>(0.65)</b>	<b>(0.76)</b>

As of 31 December 2018, the Company had only share options outstanding as the warrants were exercised during 2017. Number of potentially dilutive instruments currently outstanding totalled 1,540,900 as of 31 December 2018 (31 December 2017: 1,540,900). 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.

## 12. Intangible assets and machinery and equipment

€'000	Intangible assets	Machinery and equipment
<b>Book value 1 January 2018</b>	<b>325</b>	<b>22</b>
Additions	293	2
Disposals	-	-
Depreciation/amortisation	(93)	(7)
<b>Book value 31 December 2018</b>	<b>525</b>	<b>17</b>
<b>As at 31 December 2018</b>		
Acquisition cost	823	39
Accumulated disposals	-	-
Accumulated depreciation/amortisation	(298)	(22)
<b>Book value 31 December 2018</b>	<b>525</b>	<b>17</b>
<b>As at 31 December 2017</b>		
<b>Book value 1 January 2017</b>	<b>304</b>	<b>21</b>
Additions	90	8
Depreciation/amortisation	(69)	(7)
<b>Book value 31 December 2017</b>	<b>325</b>	<b>22</b>
<b>As at 31 December 2017</b>		
Acquisition cost	530	36
Accumulated depreciation/amortisation	(205)	(14)
<b>Book value 31 December 2017</b>	<b>325</b>	<b>22</b>

### 13. Non-current prepayments and other receivables

€'000	As at 31 December	
	2018	2017
Prepayments for API	524	1,192
Production supplies	76	86
Other receivables	36	32
<b>Total non-current prepayments and other receivables</b>	<b>636</b>	<b>1,310</b>

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.

### 14. Inventories

€'000	As at 31 December	
	2018	2017
Work in process	1,231	893
Write-down of inventory	(1,231)	(893)
<b>Total inventories</b>	<b>-</b>	<b>-</b>

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 1,231 thousand (2017 EUR 893 thousand). These were recognised as research and development expenses. The Company has not reversed any previous inventory write-downs.

### 15. Current prepayments and other receivables

€'000	As at 31 December	
	2018	2017
Prepayments	1,814	1,594
Receivable for production defects	434	434
VAT receivable	349	404
Other receivables	162	425
Grant receivable	-	1,063
<b>Total current prepayments and other receivables</b>	<b>2,759</b>	<b>3,920</b>

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. The grant receivables were nil at 31 December 2018 as the FP7-project ended during 2H2018.

## 16. Cash and cash equivalents

As at 31 December

€'000	Group		Parent	
	2018	2017	2018	2017
Bank accounts	4,067	9,310	4,058	9,310
<b>Total cash and cash equivalents</b>	<b>4,067</b>	<b>9,310</b>	<b>4,058</b>	<b>9,310</b>

## 17. Shareholders' equity equivalents

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
<b>1 January 2017</b>	<b>26,311,704</b>	<b>2,691</b>	<b>32,362</b>
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
<b>31 December 2017</b>	<b>29,164,544</b>	<b>2,691</b>	<b>48,576</b>
<b>1 January 2018</b>	<b>29,164,544</b>	<b>2,691</b>	<b>48,576</b>
Issue of new shares, net of transaction costs	1,863,350	-	15,888
<b>31 December 2018</b>	<b>31,027,894</b>	<b>2,691</b>	<b>64,464</b>

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. On 19 February 2018, the number of shares was increased to 29,336,744 following the issue of 172,200 new shares, on 21 February 2018, the number of shares was increased to 30,094,744 following the issue of 758,000 new shares and on 26 February the number of shares was increased to 31,027,894 following the issue of 933,150 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. If the shares of a Finnish limited liability company have no par value according to its articles of association, the Finnish Limited Liability Companies Act allows companies the recognition of the proceeds from share issuance to the reserve for invested unrestricted equity. In such situations the board of a company can choose on a subscription by subscription basis, how much of the issue, if anything, is recorded in share capital and how much to the reserve for invested unrestricted equity that is distributable. During 2017 and 2018, the Board recognised all relevant transactions in the invested unrestricted equity reserve.

## 18. Share options and warrants

### 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 has been determined 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.

The estimated date of the allocation of D -options to the employees and key management will be 30 June 2019, which has been used in the option calculations.

