



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

Half-year report 1 January to 30 June 2020 (unaudited)

- **Development of novel cancer immunotherapy Clevegen® (*bexmarilimab*) continues in Phase I/II MATINS trial across 10 tumour types**
- **IV interferon beta-1a, Traumakine®, being investigated as potential COVID-19 treatment in two ongoing global trials with preparations for US trial underway**
- **Successful €14 million placing in April strengthens Company's balance sheet**
- **Additional grants of €3.3 million and €4.6 million loans awarded to drive R&D and CMC programmes**

Half-year report, 24 September 2020 at 9.00 AM (EEST)

TURKU, FINLAND – Faron Pharmaceuticals Oy (AIM: FARN, First North: FARON), the clinical stage biopharmaceutical company, today announces its unaudited half-year report for 1 January to 30 June 2020 (the "period").

HIGHLIGHTS

Operational (including post period):

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

Clinical Development Updates:

- Dosing of Part II of the ongoing MATINS trial commenced in February, with strong patient recruitment across 10 cancer types (ER-positive breast cancer, cholangiocarcinoma (bile duct cancer) and gall bladder cancer, colorectal cancer, gastric cancer, hepatocellular carcinoma, cutaneous melanoma, uveal melanoma, ovarian cancer, pancreatic ductal adenocarcinoma and anaplastic thyroid cancer). This basket trial also has three dosing levels for colorectal cancer (CRC) at 0.3, 1.0 and 3.0 mg/kg.
- A comprehensive review and analysis of data from the completed Part I (dose finding) stage of the trial was completed by the data monitoring committee ("DMC") with a recommendation from the DMC to rapidly expand into additional tumour types. As of today, and based on early clinical benefits, four cancer types (colorectal, ovarian, cutaneous melanoma and uveal melanoma) have been selected as the candidate expansion cancer types for Part III.
- The World Health Organization (WHO) approved *bexmarilimab* as the International Nonproprietary Name (INN) for Clevegen.
- Further detail was provided on clinical expansion plans for *bexmarilimab*, which will include the investigation of alternative dosing cycles, as pharmacodynamic (PD) markers may indicate a need for shorter frequencies, as well as further studies in additional clinical settings – in combination with standard of care (SOC) as a first-line therapy in selected advanced solid tumours and as a standalone neoadjuvant therapy for patients with early stage colon cancer.

- The Company expects to announce topline data from its first expansion cohorts of the MATINS trial in the fourth quarter of 2020 and determine the final dosage, and dosing frequency for the expansion cohorts, in the first quarter of 2021.

Data Presentations:

- Previously announced safety and efficacy data from Part I of the MATINS trial were presented at the virtual American Society of Clinical Oncology (ASCO20) Annual Meeting, showing that *bexmarilimab* was well tolerated without dose-limiting toxicities; CLEVER-1 inhibition led to immune cell activation and downregulation of several checkpoint molecules; and interferon gamma and chemokine CXCL10 responses were associated with clinical responses observed in target or non-target lesions.
- Data from Part I of the trial were also presented at the European Society of Medical Oncology (ESMO) Virtual Congress 2020, including key pharmacokinetics and Clever-1 occupancy data, evidence of very good tolerability across all dosing levels, immune activation in all subjects, promising clinical anti-tumour activity and the conversion of immunologically non-inflamed (cold) tumours into inflamed (hot) tumours in patients traditionally not responsive to currently available checkpoint inhibitors.

Business Development and Manufacturing:

- AGC Biologics, a global contract development and manufacturing organization, was selected as the commercial scale manufacturer of *bexmarilimab*. The commercial scale manufacturing process established by AGC Biologics will also provide a dossier to support future regulatory filings in Europe and the US.
- A €2,500,000 grant from the European Innovation Council (EIC) Accelerator pilot scheme was awarded to the Company to progress the MATINS trial and related business activities. The EIC Accelerator pilot scheme supports top-class innovators, entrepreneurs, small companies and scientists with funding opportunities to support developing and bringing to the market new breakthrough products, services and business models that would become future drivers of economic growth for Europe.
- Faron joined the Finnish Cancer IO consortium, a new cancer immunotherapy-focused €10 million top-level collaborative research and innovation project within Business Finland's Personalized Health Program, and was awarded a €800,000 grant from Business Finland to conduct a detailed, state-of-the-art characterization of the immunological responses seen in cancer patients in the MATINS trial. *Bexmarilimab* will be studied in experimental combinations with anti-cancer molecules from other consortium members.

