

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

Financial statement release January 1 to December 31, 2020

- **Clevegen® (*bexmarilimab*) Phase I/II MATINS study has shown early clinical benefits in six hard-to-treat solid cancers with further combination studies planned**
- **Intravenous interferon beta-1a Traumakine®, for organ damage protection, now also investigated as potential COVID-19 treatment**
- **Company's balance sheet strengthened by successful share placings of €14 million and €15 million (post period)**
- **Additional grants of €3.3 million and €4.6 million loans and loan guarantees awarded to drive R&D and CMC programmes**

Financial statement release, 25 March 2021 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 2020 and H2 2020.

HIGHLIGHTS

Operational (including post period):

Clevegen® (*bexmarilimab*) – *Faron's wholly-owned, novel precision cancer immunotherapy candidate, in Phase I/II development for difficult-to-treat cancers.*

- **Strong patient recruitment** continues in Part II of the Phase I/II MATINS trial, investigating the potential of *bexmarilimab* in patients with solid tumours who have exhausted all treatment options. 10 cancer types – cutaneous melanoma, uveal melanoma, ovarian cancer, colorectal cancer (CRC), hepatocellular cancer, ER+ breast cancer, pancreatic cancer, gastric cancer, cholangiocarcinoma, anaplastic thyroid carcinoma – are currently under investigation.
- **Clinical benefits have been observed across six cancer types** to date – CRC, ovarian cancer, cutaneous melanoma, hepatocellular cancer, cholangiocarcinoma and gastric cancer. These are primary candidates to become expansion cohorts for Part III of the study.
- **More frequent dosing**, beyond the original three week dosing interval, is being explored in all six cohort types showing early signs of clinical benefit in order to confirm the optimum dosing regimen for pivotal studies, following analysis of key pharmacokinetic and pharmacodynamic biomarkers indicating the potential for increased *bexmarilimab* efficacy.

- **Clinical expansion trials** will investigate *bexmarilimab*'s potential in additional clinical settings, with trials expected to start later in 2021 – in combination with standard of care (SOC) as a first-line therapy in selected advanced solid tumours and haematological malignancies. Additionally, trials will also investigate *bexmarilimab* as a standalone neoadjuvant therapy for patients with early stage CRC and and clear cell renal cell carcinoma.
- **Established soluble Clever-1 as potential inhibitor of T cell activation** through the testing of MATINS patients' plasma. New findings suggest that their high levels of free, soluble Clever-1 can act as a direct inhibitor of T cell activation, thereby providing a broader immunosuppressive effect than previously expected. This suggests that the inactivation of Clever-1 could be more broadly applicable, potentially enabling patients to benefit from immuno-oncology therapies which have previously been ineffective. A new patent application has been filed seeking global protection for these findings and related applications.
- **Commercial scale manufacturing contract** for the development and manufacturing of *bexmarilimab* was established with AGC Biologics.
- **€3.3 million grants to support the development of *bexmarilimab*** were received in 2020 from the European Innovation Council (EIC) Accelerator pilot scheme (€2.5 million) and the Finnish Cancer IO consortium (€0.8 million).
- **Scientific learnings on *bexmarilimab* were shared at key global conferences** including the virtual American Society of Clinical Oncology (ASCO20) Annual Meeting, the European Society of Medical Oncology (ESMO) Virtual Congress and ESMO's Immuno-Oncology Virtual Congress 2020.

Traumakine® - *Faron's investigational intravenous (IV) interferon beta-1a therapy is in development for the treatment of acute respiratory distress syndrome (ARDS) and other ischemic or hyperinflammatory conditions.*

- **Supported the global search for potential treatments for COVID-19**, with Traumakine's inclusion in two global initiatives in 2020 – the global REMAP-CAP (Randomized, Embedded, Multifactorial Adaptive Platform Trial for Community-Acquired Pneumonia), which is ongoing across more than 200 sites and 19 countries, and the WHO's Solidarity trial. The WHO trial determined in October 2020 that subcutaneous IFN beta-1a was ineffective in reducing overall mortality in hospitalised COVID-19 patients. At the time of analysis, too few patients had received an IV formulation of IFN beta to enable interpretation of the data and to draw any conclusions on its effect. WHO has yet to provide the Company with detailed dosing and safety information which is a normal regulatory requirement for drug testing and use.
- **On track to initiate a Faron-sponsored trial investigating the potential of Traumakine to treat COVID-19.** The Phase II/III HIBISCUS (**H**uman intravenous **I**nterferon **B**eta-1a **S**afety and preliminary efficacy in hospitalised subjects with **C**oronavir**US**) study will be conducted in approximately 5-10 study sites across the US in hospitalised patients with COVID-19, who do not yet require mechanical ventilation, but maximally low flow oxygen support. Use of corticosteroids concomitantly with Traumakine is not possible in the study setting but enabled in a sequenced manner, following

Traumakine treatment. Post period the Company received \$6.1 million of funding from the Coronavirus Aid, Relief, and Economic Security (CARES) Act, granted by the US Department of Defense, to support HIBISCUS.