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	1.09
Dividend adjustment	No	No	No	No
Beginning of subscription period	2 November 2015	8 October 2016	8 October 2017	8 October 2018
End of subscription period	20 September 2021	20 September 2021	20 September 2021	20 September 2021
Vesting conditions	Service until the beginning of the subscription period			

Number of share options	For the year ended 31 December 2018				For the year ended 31 December 2017			
	2015 Option Plan				2015 Option Plan			
	A	B	C	D	A	B	C	D
Outstanding at 1 January	385,000	385,900	500,000	270,000	400,000	400,000	250,000	250,000
Granted	-	-	-	-	-	-	250,000	20,000
Forfeited	-	-	-	-	-	-	-	-
Exercised	-	-	-	-	(15,000)	(14,100)	-	-
Outstanding at 31 December	385,000	385,900	500,000	270,000	385,000	385,900	500,000	270,000
Exercisable at 31 December	385,000	385,900	500,000	-	385,000	385,900	500,000	-
The weighted average fair value of the share options granted, EUR	-	-	-	-	-	-	3.23	0.53
The weighted average share price at the date of exercise, EUR	3.24	3.67	6.20	3.45	8.83	8.83	-	-

Determination of the fair value for the share options granted	2018		2017	
	2015 Option Plan		2015 Option Plan	
	C	D	C	D
Share price at grant date, EUR	4.51-9.39	0.62-4.96	4.51-9.39	9.21
Subscription price, EUR	4.51-8.39	1.09-4.96	4.51-8.39	9.21
Volatility, % (*)	42.59-52.57	55.60	42.59-52.57	42.59
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	0.11-1.25	1.42-4.01	2.87
Effect on earnings 2017, EUR thousand (**)	758	25	758	25
Effect on earnings 2018, EUR thousand	-	-	-	-

(\*) 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, turned positive of EUR 176 thousand in 2018 (negative EUR 1,189 thousand in 2017).

**Warrants**

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

Number of warrants	2018		2017	
	Warrants A	Warrants B	Warrants A	Warrants B
Outstanding at 1 January	-	-	109,800	41,600
Granted	-	-	-	-
Forfeited	-	-	-	-
Exercised	-	-	(109,800)	(41,600)
Outstanding at 31 December	-	-	-	-
Exercisable at 31 December	-	-	-	-
The weighted average share price at the date of exercise, EUR	-	-	8.72	8.72

As of 31 December 2018 there were no warrants as all of the warrants the Company had issued in 2015, were exercised during 2017.



## 19. Financial assets and liabilities

As at 31 December

€'000	Group		Parent	
	2018	2017	2018	2017
<b>Financial assets measured at amortised cost</b>				
Other receivables (*)	385	1,497	385	1,497
Cash and cash equivalents	4,067	9,310	4,058	9,310
Total financial assets measured at amortised cost	4,452	10,807	4,443	10,807
<b>Financial liabilities measured at amortised cost</b>				
Trade payables	3,534	3,196	3,533	3,196
Borrowings in form of Tekes R&D loans	2,132	2,426	2,132	2,426
Total financial liabilities measured at amortised cost	5,666	5,622	5,665	5,622

\*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 1,792 thousand (2017 EUR 2,139 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. For more information on contractual maturities of the Tekes R&D loans and interests is provided in the note 19. The accrued interest on Tekes R&D loans amounted to EUR 79 thousand (2017 EUR 65 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.

This section sets out an 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

€'000	Group		Parent	
	2018	2017	2018	2017
<b>Net debt</b>				
Cash and cash equivalents	4,067	9,310	4,058	9,310
Tekes R&D loans- repayable within one year	(245)	(338)	(245)	(338)
Tekes R&D loans- repayable after one year	(1,887)	(2,088)	(1,887)	(2,088)
<b>Net debt</b>	<b>1,935</b>	<b>6,884</b>	<b>1,926</b>	<b>6,884</b>