Traumakine® - in development for the treatment of organ failures

Clinical Development:

- Faron's intravenous (IV) interferon (IFN) beta-1a, Traumakine, was selected to be part of the two global trials investigating potential treatments for COVID-19.
- WHO's global Solidarity trial began in April 2020 investigating four treatment options against SOC to assess their relative effectiveness against COVID-19 – remdesivir; lopinavir/ritonavir; lopinavir/ritonavir with IFN beta-1a; and chloroquine or hydroxychloroquine. In July, WHO removed the hydroxychloroquine and lopinavir/ritonavir treatment arms from the trial due to insufficient evidence of benefit leaving IFN beta-1a and remdesivir as the only two drugs remaining in the trial, subject to WHO announcing further new compounds for

inclusion. IFN beta-1a now remains as a monotherapy. The WHO expects to provide a readout from the SOLIDARITY trial in the fourth quarter of 2020.

- The global REMAP-CAP (Randomized, Embedded, Multifactorial Adaptive Platform Trial for Community-Acquired Pneumonia) investigating potential treatments for patients with community acquired pneumonia, including COVID-19 patients, introduced a new treatment arm to include Faron's IV IFN beta-1a. The study is directly comparing the treatment effect of Traumakine, hydrocortisone treatments, and other study treatment options on the clinical outcomes of COVID-19 patients and those with other causes of pneumonia requiring intensive care unit (ICU) care.
- Faron announced that a third trial will investigate the potential of Traumakine to treat COVID-19. HIBISCUS (**H**uman **I**nterferon **B**eta **I**n **S**evere **C**oronavir**U**S) will be an investigator-initiated study at the Harvard Medical School's Beth Israel Deaconess Medical Center (BIDMC), focused on ICU patients with ARDS caused by viral infection (e.g. COVID-19, influenza). Commencement of the phase II/III pivotal, randomized, placebo controlled study, which aims to recruit 350 patients, remains subject to finalisation of funding arrangements and regulatory approval. Faron expects to initiate this study in the fourth quarter of 2020.
- Detailed analyses into the effects of glucocorticoids on IV IFN beta-1a activity, which arose following the INTEREST trial in 2018, were published in *Intensive Care Medicine*, a world leading journal in the field of critical care. 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 acute respiratory distress syndrome (ARDS) compared to patients administered with IV IFN beta-1a alone.

Business Development and Manufacturing:

- Faron announced plans to initiate a new state-of-the-art process for Traumakine manufacturing and was awarded a €2,100,000 low interest rate loan from Business Finland, the governmental innovation financing agency of Finland, which will be used to develop and select a new cell line that can be used for future commercial scale production of the Company's IV IFN beta-1a. The Company subsequently received a loan guarantee from Finnvera (official Export Credit Agency of Finland) for €2,500,000 loan to expand the commercial scale manufacturing.

AOC3 Antagonist Platform Technology (Haematokine™)

- 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. The project is now named Haematokine™ as the Company believes that the use of AOC3 inhibitors could regulate the expansion of hematopoietic stem cells and could become a life saving treatment for patients who have lost their bone marrow for various reasons such as hematological cancers. The Company is continuing IND-enabling studies for this program, however, the recent first review by the Finnish patent office has made the Company believe that 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. In addition to Faron Management, three external experts provided additional perspectives on both programmes. Alongside 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.
- The Company's Annual general meeting (AGM) was held on 18 May 2020. The AGM approved all the proposals of the board of directors and its committees set out in the notice of the AGM published on 14 April 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.
- Faron announced on 27 July 2020 that Cairn Financial Advisers LLP had been appointed as Nominated Adviser to the Company with immediate effect. Panmure Gordon (UK) Limited continues to act as the Company's Broker.

