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COMPANY UPDATE
21 March 2025
Finland
Healthcare

Research analysts:
Klas Palin

Faron Pharmaceuticals

Share price: EUR2.25

Fair value range: EUR2.20-2.80

Cancer meets a clever opponent

Faron Pharmaceuticals is a Finnish clinical-stage biotechnology company with a strong focus on developing its lead oncology asset, bexmarilimab (BEX). Critical top-line results from the Phase II BEXMAB study are expected in April this year. If the data is as promising as previously reported, we see strong support for advancing to a pivotal trial within the next 12 months. This could pave the way for potential accelerated approval in the relapsed/refractory (r/r) high-risk myelodysplastic syndromes (HR-MDS) setting by 2027, followed by broader approval in the first-line setting a year later. These milestones represent a significant opportunity for Faron to become a revenue-generating company. Furthermore, we believe a positive outcome from the BEXMAB study would likely attract considerable interest from potential partners.

BEX is a first-in-class antibody targeting the Clever-1 receptor, which is highly expressed in immunosuppressive macrophages. BEX's most advanced development is in haematological cancers, where it has demonstrated particularly promising results in patients with high-risk (HR) MDS in the ongoing BEXMAB study. Given the significant unmet medical need in HR-MDS and limited competition from other therapies in development, we view the commercial potential in this orphan indication as substantial, estimating peak sales in MDS alone at USD1.1bn. Additionally, BEX is positioned as a potential pipeline-in-a-product, with Faron planning further mid-stage studies in solid tumours to explore its broad therapeutic potential.

We arrive at a fair value range of EUR2.2–2.8 per share for Faron Pharmaceuticals. This valuation is closely tied to the Phase II data readout expected in April. Based on our assessment of interim and supplementary data, we assign a high probability to a favourable outcome. However, we acknowledge that clinical trial risk remains and cannot be disregarded.

Upcoming events

- AGM 2025: 21 Mar 2025
- Q2 Report: 27 Aug 2025

Changes in this report

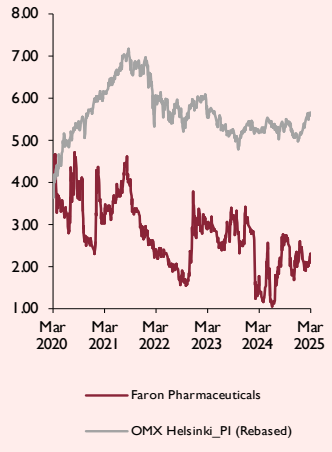
	From	To	Chg
EPS adj. 2025e	n.a.	-0.23	n.a.
EPS adj. 2026e	n.a.	-0.29	n.a.
EPS adj. 2027e	n.a.	-0.20	n.a.

Key facts

No. shares (m)	111.6
Market cap. (USDm)	273
Market cap. (EURm)	251
Net IB Debt. (EURm)	-16
Adjustments (EURm)	0
EV (2025e) (EURm)	235
Free float	74.7%
Avg. daily vol. ('000)	179
Risk	High Risk
Fiscal year end	December
Share price as of (CET)	20 Mar 2025 11:45

Key figures (EUR)	2024	2025e	2026e	2027e
Sales (m)	0	0	0	10
EBITDA (m)	-19	-24	-30	-20
EBIT (m)	-19	-24	-30	-20
EPS	-0.30	-0.23	-0.29	-0.20
EPS adj.	-0.30	-0.23	-0.29	-0.20
DPS	0.00	0.00	0.00	0.00
Sales growth Y/Y	n.a.	n.a.	n.a.	+chg
EPS adj. growth Y/Y	+chg	+chg	-chg	+chg
EBIT margin	n.m.	n.m.	n.m.	-191.4%
P/E adj.	n.m.	n.m.	n.m.	n.m.
EV/EBIT	neg.	neg.	neg.	neg.
EV/EBITA	neg.	neg.	neg.	neg.
EV/EBITDA	neg.	neg.	neg.	neg.
P/BV	neg.	32.5	19.6	23.6
Dividend yield	0.0%	0.0%	0.0%	0.0%
FCF yield	-9.2%	-9.1%	-11.7%	-7.4%
Equity/Total Assets	-78.0%	24.5%	34.0%	29.1%
ROCE	n.m.	n.m.	-145.4%	-95.2%
ROE adj.	207.9%	2,509.9%	-310.1%	-189.2%
Net IB debt/EBITDA	-0.1	0.7	0.7	1.0

Share price - 5Y



High/Low (12M) EUR2.8/1.1

Perf.	3M	6M	12M	YTD
Abs.	8.7	-13.1	44.7	-11.4
Rel.	-5.6	-20.0	35.7	-23.9

Source: Carnegie Research, FactSet, Millistream & company data

Equity story

Near term: 6–12m

Over the next twelve months, we anticipate a rich news flow from Faron. The most significant near-term event for the equity story is the upcoming top-line data readout from the completed Phase II BEXMAB study, expected in April. If the results align with previously reported findings, we see strong potential for advancement to a pivotal trial within the next 12 months. Additionally, securing a partnership would likely serve as the next major catalyst for the stock, further de-risking the company's business outlook.

Long term: 5Y+

The success of bexmarilimab is critical to Faron Pharmaceuticals' potential to evolve into a highly profitable company with a marketable product generating recurring revenues. However, as a small company with limited resources, securing a strategic partner will be essential to achieving long-term success and sustained profitability.

Key risks:

- The most significant risks associated with the equity story are related to clinical development of bexmarilimab
- As a drug developer without recurring revenues, Faron will require additional financing to support its activities
- Heavy reliance on the development of bexmarilimab, which in our model represents nearly all the company's value

Company description

Faron Pharmaceuticals is a Finnish clinical-stage biotechnology company, with its lead oncology asset, bexmarilimab, a mid-stage antibody therapy in development for haematological cancers and solid tumours, targeting myeloid cells. The company's lean organisational structure consists of 24 employees, supported by a management team of just five members. While Finland may not yet be a major player on the global biopharma stage, we believe Faron has assembled a strong team, supported by a respected and experienced scientific advisory board, to assist and guide its clinical development. Its shares have been listed on the London Stock Exchange's Alternative Investment Market (AIM) since 2015 and achieved a secondary listing on the Nasdaq First North Growth Market Finland in Helsinki in December 2019.

Key industry drivers

- Increasing incidence and prevalence of cancer
- Ever growing demand for more effective treatments

Industry outlook

- The market for cancer drugs is expected to grow at double-digit rate over the next five years (IQVIA)
- Larger pharma companies face ongoing patent expirations, which will continue to drive interest in-licensing and M&A

Largest shareholders

Timo Syrjälä	15.2%
Tom-Erik Lind	5.8%
Varma Mutual Pension Ins	4.6%

Cyclicality

Cyclicality: N/A

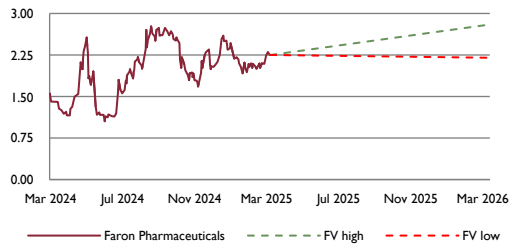
Key peers

We consider Alligator Bioscience, Bioinvent, and Cantargia the most comparable Nordic companies to Faron Pharmaceuticals, given their similar strategies and focus on oncology and antibody drug development. However, valuations can vary significantly, largely depending on each company's ability to deliver promising results in their respective development pipelines.

Valuation and methodology

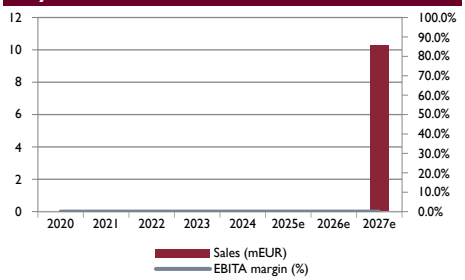
We value Faron Pharmaceuticals using a probability-adjusted cash flow model, evaluating each project individually and aggregating them in a sum-of-the-parts (SOTP) model. Our valuation includes its leading asset bexmarilimab where we see a clear path forward, discounting future cash flows with a WACC of 12–16%.

Fair value range 12m

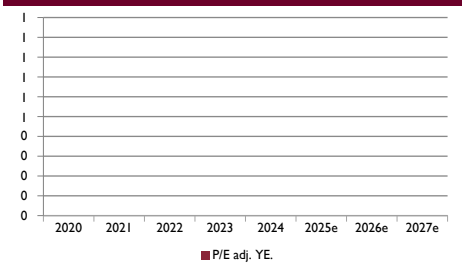


The upper end of our fair value range is based on our SOTP analysis, using a WACC of 12%, while the lower end applies a discount rate of 16%. In both scenarios, we anticipate continued progress of BEX, advancing to a pivotal trial in H1(26e). However, investor sentiment towards biotech remains weak in our lower estimate, whereas our upper estimate assumes better sentiment.

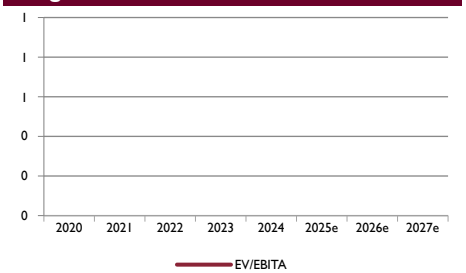
Key metrics



PE 12m forward



Long term valuation trend



Source: Carnegie Research & company data

Contents

Equity story

We initiate coverage of Faron Pharmaceuticals with a fair value range of EUR2.2–2.8 per share. Faron's lead asset, bexmarilimab (BEX), is a first-in-class immunotherapy that uniquely targets macrophages and may offer broad potential in both solid and haematological cancers. Its strong safety and tolerability profile, together with promising efficacy data, supports this expansion, offering broad opportunities for use in various combination treatments. In the near term, following the positive developments in the BEXMAB trial, we believe the primary potential lies in haematological cancers, particularly myelodysplastic syndrome (MDS), where the unmet medical need is significant. Patients diagnosed with MDS, especially those with a high-risk prognosis, face a dismal survival outlook and have limited treatment options.

Faron is a biotechnology company headquartered in Turku, Finland. Its lead asset, BEX, is a humanised IgG4 antibody that targets the common lymphatic endothelial and vascular endothelial receptor 1 (Clever-1), specifically designed to block its function. Clever-1 is highly expressed in myeloid cells such as monocytes, and is particularly prevalent on immunosuppressive, tumour-associated M2-like macrophages. By inhibiting Clever-1, BEX reprograms these immunosuppressive, pro-cancer macrophages into a pro-inflammatory state, thereby enhancing their anticancer activity. In haematological cancers, BEX also directly targets cancerous blast cells, impairing their energy production and improving the effectiveness of subsequent treatments.

Critical results approaching

The most advanced development for BEX is in haematological cancers, specifically in patients with high-risk (HR) myelodysplastic syndromes (MDS), currently being evaluated in the BEXMAB study. In this study, BEX has shown particularly promising results in combination with the standard-of-care (SoC) treatment, azacitidine (AZA). Interim results indicate an overall response rate (ORR) of 80%, compared to historical references of ~10%, as well as potential survival benefits, with an estimated median overall survival (mOS) of 13.4 months versus 5.6 months typically expected with AZA alone. Top-line data from the ongoing BEXMAB trial is expected in April 2025 and will provide critical clinical support for advancing to a registrational study. Overall, we view the data generated to date as highly promising, reinforcing preclinical findings and validating the proposed mechanism of action. Importantly, BEX appears to enhance efficacy without adding significant additional toxicity.