€'000	Group			Parent		
	Cash and cash equivalents	Borrowings	Total	Cash and cash equivalents	Borrowings	Total
<b>Net debt as at 1 Jan 2017</b>	<b>11,478</b>	<b>(2,176)</b>	<b>9,302</b>	<b>11,478</b>	<b>(2,176)</b>	<b>9,302</b>
Cash flows	(1,878)	(369)	(2,247)	(1,878)	(369)	(2,247)
Foreign exchange adj.	(290)	-	(290)	(290)	-	(290)
Other non-cash movements	-	119	119	-	119	119
<b>Net debt as at 31 Dec 2017</b>	<b>9,310</b>	<b>(2,426)</b>	<b>6,884</b>	<b>9,310</b>	<b>(2,426)</b>	<b>6,884</b>
<b>Cash flows</b>	<b>(5,279)</b>	<b>347</b>	<b>(4,933)</b>	<b>(5,288)</b>	<b>347</b>	<b>(4,941)</b>
<b>Foreign exchange adj.</b>	<b>36</b>	<b>-</b>	<b>36</b>	<b>36</b>	<b>-</b>	<b>36</b>
Other non-cash movements	-	(53)	(53)	-	(53)	(53)
<b>Net debt as at 31 Dec 2018</b>	<b>4,067</b>	<b>(2,132)</b>	<b>1,934</b>	<b>4,058</b>	<b>(2,132)</b>	<b>1,926</b>

## 20. Financial risk management

The operations of the Company expose it to financial risks. The main risk that the Company is exposed to is liquidity risk, with capital management being another important area given the nature of the Company's operations and its financing structure. The Company's risk management principles focus on obtaining funding and managing capital taking into consideration the unpredictability of the financial markets with the aim at minimizing any undesired impacts on the Company's financial performance and position. The Board of Directors define the general risk management principles and approve operational guidelines concerning specific areas including but not limited to liquidity risk, foreign exchange risk, interest rate risk, credit risk, the use of any derivatives and investment of the Company's liquid assets.

### (a) Capital management and liquidity risks

The Company's objective when managing capital is to safeguard the Company's ability to continue as a going concern (refer to notes 2.3 and 16).

Significant financial resources are required to advance the drug development programs into commercialized pharmaceutical products. The Company relies on its ability to fund the operations of the Company through three major sources of financing – equity financing, research and development grants and loans and licensing agreements.

The Company has been able to fund its operations with equity and R&D loans. While equity financing has been available in the past (the last such financing was a EUR 15.8 million share issue in February 2018), there can be no assurance that sufficient funds can be secured in order to permit the Company to carry out its planned activities. In general, capital market conditions are volatile. The prevailing financial market situation and the overall investor's sentiment dictate whether the Company is able to secure additional financing in the future, which can be considered a risk. To partly manage this risk, the Company and its management is in constant dialogue with financial investors, investment banks, debt providers and other market participants.

The Company also relies on different sources of research and development grants and loans. These funds, which are provided through regional, national or EU level institutions, have been historically available to the Company. The Company strictly complies with all rules and legal obligations pertaining to these funding programs and is in regular contact with the funding agencies providing these. Availability of such funds in the future cannot be guaranteed and thus this poses a potential risk to the Company's funding in the future.

Finally entering into commercialization, collaboration and licensing agreements with larger pharmaceutical companies entitles the Company to receive up-front and milestone payments related to agreed regulatory or commercial points, as well as royalty payments once commercialization has been successful. Activities in the area of business development are targeted at securing such agreements. Consideration of these activities is part of the management's duties and is monitored by the Board of Directors, which ultimately decides on entering into such agreements.

There can be no assurance that sufficient financing can be secured in order to permit the Company to carry out its planned activities. To protect the continuity of the Company's operations, sufficient liquidity and capital has to be maintained. The Company aims to have funds to finance its operations for the foreseeable future. The Company can influence the amount of capital by adapting its cost basis considering available financing. Management monitors liquidity on the basis of the amount of funds. These are reported to the Board of Directors on a monthly basis.

The Company's Board of Directors approves the operational plans and budget and monitors the implementation of these plans and the financial status of the Company on a monthly basis.

As at 31 December 2018, the contractual maturity of loans and interests was as follows:

€'000	2019	2020	2021	2022- thereafter	Total
<b>R&amp;D loans</b>					
Repayment of loans	245	245	338	1,304	2,132
Interest expenses	23	21	17	23	85
<b>Total</b>	<b>268</b>	<b>265</b>	<b>356</b>	<b>1,328</b>	<b>2,217</b>

As at 31 December 2017, the contractual maturity of loans and interests was as follows:

€'000	2018	2019	2020	2021- thereafter	Total
<b>R&amp;D loans</b>					
Repayment of loans	347	338	338	1,403	2,426
Interest expenses	25	21	18	42	106
<b>Total</b>	<b>372</b>	<b>359</b>	<b>356</b>	<b>1,445</b>	<b>2,532</b>