Impact of COVID-19

During the pandemic our ability to secure funding and remote working operations to our portfolio companies is key to continued success. Even during exceptional circumstances, we were able to continue to operate our business almost normally and the development of our clinical trials proceeded as planned.

Additionally, Faron closely followed and strictly complied to 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

- Cash balances of €11.6 million at 30 June 2020 (2019: €2.9 million).
- Operating loss of €7.1 million for the six months ended 30 June 2020 (2019: €6.3 million).
- Net assets of €7.3 million as at 30 June 2020 (2019: €-1.8 million).
- In April 2020 the Company raised a total of €14 million gross (€13 million net) in a share placing, effected via a private placement of new Ordinary Shares to a limited number of institutional investors in the Nordic region and a concurrent proposed private placement of new Ordinary Shares to UK institutional investors.
- Additional grants of €3.3 million, loan of €2.1 million and a loan guarantee for €2.5 million were awarded in H1 and partially post period. Those non-diluting funds (in total of €7.9 million) funds will be dispersed to the Company in H2 and thereafter, and thus are not included in H1 cash balances.

Consolidated key figures, IFRS

€'000	Unaudited	Unaudited	
	1-6/2020	1-6/2019	1-12/2019
	6 months	6 months	12 months
Revenue	0	0	0
Research and Development expenses	(5,534)	(4,982)	(10,237)
General and Administrative expenses	(2,354)	(1,361)	(3,049)
Loss for the period	(7,343)	(6,412)	(13,262)

	Unaudited	Unaudited	
	1-6/2020	1-6/2019	1-12/2019
	6 months	6 months	12 months
Loss per share EUR	(0.16)	(0.19*)	(0.36)
Number of shares at end of period	46,799,747	37,233,894	43,290,747
Average number of shares	44,584,199	33,819,699	36,850,577

€'000	Unaudited 30	Unaudited	
	Jun 2020	30 Jun 2019	31 Dec 2019
Cash and cash equivalents	11,627	2,892	7,059
Equity	7,313	(1,761)	1,610
Balance sheet total	14,343	5,103	10,209

*correction to interim results announced on 23 September 2019, the Loss per share is EUR 0.19 instead of EUR 0.17

Commenting on the results, Dr Markku Jalkanen, CEO of Faron, said: “I am delighted to report the significant progress we have made so far in 2020, advancing the Faron pipeline and investing to secure the future of our clinical programmes. Our novel precision cancer immunotherapy, *bexmarilimab*, continues to deliver very promising results in a development programme that has rapidly expanded this year and our confidence in this novel therapy has been strengthened by the MATINS Part I data, showing that *bexmarilimab* has led to CLEVER-1 inhibition with immune cell activation and downregulation of several checkpoint molecules. With the MATINS trial now advancing across ten cancer cohorts we stand to learn much more about the potential of this novel therapy in the coming months and we look forward to continuing our discussions with regulators about the future development plan of this program.

“As the scientific community has rallied in 2020 to identify therapies for COVID-19 patients, I am proud that Faron has been able to support two global initiatives and a planned US trial, to investigate the potential of Traumakine for the treatment of ARDS and COVID-19. We look forward to the upcoming WHO SOLIDARITY trial data in fourth quarter of this year and expect to initiate our HIBISCUS US study with Harvard University in the fourth quarter of this year.

“The Company’s successful fundraise in April and a number of additional non-dilutive funds put the Company in a strong financial position to progress our clinical programmes and I would like to thank all our shareholders for their continued support.”

September 24, 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 webcast and conference call for analysts to provide an update on the results, followed by a Q&A session, at 7.30am EST / 12:30pm BST / 2:30pm EEST. A presentation to accompany the call will be available on the Faron website (<https://www.faron.com/investors/results>) at 7.00am EST / 12.00pm BST / 2.00pm EEST

The webcast can be accessed here

<https://www.lsegissuerservices.com/spark/FaronPharmaceuticalsOy/events/f2025553-c840-4c5c-9f34-d6e3b6d58fa3>

Dial-in details are:

UK: 0800 028 8438

Finland: 0931 583 827

US: (918) 922-6506

Conference ID: 5946048

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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-Clever-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 standard treatments including immune checkpoint molecules. 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 and Chief Executive Officer's Review