Few competitors in late stage of development

In addition to its promising data for HR-MDS patients, we find limited competition in the near term for BEX, with only a few therapies being investigated in the later stages of development. In our view, the main competitor is venetoclax, with top-line data expected in H1(25). We believe the results from previous studies of venetoclax in combination with AZA have been promising and suggest a survival benefit compared to the expected mOS with AZA alone. However, the high incidence of severe adverse events remains a concern and, in our view, could limit the uptake of this regimen in the HR-MDS setting if approved. Our estimates for BEX in HR-MDS indicate a significant commercial opportunity, even if venetoclax is approved. We forecast an opportunity for BEX to achieve accelerated approval in 2027, with initial sales beginning in the second-line HR-MDS setting, followed by broader approval including the first-line setting a year later. Given the limited competition, we believe BEX has significant potential in HR-MDS and forecast peak sales of USD1.1bn by 2036.

Expansion into solid tumours

The potential for BEX extends beyond MDS. In the MATINS study, BEX demonstrated a favourable safety and tolerability profile in patients with solid tumours, although clinical efficacy as a monotherapy was limited. Nevertheless, we believe the MATINS study has been instrumental in deepening the understanding of BEX in patients and has laid the foundation for its continued development in combination with other anticancer therapies in solid tumours. Several

combination studies are planned for the next 12 months, including Faron's own MATINS-2 study. We believe the opportunity in solid tumours could be considerable in the right therapeutic context. For these indications, we forecast non-risk-adjusted peak sales of USD1.0bn by 2038, following a potential launch in 2030.

Opportunity for a partner deal

Securing a partner for BEX is central to Faron's overall strategy following a positive data readout from the ongoing Phase II BEXMAB trial. We believe that a strong Phase II data readout from the BEXMAB trial could trigger significant partnering interest. In our model, we assume a licensing agreement will be signed in 2026, following the data readout for mOS in H2(25).

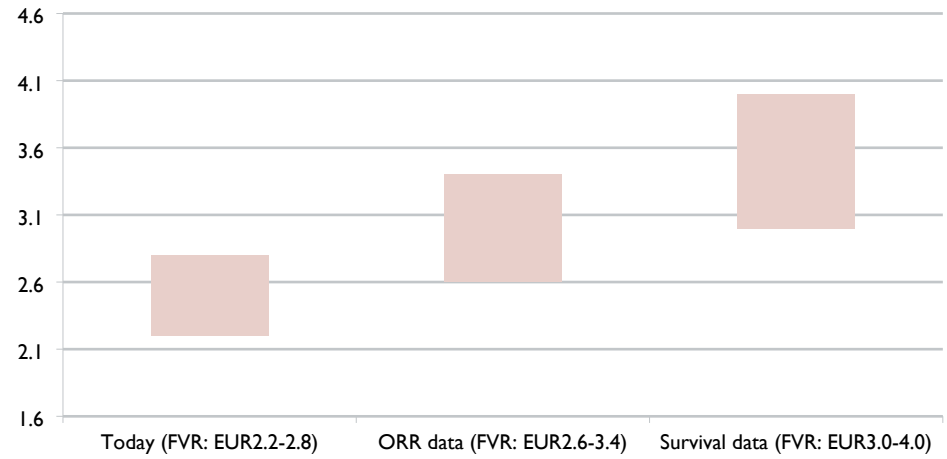
Oncology remains a top licensing priority for pharmaceutical companies, underpinned by strong market fundamentals. With another patent cliff approaching, we believe interest in later-stage assets will remain robust and favourable, aligning well with BEX's current positioning and Faron's strategic objectives.

Valuation

We value Faron Pharmaceuticals with a fair value range of EUR2.2–2.8 per share. Our valuation is based on a risk-adjusted cash flow model (rNPV), where each project is assessed over its patent lifespan and then aggregated in a sum-of-the-parts (SOTP) analysis. We have applied a WACC range of 12–16%, with the lower end of our valuation range derived using a WACC of 16%, and the upper end using a WACC of 12%, reflecting varying levels of market risk appetite.

An investment in Faron is inherently dependent on the outcome of the BEXMAB study. A positive readout could lead us to raise our likelihood of approval (LOA), thereby reducing the risk adjustment applied to our estimated cash flow streams. All else being equal, increasing the LOA to 40% would raise our fair value range to EUR2.6–3.4 per share. Furthermore, positive survival data could increase our fair value range even further, to EUR3.0–4.0 per share.

Fair value range scenarios following data readouts (EUR per share)



Source: Carnegie Research

Risks and challenges

We see several reasons to be optimistic about a positive outcome in the BEXMAB study. That said, development risks should not be overlooked, as no robust controlled study data have been released to date. Additionally, Faron is a small company with limited resources and no commercial infrastructure. While we believe the company is well-positioned to attract partnering interest, particularly following positive data, the absence of a partnership would require Faron to finance future pivotal studies and invest in building its own commercial capabilities.

Expected news flow

As a company without marketed products and focused on developing innovative treatments, we believe Faron's share price is highly sensitive to news flow. Over the next 12 months, we expect a rich stream of updates, with clinical data and a potential licensing agreement the key catalysts for the stock.

Potential news flow coming 12 months and our view of its impact on the valuation

Timing	Impact	Event	Comment
Q2(25e)	Major	Topline study results bexmarilimab in MDS	BEXMAB Phase II
Q2/Q3(25e)	Modest	Potentially Breakthrough Therapy designation	FDA decision
H2(25e)	Minor	First-patient in	BLAZE Phase I/II
H2(25e)	Major	Follow-up, survival data bexmarilimab in MDS	BEXMAB Phase II
Q4(25e)	Minor	First-patient in	BEXAR Phase I/II
2025-2026e	Major	Licensing partner deal	n.a.
H1(26e)	Modest	Initiation of a pivotal trial in MDS	Phase III
Q1(26e)	Minor	First-patient in	MATINS-02

Source: Carnegie Research

Company overview

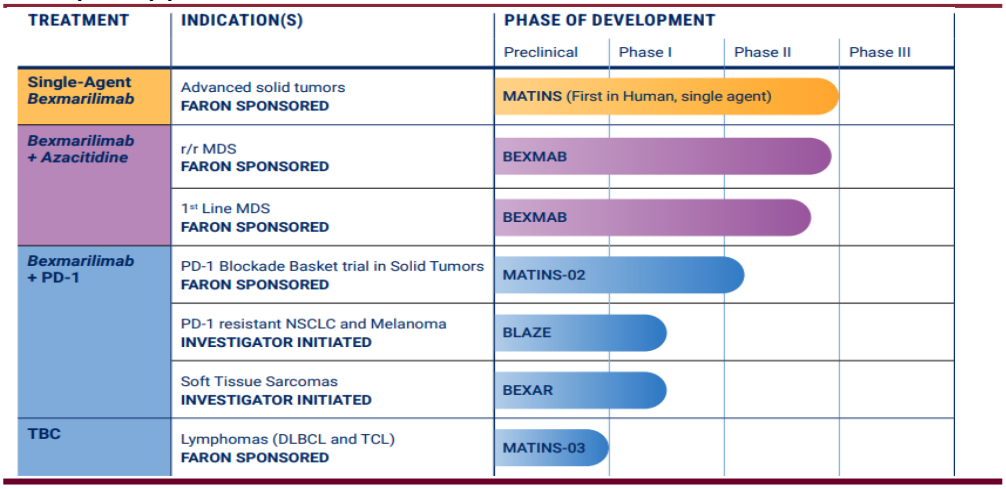
Faron Pharmaceuticals is a Finnish clinical-stage biotechnology company, with its lead oncology asset, bexmarilimab, progressing towards a registrational trial, building on promising mid-stage clinical data. As part of its overarching strategy, we expect Faron to intensify partnering discussions in 2025, with the objective of securing a licensing agreement prior to entering the final stage of development.

Faron Pharmaceuticals (Faron), headquartered in Turku, Finland, was founded in 2007 by Dr Sirpa Jalkanen and Dr Markku Jalkanen, with the latter leading the company until 2024. As of May 2024, the company's CEO is the co-founders' son, Juho Jalkanen. The company's lean organisational structure consists of 24 employees, supported by a management team of just five members. While Finland may not yet be a major player on the global biopharma stage, we believe Faron has assembled a strong team, supported by a respected and experienced scientific advisory board, to assist and guide its clinical development. Its shares have been listed on the London Stock Exchange's Alternative Investment Market (AIM) since 2015 and achieved a secondary listing on the Nasdaq First North Growth Market Finland in Helsinki in December 2019.

Faron's lead asset, bexmarilimab (BEX), is a mid-stage antibody therapy in development for haematological cancers and solid tumours, targeting myeloid cells. The company has built a patent portfolio around BEX, securing protection for the compound until 2037. A Phase I/II monotherapy study in solid tumours, the MATINS trial, was completed in 2020, providing valuable insight into its favourable safety profile and initial efficacy signs. The next step involves initiating combination studies in solid tumours to evaluate the addition of PD-1 inhibitor immunotherapies to BEX.

The most advanced development is in haematological cancers, where BEX has shown particularly promising results in patients with myelodysplastic syndromes (MDS), the BEXMAB study. Top-line data from the ongoing BEXMAB trial is expected in April 2025, providing clinical support for advancing to the next step, a registrational study for this indication, anticipated to begin within the next 12 months. We believe this presents a major opportunity for Faron to accelerate towards becoming a commercial-stage company.

Development pipeline overview



Source: Faron Pharmaceuticals

Preparations for the next phase are already under way, with significant interactions initiated with regulatory authorities, particularly the FDA, which has granted BEX a Fast Track designation for MDS. The FDA and EMA also recently granted orphan drug designation, further strengthening its position and contributing to a smoother regulatory pathway. We believe a breakthrough

therapy designation from the FDA could be within reach later this year, contingent on a positive BEXMAB study readout.

Faron's strategy is to advance its projects through Phase II to establish clinical proof-of-concept, with the goal of securing a partner for late-stage development and commercialisation. In our view, manufacturing is nearly as critical as clinical data in securing a partnership and is essential for advancing BEX into a registrational trial. As we understand it, Faron has made significant investments and progress in this area in recent years, positioning itself well for the next stages of development and potential partnerships.

Faron has two additional assets in development, traumakine and haematokine; however, we believe these programmes have been deprioritised for the time being, and are not in our focus in this report.

Company history

2007	Founded in Turku, Finland, established to capitalize on advancements in immunology research
2008	Discovered the significance of the Clever-1 receptor and initiated the development of bexmarilimab to target this pathway
2009	Initiated a clinical study with its compound Traumakine
2015	The shares were listed on the London Stock Exchange's Alternative Investment Market (AIM)
2018	Initiated the first-in-human clinical study with bexmarilimab, the MATINS study
2019	Listed its shares on the Nasdaq First North Growth Market Finland in Helsinki
2020	Completed the Phase I part of the MATINS trial and entered a partnership with the 59th Medical Wing of the US Air Force and the US Army Institute of Surgical Research to advance the development of Traumakine. Additionally, Faron acquired the rights to Haematokine and initiated its preclinical development
2021	A Phase II/III study for Traumakineas as a first-line treatment for hospitalized COVID-19 patients was started, supported by funding from the US Department of Defense. Preliminary results from the MATINS trial were released, and a composition of matter patent for bexmarilimab was granted by the US Patent Authority, providing protection until 2037
2022	Initiated planning for the next phase of bexmarilimab development in solid tumors following promising follow-up results. The company discontinued the Phase II/III study with Traumakine and launched the BEXMAB study, reporting the first promising data at the ASH 2022 conference
2023	Provided further data from the ongoing BEXMAB study, indicating a clear advantage for bexmarilimab in relapsed and refractory AML and MDS patients
2024	Dr Markku Jalkanen leaves his role as CEO, replaced by Juho Jalkanen. Bexmarilimab granted Fast Track designation in MDS, and gets feedback from the FDA regarding a registrational clinical development plan for bexmarilimab
2025	FDA and EMA grants bexmarilimab orphan drug designation for the treatment of MDS

Source: Carnegie Research, Faron Pharmaceuticals

A new tool for the treatment of cancers

Bexmarilimab is a first-in-class immunotherapy that uniquely targets macrophages and may offer broad potential in both solid and haematological cancers. Its strong safety and tolerability profile supports this expansion, with the opportunity for use in various combination treatments.

