



Final Results for the year ended December 31, 2019

Released : March 20, 2020

RNS Number : 8965G
Faron Pharmaceuticals Oy
20 March 2020

Faron Pharmaceuticals Oy
("Faron" or the "Company")

Financial statement release January 1 to December 31, 2019

Financial statement release, Turku, 20 March 2019 at 9.00 AM (EET)

Inside information

TURKU, FINLAND - Faron Pharmaceuticals Oy (AIM: FARN, First North: FARON), the clinical stage biopharmaceutical company, today reports its financial statements for the year ended 31 December 2019 and H2 2019.

HIGHLIGHTS

Operational (including post period):

Clevegen® - Regulator of major inhibitory immune checkpoints and wholly-owned novel cancer immunotherapy in development

- Part I of the open label phase I/II MATINS trial, initiated across multiple sites through Europe and primarily intended to investigate safety and tolerability, was completed with dose escalation reaching its planned maximum level of 10mg/kg. Clevegen demonstrated good tolerability at all dosing levels (0.1 to 10 mg/kg) without dose limiting toxicity.
- Clevegen promoted immune activation in all dosed patients, measured following treatment with Clevegen and observed as increased circulating CD8+ T cells and CD8+/CD4+ ratio, decreased regulatory T-cells (T-regs) or a substantial increase in mobile natural killer (NK) cells in the blood.
- Partial responses were observed in two patients. The first, a colorectal cancer (CRC) patient, showed a continuation of lung and lymph node metastasis shrinkage and their tumour load biochemical marker, carcinoembryonic antigen (CEA), also normalised. The second, a heavily pre-treated melanoma patient, showed a reduction in the size of the target lesion tumour (a lung metastasis) by 44 percent and other

non-target lesions stabilized. Their biochemical tumour load marker also declined and clearance of pleura fluid was observed.

- Data showing Clevegen's potential early efficacy and good tolerability were presented at the European Society of Medical Oncology (ESMO) 2019 Congress in Barcelona, Spain. At the Society's subsequent Immuno-Oncology Congress 2019 in Geneva, Switzerland, more detailed cell surface biomarker data were presented for the first time showing Clevegen's potential to downregulate a range of inhibitory immune checkpoints commonly targeted by current immuno-oncology (IO) therapies.
- The US Food and Drug Administration (FDA) approved Faron's Investigational New Drug (IND) application for Clevegen, enabling expansion of the MATINS trial into the US.
- CRC and ovarian cancer were selected by the MATINS data monitoring committee as the first and second expansion cohorts in part II of the study. Both cancer types are known to host a significant number of Clever-1 positive tumour-associated macrophages (TAM) which correlates with increased mortality rates.
- 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 were published in *Clinical Cancer Research*, a journal of the American Association for Cancer Research.
- Several new patent filings were carried out during the period to further strengthen the existing IP around Clevegen use in conditions where harmful immune suppression causes serious diseases.
- bexmarilimab is under consideration by the World Health Organization as the Proposed International Nonproprietary Name.
- Manufacturing was established to supply drug product for cohort expansions in part II of the MATINS study.
- Partnering discussions continued with the aim of supporting expansion of clinical development and exploring the potential of Clevegen in combination with existing immunotherapies and other cancer therapies.

Traumakine[®] - in development for the treatment of organ failures

- Faron remains focused on developing Traumakine as a treatment for acute respiratory distress syndrome (ARDS) taking into account the high levels of concomitant corticosteroids used as a standard of care for ARDS and some ruptured abdominal aorta aneurysm (RAAA) patients.
- Following feedback from the FDA regarding trial design, Faron submitted an amended protocol to the FDA, reflecting the FDA's feedback that further studies with interferon-beta (IFN-beta) should exclude the use of overlapping corticosteroids since they are likely to block the desired therapeutic effect of Traumakine and may have a potentially deleterious impact on patient outcomes.
- The FDA accepted Faron's proposed study protocol for the new Traumakine trial, which excludes the use of concomitant corticosteroids and which will be split in two steps. The first step will commence with INTEGRITY, a pilot randomised and placebo controlled study, which will serve as final adjustment for adequate statistical powering and sample size justification for the pivotal second step, CALIBER.
- The Company envisages that further Traumakine trials are likely to be funded through a third party.
- 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 did not result in reduced mortality or an increased number of ventilator-free survival days when compared to placebo. In the study, very high concomitant corticosteroids use (77%) was observed.

- A phase I study in healthy volunteers (pharmacokinetic/dynamic YODA study), examining the administration and concomitant use of corticosteroids with Traumakine, confirmed observations previously seen in the INTEREST study. Traumakine produced the expected levels of bioactivity, suggesting drug formulation was not a factor in the outcome of that trial and that concomitant corticosteroids use interferes in the desired IFN-beta effect on CD73.
- Interim results from the phase II INFORAAA study examining the effect of Traumakine on mortality (predominantly for multi-organ failure, MOF) and on pharmacodynamic biomarkers in surgically operated RAAA patients, showed biomarker (MxA and CD73) responses indicating a good IFN-beta response from Traumakine. A trend towards reduction of mortality was seen in patients increasing their CD73 plasma levels.
- Based on the advice from the INFORAAA independent data monitoring committee and investigators, the Company decided to close the INFORAAA trial, as unexpected high use of concomitant corticosteroids prevent the scientific implementation of the INFORAAA protocol.
- Faron filed a request for arbitration with the Arbitration Institute of the Stockholm Chamber of Commerce seeking damages from Rentschler Biopharma SE for terminating the API manufacturing process for Traumakine.
- It is the understanding of the Company that the current API manufacturing process used to manufacture Traumakine requires significant upgrading to secure MAA/BLA approval. Various options for manufacturing are currently being explored.