Introduction

The first half of 2020 has continued to build further excitement around Faron's pipeline, which we saw gain momentum in 2019. Clevegen® (*bexmarilimab*), by providing significant immune activation for cancer patients, has delivered solid achievements against our objectives for the period. Traumakine® (intravenous *interferon-beta 1a*) in turn has become a key candidate as a potential COVID-19 treatment due to its ability to act as an anti-viral and lung function supportive agent. We also announced a new pre-clinical project, now called Haematokine™, a treatment involving the regeneration of haematopoietic stem cells. Faron also attracted a total of €22 million in new funding, which includes a significant amount of non-dilutive funds (€7.9 million). In this report we are pleased to provide further information on our H1 2020 progress and also give insights into our plans and intended progress for the second half of the year.

Clevegen (*bexmarilimab*) – Commencement of Part II of MATINS study with strong patient recruitment and encouraging Part I results

Driving the clinical development of Clevegen has been Faron's priority and in the first six months of the year we have delivered strong results, with the programme continuing apace. *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 immune suppressive 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.

The ongoing MATINS trial, our first-in-human open label phase I/II clinical trial with an adaptive design, is investigating 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 all dosed 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 when the MATINS trial's data monitoring committee (DMC) approved the first expansion cohort for Part II of the trial in patients suffering from late-stage colorectal cancer (CRC). A second expansion cohort, in patients with ovarian cancer, quickly followed. Ovarian cancer is a tumour type known to host a significant number of Clever-1 positive TAMs and it presents a high unmet medical need with few available treatments for patients. As of today, additional clinical benefits have been observed in cutaneous melanoma and uveal melanoma. All these four cancer types are primary candidates to become expansion cohorts for the Part III of the MATINS study.

In March 2020, a comprehensive review and analysis of data from the completed Part I stage of the trial was undertaken by the DMC. Key findings presented to the committee included evidence of immune activation in all subjects (except those receiving the lowest 0.1 mg/kg dose) following treatment with *bexmarilimab* and emerging evidence of clinical responses. According to the RECIST response evaluation criteria, *bexmarilimab* treatment showed a clinical effect of two partial responses and seven cases of stable disease, which equated to a response rate in Part I of 36 per cent (9/25) among 0.3-10 mg/kg dose levels.

In light of these findings, the DMC recommended a rapid expansion of the study to include all cancer cohorts in the study protocol, beyond the CRC and ovarian cancer cohorts previously selected. The committee also recommended that patient recruitment for the expansion cohorts should follow standard of care for each cancer type and enable subjects with less compromised immune systems to be enrolled to the trial (i.e. earlier treatment lines whenever possible, according to the study protocol).

In total, *bexmarilimab* is now being investigated in ten cancer cohorts: ER-positive breast cancer, cholangiocarcinoma (bile duct cancer) and gall bladder cancer, colorectal cancer, gastric cancer, hepatocellular carcinoma, cutaneous melanoma, uveal melanoma, ovarian cancer, pancreatic ductal adenocarcinoma and anaplastic thyroid cancer.

At a time when health systems have been stretched to their limits by the ongoing global COVID-19 pandemic, we have been particularly pleased that patient recruitment into the MATINS trial has not been affected and we look forward to learning more about *bexmarilimab*'s potential as the trial progresses. Our confidence in *bexmarilimab* has only strengthened this year. Despite the MATINS trial patients' very advanced stage of disease and several lines of previous therapies, including PD-1 and CTLA-4 inhibitors, we remain very encouraged by the evidence emerging of this candidate's single agent efficacy. That is why we also announced this year that clinical expansion plans for *bexmarilimab* will include the investigation of alternative dosing cycles, as pharmacodynamics markers may indicate a need for shorter frequencies, as well as further studies in additional clinical settings. The Company also intends to investigate *bexmarilimab* in combination with standard of care, as a first-line therapy in selected advanced solid tumours, and as a standalone neoadjuvant therapy for patients with early stage colon cancer.