Bexmarilimab targets unwanted macrophages

Scavenger receptors are a diverse group of proteins with critical roles in the body. Found primarily on myeloid immune cells, these receptors act as 'catchers', capturing and internalising various substances such as damaged fats, dead cell components, pathogens, and other extracellular materials. They are essential for maintaining the body's balance and health, playing a key role in the immune system's defence mechanisms

Faron's lead clinical asset, bexmarilimab (BEX), is a humanised IgG4 antibody targeting the common lymphatic endothelial and vascular endothelial receptor 1 (Clever-1), designed to block its function while avoiding antibody-dependent cellular cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC). Clever-1 is a scavenger receptor highly expressed in myeloid cells such as monocytes, and is particularly prevalent in immunosuppressive tumour-associated M2-like macrophages (TAMs).

Myeloid cells play a crucial role in cancer as the most abundant cell type in solid tumours, aside from the cancer cells themselves. Data suggests they comprise nearly half of all cells in the tumour microenvironment (TME). Within this TME, immunosuppressive TAMs contribute to tumour growth and survival by promoting angiogenesis (the formation of new blood vessels). TAMs may also facilitate immune evasion by suppressing cytotoxic CD8+ T cell activity and promoting the presence of immunosuppressive regulatory T cells (Tregs). They also aid metastasis by degrading the extracellular matrix and supporting cancer cell migration.

By blocking the Clever-1 receptor, BEX reprogrammes pro-cancer TAMs into a more pro-inflammatory state. This transformation enhances their anticancer activity by promoting CD8+ T cell activation and function, enabling more effective targeting of cancer cells.

Bexmarilimab mechanism of action – haematological cancer

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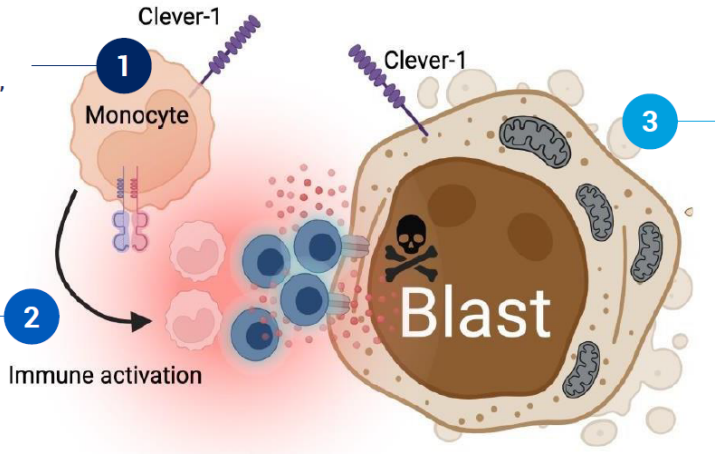
● ***Bexmarilimab*** **targets the CLEVER-1 receptor on immune cells (monocytes), reprogramming them from an immune suppressive to an immune activating state.** Monocytes are responsible for eliminating infected or cancerous cells

● **Change in the state of monocytes activates the immune system, which enables the immune system to find and destroy cancer cells**



● ***Bexmarilimab*** **deactivates the energy production of the cancer cells.** This enables existing therapies, which previously did not work, to destroy cancer cells

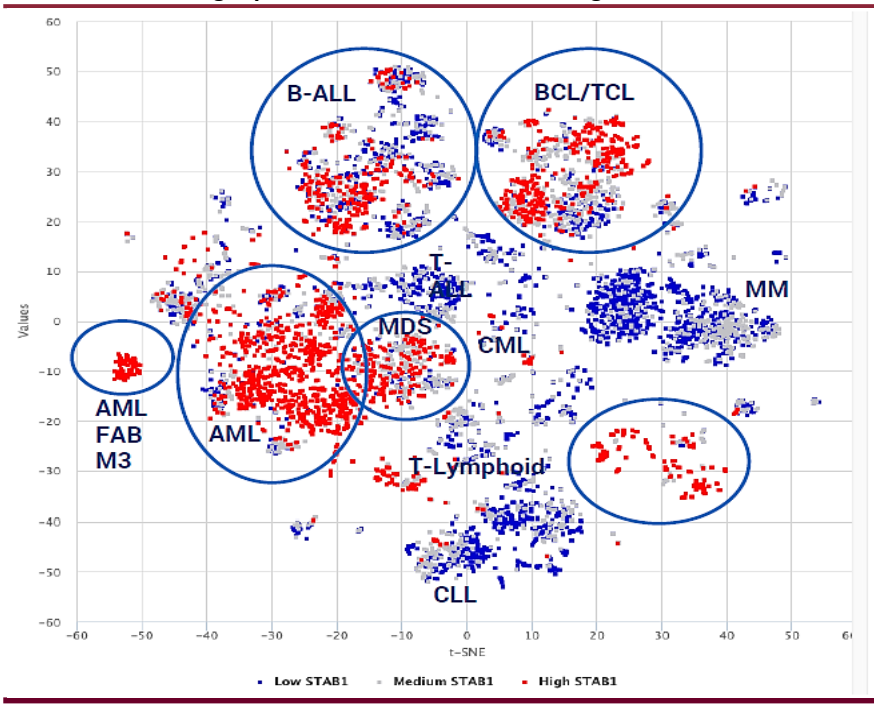
Source: Faron Pharmaceuticals

Preclinical studies further support BEX's relevance in haematological cancers by directly targeting cancerous blast cells, impairing their energy production, and enhancing the effectiveness of subsequent treatments. Ultimately, this creates better conditions for the immune system to function effectively and eliminate these unwanted blast cells.

Faron has investigated biobank data of the relevance of Clever-1 as a target in haematological cancers, demonstrating high expression in diseases such as AML and MDS (with red dots representing Clever-1 expression (Stab1)), see picture on the next page. However, the potential for targeting blood cancers may extend beyond the current focus, as the receptor is also highly

expressed in B-cell and T-cell lymphomas, as shown in the picture. This presents an intriguing opportunity for future exploration to evaluate whether BEX could enhance treatment efficacy in these diseases. We expect Faron to pursue preclinical studies in these indications.

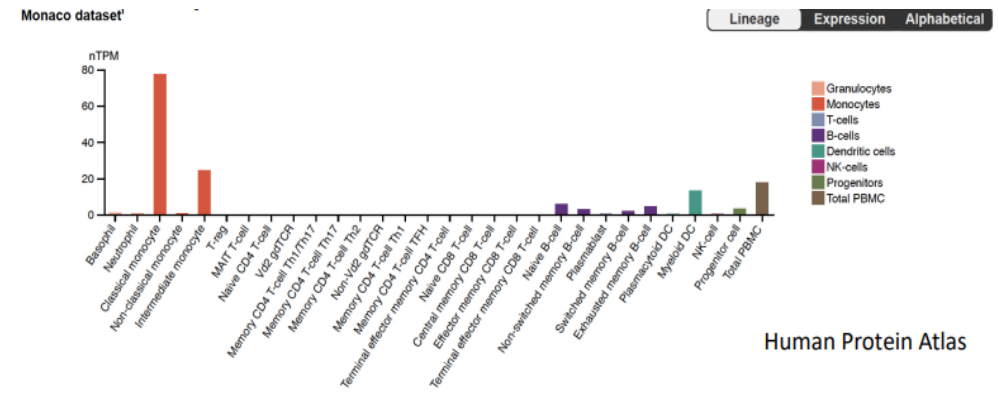
Biobank data showing expression of Clever-1 in haematological cancers



Source: Faron Pharmaceuticals

A strong safety profile is crucial for the success of a new cancer drug, as combination treatments are often used to enhance anticancer effects, and many existing therapies are associated with significant toxicity. A well-tolerated drug expands the potential for various combination treatment opportunities. Clinical data to date suggest that BEX has such a profile, with low rates of serious adverse events recorded in both the MATINS trial and the BEXMAB study. The expression data shown in the picture below indicate that Clever-1 is primarily expressed in myeloid cells, supporting its mode of action and suggesting a lower risk of unwanted effects.

Expression of Clever-1 on immune cells



Source: Faron Pharmaceuticals, Q4(23) presentation

Disease overview – MDS

In the near term, following the positive developments in the BEXMAB trial, we believe the primary potential lies in haematological cancers, particularly in MDS, where the unmet medical need is significant. Patients diagnosed with MDS, especially those with a high-risk prognosis, face a dismal survival outlook and have limited treatment options. In recent years, there has been little progress in high-risk MDS, which is why we believe the commercial opportunity for BEX could be substantial.

Disease background

Myelodysplastic syndromes (MDS), also referred to as myelodysplastic neoplasms to underscore their cancerous nature, primarily affect older individuals, with most cases occurring in those over 70 years of age. MDS represents a heterogeneous group of haematological cancers that originate in the hematopoietic stem cells (HSCs) inside the bone marrow, resulting in the inadequate production of healthy blood cells. Instead, the bone marrow produces abnormally shaped and immature blood cells, known as blast cells (blasts). These blast cells can accumulate in both the bone marrow and the bloodstream, causing a reduction in the number of mature blood cells (cytopenia). The lower levels of functional blood cells often lead to the development of anaemia, as well as neutropenia and thrombocytopenia, deficiencies that can become life-threatening.

The underlying cause of MDS is unknown in some cases, but it more commonly develops after exposure to high doses of radiation, chemotherapy, or other toxins that damage bone marrow stem cells. MDS is a relatively rare disease, with epidemiological data indicating an incidence of approximately 4–6 cases per 100,000 people per year. However, as the disease progresses more slowly in some of the patients, the prevalence rate is considerably higher.