- **Building on Faron's already strong IP portfolio for Traumakine**, the Company applied for additional patent protection for Traumakine relating to the induction of CD73 for organ protection, followed by the use of corticosteroids for the treatment of systemic inflammation. In this sequence, the best effects of both drugs are optimised in a sequence for patient benefit. This order is strongly supported by molecular analysis of IFN-beta signaling pathways in many published articles over recent months.
- **Partnership established with the 59th Medical Wing of the U.S. Air Force and U.S. Army and U.S. Army Institute of Surgical Research** to explore the use of Traumakine for organ protection in combat wounds leading to multi-organ failure from ischemia and reperfusion.
- **To support Traumakine's potential future commercial use**, AGC Biologics was selected to be the new manufacturing house for commercial scale production. A €2.1 million low interest rate loan from Business Finland and a €2.5 million loan guarantee from Finnvera, the official Export Credit Agency of Finland, are supporting the establishment of a new cell line for the manufacturing process.
- **Detailed analyses into the deleterious effects of glucocorticoids** on Traumakine activity, undertaken following the INTEREST trial results in 2018, were published in *Intensive Care Medicine*, a world-leading journal in the field of critical care, in May 2020.

Haematokine® – *An AOC3 (amine oxidase copper containing 3) protein inhibitor in development for use in regenerative medicine and to treat hematological malignancies.*

- **Faron acquired rights for this potential use of AOC3 inhibitors** in March 2020 and will be responsible for the future development of Haematokine and for the management, prosecution, maintenance and filing of patent applications.
- **IND-enabling studies for this programme are continuing** and, following a first review by the Finnish patent office, the Company believes global patent protection could be possible for the Haematokine project.

Corporate

- Faron hosted a virtual R&D Day presenting the Company's R&D strategy and insights into its two clinical stage programmes. Alongside Dr Markku Jalkanen, Chief Executive Officer, and members of the Executive Leadership and senior management teams, external perspectives were provided by Prof. Alberto Mantovani, Humanitas University, Milan, Italy; Ass. Prof. Maija Hollmén, MediCity, Turku University, Finland and Dr. Petri Bono, Terveystalo, Helsinki, Finland.

Impact of COVID-19

- During the pandemic the Company's ability to secure funding and remote working operations has been key to continued success. Even during exceptional circumstances, Faron has been able to

continue to operate its business almost normally and the development of its clinical trials proceeded as planned.

- Additionally, Faron closely followed and strictly complied with the regulations and recommendations of the Finnish National Institute for Health and Welfare (THL) and other relevant authorities to ensure the safety for its employees, study subjects and partners.

Financial

- On 31 December 2020, the Company held cash balances of €4.1 million (2019: €7.1 million).
- Loss for the period for the financial year ended 31 December 2020 was €16.9 million (2019: €13.3 million).
- Net assets on 31 December 2020 were €-1.8 million (2019: €1.6 million).
- In April 2020, the Company successfully raised a total of €14.0 million gross (€13.0 million net) from new and existing shareholders, through issuance of total of 3,500,000 new ordinary shares. The majority of these proceeds are being used to expand Clevegen in additional targets in the MATINS trial, support Traumakine in the ongoing REMAP-CAP trial and to strengthen the Company's balance sheet.
- The Company received a combination of grants, loans and loan guarantees totalling €7.9 million from Business Finland (May 2020: Grant €0.8 million, June 2020: Loan €2.1 million), The European Innovation Council (June 2020: Grant €2.5 million), Finnvera (Aug 2020: Loan guarantee €2.5 million). A total of €2.2 million of these funds were received during the period and the rest will continue to be received post period.
- Post period in February 2021, the Company raised €15 million gross (approximately €14.4 million net) from new and existing shareholders through an issuance of 3,521,127 new ordinary shares.