AOC3 Antagonist Platform Technology

- In March 2020, Faron acquired rights for the potential new use of AOC3 inhibitors. Faron will be responsible for the future development of the AOC3 protein inhibitor and for the management, prosecution, maintenance and filing of patent applications.

Corporate

- Yrjö Wichmann took up the new position of Vice President, Financing and Investor Relations and Toni Hänninen was appointed as Faron's new Chief Financial Officer.
- Faron's shares were listed on Nasdaq First North Growth Market Helsinki as of 3 December 2019.

Financial

- On 31 December 2019, the Company held cash balances of €7.1 million (2018: €4.1 million).
- Loss for the period for the financial year ended 31 December 2019 was €13.3 million (2018: €20.1 million loss).
- Net assets on 31 December 2019 were €1.6 million (2018: €0.4 million).
- During the period, in November, August, May and March 2019, the Company successfully raised a total of €15.6 million gross (€14.5 million net) from new and existing shareholders, employees and Company Directors through issuance of a total of 12,262,853 new ordinary shares. The majority of these proceeds are being used to advance Clevegen through the MATINS trial, further Traumakine development through the design and preparation of the next clinical trials and advance partnering discussions in respect of both Traumakine and Clevegen.

FINANCIAL

Consolidated key figures, IFRS

| €'000 | Unaudited 7-12/2019 6 months | Unaudited 7-12/2018 6 months | 1-12/2019 12 months | 1-12/2018 12 months |
|---|---|---|------------------------------------|------------------------------------|
| Revenue | 0 | (1) | 0 | 19 |
| Research and Development expenses | (5,255) | (4,762) | (10,237) | (16,463) |
| General and Administrative expenses | (1,688) | (1,378) | (3,049) | (3,750) |
| Loss for the period | (6,850) | (6,026) | (13,262) | (20,086) |
| | Unaudited 7-12/2019 6 months | Unaudited 7-12/2018 6 months | 1-12/2019 12 months | 1-12/2018 12 months |

| | | | | |
|---|------------|------------|------------|------------|
| Loss per share EUR | (0.16) | (0.19) | (0.31) | (0.65) |
| Number of shares at end of period | 43,290,747 | 31,027,894 | 43,290,747 | 31,027,894 |
| Average number of shares | 35,533,179 | 30,749,648 | 35,533,179 | 30,749,648 |

| €'000 | Unaudited 30 Jun 2019 | Unaudited 30 Jun 2018 | 31 Dec 2019 | 31 Dec 2018 |
|---------------------------|--------------------------------------|----------------------------------|------------------------|--------------------|
| Cash and cash equivalents | 2,892 | 11,168 | 7,059 | 4,067 |
| Equity | (1,761) | 6,722 | 1,610 | 369 |
| Balance sheet total | 5,103 | 16,716 | 10,209 | 8,002 |

Commenting on the results, Dr Markku Jalkanen, CEO of Faron, said: "Our priority in 2019 was to rapidly accelerate our immunotherapy candidate, Clevegen, through the clinic. With the continued progression of the phase I/II MATINS trial, we are very encouraged by its results so far. Clevegen is clearly exhibiting exciting properties as a potential immunotherapy capable of down regulating a range of major inhibitory immune checkpoints (PD-1, PD-L1, CTLA-4) across several cancers. With our two cohort expansions in colorectal and ovarian cancer, we will continue to rapidly progress the development of Clevegen in patients with limited effective treatment options.

"We are also pleased that, following feedback from the FDA, we have agreed the trial design for the continued clinical development of Traumakine, which we continue to believe holds great potential as a future treatment for ARDS, regardless of the underlying condition.

"We are very pleased to also have secured a further EUR 8 million through our series of fundraises in late 2019, further supporting the progress of our pipeline. I would like to

thank our new and existing shareholders, and the entire team at Faron, for their continued support."

Board of Directors' Proposal on the Dividend

The Group's loss for the accounting period was 13,261,911.93 euro (2018: 20,086,402.60 euro).

The Board of Directors does not recommend the payment of a dividend (2018: nil).

March 19, 2020

Faron Pharmaceuticals

Board of Directors

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) No 596/2014 ("MAR").