The diagnostic procedure of MDS is often based on the World Health Organisation (WHO) classification system and/or the International Consensus Classification (ICC) and involves analysis of patients:

- Number of blast cells in the blood
- Blast cells in the bone marrow
- How 'normal' the blood cells look
- Analysis for genetic changes in the cells/biomarkers specific for MDS

WHO fifth edition (WHO5) and ICC

Category	WHO Classification, fifth edition	International Consensus Classification
Category 1: 'Precursor' state	Clonal haematopoiesis: CHIP, CCUS	CCUS
Category 2: Myelodysplastic neoplasms/syndromes	MDS with defining genetic abnormalities; MDS with low blasts and isolated 5q deletion (MDS-5q); MDS with low blasts and *SF3B1* mutation (MDS-*SF3B1*); MDS with biallelic *TP53* inactivation (MDS-bi*TP53*); MDS, morphologically defined; MDS with low blasts; MDS, hypoplastic; MDS-IB: MDS-IB1, MDS-IB2, MDS with fibrosis	MDS with mutated *SF3B1*; MDS with del(5q); MDS with mutated *TP53*; MDS NOS:MDS NOS without dysplasia; MDS NOS with single lineage dysplasia; MDS NOS with multilineage dysplasia; MDS with excess blasts
Category 3: Myelodysplastic/ myeloproliferative neoplasms	CMML; CMML subtyping criteria: myelodysplastic CMML, myeloproliferative CMML; CMML subgrouping criteria: CMML-1, CMML-2; MDS/MPN with neutrophilia; MDS/MPN with *SF3B1* mutation and thrombocytosis; MDS/MPN, NOS	CMML; clonal cytopenia with monocytosis of undetermined significance; clonal monocytosis of undetermined significance; atypical chronic myeloid leukaemia; MDS/MPN with thrombocytosis and *SF3B1* mutation; MDS/MPN with ring sideroblasts and thrombocytosis, NOS; MDS/MPN, unclassifiable
Category 4: Paediatric MDS	Childhood MDS: Childhood MDS with low blasts; hypocellular; NOS; childhood MDS with increased blasts	Paediatric and/or germline mutation-associated disorders: juvenile myelomonocytic leukaemia; juvenile myelomonocytic leukaemia-like neoplasms; Noonan syndrome-associated myeloproliferative disorder; refractory cytopenia of childhood; haematological neoplasms with germline predisposition
Category 5: MDS/AML	Not applicable	MDS/AML with mutated *TP53*; MDS/AML with myelodysplasia-related gene mutations; MDS/AML with myelodysplasia-related cytogenetic abnormalities; MDS/AML, NOS

AML, acute myeloid leukaemia; CHIP, clonal haematopoiesis of indeterminate potential; CCUS, clonal cytopenia of undetermined significance; CMML, chronic myelomonocytic leukaemia; MDS, myelodysplastic syndromes; MDS-IB, MDS with increased blasts; MPN, myeloproliferative neoplasm; NOS, not otherwise specified.

Source: Li, et al., Nature reviews disease primers, 2022

In MDS, the blast count in the blood and/or bone marrow is defined as below 20% according to the WHO5 classification system, while in the ICC system, the threshold is set at above 10%. If the blast count exceeds these thresholds, the condition is typically classified as acute myeloid leukaemia (AML). According to the American Cancer Society, about 30% of MDS cases progress to secondary AML, which accounts for about 25–35% of all AML cases.

For most types of cancer, the stage of the disease is a measure of how much it has spread and is one of the most critical factors in selecting treatment options and determining a person's prognosis. However, in the case of MDS, the disease is typically already widespread in the bone marrow and blood at the time of diagnosis. Consequently, management strategies and treatment decisions are generally determined by the patient's risk category, which distinguishes lower risk from high-risk patients using the International Prognostic Scoring System (IPSS). The scoring system was introduced in 1997 and has evolved over time. Today, the second revised version (IPSS-R), introduced in 2012, remains the most widely used system, classifying MDS patients into five groups. However, the latest iteration, IPSS-M, offers several advantages as it incorporates next-generation sequencing (NGS) to enhance risk stratification by integrating molecular genetic data, including over 30 disease-driving genes. By incorporating molecular data, IPSS-M often reclassifies patients from lower- to higher-risk categories, providing a more precise and accurate assessment of their prognosis.

While the IPSS-M risk score calculation is more complex compared to IPSS-R, it has demonstrated superior prognostic accuracy. Therefore, we believe it will see broader implementation as access to NGS continues to increase. However, in the near term, we expect IPSS-R to remain the preferred choice.

IPSS-R patient risk classification and survival related to age

	IPSS-R prognostic risk categories				
Ages, y	Very low	Low	Intermediate	High	Very high
All	8.8	5.3	3.0	1.6	0.8
≤ 60	NR	8.8	5.2	2.1	0.9
	(13.0-NR)	(8.1-12.1)	(4.0-7.7)	(1.7-2.8)	(0.8-1.0)
> 60-70	10.2	6.1	3.3	1.6	0.8
	(9.1-NR)	(5.3-7.4)	(2.5-4.0)	(1.5-2.0)	(0.7-1.0)
> 70-80	7.0	4.7	2.7	1.5	0.7
	(5.9-9.0)	(4.3-5.3)	(2.4-3.1)	(1.3-1.7)	(0.6-0.8)
> 80	5.2	3.2	1.8	1.5	0.7
	(4.2-5.9)	(2.8-3.8)	(1.6-2.6)	(1.2-1.7)	(0.5-0.8)

Source: Greenberg, et al., Blood, 2012

IPSS-M patient risk classification and survival

	IPSS-M Risk Category					
Characteristic	Very Low	Low	Moderate Low	Moderate High	High	Very High
Patients — No. (%)	381 (14)	889 (33)	302 (11)	281 (11)	379 (14)	469 (17)
Risk score	≤−1.5	>−1.5 to −0.5	>−0.5 to 0	>0 to 0.5	>0.5 to 1.5	>1.5
Hazard ratio (95% CI)†	0.51 (0.39–0.67)	1.0 (Reference)	1.5 (1.2–1.8)	2.5 (2.1–3.1)	3.7 (3.1–4.4)	7.1 (6.0–8.3)
Median LFS (25–75% range) — yr‡	9.7 (5.0–17.4)	5.9 (2.6–12.0)	4.5 (1.6–6.9)	2.3 (0.91–4.7)	1.5 (0.80–2.8)	0.76 (0.33–1.5)
Median OS (25–75% range) — yr	10.6 (5.1–17.4)	6.0 (3.0–12.8)	4.6 (2.0–7.4)	2.8 (1.2–5.5)	1.7 (1.0–3.4)	1.0 (0.5–1.8)

Source: Bernard, et al., NEJM Evidence, 2022

Along with updates to the risk categories and patient classification systems, a revision of the response criteria for high-risk MDS has been proposed, transitioning from IWG2006 to IWG2023. These changes are summarised on the table on the next page.

The most significant change in IWG2023 is the exclusion of marrow (m) complete response (CR), as mCR without haematological improvements has been shown to correlate poorly with overall survival (OS). Instead, several less than CR criteria have been introduced. Other changes include lowering the haemoglobin (Hb) level threshold required for CR to 10 g/dL or higher (previously 11 g/dL).

Revised IWG 2023 response criteria for high-risk MDS

Response	IWG 2006	IWG 2023
CR	• BM: ≤5% myeloblasts; dysplasia may persist • PB: Hb ≥11 g/dL, platelets ≥100 × 10^9/L; neutrophils ≥1.0 × 10^9/L; blasts 0%	• BM: <5% myeloblasts;* dysplasia may persist • PB: Hb ≥10 g/dL, platelets ≥100 × 10^9/L; neutrophils ≥1.0 × 10^9/L; blasts 0%†
CR equivalent*	Not included	Patients with <5% BM blasts at baseline • BM: <5% myeloblasts*; dysplasia may persist • PB: Hb ≥10 g/dL, platelets ≥100 × 10^9/L; neutrophils ≥1.0 × 10^9/L; blasts 0%† • Full cytogenetic clearance of baseline abnormalities (complete cytogenetic response)
mCR	• BM: ≤5% blasts and decrease by ≥50% over pretreatment • No PB responses required	Eliminated as a response criterion‡
PR	All CR criteria except: • BM blasts decreased by ≥50% over pretreatment but still >5% • Cellularity and morphology not relevant	All CR criteria except: • BM blasts decreased by ≥50% over pretreatment but still ≥5% • Cellularity and morphology not relevant
SD	Failure to achieve at least PR, but no evidence of progression for >8 wk	Eliminated as a response criterion‡
CR_L§ (CR_{uni} and CR_{bi})	Not included	• BM: <5% myeloblasts;* dysplasia may persist • PB: blasts 0%† • CR_{uni}: PB, not meeting CR but only 1 of the following: Hb ≥10 g/dL; platelets ≥100 × 10^9/L; neutrophils ≥1.0 × 10^9/L • CR_{bi}: PB, not meeting CR but only 2 of the following: Hb ≥10 g/dL; platelets ≥100 × 10^9/L; neutrophils ≥1.0 × 10^9/L
CRh§	Not included	• BM: <5% myeloblasts;* dysplasia may persist • PB: Not meeting criteria for CR or CR_L, no Hb threshold required, platelets ≥50 × 10^9/L; neutrophils ≥0.5 × 10^9/L; blasts 0%†
HI	HI (responses >8 wk): • Erythroid response (pretreatment, <11 g/dL):Hb increase by ≥1.5 g/dL and 50% reduction of RBC transfusions. • Platelet response (pretreatment, <100 × 10^9/L):absolute increase of ≥30 × 10^9/L for patients starting with >20 × 10^9/L platelets or increase from <20 × 10^9/L to >20 × 10^9/L and by at least 100%. • Neutrophil response (pretreatment, <1.0 × 10^9/L): at least 100% increase and an absolute increase >0.5 × 10^9/L.	HI defined according to IWG 2018 response criteria:‖ • Not meeting criteria for CR (or CR equivalent) or CRuni or CR_L • $HI_{erythroid}$ (HI-E) • $HI_{platelets}$ (HI-P) • $HI_{neutrophils}$ (HI-N)
ORR	Not defined	ORR = CR (or CR equivalent)* + PR + CR_L + CRh + HI
No response	Not defined	Not meeting criteria for CR (or CR equivalent)*, PR, CR_L, CRh, or HI‡

Source: Zeidan, et al., Blood, 2023

Treatment of MDS

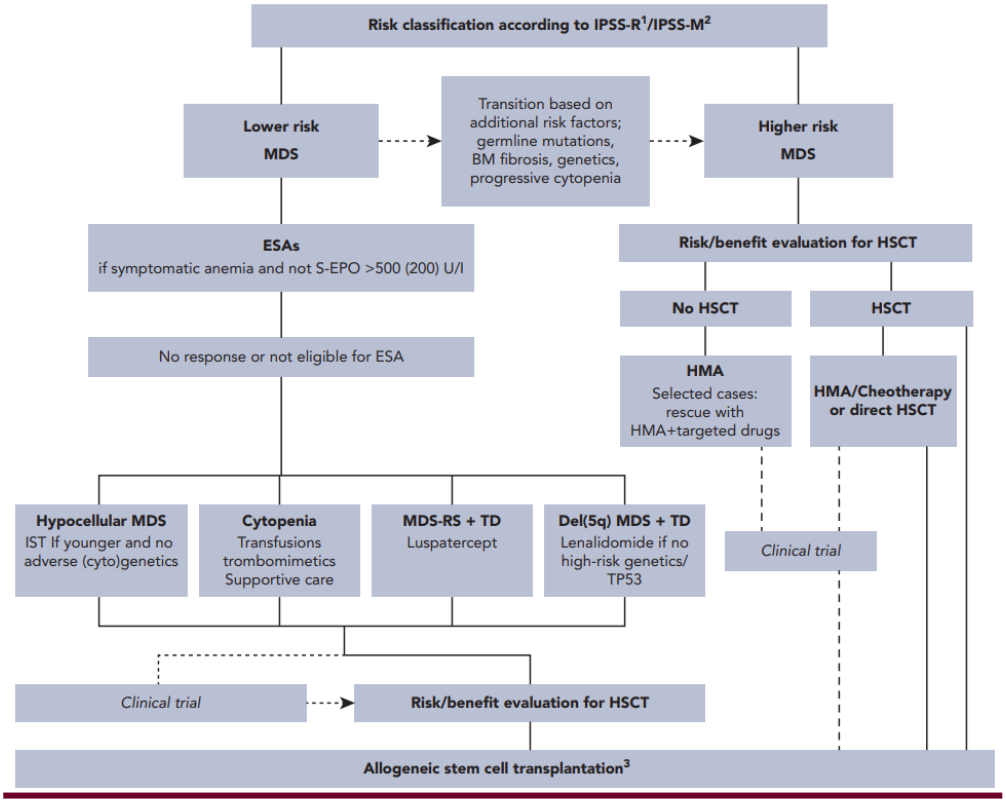
Treatment strategies for MDS rely on risk classification and are divided into low- and high-risk categories. Treatment strategies for low-risk MDS patients focus on improving quality of life, managing symptoms, and delaying progression to higher-risk disease or AML. Initially, this involves addressing specific complications of the disease, such as anaemia and low blood counts, which may include interventions like transfusions, as well as reducing the risk of bleeding events and infectious complications. The progression of the disease can be slow for some patients, which is why a watch-and-wait approach may be sufficient for them. However, some patients may need more aggressive therapy, standard-of-care strategies include chemotherapy with hypomethylating agents, such as azacitidine and decitabine, as well as lenalidomide.