Consolidated key figures, IFRS

€'000	Unaudited 7-12/2020 6 months	Unaudited 7-12/2019 6 months	1-12/2020 12 months	1-12/2019 12 months
Revenue	0	0	0	0
Other operating income	1,379	185	2,122	185
Research and Development expenses	(8,345)	(5,255)	(13,879)	(10,237)
General and Administrative expenses	(2,543)	(1,688)	(4,897)	(3,049)
Loss for the period	(9,603)	(6,850)	(16,946)	(13,262)
	Unaudited 7-12/2020 6 months	Unaudited 7-12/2019 6 months	1-12/2020 12 months	1-12/2019 12 months

Loss per share EUR	(0.22)	(0.18)	(0.37)	(0.36)
Number of shares at end of period	46,896,747	43,290,747	46,896,747	43,290,747
Average number of shares	44,606,204	38,551,293	45,712,111	36,850,577
€'000	Unaudited 30 Jun 2020	Unaudited 30 Jun 2019	31 Dec 2020	31 Dec 2019
Cash and cash equivalents	11,627	2,892	4,108	7,059
Equity	7,313	(1,761)	(1,849)	1,610
Balance sheet total	14,343	5,103	8,367	10,209

Commenting on the results, Dr Markku Jalkanen, CEO of Faron, said: “The past year has been one of the most significant in Faron’s history, with rapid expansion of our clinical development programme for *bexmarilimab*, our novel Clever-1 targeting precision immunotherapy. Seeing the latest data from the MATINS trial, showing clinical benefit across six different tumour types, has been highly rewarding and gives us great confidence in the future of this next-generation immunotherapy. Our growing understanding of Clever-1 as an immune suppressive molecule and its role in the systemic inhibition of T-cells only adds to our confidence in *bexmarilimab* and its potential as a breakthrough therapy with broad application for patients with hard-to-treat cancers or those who no longer respond to current immunotherapies.

“I am very pleased that we have been able to support ongoing global research efforts to find the much needed, effective treatments for COVID-19 patients. The science behind Traumakine, our intravenous interferon (IFN) beta-1a, and its potential to prevent multi-organ failure by upregulating the key endothelial enzyme CD73, is compelling. We continue to believe that an intravenous formulation of IFN beta-1a is what patients need, to strengthen the body’s own IFN beta signaling – the first line of defence against viral infection – and provide optimal exposure to the lung vasculature. With evidence emerging of increased interferon resistance among COVID-19 variants, suggesting the virus is evolving with new ways to evade our innate immune defences, research into the potential of exogenous interferon to reduce severe disease and mortality in COVID-10 patients remains critical.

“The Company’s successful fundraising in 2020 and, post period, in February this year, puts us in a strong position to continue the progress of our pipeline and brings us closer to our goal of developing ground-breaking new treatments from our unique scientific discoveries. I’d like to thank our shareholders for their continued support and the entire team at Faron for their exceptional efforts during a challenging year.”

Board of Directors’ Proposal on the Dividend

The Group’s loss for the accounting period was 16,946,261.84 euro (2019: 13,261,911.93 euro).

The Board of Directors does not recommend the payment of a dividend (2019: nil).

24 March 2021

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

A virtual briefing and Q&A session for analysts will be hosted by Dr. Markku Jalkanen, Chief Executive Officer, and Toni Hänninen, Chief Financial Officer, at 12:00 pm GMT / 2:00 pm EET / 8:00 am EST on the day of results. The Full-year results release for 2020, presentation, webcast details, and Annual Report 2020 will be made available at www.faron.com/investors. A replay of the analyst briefing will be made available shortly afterwards.

Webcast link: <https://www.lsegissuerservices.com/spark/FaronPharmaceuticalsOy/events/04110470-3c65-4dad-ba56-54b27e83f27f>

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Publication of financial information during year 2021

The half-year financial report for the period 1 January to 30 June 2021 is scheduled to be published on 26 August 2021. Faron's financial statements for full year 2020 will be published on 25 March 2021 and will also be available on the Company's website at <https://www.faron.com/investors/results>.

The Annual General Meeting is planned for 23 April 2021. 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 caused by dysfunction of our immune system. The Company currently has a pipeline based on the receptors involved in regulation of immune response in oncology, organ damage and bone marrow regeneration. Bexmarilimab, a novel anti-Clever-1 humanised antibody, is its investigative precision immunotherapy with the potential to provide permanent immune stimulation for difficult-to-treat cancers through targeting myeloid function. Currently in phase I/II clinical development as a potential therapy for patients with untreatable solid tumours, bexmarilimab has potential as a single-agent therapy or in combination with other standard treatments including immune checkpoint molecules. Traumakine is an investigational intravenous (IV) interferon beta-1a therapy for the treatment of acute respiratory distress syndrome (ARDS) and other ischemic or hyperinflammatory conditions. Traumakine is currently being evaluated in global trials as a potential treatment for hospitalised patients with COVID-19 and with the 59th Medical Wing of the US Air Force and the US Department of Defense for the prevention of multiple organ dysfunction syndrome (MODS) after ischemia-reperfusion injury caused by a major trauma. 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

2020 was a year of significant activity for Faron. Despite the challenges that the global pandemic presented to business continuity and clinical trials across the life sciences sector, the Company's focus on pipeline delivery continued unabated and delivered impressive results.