Conference call information

Faron will host a conference call for analysts to provide an update on the results followed by a Q&A session at 09:30 GMT / 11:30 EET. A presentation to accompany the call will be available on the Faron website

(<https://www.faron.com/investors/results>) at 09:00 GMT / 11:00 EET

Dial-in details are:

International: +44 (0) 20 7192 8000

Finland: (09) 4245 0806

Conference ID: 7377079

For more information please contact:

Faron Pharmaceuticals Oy

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

Panmure Gordon (UK) Limited, Nomad and Broker

Emma Earl, Freddy Crossley (Corporate Finance)
James Stearns (Corporate Broking)
Phone: +44 207 886 2500

Sisu Partners Oy, Certified Adviser on Nasdaq First North

Juha Karttunen, Jussi Majamaa

Phone: +358 (0)40 555 4727

Consilium Strategic Communications

Mary-Jane Elliott, David Daley, Lindsey Neville

Phone: +44 (0)20 3709 5700

E-mail: faron@consilium-comms.com

Publication of financial information during year 2020

The half-year financial report for the period 1 January to 30 June 2020 is scheduled to be published on 24 September 2020. Faron's financial statements for full year 2019 will be published on 25 March and will also be available on the Company's website at

<https://www.faron.com/investors/results>.

The Annual General Meeting is planned for 15 April 2020. A separate stock exchange notice will be issued by Faron's Board of Directors to convene the meeting.

About Faron Pharmaceuticals Ltd

Faron (AIM:FARN, First North: FARON) is a clinical stage biopharmaceutical company developing novel treatments for medical conditions with significant unmet needs. The Company currently has a pipeline based on the receptors involved in regulation of immune response in oncology and organ damage. Clevegen, its precision immunotherapy, is a novel anti-Cleaver-1 antibody with the ability to switch immune suppression to immune activation in various conditions, with potential across oncology, infectious disease and vaccine development. Currently in phase I/II clinical development as a novel macrophage checkpoint immunotherapy for patients with untreatable solid tumours, Clevegen has potential as a single-agent therapy or in combination with other immune checkpoint molecules or standard of care therapies. Traumakine, the Company's pipeline candidate to prevent vascular leakage and organ failures, has completed a phase III clinical trial in Acute Respiratory Distress Syndrome (ARDS). Plans for its future development are being finalised to avoid interfering steroid use together with Traumakine. Faron is based in Turku, Finland. Further information is available at www.faron.com

Caution regarding forward looking statements

Certain statements in this announcement, are, or may be deemed to be, forward looking statements. Forward looking statements are identified by their use of terms and phrases such as "believe", "could", "should", "expect", "hope", "seek", "envisage", "estimate", "intend", "may", "plan", "potentially", "will" or the negative of those, variations or comparable expressions, including references to assumptions. These forward-looking statements are not based on historical facts but rather on the Directors' current expectations and assumptions regarding the Company's future growth, results of operations, performance, future capital and other expenditures (including the amount, nature and sources of funding thereof), competitive advantages, business prospects and opportunities. Such forward looking statements reflect the Directors' current beliefs and assumptions and are based on information currently available to the Directors.

A number of factors could cause actual results to differ materially from the results and expectations discussed in the forward-looking statements, many of which are beyond the control of the Company. In particular, the early data from initial patients in the MATINS trial may not be replicated in larger patient numbers and the outcome of clinical trials may not be favourable or clinical trials over and above those currently planned may be required before the Company is able to apply for marketing approval for a product. In addition, other factors which could cause actual results to differ materially include the ability of the Company to successfully licence its programmes within the anticipated timeframe or at all, risks associated with vulnerability to general economic and business conditions, competition, environmental and other regulatory changes, actions by governmental authorities, the availability of capital markets or other sources of funding, reliance on key personnel, uninsured and underinsured losses and other factors. Although any forward-looking statements contained in this announcement are based upon what the Directors believe to be reasonable assumptions, the Company cannot assure investors that actual results will be consistent with such forward looking statements. Accordingly, readers are cautioned not to place undue reliance on forward looking statements. Subject to any continuing obligations under applicable law or any relevant AIM Rule requirements, in providing this information the Company does not undertake any obligation to publicly update or revise any of the forward-looking statements or to advise of any change in events, conditions or circumstances on which any such statement is based.

Chairman's statement

2019 was a significant year for Faron. The highly experienced management team made significant progress executing the Company's strategy and maintaining momentum in the delivery of its novel pipeline.

The development programme for Faron's wholly-owned novel precision cancer immunotherapy candidate, Clevegen, has accelerated rapidly. Promising early clinical data continued to give us confidence in the potential of Clevegen as a next-generation immuno-oncology therapy and one that could potentially be used in combination therapy. The strength of the early clinical data generated in 2019 enabled the Clevegen team to quickly identify a group of patients thought most likely to respond to treatment. Selection of the first expansion cohort in colorectal cancer was a significant achievement and is testament to the focus Faron has placed on Clevegen's development this year. The US Food and Drug Administration (FDA) approval of the Company's Investigational New Drug (IND) application for Clevegen was a major development milestone enabling expansion of Clevegen's clinical development in the US.

Harnessing the immune system to fight cancer has transformed the way patients are treated and scientists continue to make new discoveries in the field of immune-oncology every day. It is exciting to see the Clevegen programme generating such interest in this field, from the scientific community and commercial organisations. The wealth of data generated in 2019 strengthens Faron's confidence in the programme's future.