Patient recruitment for the several cohorts has already completed and the rest are expected to follow in the next few months. The data from these cohorts will allow the Company to obtain advice from regulatory authorities for the continuation into Part III of the study. Patient recruitment for a small number of additional cohorts is expected to complete around early Q4 2020 and discussions with the FDA likely to follow in early 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. This is a significant milestone in our *bexmarilimab* programme. AGC Biologics has decades of experience in manufacturing of biotechnological products, including commercial market supplies of FDA, PDMA and EMA approved products. The commercial scale manufacturing process it establishes for *bexmarilimab* will provide a dossier to support future regulatory filings in Europe and the US.

We have also continued our partnering discussions with third parties, including leading pharmaceutical companies, with the aim of supporting expansion of clinical development and exploring the potential of *bexmarilimab* in combination with existing immunotherapies and other cancer therapies. While these remain important to our strategy, Faron's strong financial position does provide the Company with greater flexibility to independently advance this candidate further in its development programme.

Traumakine – Lung protection and anti-COVID-19 in one treatment under development

Traumakine is currently involved in three major clinical studies sponsored by the global scientific community in its search for therapies against COVID-19. These explore the potential of the Company's intravenous (IV) interferon (IFN) beta-1a, Traumakine, to reduce intensive care need and mortality for COVID-19 patients but also as a future treatment for acute respiratory distress syndrome (ARDS) and one that could have significant impact on the intensive-care burden from COVID-19. This is well justified, and our greater understanding from previous trials on the interference from corticosteroids on the efficacy of our investigational IV IFN beta-1a has enabled us to refocus our efforts on this asset, which we continue to believe holds great potential as a future treatment for ARDS. Alongside the acceleration of *bexmarilimab*'s development programme, Faron began 2020 continuing to work with regulatory authorities to determine the next steps in Traumakine's future development pathway. We were pleased therefore, when in March the U.S. Food and Drug Administration (FDA) accepted the Company's proposed protocol design for the next Traumakine study in ARDS patients. That trial protocol reflected the feedback and conclusions from the FDA that further studies with our IV IFN beta-1a should exclude the use of concomitant glucocorticoids since they are likely to block its desired therapeutic effect, and may have a potentially deleterious impact on patient survival. Since March, the FDA has indicated that a separate arm in this study is required, to test a separate effect of a corticosteroid called dexamethasone. This study called HIBISCUS has now been designed together with Harvard University in the US. The Company expects approval of this study in due course and for recruitment to start during Q4 2020.

In April we joined two global initiatives investigating the potential of multiple therapies to treat COVID-19, by providing supplies of Traumakine to REMAP-CAP, the Randomized, Embedded, Multifactorial Adaptive Platform Trial for Community-Acquired Pneumonia program, and the World Health Organization's (WHO's) Solidarity trial.

One of the body's main first lines of defence against viral infection is endogenous IFN-beta production, but recent findings have shown that seriously ill COVID-19 patients have compromised interferon responses. We believe Traumakine treatment can further strengthen the body's natural defences. 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.

While both global initiatives are ongoing, Faron is also supporting a third trial to investigate the potential of the Company's IV IFN beta-1a to treat COVID-19. HIBISCUS (**H**uman **I**nterferon **B**eta **I**n **S**evere **C**oronavir**U**S), will be an investigator initiated study at Harvard Medical School's Beth Israel Deaconess Medical Center (BIDMC), focused on ICU patients with ARDS caused by viral infection (e.g. COVID-19, influenza). Commencement of this Phase II/III pivotal, randomized, placebo-controlled study, remains subject to finalisation of funding arrangements and regulatory approval. The study will test Traumakine against both placebo and dexamethasone, which is now a part of the standard of care in the US.

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.

As a sign of our continued commitment to the Traumakine programme and looking ahead to its future, the Company announced (August, post-period) that AGC Biologics, the commercial scale manufacturer of *bexmarilimab*, will be the new manufacturing house for the commercial scale production of Traumakine's active pharmaceutical ingredient – interferon beta-1a.

Haematokine™ – Hematopoietic stem cell expansion

In March the Company 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 ACO3 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 reviving failing transplants are expensive and often unsuccessful. With Haematokine, the Company believes, we can expand stem cells by regulating AOC3 activity.