## (b) Market risk

### *i. Foreign exchange risk*

The Company operates internationally but is mainly exposed to translation risk in respect of Pound Sterling ("GBP") denominated cash and cash equivalents balances. The Company's policy is not to hedge translation risk. As of 31 December 2018, the Company had cash and cash equivalents of EUR 4,058 thousand and GBP 0 thousand (2017: EUR 359 thousand and GBP 7,941 thousand) and the foreign exchange gains and losses recorded arise mainly from the GBP cash balances. The Company is not exposed to significant transaction risk, as the Company mainly operates in its functional currency, the EUR.

### *ii. Interest rate risk*

The Company's interest rate risk arises from Tekes R&D loans, which interest is the base rate defined by the Finnish Ministry of Finance minus three (3) percentage points, subject to minimum rate of 1%. During the periods presented, the interest has been below the minimum level and the Company has paid the minimum interest of 1% on the loans. During the periods presented, the Company has not been exposed to variable interest rate risk and accordingly the Company has not entered into derivative contracts.

## (c) Credit and counterparty risk

The Company works with partners and financial institutions with good credit ratings. Management monitors credit ratings of the financial institutions that hold the Company's bank deposits regularly. Further, the Company currently derives its revenue from restricted number of reputable licence partners in specific territories. This risk of concentration of creditors is partly mitigated by the fact that these partners are financially solid. These licence agreements are governed by contractual relationships that typically address and describe remedies for situations in which interests of the Company and the partner are no longer aligned.

## 21. Trade payables and other current liabilities

As at 31 December

€'000	Group		Parent	
	2018	2017	2018	2017
Trade payables	3,534	3,196	3,533	3,196
Accrued research & development costs	749	350	749	350
Accrued payroll	527	969	527	969
Other liabilities	281	302	281	302
Clinical trial hospital fees	268	1,241	268	1,241
Other accruals	142	84	142	84
Advances received	-	976	-	976
Accrued milestone payment	-	600	-	600
<b>Total</b>	<b>5,501</b>	<b>7,718</b>	<b>5,500</b>	<b>7,718</b>

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. For further information about grant income (note 5). Other liabilities comprise mainly of unpaid prepayment to FP7 -grant consortium members.

## 22. 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	2018	2017
No later than 1 year	179	172
Later than 1 year and no later than 5 years	82	231
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. At the end of financial year 2019 the Company has non-cancellable leasing commitments of EUR 10 thousand. As a result of the new standard, the Company has reviewed all of the group's leasing arrangements over the last year. The Company intends to apply the simplified transition approach and will not restate comparative amounts for the year prior to first adoption. All lease arrangements are both short-term and low value leases.

### **Contractual contingencies**

The Company has contingent milestone payments of EUR 1,400 thousand to a subcontractor that will become payable only upon the Company achieving certain milestones in 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 additional milestone payments. First milestone payment of EUR 427 thousand payable when production system reached certain material yield threshold was charged 2018. The remaining ones become payable 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.

## 23. Related party transactions

Parent and subsidiary relations of Faron Pharmaceutical Group on 31 December 2018:

Companies owned by the parent company	Country	Group holding%	Group voting%
Faron Europe GmbH	Switzerland	100	100
Faron USA LLC	USA	100	100

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 10,98%. A&B (HK) Company Limited does not have a representative on the Board of Directors since September 2018.
- 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, 2017 and 2018.

### Key management personnel

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

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

### Year ended 31 December

€'000	2018	2017
<b>Compensation of key management personnel*</b>		
Salaries and other short-term employee benefits	1,535	1,668
Post-employment benefits	288	220
Share-based payments	(176)	681
<b>Total</b>	<b>1,647</b>	<b>2,569</b>

The Management team was awarded 0 share options during 2018 (2017: 249,850 share options). At the end of the 2018, the number of outstanding options and share granted to the Management team amounted to 663,450 share options (at the end of 2017: 663,450 share options).

Non-executive Directors were awarded 0 share options during 2018, (2017: 40,000 share options). At the end of 2018, the number of outstanding options and share options granted to the non-executive directors amounted to 600,000 share options (at the end of 2017: 600,000 share options).