Alongside Clevegen's development progress in 2019, the Company continued to build on its understanding of the results from Traumakine's INTEREST trial. Data from a late-stage trial undertaken by our Japanese partner Maruishi were consistent with our study results a year earlier and supported our observation that corticosteroid use interferes with Traumakine efficacy. This observation has since been confirmed by the FDA who, following discussions about the future development path for Traumakine, advised that further studies should exclude the concomitant use of steroids. The body of evidence generated during Traumakine's development programme is clearly a matter of interest for opinion leaders involved in the treatment of acute respiratory distress syndrome (ARDS) patients and the debate around whether corticosteroids have any beneficial role in ARDS patients continues.

Recent guidance from the World Health Organization (WHO) on the clinical management of severe acute respiratory infection related to the novel coronavirus that emerged in China at the end of 2019 advises against the routine use of corticosteroids. The emergence of this novel virus, and the risk of ARDS among infected patients, is a reminder of the need for new treatments to tackle this potentially fatal condition.

During the year our fundraising activities and our listing on the Nasdaq First North Growth Market in Finland received strong shareholder support enabling us to build a more secure financial position for the Company and give the pipeline its greatest chances of success. It was also encouraging to see the Company's share price performance in 2019, its growth reflecting the progress of the business and the strength of Faron's pipeline potential.

On behalf of the Board, I would like to thank all those who have played a part in Faron's progress in 2019 - the management team, staff and Board for their hard work and commitment, our partners and steering committee members for their support and expertise, and the investigators and patients involved in our clinical trials. I would also like to pay particular thanks to our CEO, Markku Jalkanen who, while guiding Faron through difficult circumstances, has successfully led its transition to becoming a leading immunotherapy company.

We look forward to continued progress with our pipeline products Clevegen and Traumakine in 2020.

Dr Frank Armstrong
Chairman
March 19, 2020

Chief Executive Officer's Review

Overview

Faron is focused on immuno-oncology, organ trauma and vascular damage. Our goal is to save lives by developing unique scientific discoveries into ground-breaking new treatments for hard-to-treat and rare diseases. Our work is rooted in two scientific principles. First, a deep knowledge of the pharmacology of our drug candidates. And second, understanding the science of the targeted conditions at the molecular level, to most effectively influence their underlying causes.

Our focus for 2019 has been to continue to progress our wholly-owned novel precision cancer immunotherapy candidate, Clevegen, through the first-in-human clinical study, MATINS, in selected metastatic or inoperable solid tumours. We have also been working

closely with the regulatory authorities to determine the future development pathway for Traumakine in ARDS and organ failures.

Clevegen Development

We have made significant, and exciting, clinical progress with Clevegen during 2019. 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). Clevegen is differentiated from other immunotherapies through its specific targeting of M2 TAMs which facilitate tumour growth. Through myeloid cell plasticity, Clevegen can convert these M2 TAMs to M1s, leaving existing M1 TAMs intact and allowing both to support immune activation against tumours. We believe it has the potential to function as a novel macrophage checkpoint immunotherapy both as a monotherapy and in combination with other immuno-oncology therapies or standard of care treatments.

MATINS Trial

The MATINS (Macrophage Antibody To INhibit immune Suppression) study is a first-in-human open label phase I/II clinical trial with an adaptive design to investigate the safety and efficacy of Clevegen in selected metastatic or inoperable solid tumours. The selected tumours under investigation are cutaneous melanoma, hepatobiliary/hepatocellular, pancreatic, ovarian and colorectal cancer, all known to host a significant number of Clever-1 positive TAMs. Together these five target groups consist of approximately 2 million annual cases worldwide. Cancer patients with high Clever-1 expression are identified with a simple blood myeloid cell staining with Clevegen ("liquid biopsy").

Part I of the MATINS study was conducted to establish tolerability, safety and dose escalation to optimize dosing. Subjects in Part I of the study received doses of 0.1 mg/ kg, 0.3 mg/kg, 1.0 mg/kg, 3.0 mg/kg and 10 mg/kg. All dose levels tested showed good tolerability with no dose limiting toxicity signals and all subjects dosed in the study experienced a switch in their immune cell profiles following treatment with Clevegen towards increased immune activation, observed as increased circulating CD8+ T cells and CD8+/CD4+ ratio, decreased regulatory T-cells (T-regs) or a substantial increase in mobile natural killer (NK) cells in the blood.

Based on results from the initial part of the MATINS trial, Faron announced in April 2019 that late-stage colorectal cancer (CRC) had been chosen for the first expansion cohort for the second part of the trial. Following the successful conclusion of the dose escalation in Part I, and with approval from the MATINS trial's data monitoring committee (DMC), Faron initiated this first expansion cohort, Part II, in January 2020. A total of 10 late-stage CRC patients are expected to be dosed at the approved initial dose level of 0.3 mg/kg cohort, including two patients who had previously received this dose in the earlier Part I of the study. Furthermore, in January 2020, we announced that ovarian cancer has been selected as the second expansion cohort in the trial. Both these tumour types are known to host a significant number of Clever-1 positive TAMs which correlates with increased mortality rates among these patients.