The development programme for *bexmarilimab*, Faron's wholly-owned novel precision cancer immunotherapy candidate, made important clinical progress in 2020 following completion of the dose-finding Part I of the MATINS clinical trial. While intended to investigate safety and tolerability, this part of the trial also delivered exciting data on the potential of this therapy to promote immune activation, and early signs of clinical benefit. With ten different hard-to-treat cancers now under investigation in the second part of the trial, the Company is gaining greater insights into the future clinical use and commercial potential of this unique Clever-1 targeting therapy, with a clear focus on patient populations whose cancers are known to demonstrate significant levels of the Clever-1 receptor.

The Faron team's analyses of data from the trial, alongside the broader scientific community's growing understanding of the role of Clever-1 as an immune suppressive molecule, have provided a much clearer understanding of the next steps required for *bexmarilimab*'s clinical development and support its potential as

a breakthrough therapy for the future. Harnessing the immune system to fight cancer using immunotherapy has, undoubtedly, been one of the most exciting breakthroughs in modern science and the first wave of pioneering treatments changed the face of cancer treatment. We know these therapies do not work for everyone and many patients who initially respond will eventually relapse. Combining immunotherapies with complementary approaches is becoming increasingly important in cancer treatment and *bexmarilimab's* expanded clinical development programme, investigating its combination with existing treatments, will provide important evidence of its potential use as a future combination therapy.

The emergence of COVID-19 and its serious complications, including acute respiratory distress syndrome (ARDS), mobilised medical and scientific communities in 2020. I was very pleased that Faron answered the global call for potential therapies that might contribute to the fight against the pandemic, by providing Traumakine, Faron's intravenous (IV) interferon (IFN) beta-1a, to two global initiatives investigating multiple therapies to treat severe COVID-19 patients – the REMAP-CAP (Randomized, Embedded, Multifactorial Adaptive Platform Trial for Community-Acquired Pneumonia) and the World Health Organization's (WHO) Solidarity trial.

Faron has generated a wealth of data to support the hypothesis that Traumakine can strengthen the body's natural defences and provide increased protection against serious lung complications. Sadly, the first global initiative to report data –WHO's Solidarity trial – did not generate supportive results, with too few patients receiving an IV formulation of IFN beta to enable interpretation of the data and to draw any conclusions on the effect of IV IFN beta.

Faron's earlier observations from Traumakine's development programme in ARDS patients, that corticosteroid use interferes with Traumakine's efficacy, are a significant consideration in trialling the potential of this therapy in COVID-19 patients. A third trial investigating Traumakine in COVID-19 patients, the Company's US phase II/III HIBISCUS trial, in which the use of corticosteroids is only possible following treatment with Traumakine, will yield important results. Interest in IFN beta as a COVID-19 therapy continues to be strong and I am proud that Faron remains actively involved in research to further build the treatment armamentarium against COVID-19.

Through 2020, as the world adapted to life during a pandemic, Faron as a company showed remarkable resilience in the face of such unexpected pressures. Thanks to the strength shown by everyone across the Company, who quickly responded to a very different working environment, all business operations were maintained, clinical progress accelerated and engagement with the scientific community continued at a number of virtual congresses.

Faron's successful financing, both the capital fundraising and securing non-dilutive funding, was a major undertaking, particularly in a virtual world. It puts the Company in a strong financial position to progress its clinical programmes and related business activities, as well as to explore further scientific opportunities within the Faron pipeline.

On behalf of the Board, I would like to thank everyone who has contributed to Faron maintaining its momentum in a difficult year – each and every member of staff and my colleagues on the Board for their commitment to the Company; our partner organisations and steering committee members for their support and expertise; Faron’s investors for showing continued confidence in the Company and, importantly, the clinicians and patients across our trial network. Particular thanks must also go to our Chief Executive Officer, Markku Jalkanen, and Chief Financial Officer, Toni Hänninen, for their leadership throughout 2020.

We look forward to continued progress in 2021.

Dr Frank Armstrong
Chairman
24 March 2021

Chief Executive Officer’s Review

Overview

Faron has three assets (Clevegen® – *bexmariliumab*; Traumakine® and Haematokine®), all focusing on harnessing our immune system. We believe that the three target molecules Clever-1, CD73 and AOC3 provide new medical treatment options either to activate, suppress or maintain the power of our immune system. 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 2020 has been to continue to progress our wholly-owned novel precision cancer immunotherapy candidate, *bexmarilimab*, 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 finalize the HIBISCUS study protocol for Traumakine in acute respiratory distress syndrome (ARDS) and organ failures, and were pleased to provide Traumakine to global initiatives investigating multiple therapies to treat severe COVID-19 patients, although our focus to protect central organ provides significant wider application potential. The third asset around AOC3, Haematokine, could help to recover lost renewal of blood cells and activate our immune defence and other vital blood functions.