In the low-risk category, progress has been made with the introduction of new therapies, such as Reblozyl (luspatercept) from Bristol Myers Squibb and Rytelo (imetelstat) from Geron, approved in 2019 and 2024, respectively. Both treatments are approved in the US for the treatment of adults with transfusion-dependent anaemia associated with low-risk MDS. We note that market expectations for these drugs are quite high, with sales for Reblozyl projected to reach USD2.9bn by 2030 and sales for Rytelo estimated to reach USD1.0bn by 2030, according to Evaluate Pharma. Both drugs mainly have shown to improve anaemia in larger trials, supporting the approval.

The greatest unmet medical need is among patients with high-risk (HR) MDS, who typically require more aggressive therapy. Notably, there have been no major advancements in the treatment of HR-MDS for almost 20 years. Recently, only one drug has been approved by the FDA for the relapsed and refractory (r/r) HR-MDS setting. Tibsovo (ivosidenib) from Servier Pharmaceuticals. However, its approval was based on a very small study involving only 18 patients with r/r HR-MDS carrying the IDH1 mutation (less than 5% of MDS patients).

The only curative option remains allogeneic stem cell transplantation. However, we believe that the majority of HR-MDS patients are not eligible for this procedure. In addition, access to transplants is limited, and finding a suitable match can be challenging. For these patients, hypomethylating agents (HMAs), such as azacitidine and decitabine, remain the only available options for achieving sustainable responses in the first line setting, as they are the only approved drugs that have demonstrated a clinically meaningful effect. For patients who relapse or are refractory to HMAs, there are currently no approved treatments. The overall treatment algorithm for MDS patients is displayed in the picture below.

Treatment algorithm for MDS



Source: Hellström-Lindberg, et al., Blood, 2023

The table on the next page summarises the available treatment alternatives for MDS.

Treatment options for MDS in 2023, licensed or recommended according to guidelines

Procedure/ treatment option United Sates: formally licensed US EU: formally licensed EU	Lower-risk MDS	Higher-risk MDS	MDS-RS	Del(5q) MDS	Comment
Transfusion therapy	Yes	Yes	Yes	Yes	Indicated for symptomatic anemia
Chelation therapy in TD patients*	Yes	If planned HSCT	Yes	Yes	If estimated survival >1-2 y *US and *EU
ESAs	Yes US and EU	Rarely	Yes US and EU	Yes US and EU	Firstline treatment for symptomatic anemia of all lower-risk MDSs. Poor response rate if S-EPO >500 (200) U/L.
Trombomimetics	If severe thrombocytopenia	No	No	No	Not licensed for MDS but can be used as in immune-mediated thrombocytopenia
Luspatercept	Yes US	No	Yes US, EU	No	Currently licensed only for MDS-RS; recent phase 3 study shows efficacy in other lower-risk MDSs as well
Immunosuppressive treatment	Occasionally	No	No	No	Younger patients; severe pancytopenia and hypo/ normoplastic BM without high-risk genetics
Lenalidomide	No	No	No	Yes	Licensed for TD del(5q) MDS, at ESA failure/ineligibility
HMAs	Yes US	Yes US and EU	No	No	Could be used in LR-MDS if aggravating cytopenia or progression
Aza	Yes US	Yes US and EU	No	Yes US	Firstline treatment for higher-risk MDS. In United States also approved for lower-risk MDS.
Decitabine	Yes (IPSS ≥ INT-1) US	Yes US	No	Yes (IPSS ≥ INT-1) US	Licensed for AML in the EU Licensed for AML and MDS in the US
Oral decitabine/ cedazuridine	Yes (IPSS ≥ INT-1) US	Yes (IPSS ≥ INT-1)	No	Yes (IPSS ≥ INT-1) US	Not inferior to HMA in randomized studies
HMA + venetoclax	No	See comment	No	No	Licensed for AML only. Phase 3 study for MDS is pending. Caution if used as a rescue treatment for MDS: toxicity is usually higher than in AML.
Targeted AML drugs (*IDH1 + 2* inhibitors)	No	See comment	No	No	Not licensed for MDS. In clinical trials including AML and MDS. For other targeted drugs, see text.
Chemotherapy	No	See comment	No	No	Inferior to aza (not tested for CPX). May be relevant for MDS with AML-like genetics and as bridging therapy to allo-HSCT.
Allo-HSCT	If adverse risk profile	Yes	Occasionally, if refractory TD	If refractory TD or high-risk genetics	Complex decision making involving MDS risk, comorbidities, and patients' preferences

Source: Hellström-Lindberg, et al., Blood, 2023

HMAs – the cornerstone in HR-MDS patients

Since the FDA approval of Vidaza (azacitidine) by Pharmion (now part of Bristol Myers Squibb) in 2004 and Dacogen (decitabine) by Eisai in 2006, hypomethylating agents (HMAs) have become the standard of care in the frontline setting for HR-MDS patients who are not eligible for allogeneic stem cell transplantation (allo-HSCT). Additionally, a combination tablet of decitabine and cedazuridine, (Inqovi by Otsuka Pharmaceutical) was approved in both Europe and the US in 2020. In the US, azacitidine is approved for both lower-risk and HR-MDS, as well as AML, including all subtypes, while decitabine and the combination tablet are approved for MDS with an IPSS score of intermediate or higher. The National Comprehensive Cancer Network (NCCN) in the US recommends using HMAs primarily for patients with intermediate- or HR-MDS, who are not eligible for intensive therapy.

Azacitidine (AZA) was also approved by the EMA in 2009 for the treatment of patients with AML and MDS, but only for patients with high-risk diseases. The original branded products, Vidaza and Dacogen, have now lost their patent protection, making these drugs available as more affordable generics.

In cancer, abnormal DNA methylation can silence tumour suppressor genes, enabling uncontrolled cell growth. While the exact mechanism of action is not fully understood, the biochemical effect of HMAs includes the inhibition of DNA methyltransferase enzymes, which are responsible for adding methyl groups to DNA. This hypomethylation reactivates tumour suppressor genes, restoring their ability to regulate cell growth and division. Additionally, HMA disrupts RNA metabolism, leading to reduced protein synthesis in cancer cells. By modulating epigenetic changes and impairing the survival of cancer cells, AZA slows disease progression and promotes the reactivation of normal cellular functions. A mechanism fundamentally different from BEX.

Data supporting approvals of HMAs

The approval of AZA for MDS was supported by a randomised, open-label, controlled trial involving 191 patients. Participants received either subcutaneous AZA plus supportive care or supportive care alone. The study reported an overall response rate of 15.7% (CR 5.6% + PR 10.1%) in the AZA group, with no responders in the observation group. Additionally, about 19% of AZA-treated patients experienced hematologic improvements, such as becoming transfusion-independent. Common adverse events associated with AZA included nausea, vomiting, neutropenia, thrombocytopenia, and injection site reactions.

In 2007 positive results were reported from an international Phase III study (AZA-001) including 358 patients with HR-MDS. AZA demonstrated statistically significant survival benefit compared to placebo (best supportive care, low-dose cytarabine or intensive chemo) with an mOS of 24.4 months vs 15.0 months ($p<0.0001$). Positive data was reported in all subgroups, including elderly patients. The response rate for AZA was higher compared to best supportive care and low-dose cytarabine, but not compared to intensive chemo. Data suggests that about half of the patients responded to the treatment with AZA.

Decitabine (DEC) was approved following a Phase III study that included 170 HR-MDS patients randomised to either DEC or best supportive care. Complete responses were reported in 9% of patients receiving DEC vs 0% in the control arm. A statistically significant mOS benefit was observed, with 12.0 months in the DEC group vs 6.8 months in the control arm ($p=0.03$). However, these results were not replicated in a European study, leading to the failure to gain approval from the EMA.

Second line data very dismal in HR-MDS patients

Patients failing 1L HMA treatment face a poor prognosis. In a study involving 435 HR-MDS patients who had failed HMA treatment, an mOS of 5.6 months and an ORR below 10% were reported. Factors associated with significantly worse survival included increasing age, male sex, high-risk cytogenetics, higher bone marrow blast count, and the absence of prior hematologic response to AZA.

We believe the introduction of HMAs nearly 20 years ago was a significant advancement for patients with HR-MDS. These drugs have an acceptable safety profile and have been shown to induce haematological improvements while eradicating malignant clones. However, their effects are transient, and additional treatment options for patients are badly needed.

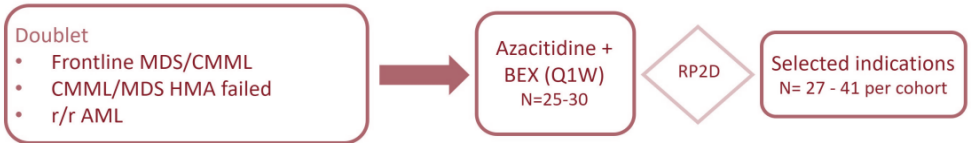
Compelling clinical data in HR-MDS for BEX

The results reported for BEX in patients with HR-MDS in the BEXMAB study have been consistently promising, demonstrating a strong safety profile alongside encouraging efficacy data. If the top-line data from the completed Phase I/II study, expected in April this year, aligns with previous reported findings, we see potential for progression to a pivotal study within the next 12 months. We also believe that a positive outcome would likely generate significant interest from potential partners.

BEXMAB study initiated

The BEXMAB Phase I/II study was initiated in the autumn of 2022, to evaluate BEX in combination with standard of care for safety and preliminary efficacy in myeloid malignancies, such as AML and MDS. In the first part of the study (Phase I), BEX was evaluated at escalating doses in both first line (1L) patients and those who had relapsed or were refractory (r/r) to 1L treatment.

Study design – BEXMAB trial

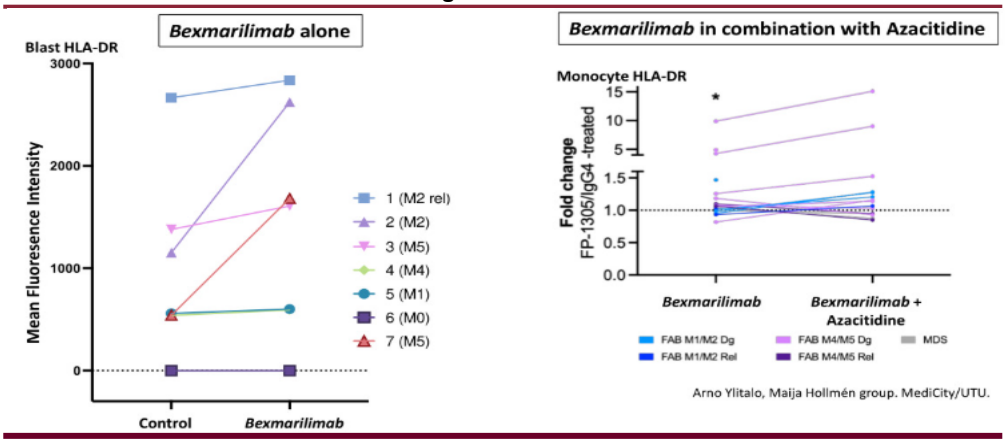


Source: Faron Pharmaceuticals

The rationale behind the BEXMAB study is based on the high Clever-1 expression observed in AML and MDS, as well as preclinical data showing a negative correlation between Clever-1 expression and bone marrow T-cell frequency. Blocking this receptor may help reverse immunosuppression in the bone marrow.

