Faron Pharmaceuticals Ltd | Company announcement | August 27, 2025 at 09:00:00 EEST

Significant clinical and financial milestones achieved in first half of 2025

TURKU, Finland â€“ Faron Pharmaceuticals Ltd (AIM: FARN, First North: FARON), a clinical-stage biopharmaceutical company pursuing a CLEVER approach to reprogramming myeloid cells to activate anti-tumor immunity in hematological and solid tumor microenvironments, has published its unaudited half-year financial results for the six months ended 30 June 2025, on 27 August 2025.

Figures in parentheses refer to the corresponding period of previous year, unless otherwise indicated.
This half-year report is unaudited.

Januaryâ€“June 2025 in brief

- On 31 January 2025, Faron announced the identification of the final patient for the BEXMAB phase II dose optimization study in refractory or relapsed myelodysplastic syndrome (r/r MDS), as well as the BEXMAB phase I/II study in frontline high-risk (HR) MDS.
- On 5 February 2025, Faron carried out a significantly oversubscribed private placement of newly issued treasury shares, raising gross proceeds of EUR 12 million in total.
- On 27 February 2025, Faron received a positive opinion on orphan drug designation for *bexmarilimab* for the treatment of MDS by EMA, and on 3 March 2025, the FDA granted an orphan drug designation for *bexmarilimab* in MDS.
- On 21 March 2025, Mr. Colin Bond and Dr. Juho Jalkanen, the CEO of the Company, were appointed as members to the Board of Directors.
- On 3 April 2025, Faron entered into an up to EUR 35 million unsecured convertible bond arrangement with Heights Capital Management Inc. (â€œHCMâ€) to repay its secured loan to IPF Partners and strengthen its financial position and issued first tranche of bonds with a principal amount of EUR 15 million.
- On 15 April 2025, Faron announced positive phase II results in HR-MDS.
- During the review period, Faron gave multiple oral presentations of *bexmarilimab* data at the several prestigious scientific forums in the field; in May, the 18th International Congress on Myelodysplastic Syndromes (MDS 2025); in Mayâ€“June, the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting; and in June, the 30th European Hematology Associationâ€™s (EHA 2025) Congress.
- On 28 May 2025, Faron appointed seasoned commercial development expert, Ralph Hughes, as Chief Business Officer.
- On 30 May 2025, Faron announced the publication of full phase I BEXMAB study data in one of the top medical journals â€“ the Lancet Haematology.
- On 12 June 2025, Faron presented the updated phase II data from the BEXMAB study, showing strong efficacy and survival outcomes with *bexmarilimab* in HR-MDS supporting the advancement to phase III.
- Faronâ€™s other operating income was EUR 0 (0)
- R&D expenses were EUR 7.1 (6.7) million
- Operating loss for the reporting period was EUR -11.9 (-11.3) million
- Loss per share was EUR 0.18 (0.20)
- On 30 June 2025, cash and cash equivalents were EUR 13.5 (30.0) million
- Net assets were EUR -16.2 million (1.4) million

Significant events after the reporting period

- On 7 July 2025, Faron announced the acceptance of two studies involving its lead candidate*, bexmarilimab*, for presentation at the 19th IUIS International Congress of Immunology in Vienna, Austria, in August 2025.
- On 11 July 2025, Business Finland informed Faron that they had approved the Companyâ€™s application to forgive an R&D loan related to the development of Traumakine. The forgiveness applies also to accumulated interest. This will have a positive impact of EUR 1.3 million on Operating Profit on the second half of 2025.
- On 30 July 2025, Faron announced that new clinical and translational data from the phase I/II BEXMAB study evaluatingÂ bexmarilimabÂ in combination with azacitidine in HR-MDS will be orally presented at the 2025 European Society for Medical Oncology (ESMO) Congress, in October 2025, in Berlin, Germany.
- On 6 August 2025, Faron announced an increase in the complete remission (CR) rate in patients with frontline or treatment-naÃ¯ve HR-MDS, based on updated efficacy data from its phase I/II BEXMAB trial. According to the investigator-assessed response using IWG 2006 criteria, as per protocol, the CR rate has increased to 43% (9 out of 21

patients), a substantial improvement from the 28% rate, seen in the earlier data cut. This data builded on the phase II early results featured in recent oral presentation at the 2025Â American Society of Clinical Oncology (ASCO)Â meeting.

- On 18 August 2025, Faron announced positive feedback received from the U.S Food and Drug Administration (FDA) as part of the Companyâ€™s recent BEXMAB studyâ€™s end-of-phase II (EOP2) meeting. Faron will advance bexmarilimab into a registrational phase II/III study for patients with the treatment-naÃ¯ve (frontline) HR-MDS. The FDA confirmed IWG 2023-defined CR + CReq as an acceptable primary endpoint with overall survival (OS) as a co-primary endpoint to support an application for accelerated approval making the entire HR MDS market accessible to Faron with one single trial and accelerated approval possibility for all HR MDS patients.