In November 2019, the FDA approved the Company's Investigational New Drug (IND) application for Clevegen (FP-1305), enabling expansion of the MATINS trial into the US. We anticipate opening the first site in mid-2020. In due course, we also plan to file applications for Breakthrough Therapy status in the US and PRIME status in Europe, further facilitating regulatory interactions during the development of Clevegen.

Clevegen's ability to down regulate a range of major inhibitory checkpoints reaffirms our belief in its potential as a master regulator of immunity and a highly effective immunotherapy. It indicates that Clevegen treatment could potentially allow increased efficacy of other immuno-oncology therapies through the biomarker analysis of patient's blood cells post Clevegen induced immune activation, finally offering a biological rationale to guide combination therapies. 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 2020.

Traumakine Development

With no currently approved pharmacological treatments available, acute respiratory distress syndrome (ARDS) remains a significant problem for patients and healthcare systems. During 2019, the Company has continued to further understand the correlation between the combined use of corticosteroids and IFN-beta and has been working closely with the regulatory authorities in order to determine the next steps in Traumakine's future development pathway.

In April 2019, Faron announced top-line data from the Phase III trial with Japanese partner Maruishi Pharmaceutical Co., Ltd. Results from this trial were in line with the Company's expectations, and previously announced results observed in the INTEREST trial, showing that treatment with Traumakine did not result in reduced mortality or an increased number of ventilator free survival days when compared to placebo. In order to further examine the effects of concomitant steroid use and Traumakine, as seen in both the INTEREST trial and the Japanese study, Faron conducted the pharmacokinetic/dynamic YODA study in healthy volunteers. Results from this study, announced in June 2019, were consistent with the INTEREST data, supporting the conclusion that coadministration of steroids with Traumakine in patients inhibits IFN-beta action.

Also, in June 2019, Faron announced interim results from the Phase II INFORAAA study, which examined the effect of Traumakine on mortality (predominantly for multi-organ failure, MOF) and pharmacodynamic biomarkers of surgically operated ruptured abdominal aorta aneurysm (RAAA) patients. Based on the advice from the INFORAAA independent data monitoring committee and investigators, the Company decided to close the INFORAAA trial, as unexpected high use of concomitant corticosteroids was preventing the scientific implementation of the INFORAAA protocol.

Interestingly, in January 2020, the World Health Organization (WHO) published a recommendation recognising the risk of using corticosteroids on patients with coronavirus. This recommendation aligns with our findings from the post-hoc analysis of the INTEREST study and strengthens our belief that the whole medical community should be more diligent with regard to the combined use of corticosteroids and type I interferons. Faron's scientific network has also confirmed this interaction at a molecular level in lung endothelial cells.

The Company remains committed to progressing Traumakine for the treatment of ARDS and, following the Company's revised protocol submission in February 2020, the FDA have now accepted the protocol design for the next Traumakine study. The study design reflects the feedback and conclusions from the FDA that further studies with IFN beta should exclude the use of concomitant glucocorticoids since they are likely to block the desired therapeutic effect of Traumakine and may have a potentially deleterious impact on patient survival. We are planning to split the clinical development of Traumakine in ARDS into two steps, commencing with INTEGRITY, a pilot randomised and placebo controlled

study with approximately 60 patients. The INTEGRITY data will then serve as final adjustment for adequate statistical powering and sample size justification for the pivotal CALIBER study, subjected for FDA review. We expect that the sample size of the CALIBER study will not exceed 200 patients based on the post hoc analysis of the INTEREST trial data. We envisage that future Traumakine trials (including INTEGRITY and CALIBER) are likely to be funded through a third party or parties.

AOC3 Antagonist Platform Technology

In March 2020, Faron announced it had acquired rights for the potential new use of AOC3 inhibitors covered by a recently filed patent application. The AOC3 enzymatic domain, a semicarbazide-sensitive amine oxidase, is known to produce hydrogen peroxide, a potent inflammatory mediator. Being expressed by many inflamed vascular endothelial cells, the AOC3 overexpression has been connected with many vascular diseases.

Faron will be responsible for future development of the invention and for the management, prosecution and maintenance of any patent applications as well as for the filing of new patent applications for the AOC3 protein inhibitor. Pre-clinical studies with humanized AOC3 mice and with ex vivo human cells in relation to the Invention are currently ongoing and further information will be provided later in the year.

Corporate

On 3 December 2019, Faron started trading on Nasdaq First North Growth Market ("Nasdaq First North"), a multilateral trading facility operated by Nasdaq Helsinki Ltd. The ISIN code of Faron's ordinary shares is FI4000153309 and the trading code on Nasdaq First North is FARON. This is in addition to Faron's listing, since November 2015, on AIM.

In October 2019, Faron received a letter from Rentschler Biopharma SE ("Rentschler") in which Rentschler stated that it was terminating the agreement concerning the API manufacturing for Traumakine. Following a detailed investigation by Faron into the circumstances around manufacturing arrangements, the Company has since concluded that, in its view, Rentschler was in breach of the underlying agreement between the parties. Faron has filed a request for arbitration, funded by a third party on a non-recourse basis, with the Arbitration Institute of the Stockholm Chamber of Commerce seeking damages.