Preclinical studies with BEX have demonstrated that the treatment enhances antigen presentation by upregulating HLA-DR on the surface of monocytes. This has also been seen in studies on the combination of BEX plus AZA suggest that BEX can counteract AZA's suppressive effects on antigen presentation, instead promoting HLA-DR upregulation. This further supports its potential in combination therapies, as illustrated in the image below.

Preclinical data bexmarilimab in haematological models



Source: Faron Pharmaceuticals

Following positive developments in Phase I and interactions with the FDA, Faron decided to advance the BEXMAB trial to Phase II, now primarily focusing on HR-MDS patients who have failed 1L therapies (r/r HR-MDS), particularly those who have progressed after AZA treatment.

The Phase II part of the BEXMAB study began in December 2023, further evaluating different doses of BEX (1 mg/kg, 3 mg/kg, and 6 mg/kg) in combination with 75 mg/m² of AZA.

Where we stand today

Throughout the BEXMAB trial, Faron has consistently provided market updates on the safety and efficacy of the treatment. In late November 2024, the company presented an interim readout of Phase II, which, at that point, included 20 r/r HR-MDS patients. The results were subsequently presented in greater detail at the 66th Annual Meeting of the American Society of Hematology (ASH) in December 2024 (data cut-off 25 November). Of the 20 patients, five were still on treatment at the data cut-off.

The Phase II trial targets a challenging patient population, with about half treated so far having progressed after at least two prior treatments. Notably, eight patients (40%) had progressed on the venetoclax + HMA combination. Additionally, 18 patients (90%) were classified as having a high or very high-risk prognosis, while nine (45%) were identified as carrying TP53 mutations, which are typically associated with aggressive disease.

Baseline patient data BEXMAB Phase II

Patient baseline characteristics		r/r MDS; n (%)
Age (years); median (range)		72.5 (52-84)
ECOG PS	0	7 (35)
	1	13 (65)
IPSS-R	Intermediate (>3– ≤4.5 points)	2 (10)
	High (>4.5 - ≤6 points)	8 (40)
	Very high (> 6 points)	10 (50)
Mutations	TP53	9 (45)
	RUNX1	4 (20)
N and type of previous therapy lines	1	10 (50)
	2	7 (35)
	≥3	3 (15)
	Venetoclax + HMA	8 (40)
	Immunotherapy + AZA	3 (15)

Source: Abstract presentation ASH 2024

The safety and tolerability of BEX have remained very favourable, with only a limited number of BEX-related adverse events reported in the BEXMAB trial to date. Only seven patients (35%) experienced BEX-related adverse events, with none reporting grade 3 or higher adverse events. Given the high age and poor health status of the target population, we believe this is a particularly important and differentiating factor compared to most other available treatments and pipeline projects for HR-MDS.

Registered adverse events in the BEXMAB Phase II

	Event count n	Subject count n (%*)
TEAEs, total	184	19 (95)
Grade ≥3	58	14 (70)
BEX-related AEs, total	25	7 (35)
Grade ≥3	0	0

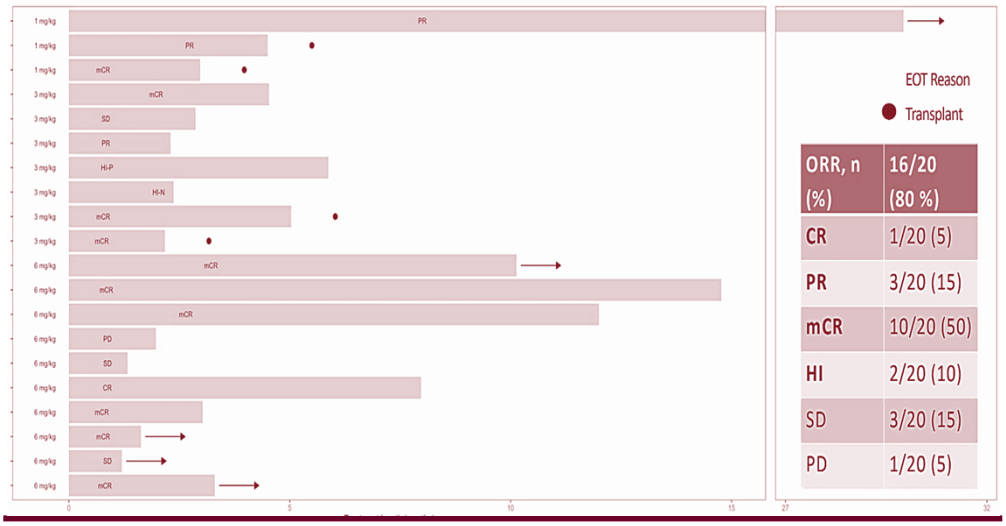
Source: Abstract presentation ASH 2024

In addition to good safety and tolerability, the reported efficacy data looks promising. Interim data indicates an 80% ORR to the combination treatment, with an additional 15% of patients achieving stable disease (SD). While only one patient (5%) achieved a CR, we believe these results are impressive. The company noted that six of the 10 patients with mCR also showed haematological improvement, reducing the risk of other complications, which we believe is very important in this fragile patient population.

Notably, four patients became eligible for potentially curative stem cell transplantation following treatment. Faron also reported that several patients achieved transfusion independence while on treatment; however, no additional details were provided.

The graph below illustrates survival and response for each patient, with the longest-surviving patient remaining on treatment for more than 2.5 years.

Swimmer plot – response and survival data from the BEXMAB trial

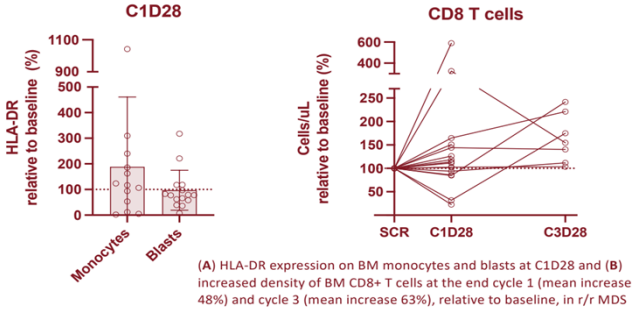


Source: Abstract presentation ASH 2024

The estimated mOS reported at ASH remained unchanged at 13.4 months, consistent with earlier updates from the BEXMAB study. This is notable, as the expected OS for this patient population is only 5.6 months.

Further analysis revealed upregulation of HLA-DR expression on bone marrow monocytes and blast cells during treatment, demonstrating enhanced antigen presentation and supporting immune system activation, in line with preclinical data. This was further confirmed through biopsies, which showed an increase in CD8+ T cells. Additionally, Faron analysed Clever-1 expression, which appears to remain unchanged during treatment, indicating no emerging resistance mechanisms.

Data analysis of antigen presentation (C1D28) and cytotoxic CD8+ T-cells relative to baseline



(A) HLA-DR expression on BM monocytes and blasts at C1D28 and (B) increased density of BM CD8+ T cells at the end cycle 1 (mean increase 48%) and cycle 3 (mean increase 63%), relative to baseline, in r/r MDS patients patients treated with BEX+AZA.

Source: Abstract presentation ASH 2024

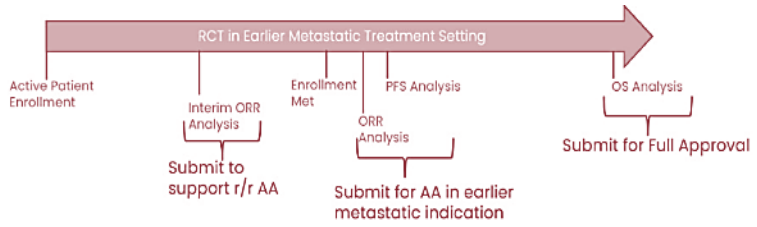
Overall, we view the BEXMAB data generated to date as highly promising, supporting preclinical findings and the proposed mechanism of action. The data demonstrates BEX's activity, including its ability to resensitise patients to HMA drugs, potentially leading to survival benefits. However, the findings are based on a small patient cohort and lack a control arm, making it difficult to definitively confirm the added benefit of BEX to AZA.

The next phase for BEX

The top-line safety and response data for the complete Phase II part of the BEXMAB study is expected in April 2025, with a total of 35 patients included in the r/r HR-MDS setting, and 20 frontline HR-MDS patients. Further details from the study are also expected to be presented at upcoming conferences, with complementary survival data anticipated in H2(25). Management appears highly confident in the continued positive trajectory of the upcoming top-line readout, expecting the data from the additional patients to align with the previous results reported, which would represent a strong outcome for the BEXMAB study.

Preparations for a registrational study in HR-MDS patients are progressing, with the company indicating that the trial may start near the end of 2025. Faron has already held discussions with the FDA regarding such a study. During these discussions, the FDA proposed enrolling 1L patients instead of conducting a registrational trial in the r/r HR MDS population. The rationale for this proposal is based on concerns from the FDA about including an AZA + placebo control arm, as it would involve patients who have already failed HMA therapies and have a poor survival prognosis with such treatments. While a registrational trial may primarily focus on frontline patients, there appears to be an opportunity for accelerated approval in the r/r setting based on an interim readout. If the timeline holds, an interim readout could be available within a year of initiation of the study, with the full data set following about a year later, supporting submission first in the r/r setting and subsequently in the frontline setting.

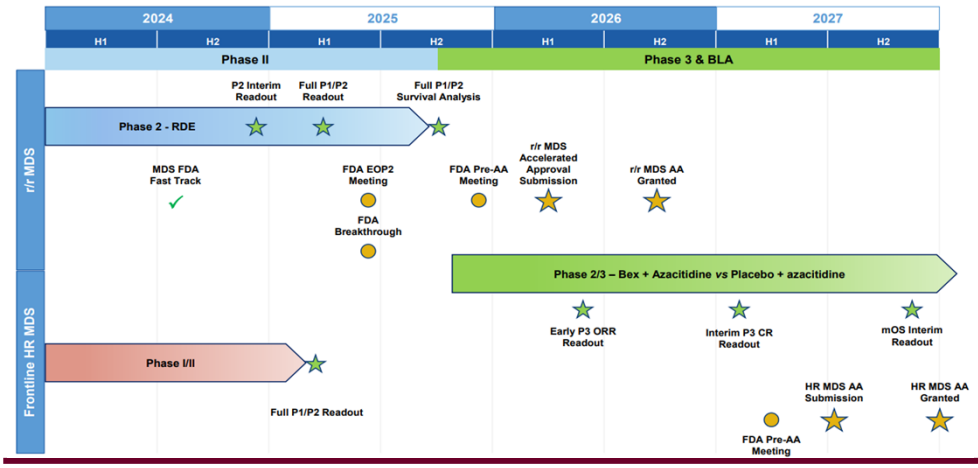
Proposed Phase III study event timeline



Source: Faron Pharmaceuticals

For now, the details of the registrational study have not yet been presented, and we believe the final data readout from the BEXMAB study will be crucial for its finalisation. However, an indicative timeline and key upcoming milestones for BEX in HR-MDS are outlined in the latest company presentation, presented in the picture below.