***Bexmarilimab* (Clevegen)**

During 2020, we have continued to make strong progress in accelerating the clinical development of *bexmarilimab* despite the challenges of COVID-19. *Bexmarilimab* 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) by inactivating the function of CLEVER-1 receptor. *Bexmarilimab* is differentiated from

other immunotherapies through its specific targeting of M2 TAMs, which facilitate tumour growth. Through myeloid cell plasticity, *bexmarilimab* 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 study

The ongoing Phase I/II 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 *bexmarilimab* in selected metastatic or inoperable solid tumours.

The completed Part I of the MATINS trial, primarily intended to investigate safety and tolerability, has already shown that *bexmarilimab* administration promoted immune activation in MATINS patients, with data also indicating that *bexmarilimab* can down regulate a range of major inhibitory immune checkpoints (like PD-1, CTLA-4, etc.) that current immuno-oncology therapies aim to suppress. *Bexmarilimab* has also been well tolerated, showing no significant adverse events even at the highest dosing levels.

Clinical progress accelerated early in 2020 and today six out of 10 test cohorts have demonstrated early clinical benefits, being currently primary candidates to become expansion cohorts for Part III of the MATINS study as a monotherapy in patients who have exhausted all treatment options. All these solid cancer types (colorectal cancer, ovarian cancer, cutaneous melanoma, hepatocellular cancer, cholangiocarcinoma – also known as bile duct cancer – and gastric cancer) require additional treatment options and therefore present a significant commercial opportunity.

As a result of key pharmacokinetic and pharmacodynamic biomarkers indicating that more frequent dosing could potentially increase *bexmarilimab* treatment efficacy, compared to the original dosing interval of every three weeks, the regulatory authorities approved an expansion of MATINS to include two additional CRC cohorts receiving 1 mg/kg dosed at either weekly or two week intervals, which are on-going currently. The aim is to reach enough data to finalise dosing regimen for *bexmarilimab* prior entering pivotal studies. Recently the MATINS study data monitoring committee (DMC) also proposed to study more frequent dosing and higher doses across all six cohort types showing early signs of clinical benefit and plans for this are underway.

An additional post period important finding was the discovery of an abundant amount of free, soluble Clever-1 in the plasma of MATINS study patients. Further experimental testing of isolated Clever-1 has indicated that this soluble form is a direct inhibitor of T cell activation and its inactivation could potentially result in an improved immune response and therefore enable patients to benefit from immuno-oncology therapeutics which have previously been ineffective. A new patent application has been filed seeking global protection for these findings and related applications.

Clinical expansion

Many findings support *bexmarilimab* combination with negative immune check point inhibitors: i) synergistic effect has been observed in animal models, ii) human tumours with high Clever-1 transcript are resistant to current immuno-oncology therapies and iii) *bexmarilimab* administration can down regulate these inhibitors. These facts have led Faron to design *bexmarilimab* combination studies with standard of care, as a first-line therapy in selected advanced solid tumours and haematological malignancies, and as a standalone neoadjuvant therapy for patients with early stage colon cancer, all of which Company hopes to start in 2021.

Alongside *bexmarilimab*'s clinical progress in 2020, the Company has undertaken further work to prepare for its future, by appointing global contract development and manufacturing organisation, AGC Biologics, as the commercial scale manufacturer. AGC Biologics has decades of experience in manufacturing of biotechnological products, including commercial market supplies of FDA (US), PDMA (Japan), MHRA (UK) and EMA (continental Europe) approved products.

Traumakine

Faron is encouraged by recent vaccine developments to curb the spread of COVID-19 but the need for effective treatment options to reduce intensive care need and mortality for COVID-19 and other virally infected (e.g. influenza) patients remains critical. As such, the Company remains involved in international efforts supported by the global scientific community to explore the therapeutic and antiviral effects of the Company's intravenous (IV) interferon (IFN) beta-1a, Traumakine, and to continue to develop the asset as a future treatment for acute respiratory distress syndrome (ARDS).

Having demonstrated a compelling argument as one of the body's main first lines of defence against viral infection, recent findings have also shown that seriously ill COVID-19 patients have compromised interferon responses (Feulliet et al. 2021). These findings continue to drive confidence that treatment with Traumakine can strengthen the body's natural defences if administered intravenously. Specifically, the intravenous dosing of Faron's IFN beta-1a provides the lung vasculature with optimal exposure to IFN, which we believe is a critical aspect of Traumakine's potential to increase protection against serious lung complications.