Consolidated key figures, IFRS

EUR â€™000 unless otherwise indicated	1-6/2025	1-6/2024	1-12/2024 (audited)
Other operating income	0	0	0
Research and development expenses	(7,115)	(6,662)	(11,744)
General and administrative expenses	(4,794)	(4,628)	(6,929)
Operative loss for the reporting period	(11,909)	(14,395)	(18,673)
Loss per share EUR	(0,18)	(0.20)	(0.29)
Number of shares at end of period	111,954,597	104,624,864	104,624,864
Average number of shares	107,403,444	70,452,291	88,518,654
Cash and cash equivalents	13,532	29,979	9,503
Equity	(16,246)	1,379	(9,762)
Balance sheet total	16,204	35,460	12,521

Outlook for 2025

Due to the nature of Faron Pharmaceuticalsâ€™ business, the company does not provide a short-term outlook.

CEO Statement

â€lâ€™m extremely proud of our people and what we have accomplished in the first half of 2025. We have achieved a number of our main business goals: fully enrolled our BEXMAB phase II study, published very strong phase II efficacy data for *bexmarilimab* and had the privilege to present it at the worldâ€™s leading oncology conferences, we received a series of regulatory designations, enhanced our management team and substantially strengthened our financial position. These are absolutely outstanding results from a team of our size.

Strong BEXMAB data supports path to single registrational trial for the entire HR MDS population

In the first half of the year, the clinical development program for our lead asset, *bexmarilimab* made strong and consistent progress. In January, we identified the final patient for the BEXMAB phase II part in refractory or relapsed myelodysplastic syndrome (r/r MDS), as well as the BEXMAB phase I/II study in frontline high-risk (HR) MDS.

In June, at EHA we presented the phase II response data from the BEXMAB study, showing strong response rates in frontline HR MDS and r/r MDS, as well exceptional survival in r/r MDS, for which the follow-up data is more mature. The results support the advancement into single phase II/III registrational trial in frontline HR MDS making the entire HR MDS market accessible for Faron at one go. This was later confirmed in August in BEXMABâ€™s EOP2 meeting with the FDA.

Especially for r/r MDS patients, for whom treatment options are limited, our data were highly encouraging. *Bexmarilimabâ€™s* estimated median overall survival (mOS) was approximately 13.4 months, compared to the 5-6 months that would typically be expected under standard of care. The BEXMAB study also demonstrated significant efficacy in patients with r/r MDS with a high objective response rate (ORR) of 63%. An ORR of 81% and an outstanding CR rate of 43% was observed in frontline HR MDS patients according to the study protocol criteria. These results, especially the new frontline MDS patient data, suggest a potential to transform the treatment paradigm for the entire disease.

In the spring, both the European Medicines Agency (EMA) and U.S. Food and Drug Administration (FDA) granted us opinion on Orphan Drug Designation for *bexmarilimab* for the treatment of MDS. The FDA and EMA designations allow us to receive important regulatory guidance and protocol assistance for the development of *bexmarilimab*. The FDA designation also

qualifies the sponsor of the drug for certain development incentives, including tax credits for qualified clinical testing and prescription drug user fee exemptions. In addition, Orphan Drug Designations offer market exclusivity once the medicine is on the market.

Strengthening our financial position

We substantially strengthened our financial by an oversubscribed EUR 12 million placing in February and an up to EUR 35 million convertible bond arrangement in April. The first tranche of bonds with a principal amount of EUR 15 million was issued in April, and we have the option to issue two additional tranches, each with a principal amount of EUR 10 million. The proceeds from the first tranche were used to repay the outstanding loan from IPF Partners and for general corporate purposes, extending our cash runway into the first quarter of 2026. The bond arrangement also increased our flexibility by reducing restrictive cash covenants and releasing our patents that were pledged as a security for a loan from IPF Partners.

Challenging operating environment

Capital markets and uncertainty in the biopharma and life sciences sectors remained challenging in the first half of this year. This was partly driven by the concerns related to constrained access to funding, drug-pricing policy changes and cautious dealmaking amid regulatory and macroeconomic uncertainties. However, as the first six months of this year prove, there is always demand for high-quality biopharmaceutical companies â€“ like Faron â€“ that can show consistent progress and positive data from their clinical development programs. Late stage and close to market assets remain attractive to large pharmaceutical companies.

The FDA has become stricter on oncology drug approvals, moving away from single arm trials and surrogate endpoints and putting more weight on randomized data against a comparator with survival as the most important endpoint. This has had little impact on us, since thanks to our scientific advice meeting with the FDA last year, we have already been building the case around *bexmarilimab* with survival in our mind and using a randomized setting against a comparator, i.e. the frontline setting in HR MDS. We were very happy to see that the FDA was willing to accept a response based surrogate endpoint at an interim read out as the basis of accelerated approval in frontline HR MDS, which highlights the big unmet need in this indication.

New blood to our Board and Management Team

In the first half of this year, we reinforced our management team and Board of Directors. In March, Mr. Colin Bond joined our Board, bringing extensive international experience from the finance, CDMO and biopharma industries. At the same time, I was also proud to assume the role of a member of Faronâ€™s Board, while continuing as CEO. In May, Mr. Ralph Hughes joined our management team to strengthen Faron's commercial strategy, business development and market assessment functions. These appointments enhance our expertise enabling us to better navigate the complexities of our competitive and rapidly evolving sector and to reach our strategic objectives.