Proposed timeline and milestones in MDS (2024-2027)



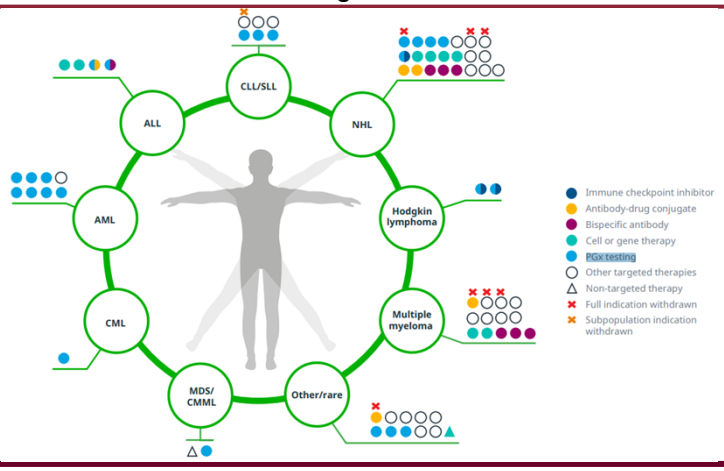
Source: Faron Pharmaceuticals, 2025

Competition – MDS

We find competition in the HR-MDS setting to be limited, with only a few therapies currently being investigated in the later stages of development. In our view, the main competitor is venetoclax, with top-line data expected in the first half of 2025.

An examination of approved treatments in haematological cancers reveals that limited progress has been made in MDS over the past decade. This is especially true for HR-MDS, where only one novel active substance has been approved since 2006, and this address only a small population. A key factor contributing to this stagnation is the high failure rate in late-stage drug development, with numerous major setbacks recorded for high-profile projects.

Approved novel active substances in haematological cancers 2014-2023



Source: Iqvia, Global Oncology Trends, 2024

One of the targets in MDS that has drawn the most attention and investment over the past five years is CD47, a macrophage checkpoint. This enthusiasm led to several major partnerships and deals involving companies such as Gilead, Novartis, and Pfizer. However, the failure in 2023 of magrolimab, an anti-CD47 monoclonal antibody developed by Gilead, in the HR-MDS setting has dampened momentum in this field, raising doubts about the future viability of anti-CD47 strategies for this indication. Magrolimab was evaluated in the ENHANCE trial, a randomised, double-blind Phase III study, in combination with AZA as a 1L treatment for HR-MDS. The trial enrolled 539 patients, with CR and OS as the primary endpoints. Following a planned futility analysis, the trial was discontinued. At this point, the magrolimab arm demonstrated worse survival outcomes and lower response rates compared to the control arm. We believe one of the key challenges in targeting CD47 is its broad expression on immune cells, which frequently results in significant adverse events.

Selection of recently failed studies in HR-MDS

Drug	Date	Development phase	Target	Developer	Treatment	Setting	Comment
Tamibarotene	Nov 2024	III	Selective agonist of RAR	Syros Pharmaceuticals	Drug + AZA vs. AZA + placebo	1L HR-MDS (RARA gene overexpression)	Primary end point of improving the complete response (CR) rate over azacitidine alone was not met
Sabatolimab	July 2024	III	TIM-3	Novartis	Drug + AZA vs. AZA + placebo	1L HR-MDS	Did not improve survival or response rates
Magrolimab	July 2023	III	CD47	Gilead	Drug + AZA vs. AZA + placebo	1L HR-MDS	Discontinued due to futility, failing to improving survival

Source: Carnegie Research

Venetoclax – most promising competitor in late stage

One of the closest competitors to BEX on our radar is Venclexta (venetoclax), marketed by AbbVie (and, in the US, in collaboration with Roche). Venetoclax is a once-daily oral BCL-2 inhibitor that has been approved for newly diagnosed acute myeloid leukaemia (AML) patients, as well as for chronic lymphocytic leukaemia (CLL) and small lymphocytic lymphoma (SLL). BCL-2 is a protein that allows cancer cells to evade programmed cell death (apoptosis). Overexpression of BCL-2 has been identified in haematological cancers, particularly in CLL, SLL, and AML, making them resistant to traditional chemotherapy. By inhibiting BCL-2, venetoclax may restore the cell's ability to undergo apoptosis, reactivating the cell's 'death switch'.

Following promising data from a Phase Ib study evaluating the combination of venetoclax and AZA in HR-MDS patients, the Phase III VERONA trial was initiated in 2021. This ongoing, placebo-controlled, study is enrolling treatment-naïve (1L), HR-MDS patients to assess the efficacy of the venetoclax and AZA combination compared to AZA alone. The study is enrolling patients across ~200 global sites, targeting about 500 participants. Eligible patients must have an intermediate or higher IPSS-R risk score and be ineligible for HSCT. Initially, the primary endpoints were CR rate (per IWG 2006 criteria) and mOS, but this has been modified to focus solely on mOS. As we understand, top-line data is expected to be presented in H1(25). Venetoclax has been granted breakthrough therapy designation by the FDA in HR-MDS.

In a Phase Ib dose-escalation study, 44 patients diagnosed with r/r HR-MDS received venetoclax plus AZA. The results demonstrated a 7% CR rate and a 32% mCR rate, with 43% of mCR patients also showing haematological improvement. Patients entering the trial had received a median of one prior treatment, primarily HMAs. The median time to response was 1.2 months, with a median response duration of 8.6 months and an mOS of 12.6 months. Given the dismal expected mOS of about 5.6 months following HMA failure, these results appear promising, particularly considering the durability of responses observed. However, the combination was associated with a high incidence of adverse events.

Adverse events in Phase Ib for the combination of venetoclax and AZA

	Venetoclax 100 mg + azacitidine 75 mg/m² (*N* = 10) *n* (%)	Venetoclax 200 mg + azacitidine 75 mg/m² (*N* = 7) *n* (%)	Venetoclax 400 mg + azacitidine 75 mg/m² (*N* = 27) *n* (%)	All venetoclax 400 mg + azacitidine 75 mg/m² (*N* = 44) *n* (%)	Venetoclax monotherapy (400 or 800 mg) (*N* = 26) *n* (%)	Total (*N* = 70) *n* (%)
Any adverse event	10 (100·0)	7 (100·0)	27 (100·0)	44 (100·0)	26 (100·0)	70 (100·0)
Hematologic						
Febrile neutropenia	3 (30·0)	4 (57·1)	8 (29·6)	15 (34·1)	6 (23·1)	21 (30·0)
Thrombocytopenia	4 (40·0)	1 (14·3)	9 (33·3)	14 (31·8)	4 (15·4)	18 (25·7)
Neutropenia	4 (40·0)	2 (28·6)	6 (22·2)	12 (27·3)	5 (19·2)	17 (24·3)
Anemia	2 (20·0)	0	6 (22·2)	8 (18·2)	4 (15·4)	12 (17·1)
Non-hematologic						
Nausea	4 (40·0)	5 (71·4)	12 (44·4)	21 (47·7)	10 (38·5)	31 (44·3)
Constipation	6 (60·0)	3 (42·9)	11 (40·7)	20 (45·5)	4 (15·4)	24 (34·3)
Diarrhea	6 (60·0)	1 (14·3)	10 (37·0)	17 (38·6)	9 (34·6)	26 (37·1)
Fatigue	3 (30·0)	1 (14·3)	12 (44·4)	16 (36·4)	7 (26·9)	23 (32·9)
Pneumonia	2 (20·0)	1 (14·3)	7 (25·9)	10 (2·7)	4 (15·4)	14 (20·0)
Decreased appetite	3 (30·0)	3 (42·9)	5 (18·5)	11 (25·0)	3 (11·5)	14 (20·0)
Dyspnea	3 (30·0)	1 (14·3)	5 (18·5)	9 (20·5)	5 (19·2)	14 (20·0)
Any ≥ grade 3 adverse event	10 (100·0)	7 (100·0)	25 (92·6)	42 (95·5)	22 (84·6)	64 (91·4)
Febrile neutropenia	3 (30·0)	4 (57·1)	8 (29·6)	15 (34·1)	6 (23·1)	21 (30·0)
Thrombocytopenia	4 (40·0)	1 (14·3)	9 (33·3)	14 (31·8)	4 (15·4)	18 (25·7)
Neutropenia	4 (40·0)	2 (28·6)	6 (22·2)	12 (27·3)	5 (19·2)	17 (24·3)
Anemia	2 (20·0)	0	6 (22·2)	8 (18·2)	4 (15·4)	12 (17·1)
Pneumonia	2 (20·0)	1 (14·3)	7 (25·9)	10 (22·7)	4 (15·4)	14 (20·0)
Any serious AEs	7 (70·0)	4 (57·1)	16 (59·3)	27 (61.4)	20 (76·9)	47 (67·1)
Febrile neutropenia	3 (30·0)	3 (42·9)	4 (14·8)	10 (22·7)	3 (11·5)	13 (18·6)
Pneumonia	2 (20·0)	1 (14·3)	5 (18·5)	8 (18·2)	4 (15·4)	12 (17·1)
Any TEAE with a reasonable possibility of being related to venetoclax	9 (90·0)	6 (85·7)	26 (96·3)	41 (93·2)	22 (84·6)	63 (90·0)
Any TEAE with a reasonable possibility of related to azacitidine	10 (100·0)	6 (85·7)	27 (100·0)	43 (97·7)	0	43 (61·4)

Note: Listed AEs include ≥20% in all treated patients; Grade ≥3 or higher AEs include ≥15% in all treated patients; Serious AEs in ≥10% in all treated patients.

Source: Zeidan et al., American Journal of Hematology, 2022

Venetoclax has also been investigated in combination with AZA in the frontline setting, including treatment-naïve HR-MDS patients. In this Phase Ib study, 107 patients were recruited and received venetoclax (400 mg) alongside AZA. The best response rates were 30% for CR and 50% for mCR, with 37% of mCR patients also showing haematological improvement, leading to an ORR of 80%. Median OS reached 26.0 months, with 1-year and 2-year survival rates of 71% and 51%, respectively.

Similar to the previous trial, the combination was associated with several adverse events, including constipation (53%), nausea (50%), neutropenia (49%), thrombocytopenia (45%), febrile neutropenia (42%), and diarrhea (41%).

We believe the results are promising and indicate a survival benefit compared to the expected mOS for AZA alone. However, the high incidence of severe adverse events is a concern and, we believe, could limit uptake in the HR-MDS setting if approved.

Vibecotamab showing promising data on ASH annual meeting 2024

Vibecotamab is a bispecific antibody targeting CD3-CD123. Originally developed by Xencor and licensed to Novartis in 2016, but the drug was discontinued by Novartis in 2021. Currently, we believe no biopharma companies are actively pursuing its development. However, investigators are conducting a trial in r/r HR-MDS/CMML/AML, and new data from a Phase II study was presented at the ASH Annual Meeting in 2024.

A total of 23 patients have received treatment (11 with MDS/CMML and 12 with AML MRD) in a low-blast state following HMA failure and MRD-positive AML. This is a two-arm study, with the MDS cohort including patients with an IPSS-R prognosis of intermediate or higher risk or CMML (CMML-1 or CMML-2). The primary objective for the MDS/CMML cohort is the response rate (CR + mCR + PR + HI + clinical benefit) within four cycles.

According to the revised IWG 2023 MDS response criteria, five of the nine MDS patients (56%) achieved complete remission with limited count recovery (CR_L). Both CMML patients achieved mCR, with one also achieving hematologic improvement in neutrophils. Among the nine patients with baseline bone marrow blasts ≥5% at trial enrolment, six (67%) achieved mCR, with or without HI. The best response occurred after the first cycle in all patients. Notably, CD123 expression was not associated with the likelihood of response. Vibecotamab safety profile seems good, with no patients requiring dose reductions or discontinuation due to adverse events.