In May 2019, Yrjö Wichmann left his role as the Company's Chief Financial Officer to take up the new position of Vice President, Financing and Investor Relations. Mr Wichmann remains a member of the senior management team but stepped down from the Board with effect from 28 May 2019. We were delighted to welcome Mr Toni Hänninen as Faron's new CFO, effective from 1 June 2019, being responsible for both internal and external reporting.

The Annual General Meeting held on 28 May 2019 resolved the number of members of the Board as six. Frank Armstrong, Markku Jalkanen, Matti Manner, Leopoldo Zambelletti, Gregory Brown and John Poulos were re-elected to the Board for a term that ends at the end of the next AGM.

Financial

During the period, the Company successfully raised approximately EUR 15.6 million (gross), EUR 14.5 million (net) from new and existing shareholders, employees and Company Directors. The majority of these proceeds are being used to advance Clevegen through the MATINS trial, further Traumakine development through the design and

preparation of the next clinical trials and advance partnering discussions in respect of both Traumakine and Clevegen.

Outlook

Our focus for 2020 will be to continue to expedite Clevegen's clinical development through part II and part III of the MATINS trial and to report these data to regulatory authorities. We will also continue to work in close collaboration with the regulatory authorities in order to progress the INTEGRITY and CALIBER clinical trials and secure Traumakine's future development pathway. We are continuing to make progress with potential partners regarding both Clevegen and Traumakine, whilst also exploring funding opportunities to ensure we can continue to progress both products. I would like to thank our shareholders for their continued belief in the Company and the management team for their hard-work and dedication and look forward to updating the market on our progress throughout the course of the year.

The Board anticipates the following pipeline progress and catalysts during 2020:

Clevegen:

- Completion of all biomarker analyses from MATINS Part I patients to guide Clevegen dosing
- Initiation of the second expansion cohort, ovarian cancer, during H1-2020
- Initial data from the first expansion cohort (CRC) expected in Q2-2020
- Expansion of the MATINS trial to leading cancer centres in France and Spain in Q2-2020
- Opening of US study sites to facilitate rapid expansion of the MATINS trial in Q2-2020
- Partnering update during 2020

Traumakine:

- Further updates in relation to INTEGRITY and CALIBER during 2020
- Continuation plans to be announced in H2-2020

AOC3 Antagonist Platform Technology:

- Additional information from pre-clinical studies with humanized AOC3 mice and with ex vivo human cells during 2020

Dr Markku Jalkanen
Chief Executive Officer
March 19, 2020

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 several successful fundraises during 2019. The Company's net cash flow showed €3.0 million positive due to a reduction in expenses and said fundraises. 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 2019 (2018: €nil).

The Company recorded €0.2 million (2018: €0.2 million) of other operating income. This consisted of the reimbursement of already occurred legal expenses by the third-party recovery services provider as announced by the Company on 30 December 2019.

Research and development costs

The R&D costs decreased by €6.3 million from €16.5 million in 2018 to €10.2 million in 2019. The costs of outsourced clinical trial services were reduced by €3.4 million from €5.3 to €1.9 million. The cost of materials and services used in the R&D was reduced by €1.7 million from €7.3 to €5.6 million.

General and administration costs

Administrative expenses decreased by €0.8 million from €3.8 million in 2018 to €3.0 million in 2019. The decrease was mainly due to the €1.4 million decrease in external costs related to the development of internal financial and reporting processes during 2018, but this was partially offset by an increase of €0.7 million in the other administrative expenses.

Taxation

The Company's tax credit for the fiscal year 2019 can be recorded only after the Finnish tax authorities have approved the tax report and confirmed the amount of tax-deductible. The total amount of cumulative tax losses carried forward approved by tax authorities on 31 December 2019 was €16.1 million (2018: €11.2 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 €58.6 million of R&D costs incurred in the financial years 2010 - 2019 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 €13.3 million (2018: €20.1 million). Net loss for the year was €13.3 million (2018: €20.1 million), representing a loss of €0.31 per share (2018: €0.65 per share) (adjusted for the changes in number of issued shares).

Cash Flows

Net cash flow was €3.0 million positive for the year ended 31 December 2019 (2018: €5.3 million negative). Cash used for operating activities decreased by €9.0 million to €11.5 million for the year, compared to €20.5 million for the year ended 31 December 2018. This decrease was mostly driven by a decrease in R&D investments.

Net cash inflow from financing activities was €14.5 million (2018: €15.5 million) due to the successful equity placings completed in during 2019.

Fundraising

During the period, 1 January to 31 December 2019, the Company successfully raised a total of €15.6 million gross (€14.5 million net) across several fundraises from new and existing shareholders, employees and Company Directors. The majority of these proceeds are being used to advance Clevegen through the MATINS trial, further Traumakine development through the design and preparation of the next clinical trials and advance partnering discussions in respect of both Traumakine and Clevegen.