In 2020, we joined two global initiatives investigating the potential of multiple therapies to treat COVID-19, by providing supplies of Traumakine to the REMAP-CAP programme and the World Health Organization's (WHO) Solidarity trial. The data readout from the WHO Solidarity trial was announced in October 2020 and concluded that subcutaneous IFN beta-1a was ineffective in treating hospitalised COVID-19 patients. Interestingly, the use of concomitant steroids had no impact on this outcome, confirming again that subcutaneous dosing has limited exposure to the lungs and should not be practiced. Traumakine continues to be investigated as part of the ongoing global REMAP-CAP programme, which is evaluating potential treatments for community-acquired pneumonia, including in COVID-19 patients, and is currently ongoing across more than 200 sites and 19 countries.

Faron is also initiating a third trial investigating the potential of Traumakine to treat COVID-19 – the US Human intravenous Interferon Beta-1a Safety and preliminary efficacy in hospitalised subjects with CoronavirUS (HIBISCUS) trial – which, in January 2021, received \$6.1 million from the US Department of Defense (DOD) as part of the Coronavirus Aid, Relief, and Economic Security (CARES) Act. The HIBISCUS trial is a phase II/III study to evaluate the potential of Traumakine to treat COVID-19 and will be conducted in approximately 5-10 study sites across the US in hospitalised patients with COVID-19, who do not yet require mechanical ventilation, but maximally low flow oxygen support. Use of corticosteroids concomitantly with Traumakine is not possible in the study setting but enabled in a sequenced manner after Traumakine. Supporting this protocol, a detailed analysis into the effects of glucocorticoids on IV IFN beta-1a activity, which arose following the INTEREST trial in 2018, was published in *Intensive Care Medicine*, a world leading journal in the field of critical care, in May 2020. The results showed that the desired mechanism of action of IV IFN beta-1a in the lung vasculature – the upregulation of CD73 – is blocked by the administration of glucocorticoids, and co-administration of glucocorticoids with IV IFN beta-1a increases mortality in patients with ARDS compared to patients administered with IV IFN beta-1a alone.

Subject to data from these trials supporting Traumakine's profile, the Company will work with regulatory authorities and other parties to identify the best path to ensure its future availability to patients.

To progress Traumakine manufacturing and support its potential future commercial use, in August 2020 Faron announced plans to initiate a new state-of-the-art process for Traumakine manufacturing with a €2.1 million low interest rate loan from Business Finland, the governmental innovation financing agency of Finland. This will be used to develop and select a new cell line that can be used for future commercial scale production of Traumakine. The Company subsequently received a loan guarantee from Finnvera for €2.5 million to expand the commercial scale manufacturing.

Haematokine

In March 2020, Faron announced it had acquired rights for the potential new use of AOC3 inhibitors. The AOC3 enzymatic domain, a semicarbazide-sensitive amine oxidase, is known to produce hydrogen peroxide, a potent inflammatory mediator. AOC3 in vivo, ex vivo and in vitro studies have revealed that AOC3's enzymatic end product hydrogen peroxide (H₂O₂) controls expansion of hematopoietic stem cells. Hematopoietic Stem Cell Transplantation (HSCT) is today the standard of care in all haematological malignancies. This is due to the fact that transplant failure is a lethal complication and a result of poor expansion of transplanted cells, which can occur in up to 30 per cent of patients. In addition, secondary transplantation and treatments to revive failing transplants are expensive and often unsuccessful. With Haematokine, we believe we can expand stem cells by regulating AOC3 activity.

Pre-clinical studies with humanised AOC3 mice and with ex vivo human cells are currently ongoing and further information will be provided later in the year.

Corporate

In June 2020, we hosted a virtual R&D Day presenting the Company's R&D strategy and insights into our clinical stage programmes. In addition to Faron's management, external perspectives were provided by Prof. Alberto Mantovani, Humanitas University, Milan, Italy; Ass. Prof. Maija Hollmén, MediCity, Turku University, Finland and Dr. Petri Bono, Terveystalo, Helsinki, Finland.

At the Annual General Meeting held on 18 May 2020, the number of members of the Board was confirmed 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.

The Company also announced in July 2020 that Cairn Financial Advisers LLP had been appointed as Nominated Adviser to the Company with immediate effect with Panmure Gordon (UK) Limited continuing to act as the Company's Broker.

Financial

During the period, the Company successfully raised approximately €14.0 million (gross), €13.0 million (net) from new and existing shareholders. Additionally, the Company was also awarded grants and loans from Business Finland and from the European Innovation Council (EIC) Accelerator pilot scheme and a Finnvera loan guarantee in total of €7.9 million.

Post period in February 2021, the Company raised €15.0 million gross (approximately €14.4 million net) from new and existing shareholders through an issuance of 3,521,127 new ordinary shares.