Financial review

In April the Company successfully raised approximately €14 million (£12.9 million) through a private placement of new ordinary shares to institutional investors in the UK and the Nordic region. The majority of these proceeds are being used to advance our *bexmarilimab* clinical programme and expand manufacturing, while also significantly strengthening the Company's balance sheet to support other ongoing activities.

During the period the Company was awarded two grants to support its activities: An €0.8 million grant from Business Finland to conduct detailed, state-of-the-art characterization of the immunological responses seen in cancer patients in the *bexmarilimab* MATINS trial and a €2.5 million grant from the European Innovation Council (EIC) Accelerator pilot scheme to progress the MATINS trial and related business activities.

The Company was also awarded a €2.1 million low interest rate loan from Business Finland, which is being used to develop and select a new cell line for use in the future commercial scale production of Traumakine. Additionally, post period, the Company received a loan guarantee for a €2.5 million loan, which will be used to further expand that cell line. The Company has partnered with Danske Bank A/S Finland Branch for the loan arrangement.

These grants and loans, totalling €7.9 million, are non-dilutive. Proceeds of these grants and loans are not included in the H1 cash balances as the proceeds will be dispersed to the Company post period.

Statement of comprehensive income

The loss from operations for the six months ended 30 June 2020 was EUR 7.1 million (six months ended 30 June 2019: loss of EUR 6.3 million). No revenue was generated during the period or prior revenue. Research and development expenditure increased by EUR 0.5 million to EUR 5.5 million (2019: EUR 5.0 million). Administrative expenses increased by EUR 1.0 million to EUR 2.4 million (2019: EUR 1.4 million).

The loss after tax for the period was EUR 7.3 million (2019: loss of EUR 6.4 million) and the basic loss per share was EUR 0.16 (2019: loss per share of EUR 0.19).

Statement of financial position and cash flows

At 30 June 2020, net assets amounted to EUR 7.3 million (30 June 2019: EUR -1.8 million). The net cash flow for the first six months in 2020 was EUR 4.4 million (2019: EUR -1.1 million). As at 30 June 2020, total cash and cash equivalents held were EUR 11.6 million (2019: EUR 2.9 million).

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 was terminating the agreement concerning Traumakine API manufacturing. The Company considers that this statement is without merit and that Rentschler has breached the agreement. Faron has filed a request for arbitration to seek damages. The arbitration proceeding is ongoing and the final arbitration award is expected to be issued by the arbitration tribunal during mid year 2021. To fund the proceedings, the Company has entered into a litigation funding agreement with a third-party recovery services provider offering non-recourse financing services which, subject to final quantum, is expected to cover both the Company's and the adverse party's legal expenses and which, in the event of success, would receive a typical portion of any damages awarded.

Corporate

On 16 June 2020, the Company hosted a virtual R&D Day presenting its R&D strategy and insights into the Clevegen and Traumakine programmes. Faron management representatives were joined by Prof. Alberto Mantovani, Humanitas University, Milan, Italy; Ass. Prof. Maija Hollmén, MediCity, Turku University, Finland, and Dr. Petri Bono, Terveystalo, Helsinki, Finland, who provided additional perspectives on both programmes. The event, well attended, was an opportunity for the Company to showcase the strength of its clinical programmes and plans for the future.

The Company's Annual general meeting (AGM), held on 18 May 2020, approved all the proposals of the board of directors and its committees set out in the notice of the AGM published on 14 April 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.

Summary & outlook

Our focus for H2 2020 will be the expedition of Clevegen's clinical development through Parts II and III of the MATINS trial and to report these data to regulatory authorities. We will also continue to support the ongoing COVID-19 research initiatives investigating the potential of the Company's IV IFN beta-1a, Traumakine. The successful financing undertaken in H1 and post period 2020 puts the Company in a strong financial position to progress both clinical programmes and related business activities, while partnering discussions continue.

On behalf of the Board we would like to thank the whole Faron team for their commitment, resilience and agility during the challenging times of 2020. Their response has enabled the Company to make significant achievements against its objectives and has secured a strong position for the second half of 2020.

We look forward to updating the market on our progress throughout the course of the year.