- In March 2019, €3.1 million gross (€2.9 net) through issuance of new ordinary shares.
- In May 2019, €1.3 million gross (€1.3 net) through issuance of new ordinary shares.
- In August 2019, €2.5 gross (€2.2 net) million through issuance of new ordinary shares.

- In November 2019, €8.7 million gross (€8.0 net) through issuance of new ordinary shares.

Financial Position

As at 31 December 2019, total cash and cash equivalents held were €7.1 million (2018: €4.1 million). The Company continues to exercise 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 and Liquidity Risks - Guidance for directors of companies that do not apply the UK Corporate Governance Code". The Company and its subsidiaries (the "Group") 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 €13.3 million during the year ended 31 December 2019. It had total equity of €1.6 million including an accumulated deficit of €80.0 million. As at that date, the Group had cash and cash equivalents of €7.1 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 fourth quarter of 2020. The Directors are continuing to explore sources of finance available to the Group and they believe 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 issuance of these financial statements, these circumstances represent a 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.

Headcount

Average headcount of the Company for the year was 24 (2018: 25).

Shares and Share Capital

During the period 1 January to 31 December 2019, the Company, using the share authorities granted at the Annual General Meetings held on 31 May 2018 and on 28 May

2019, as well as at an Extraordinary General Meeting held on 25 October 2019, issued a total of 12,262,853 new ordinary shares.

- On 28 March 2019, 4,448,625 shares at an issuance price of € 0.7020 (£0.60) per share.
- On 13 May 2019, 1,757,375 shares at an issuance price of € 0.7598 (£0.65) per share.
- On 5 August 2019, 941,840 shares at an issuance price of € 1.1900 (£1.06) per share.
- On 27 August 2019, 1,179,513 shares at an issuance price of € 1.1900 (£1.06) per share.
- On 12 November 2019, 3,935,500 shares at an issuance price of €2.1980 (£1.90) per share.

The subscription price net of costs 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 2019 the total number of voting rights was 43,290,747.

Legal proceedings

As announced by the Company on 2 October 2019 and 30 December 2019, the Company has received a letter from Rentschler Biopharma SE in which Rentschler stated that it terminates the agreement concerning the Traumakine API manufacturing. The Company considers that this statement is without merit and has filed a request for arbitration to seek damages. To fund the proceedings, the Company has entered into a litigation funding agreement with a third-party recovery services provider which, in the event of success, would receive a typical portion of any damages awarded.

Toni Hänninen
Chief Financial Officer
March 19, 2020

Consolidated Income Statement, IFRS

| <i>€'000</i> | Unaudited 7-12/2019 6 months | Unaudited 7-12/2018 6 months | 1-12/2019 12 months | 1-12/2018 12 months |
|-------------------------------------|---|---|--------------------------------|--------------------------------|
| Revenue | 0 | (1) | 0 | 19 |
| Other operating income | 185 | 191 | 185 | 205 |
| Research and development expenses | (5,255) | (4,762) | (10,237) | (16,463) |
| General and administrative expenses | (1,688) | (1,378) | (3,049) | (3,750) |
| Operating loss | (6,758) | (5,951) | (13,101) | (19,989) |
| Financial expense | (151) | (70) | (224) | (397) |
| Financial income | 69 | (3) | 74 | 302 |
| Loss before tax | (6,840) | (6,024) | (13,251) | (20,084) |
| Tax expense | (10) | (2) | (11) | (2) |
| Loss for the period | (6,850) | (6,026) | (13,262) | (20,086) |
| Other comprehensive income | - | - | - | - |

| | | | | |
|--|----------------|----------------|-----------------|-----------------|
| Total comprehensive loss for the period | (6,850) | (6,026) | (13,262) | (20,086) |
| Loss per ordinary share | | | | |
| Basic and diluted loss per share, EUR | (0.16) | (0.19) | (0.31) | (0.65) |

Consolidated Balance Sheet, IFRS

€'000

**31 December
2019**

**31 December
2018**

Assets

Non-current assets

| | | |
|-----------------------------------|--------------|--------------|
| Machinery and equipment | 13 | 17 |
| Right-of-use-assets | 386 | - |
| Intangible assets | 529 | 525 |
| Prepayments and other receivables | 77 | 636 |
| Total non-current assets | 1,005 | 1,177 |

Current assets

| | | |
|-----------------------------------|--------------|--------------|
| Prepayments and other receivables | 2,145 | 2,759 |
| Cash and cash equivalents | 7,059 | 4,067 |
| Total current assets | 9,204 | 6,825 |

| | | |
|---------------------|---------------|--------------|
| Total assets | 10,209 | 8,002 |
|---------------------|---------------|--------------|

Equity and liabilities

Capital and reserves attributable to the equity holders of the Company

| | | |
|--|--------------|------------|
| Share capital | 2,691 | 2,691 |
| Reserve for invested unrestricted equity | 78,916 | 64,464 |
| Accumulated deficit | (79,997) | (66,786) |
| Translation difference | - | - |
| Total equity | 1,610 | 369 |