Outlook

Our focus for 2021 will be to continue to progress *bexmarilimab*'s clinical development through Part II and Part III of the MATINS trial and new combination studies, to further develop our understanding of its potential future clinical use and commercial potential. We are excited to commence the HIBISCUS trial for Traumakine in the US and will continue to provide assistance with global efforts in fighting COVID-19. 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 and all the employees at Faron for their hard-work and dedication during this challenging year and look forward to updating the market on our progress throughout the course of 2021.

The Board anticipates the following pipeline progress and catalysts during 2021:

Clevegen:

- Summary of data from MATINS Part I
- Final CLEVER-1 occupancy data
- Top line data from MATINS Part II

- First patient in neoadjuvant CRC and RCC
- Final dosage and dose frequency decision
- Selection of first pivotal cohort from MATINS trial
- First patient in NSCLC PD(L)1 combination
- First patient in haematological malignancies
- Pre-clinical evaluation in multiple new tumour types

Traumakine:

- Initiation of HIBISCUS
- Anticipated REMAP-CAP interim read out
- Formation of a Traumakine Scientific Advisory Board
- Interim analysis from HIBISCUS
- Preclinical work on solid organ transplant
- Partnering update during 2021

AOC3 Antagonist Platform Technology:

- Additional information from pre-clinical studies with humanised AOC3 mice and with ex vivo human cells during 2021

Dr Markku Jalkanen
Chief Executive Officer
24 March 2021

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 during 2020. The Company's net cash flow showed €2.8 million negative due to an increase of R&D and G&A expenditure, partially offset by other income. 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 2020 (2019: €nil).

The Company recorded €2.1 million (2019: €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 increased by €3.6 million from €10.2 million in 2019 to €13.9 million in 2020. The costs of outsourced clinical trial services were increased by €2.5 million from €1.9 to €4.4 million. The cost of employee benefits in the R&D was increased by €0.8 million from €2.1 to €2.9 million, mainly driven by additional headcount.

GENERAL AND ADMINISTRATION COSTS

Administrative expenses increased by €1.9 million from €3.0 million in 2019 to €4.9 million in 2020. The increase was mainly due to the €1.2 million increase in other G&A costs, mainly driven by legal expenses, which were offset by other income. Further, employee benefits increased by €0.5 million mainly driven by additional headcount.

TAXATION

The Company's tax credit for the fiscal year 2020 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 2020 was €38.2 million (2019: €16.1 million). The Company estimates that it can utilise most of these during the years 2020 to 2021 by offsetting them against future profits. In addition, Faron has €55.0 million of R&D costs incurred in the financial years 2010 - 2020 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 €16.9 million (2019: €13.3 million). Net loss for the year was €16.9 million (2019: €13.3 million), representing a loss of €0.37 per share (2019: €0.36 per share) (adjusted for the changes in number of issued shares).

CASH FLOWS

Net cash flow was €2.8 million negative for the year ended 31 December 2020 (2019: €3.0 million positive). Cash used for operating activities increased by €6.0 million to €17.5 million for the year, compared to €11.5 million for the year ended 31 December 2019. This increase was mostly driven by an increase in R&D investments. Net cash inflow from financing activities was €14.8 million (2019: €14.6 million) mainly due to the successful equity placing completed in April 2020.

FUNDRAISING

In April 2020, the Company successfully raised a total of €14.0 million gross (€13.0 million net) through a fundraise from new and existing shareholders. The majority of these proceeds are being used to commence expansion of Clevegen through the MATINS trial, to support Traumakine in the ongoing REMAP-CAP trial and to strengthen the Company's balance sheet.

Post period in February 2021, the Company raised €15.0 million gross (approximately €14.4 million net) from new and existing shareholders through an issuance of 3,521,127 new ordinary shares.

FINANCIAL POSITION

As at 31 December 2020, total cash and cash equivalents held were €4.1 million (2019: €7.1 million).

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 €16.9 million during the year ended 31 December 2020. It had a negative equity of €1.8 million including an accumulated deficit of €96.6 million. As at that date, the Group had cash and cash equivalents of €4.1 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 2021. 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 30 (2019: 24).

SHARES AND SHARE CAPITAL

During the period 1 January to 31 December 2020, the Company, using the share authorities granted at the Extraordinary General Meetings held on 25 October 2019, issued a total of 3,500,000 new ordinary shares at an issuance price of €4.00 (£3.48) 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 2020 the total number of voting rights was 46,896,747.

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. The arbitration is ongoing and the final arbitration award is expected to be issued by the arbitration tribunal during the autumn 2021.