Consolidated Income Statement, IFRS

<i>€'000</i>	Unaudited 1-6/2020 6 months	Unaudited 1-6/2019 6 months	1-12/2019 12 months
Revenue	0	0	0
Other operating income	743	0	185
Research and development expenses	(5,534)	(4,982)	(10,237)
General and administrative expenses	(2,354)	(1,361)	(3,049)
Operating loss	(7,145)	(6,343)	(13,101)
Financial expense	(230)	(73)	(224)
Financial income	31	5	74
Loss before tax	(7,343)	(6,411)	(13,251)
Tax expense	0	(0)	(11)
Loss for the period	(7,343)	(6,412)	(13,262)
Other comprehensive income			-
Total comprehensive loss for the period	(7,343)	(6,412)	(13,262)
Loss per ordinary share			
Basic and diluted loss per share, EUR	(0.16)	(0.19*)	(0.36)

Consolidated Balance Sheet, IFRS

	Unaudited 30 June 2020	Unaudited 30 June 2019	31 December 2019
€'000			
Assets			
Non-current assets			
Machinery and equipment	13	14	13
Right-of-use-assets	456	0	386
Intangible assets	560	522	529
Prepayments and other receivables	80	595	77
Total non-current assets	1,109	1,131	1,005
Current assets			
Prepayments and other receivables	1,607	1,080	2,145
Cash and cash equivalents	11,627	2,892	7,059
Total current assets	13,234	3,972	9,204
Total assets	14,343	5,103	10,209
Equity and liabilities			
Capital and reserves attributable to the equity holders of the Company			
Share capital	2,691	2,691	2,691
Reserve for invested unrestricted equity	91,960	68,695	78,916
Accumulated deficit	(87,339)	(73,146)	(79,997)
Translation difference	1	0	-
Total equity	7,313	(1,761)	1,610
Non-current liabilities			
Borrowings	2,303	2,363	2,263
Lease liabilities	288	0	261
Total non-current liabilities	2,591	2,363	2,524
Current liabilities			
Borrowings	0	0	163
Lease liabilities	181	0	135
Trade payables	2,729	2,868	2,967
Other current liabilities	1,529	1,633	2,810
Total current liabilities	4,439	4,501	6,075

Total liabilities	7,030	6,864	8,599
Total equity and liabilities	14,343	5,103	10,209

Consolidated Statement of Changes in Equity, IFRS

€'000	Share capital	Reserve for invested unrestricted equity	Translation difference	Accumulated deficit	Total equity
Balance as at 1 January 2019	2,691	64,464		(66,786)	369
Comprehensive loss for the first six months 2019	-	-		(6,412)	(6,412)
Transactions with equity holders of the Company					
Issue of ordinary shares, net of transaction costs EUR 230 thousand	-	4,230		-	4,230
Share-based compensation	-	-		51	51
	-	4,230		51	4,281
Balance as at 30 June 2019	2,691	68,695		(73,146)	(1,761)
Comprehensive loss for the last six months 2019	-	-		(6,850)	(6,850)
Transactions with equity holders of the Company					
Issue of ordinary shares, net of transaction costs EUR 919 thousand	-	10,222		-	10,222
Share-based compensation	-	-		-	-
	-	-		-	-
Balance as at 31 December 2019	2,691	78,916		(79,997)	1,610
Comprehensive loss for the first six months 2020	-	-	1	(7,343)	(7,342)
Transactions with equity holders of the Company					
Issue of ordinary shares, net of transaction costs EUR 952 thousand	-	13,044		-	13,044
Share-based compensation	-	-		-	-
	-	13,044	0	-	13,044
Balance as at 30 June 2020	2,691	91,960	1	(87,339)	7,313