Non-current liabilities

| | | |
|--------------------------------------|---------------|--------------|
| Borrowings | 2,263 | 1,887 |
| Lease liabilities | 261 | - |
| Total non-current liabilities | 2,524 | 1,887 |
| <i>Current liabilities</i> | | |
| Borrowings | 163 | 245 |
| Lease liabilities | 135 | - |
| Trade payables | 2,967 | 3,534 |
| Other current liabilities | 2,810 | 1,967 |
| Total current liabilities | 6,075 | 5,745 |
| Total liabilities | 8,599 | 7,633 |
| Total equity and liabilities | 10,209 | 8,002 |

Consolidated Statement of Changes in Equity, IFRS

| €'000 | Share capital | Reserve for invested unrestricted equity | Translation difference | Accumulated deficit | Total equity |
|---|---------------|--|------------------------|---------------------|---------------|
| Balance as at 31 December 2017 | 2,691 | 48,576 | - | (46,524) | 4,743 |
| Comprehensive loss for the period | - | - | - | (20,086) | (20,086) |
| Transactions with equity holders of the Company | | | | | |
| Issue of ordinary shares, net of transaction costs EUR 1,149 thousand | - | 15,888 | - | - | 15,888 |
| Share-based compensation | - | - | - | (176) | (176) |
| | - | 15,888 | - | (176) | 15,712 |
| Balance as at 31 December 2018 | 2,691 | 64,464 | - | (66,786) | 369 |
| Comprehensive loss for the period | - | - | - | (13,262) | (13,262) |

Transactions with equity holders of the Company

Issue of ordinary shares,

net of transaction costs

| | | | | | |
|--------------------------|---|---------------|---|-----------|---------------|
| EUR 1,149 thousand | - | 14,452 | - | - | 14,452 |
| Share-based compensation | - | - | - | 51 | 51 |
| | - | 14,452 | - | 51 | 14,503 |

Balance as at 31

| | | | | | |
|----------------------|--------------|---------------|----------|-----------------|--------------|
| December 2019 | 2,691 | 78,916 | - | (79,997) | 1,610 |
|----------------------|--------------|---------------|----------|-----------------|--------------|

Consolidated Cash Flow Statement, IFRS

| | Unaudited 7-12/2019 6 months | Unaudited 7-12/2018 6 months | 1-12/2019 12 months | 1-12/2018 12 months |
|--|---|---|--------------------------------|--------------------------------|
|--|---|---|--------------------------------|--------------------------------|

€'000

Cash flow from

operating activities

| | | | | |
|---|----------------|----------------|-----------------|-----------------|
| Loss before tax | (6,840) | (6,024) | (13,251) | (20,084) |
| Adjustments for: | | | | |
| Depreciation and amortisation | 190 | 58 | 238 | 100 |
| Interest expense | 119 | 74 | 158 | 121 |
| Tax expense | 11 | - | 11 | - |
| Unrealised foreign exchange loss (gain), net | (36) | (1) | (7) | (36) |
| Share-based compensation | 0 | (326) | 51 | (176) |
| Adjusted loss from operations before changes in working capital | (6,556) | (6,220) | (12,800) | (20,075) |
| Change in net working capital: | | | | |
| Prepayments and other receivables | (547) | 1,716 | 1,173 | 1,836 |
| Trade payables | 99 | (1,368) | (567) | 338 |
| Other liabilities | 1,081 | (1,053) | 731 | (2,595) |
| Cash used in operations | (5,923) | (6,926) | (11,463) | (20,496) |
| Taxes paid | (9) | (2) | (9) | (2) |
| Interest paid | (25) | (14) | (51) | (27) |
| Net cash used in operating activities | (5,957) | (6,042) | (11,523) | (20,525) |

Cash flow from

investing activities

| | | | | |
|--|-------------|--------------|--------------|--------------|
| Payments for intangible assets | (59) | (161) | (100) | (293) |
| Payments for equipment | - | - | - | (2) |
| Net cash used in investing activities | (59) | (161) | (100) | (295) |

| | | | | |
|---|---------------|----------------|---------------|----------------|
| Cash flow from financing activities | | | | |
| Proceeds from issue of shares | 11,166 | - | 15,627 | 17,023 |
| Share issue transaction cost | (944) | - | (1,175) | (1,135) |
| Proceeds from borrowings | 76 | - | 307 | - |
| Repayment of borrowings | - | - | - | (347) |
| Payment of lease liabilities | (151) | - | (151) | - |
| Net cash from financing activities | 10,147 | - | 14,608 | 15,541 |
| Net increase (+) / decrease (-) in cash and cash equivalents | 4,131 | (7,103) | 2,985 | (5,279) |
| Effect of exchange rate changes on cash and cash equivalents | 36 | 1 | 7 | 36 |
| Cash and cash equivalents at 1 January | 2,892 | 11,168 | 4,067 | 9,310 |
| Cash and cash equivalents at 31 December | 7,059 | 4,067 | 7,059 | 4,067 |

This information is provided by RNS, the news service of the London Stock Exchange. RNS is approved by the Financial Conduct Authority to act as a Primary Information Provider in the United Kingdom. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact rns@lseg.com or visit www.rns.com.

END

FR DDGDXXXBDGGC