## Management and Board shareholding

### Management\* shareholding, 31 December 2018

Number of shares (pcs)	4,884,373
Shareholding, percentage	15.7 %

### Board\*\* shareholding, 31 December 2018

(excluding the shareholding of CEO and CFO)

Number of shares (pcs)	689 369
Shareholding, percentage	2.2 %
Total number of shares outstanding at 31 December 2018 (pcs)	31,027,894

\*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 2018 than already disclosed.



## 24. Events after the balance sheet date

In January 2019, the Company received the fourth and last instalment of the Clevegen Tekes R&D –loan of EUR 307 thousand. In March 2019, the Company raised net proceeds of approximately EUR 2,900 thousand through a directed share issue and at 31 March 2019 it had EUR 4,877 thousand cash and equity of EUR 731 thousand.

### Result and dividend

The statement of comprehensive income is on page 2.

The loss for the accounting period was 20,075,949.50 euro (2017: 21,060,639.95 euro).

The Board of Directors does not recommend the payment of a dividend (2017: nil).

Board signatures

London, 3 May 2019

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Frank Armstrong, chairman

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Markku Jalkanen

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Gregory Brown

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Matti Manner

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John Poulos

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Yrjö Wichmann

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Leopoldo Zambeletti

### The Auditor's Note

The report on the audit performed has been issued today

Helsinki, 3 May 2019

PricewaterhouseCoopers Oy

Authorised Public Accountants

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Panu Vänskä

Authorised Public Accountant (KHT)



## ***Auditor's Report (Translation of the Finnish Original)***

To the Annual General Meeting of Faron Pharmaceuticals Oy

### ***Report on the Audit of the Financial Statements***

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#### ***Opinion***

In our opinion the financial statements give a true and fair view of the group's and the parent company's financial performance and financial position and cash flows in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU.

#### **What we have audited**

We have audited the financial statements of Faron Pharmaceuticals Oy (business identity code 2068285-4) for the year ended 31 December 2018. The financial statements comprise:

- the consolidated balance sheet, statement of comprehensive income, statement of changes in equity, statement of cash flows and notes
  - the parent company's balance sheet, statement of comprehensive income, statement of changes in equity, statement of cash flows and notes.
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#### ***Basis for Opinion***

We conducted our audit in accordance with good auditing practice in Finland. Our responsibilities under good auditing practice are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of our report.

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

#### **Independence**

We are independent of the parent company and of the group companies in accordance with the ethical requirements that are applicable in Finland and are relevant to our audit, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

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#### ***Material Uncertainty Related to Going Concern***

We draw attention to the notes in financial statements on page 7, item 2.2 "Going concern". As mentioned in the note the additional finance is not committed at the date of approval of the financial statements. This together with other items mentioned in the note indicates, that a material uncertainty exists that may cast significant doubt on the Company's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

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#### ***Responsibilities of the Board of Directors and the Managing Director for the Financial Statements***

The Board of Directors and the Managing Director are responsible for the preparation of financial statements that give a true and fair view in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU and comply with statutory requirements. The Board of Directors and the Managing Director are also

responsible for such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the Board of Directors and the Managing Director are responsible for assessing the parent company's and the group's ability to continue as a going concern, disclosing, as applicable, matters relating to going concern and using the going concern basis of accounting. The financial statements are prepared using the going concern basis of accounting unless there is an intention to liquidate the parent company or the group or to cease operations, or there is no realistic alternative but to do so.

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### *Auditor's Responsibilities for the Audit of the Financial Statements*

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

As part of an audit in accordance with good auditing practice, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the parent company's or the group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting and based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the parent company's or the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the parent company or the group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events so that the financial statements give a true and fair view.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

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

## *Other Reporting Requirements*

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### *Other Information*

The Board of Directors and the Managing Director are responsible for the other information. The other information comprises of the Strategic Report, Directors' Report, Directors' Remuneration Report and the Statement of Responsibilities included in the Annual Report, but does not include the financial statements and our auditor's report thereon. Our opinion on the financial statements does not cover the other information.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated.

In our opinion the information given in in the Strategic Report, Directors' Report, Directors' Remuneration report and the Statement of Responsibilities is consistent with the information in the financial statements.

If, based on the work we have performed on the other information that we obtained prior to the date of this auditor's report, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Helsinki 3 May 2019

**PricewaterhouseCoopers Oy**  
Authorised Public Accountants

Panu Vänskä  
Authorised Public Accountant (KHT)



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