Consolidated Cash Flow Statement, IFRS

€'000	Unaudited 1-6/2020 6 months	Unaudited 1-6/2019 6 months	1-12/2019 12 months
Cash flow from operating activities			
Loss before tax	(7,343)	(6,411)	(13,251)
Adjustments for:			
Depreciation and amortisation	130	48	238
Interest expense	93	39	158
Tax expense	0		11
Unrealised foreign exchange loss (gain), net	(125)	29	(7)
Share-based compensation	0	51	51
Adjusted loss from operations before changes in working capital	(7,245)	(6,245)	(12,800)
Change in net working capital:			
Prepayments and other receivables	534	1,679	1,173
Trade payables	(237)	(641)	(567)
Other liabilities	(1,333)	(334)	731
Cash used in operations	(8,281)	(5,541)	(11,463)
Taxes paid	0	0	(9)
Interest paid	(29)	(26)	(51)
Net cash used in operating activities	(8,310)	(5,567)	(11,523)
Cash flow from investing activities			
Payments for intangible assets	(77)	(41)	(100)
Payments for equipment	(2)	(0)	-
Net cash used in investing activities	(79)	(41)	(100)
Cash flow from financing activities			
Proceeds from issue of shares	13,997	4,461	15,627
Share issue transaction cost	(952)	(230)	(1,175)
Proceeds from borrowings	0	231	307
Repayment of borrowings	(122)	(0)	-
Payment of lease liabilities	(91)		(151)
Net cash from financing activities	12,832	4,461	14,608
Net increase (+) / decrease (-) in cash and cash equivalents	4,443	(1,147)	2,985

Effect of exchange rate changes on cash and cash equivalents	125	(29)	7
Cash and cash equivalents at 1 January	7,059	4,067	4,067
Cash and cash equivalents at the end of period	11,627	2,892	7,059

Notes to the financial statements

1. Corporate information

Faron Pharmaceuticals Ltd (the “Company”) is a clinical stage biopharmaceutical company incorporated and domiciled in Finland, with its headquarters at Joukahaisenkatu 6, 20520 Turku, Finland. The Company currently has a pipeline based on the endothelial receptors involved in regulation of immune response, in oncology and organ damage.

The Company has been listed on the London Stock Exchange's AIM market since 17 November 2015, with a ticker FARN, and since 3 December 2019, the Company has been listed on the Nasdaq First North Growth Market list with a ticker FARON.

2. Summary of significant accounting policies

2.1. Basis of preparation

The unaudited H1 report have been prepared in accordance with the International Financial Reporting Standards of the International Accounting Standards Board (IASB) and as adopted by the European Union (IFRS) and the interpretations of the International Financial Reporting Standards Interpretations Committee (IFRS IC). The financial statements have been prepared on a historical cost basis, unless otherwise stated.

The H1 report has been prepared on the basis of a full retrospective application of IFRS 15, Revenue from Contracts with Customers, with the adoption date as of 1 January 2017.

The principal accounting policies applied in the preparation of these interim financial statements are set out below. The Company has consistently applied these policies to all the periods presented, unless otherwise stated. The areas of the financial statements involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the financial statements, are disclosed in note 2.2.

The unaudited consolidated financial statements incorporate the parent company, Faron Pharmaceuticals Ltd, and all subsidiaries in which it holds over 50% of the voting rights (the “Group”).

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

2.2. Going concern

The Company has forecasted its estimated cash requirements over the next twelve months. In order to make these forecasts the Company has made a number of assumptions regarding the quantity and timing of future expenditure and income as well as other key factors. Though these estimates have been made with caution and care, they continue to contain a significant amount of uncertainty. Based on the forecast the Company believes that it has adequate financial resources to continue its operations into Q1 2021 and therefore these unaudited financial statements have been prepared on a going concern basis. In its meeting on 23 September 2020 the Board of Directors of the Company approved the publishing of these interim financial statements.

Company has taken several acts to secure further financing during rest of the year 2020. The Directors believe that the Company can gain access to further resources to sustain operations over the next 12 months. At this stage the Company can not disclose any of these options.

Because the additional finance is not committed at the date of issuance of these H1 reports, 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.

AIM Rules for Companies disclosure

Frank Armstrong, Chairman of the Company, was Chairman of Redx Pharma plc from 1 September 2014 until his resignation on 20 April 2017. On 24 May 2017, Redx Pharma plc was put into administration by Liverpool City Council as a result of non-payment of an outstanding loan of £2 million and the ordinary shares in Redx Pharma plc were suspended from trading on AIM. On 3 November 2017, Redx Pharma plc exited administration with all creditors paid and trading in the shares of Redx Pharma plc resumed on AIM.