Toni Hänninen
Chief Financial Officer
24 March 2021

Consolidated Income Statement, IFRS

€'000	Unaudited 7-12/2020 6 months	Unaudited 7-12/2019 6 months	1-12/2020 12 months	1-12/2019 12 months
Revenue	0	0	0	0
Other operating income	1,379	185	2,122	185
Research and development expenses	(8,345)	(5,255)	(13,879)	(10,237)
General and administrative expenses	(2,543)	(1,688)	(4,897)	(3,049)
Operating loss	(9,509)	(6,758)	(16,654)	(13,101)
Financial expense	(160)	(151)	(389)	(224)
Financial income	76	69	107	74
Loss before tax	(9,593)	(6,840)	(16,936)	(13,251)
Tax expense	(10)	(10)	(10)	(11)
Loss for the period	(9,603)	(6,850)	(16,946)	(13,262)
Other comprehensive income		-		-
Total comprehensive loss for the period	(9,603)	(6,850)	(16,946)	(13,262)
Loss per ordinary share				
Basic and diluted loss per share, EUR	(0.22)	(0.16)	(0.37)	(0.36)

Consolidated Balance Sheet, IFRS

€'000

31 December 2020

31 December 2019

Assets
Non-current assets

Machinery and equipment	14	13
Right-of-use-assets	361	386
Intangible assets	565	529
Prepayments and other receivables	56	77
Total non-current assets	996	1,005

Current assets

Prepayments and other receivables	3,263	2,145
Cash and cash equivalents	4,108	7,059
Total current assets	7,371	9,204

Total assets	8,367	10,209
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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	92,015	78,916
Accumulated deficit	(96,557)	(79,997)
Translation difference	2	-
Total equity	(1,849)	1,610

Non-current liabilities

Borrowings	2,728	2,263
Lease liabilities	199	261
Other liabilities	786	0
Total non-current liabilities	3,713	2,524

Current liabilities

Borrowings	122	163
Lease liabilities	176	135
Trade payables	4,608	2,967

Other current liabilities	1,597	2,810
Total current liabilities	6,503	6,075
Total liabilities	10,216	8,599
Total equity and liabilities	8,367	10,209

Consolidated Statement of Changes in Equity, IFRS

€'000

	Share capital	Reserve for invested unrestricted equity	Translation difference	Accumulate d deficit	Total equity
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
Comprehensive loss for the period	-	-	2	(16,946)	(16,944)
Transactions with equity holders of the Company					
Issue of ordinary shares, net of transaction costs EUR 1,004 thousand	-	13,098	-	-	13,098
Share-based compensation	-	-	-	386	386
	-	13,098	-	386	13,484

Balance as at 31

December 2020	2,691	92,015	2	(96,557)	(1,849)
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Consolidated Cash Flow Statement, IFRS

€'000	Unaudited 7-12/2020 6 months	Unaudited 7-12/2019 6 months	1-12/2020 12 months	1-12/2019 12 months
Cash flow from operating activities				
Loss before tax	(9,593)	(6,840)	(16,936)	(13,251)
Adjustments for:				
Received grant	(587)	-	(587)	-
Depreciation and amortisation	153	190	283	238
Interest expense	56	119	149	158
Tax expense	10	11	10	11
Unrealised foreign exchange	242	(36)	117	(7)
loss (gain), net				
Share-based compensation	386	-	386	51
Adjusted loss from operations before changes in working capital	(9,333)	(6,556)	(16,578)	(12,800)
Change in net working capital:				
Prepayments and other receivables	(1,631)	(547)	(1,097)	1,173
Trade payables	1,878	99	1,641	(567)
Other liabilities	(83)	1,081	(1,416)	731
Cash used in operations	(9,169)	(5,923)	(17,450)	(11,463)
Taxes paid	(1)	(9)	(1)	(9)
Interest paid	1	(25)	(28)	(51)
Net cash used in operating activities	(9,169)	(5,957)	(17,479)	(11,523)
Cash flow from investing activities				
Payments for intangible assets	(60)	(59)	(137)	(100)
Payments for equipment	(3)	-	(5)	-
Net cash used in investing activities	(63)	(59)	(142)	(100)
Cash flow from financing activities				

Proceeds from issue of shares	106	11,166	14,103	15,627
Share issue transaction cost	(52)	(944)	(1,004)	(1,175)
Proceeds from borrowings	630	76	630	307
Repayment of borrowings	-	-	(122)	-
Proceed from grants	1,375	-	1,375	-
Payment of lease liabilities	(104)	(151)	(195)	(151)
Net cash from financing activities	1,955	10,147	14,787	14,608
Net increase (+) / decrease (-) in cash and cash equivalents	(7,277)	4,131	(2,834)	2,985
Effect of exchange rate changes on cash and cash equivalents	(242)	36	(117)	7
Cash and cash equivalents at 1 January	11,627	2,892	7,059	4,067
Cash and cash equivalents at 31 December	4,108	7,059	4,108	7,059