Unique achievements for Faron in scientific forums

The medical industry continues to recognize the therapeutic potential of *bexmarilimab*. We were proud to present our data in oral sessions at all three leading oncology conferences: the European Hematology Associationâ€™s (EHA) Congress, American Society of Clinical Oncology Annual Meeting (ASCO) and International Congress on Myelodysplastic Syndromes (MDS 2025). Securing oral presentation in all three conferences â€“ recognized as the premier scientific forums in our field â€“ and having our data published in Lancet are exceptional for any company and especially in the context of Finnish drug development, and we are humbled by them. I could not be prouder and more grateful of our incredible team. I would also like to deeply thank all our shareholders who have supported this important work to bring a new cancer treatment to life.

Solid tumor research progressing as planned

Our research on solid tumors continues to make important progress. In May 2025, two articles were published in the Journal for ImmunoTherapy of Cancer, highlighting the significance of CLEVER-1 in solid tumors and deepening our understanding of the tumor microenvironment's influence. The results suggested that bexmarilimab stimulated response in immunologically-cold tumors and inhibited inflammation in treatment resistant tumors. The results can potentially impact the design of future trials for *bexmarilimab* in solid tumors. The BLAZE trial for the treatment of checkpoint inhibitor refractory metastatic lung cancer and melanoma has gained ethical approval and is in its final stages of contracting. In addition, Faron has reached an agreement with the Helsinki University Hospital to join the national FINPROVE Study to investigate *bexmarilimab* in combination with standard chemotherapy for the treatment of metastatic breast cancer. This will be the first ever *bexmarilimab* trial that will use prospective

patient selection for Clever-1 positivity.

Outlook

Many BEXMAB patients in r/r MDS remain on drug and are doing well, so giving the final survival readout is delayed, which is a good thing. Same goes to frontline patients where many have moved on to transplant and if all go well for the patients, we will not be getting survival data for frontline HR MDS any time soon. Next, weâ€™ll be reporting on the dynamic positive changes that happen in the body when treated with Bex and Aza together at the annual ESMO congress, and then further follow-up data at ASH towards the end of the year. Meanwhile we will be interacting with EMA and other regulatory agencies on the phase II/III trial. We are decisively progressing toward the initiation of the phase II/III registrational trial for HR MDS in parallel with partnering discussions. We are now well equipped to enter the next phase of commercial discussions and are continuously exploring different options we have to ensure maximising Faronâ€™s shareholder value while progressing the development of *bexmarilimab* in both solid tumors and hematological malignancies. Faronâ€™s financial position is good. Our current cash runway extends until 2026, and with the remaining two tranches of convertible bonds we have the needed flexibility to make the next business decisions. This gives us the opportunity to maximize shareholder value as we prepare to progress *bexmarilimab* into its final stage of development for the treatment of HR MDS.

Faronâ€™s first half of 2025 was remarkable, and I am looking forward to the second half of this year with eager anticipation. If H1 was the time of strong and steady development, then H2 is the time for business.â€

Virtual briefing and Q&A session

A virtual briefing and Q&A session for investors, analysts and media will be hosted by Dr. Juho Jalkanen, Chief Executive Officer, YrjÃ¶ Wichmann, Chief Financial Officer and Dr. Petri Bono, Chief Medical Officer, at 09:00 am (EDT) / 2:00 pm (BST) / 4:00 pm (EEST) on Wednesday, 27 August 2025. Webcast registration link: Faron 2025 Half-Year Financial Results

The half-year report and replay of the webcast will be available on the Companyâ€™s website at www.faron.com/investors.

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AboutÂ bexmarilimab
*Bexmarilimab*Â is Faronâ€™s wholly owned, investigational immunotherapy designed to overcome resistance to existing treatments and optimize clinical outcomes, by targeting myeloid cell function and igniting the immune system.Â *Bexmarilimab*Â binds to Clever-1, an immunosuppressive receptor found on macrophages leading to tumor growth and metastases (i.e. helps cancer evade the immune system). By targeting the Clever-1 receptor on macrophages,Â *bexmarilimab*Â alters the tumor microenvironment, reprogramming macrophages from an immunosuppressive (M2) state to an immunostimulatory (M1) one, upregulating interferon production and priming the immune system to attack tumors and sensitizing cancer cells to standard of care.

About Faron Pharmaceuticals Ltd.

Faron (AIM: FARN, First North: FARON) is a global, clinical-stage biopharmaceutical company, focused on tackling cancers via novel immunotherapies. Its mission is to bring the promise of immunotherapy to a broader population by uncovering novel ways to control and harness the power of the immune system. The Companyâ€™s lead asset isÂ *bexmarilimab*, a novel anti-Clever-1 humanized antibody, with the potential to remove immunosuppression of cancers through reprogramming myeloid cell function.Â *Bexmarilimab*Â is being investigated in Phase I/II clinical trials as a potential therapy for patients with hematological cancers in combination with other standard treatments. Further information is available atÂ www.faron.com.

Attachments

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