At this stage, the data appears promising but not overwhelmingly strong. Without the involvement of a commercial partner, further advancement of this project is unlikely, we believe.

Responses for Vibecotamab in r/r HR-MDS (IWG2006 & IWG2023)

Response rates, N (%) / median [range]	MDS/CMML after HMA failure (N=11)
MDS/CMML best response	
IWG 2006	
mCR	6 (55)
HI	1 (9)
Stable disease	1 (9)
Progressive disease	2 (18)
Not evaluable/Early death	1 (9)
IWG 2023 (MDS only)	
CR_L	5/9 (56)
No response	1/9 (11)
Progressive disease	2/9 (22)
Not evaluable/Early death	1/9 (11)
AML MRD best response	
MRD negativity	-
No response	-
Best response after 1 cycle	7/7 (100)
Median CD123 of responders	59% [43%-90%]
Median CD123 of non-responders	79% [77%-94%]
Median MRD of responders	-
Median MRD of non-responders	-

Source: Nguyen et al., ASH Annual meeting 2024

The table below presents a selection of drugs in development for MDS, clearly highlighting the limited late-stage activity. This list focuses on drugs in development by companies, excluding purely investigator-led clinical trials.

Selection of drugs in development for MDS

Drug	Development phase	Target	Developer	Patient setting
Venetoclax	III	BCL-2	Abbvie	1L HR-MDS
LYT-200	II	αGAL-9 mAb	Puretech Health	1L HR-MDS
BGB-11417	Phase Ib/II	BCL-2	Beigene	AML/MDS
APL-4098	Phase Ib/II	GCN2	Apollo Therapeutics	r/r AML/HR-MDS
Lisaftoclax	Phase Ib/II	BCL-2	Ascentage Pharma	1L HR-MDS / r/r HR-MDS
Emavusertib	Phase I/II	IRAK-4	Curis	AML/MDS
CLX-712	Phase I/II	CLK inhibitor	Chordia Therapeutics,	r/r AML/HR-MDS
CLN-049	Phase I	Bispecific antibody FLT-CD3	Cullinan Therapeutics	AML/MDS
BMS-986497	Phase I	Anti-CD33 GSPT1 Degrader	Bristol Myers Squibb	AML/MDS
BYON4413	Phase I	Antibody drug cuniugate, CD123	Byondis	AML/MDS
ABD-3001	Phase I	ALDH1 inhibitor	Advanced BioDesign	r/r AML/HR-MDS
GLB-001	Phase I	CK1alfa	GluBio Therapeutics	r/r AML/HR-MDS
VIP943	Phase I	CD123	Vincerx Pharma	r/r AML/HR-MDS
BH-30236-01	Phase I	CLK inhibitor	Blossomhill Therapeutics	r/r AML/HR-MDS
MP0533	Phase I	CD33 x CD123 x CD70 x CD3	Molecular Partners	r/r AML AML/MDS
SGR-2921	Phase I	CDC7 inhibitor	Schrödinger	r/r AML/HR-MDS
REM-422	Phase I	MYB mRNA degrader	Remix Therapeutics	AML/HR-MDS

Source: Carnegie Research, Clinicaltrials.gov

The solid cancer opportunity

BEX's clinical journey began in solid tumours with the MATINS study, which demonstrated promising safety and tolerability but limited clinical efficacy as a monotherapy. However, we believe the MATINS study has been instrumental in improving the understanding of BEX in patients, supporting its next steps in combination with other anticancer drugs.

Matins trial basics

In December 2018 Faron initiated its first-in-human clinical trial, the Matins phase I/II study. The trial enrolled patients at sites in Finland and UK with refractory advanced or metastatic solid tumours. Primary objective of the study was to evaluate the safety, tolerability, and early efficacy of BEX.

In the phase I part of the trial, running over 13 months, BEX was studied at five different doses (0.1, 0.3, 1.0, 3.0, and 10.0 mg/kg) administered every three weeks, with 30 patients enrolled. No dose-limiting toxicities were observed, and a maximum tolerated dose was not reached. However, based on the safety, biomarker, and efficacy data, the Data Monitoring Committee (DMC) recommended proceeding to the second part of the study (Phase II) with a dose of 1.0 mg/kg administered every three weeks. Blood sample analysis indicated Clever-1 receptor occupancy of more than 50%, but these levels significantly declined by day 8 of the treatment cycle. At higher doses (3–10 mg/kg), receptor occupancy was higher and sustained for 8–15 days, indicating improved target engagement at these dose levels.

The Phase II study was designed as a basket trial, enrolling patients across ten different cohorts of solid tumour indications. Most patients in Phase II received the recommended doses; however, to address findings from the blood sample analysis, BEX was also evaluated at alternative doses and dosing schedules: 1–3 mg/kg Q1W, 1–3 mg/kg Q2W, or 3–30 mg/kg Q3W.

A total of 216 patients were recruited for the Matins trial, and overall, BEX demonstrated a very favourable safety and tolerability profile, with only a small percentage of patients experiencing grade 3 (5%) or grade 4 (2%) adverse events.

Safety and efficacy data (RECIST 1.1) – The Matins trial

Treatment Related Adverse Events	Patients (%)
Any grade	94 (45)
Grade 3	11 (5)
Grade 4	4 (2)

Most Frequent TRAEs	Grade 1/2	Grade 3	Grade 4/5
Fatigue	34 (16)	1 (<1)	0
Pyrexia	12 (6)	0	0
Nausea	10 (5)	1 (<1)	0
Anemia	9 (4)	2 (<1)	0
Blood ALP increased	9 (4)	0	0
Decreased appetite	8 (4)	0	0
AST increased	7 (3)	1 (<1)	0

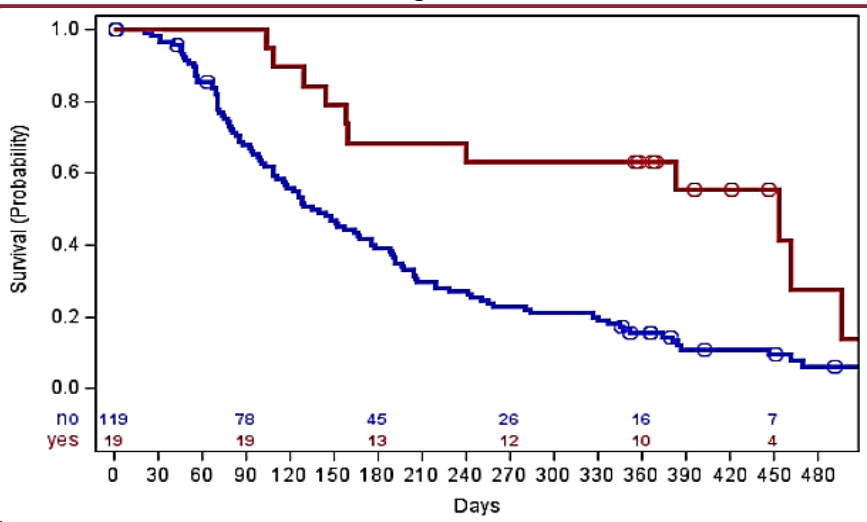
Confirmed Responses (RECIST)	n (%)
Complete response (CR)	0 (0)
Partial Response (PR)	1 (0.5)
Stable Disease (SD)	26 (13)
Progressive Disease (PD)	178 (87)
Disease control (SD+PR) per cohort	27 (13)
Colorectal cancer	2 (4)
Cutaneous melanoma	**5 (22)**
Cholangiocarcinoma	**5 (23)**
Gastric adenocarcinoma	**6 (21)**
Hepatocellular cancer	**4 (36)**
Ovarian cancer	1 (7)
ER+ Breast cancer	**4 (33)**
Pancreatic cancer	0 (0)
Uveal melanoma	0 (0)

Source: Faron Pharmaceuticals, CMD 2024

The MATINS study was a monotherapy trial involving heavily pretreated patients, which at least in part helps explain the low rate of clinical efficacy reported, with only one patient showing a response. We believe it is rare to observe clinical responses in early-stage monotherapy trials with immunotherapies. However, the MATINS trial clearly did not provide strong evidence of BEX monotherapy efficacy, which is why we believe the future is in combination with other anti-cancer treatments.

Faron has conducted additional research on the MATINS study data to better understand which patients may respond better to BEX treatment, leading to some important findings. For example, patients who achieved disease control (PR + SD) and had low baseline levels of the cytokine interferon gamma (IFN-γ) demonstrated better treatment outcomes, indicating a survival benefit, as illustrated in the figure below.

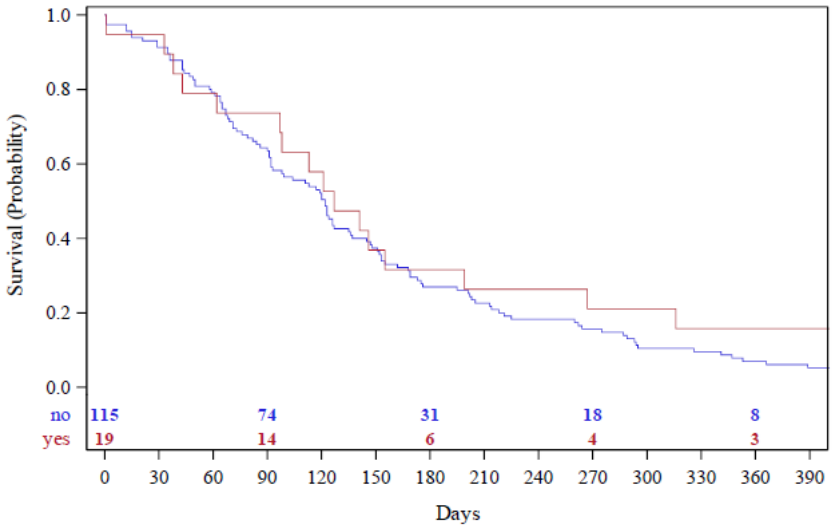
Overall survival differences between low and high IFN-γ expression at baseline



Source: Faron Pharmaceuticals, CMD 2024, blue line all patients and red line patients benefiting from treatment with low IFN-γlevels at baseline

To ensure that the selection above is not simply biased towards patients with slower-growing tumours, Faron analysed data from previous lines of therapy and found that the duration of treatment was similar in both groups of patients.

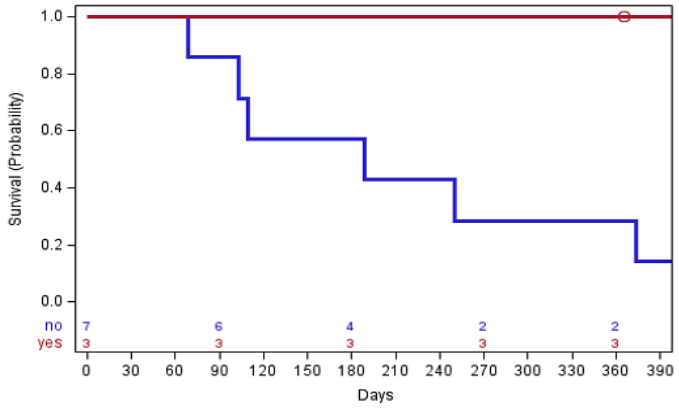
Prior therapy time to failure (n=138)



Source: Faron Pharmaceuticals, CMD 2024, blue line all patients and red line patients benefitting to treatment with low IFN-γlevels at baseline

To identify relevant patients for future studies, Faron also analysed a subgroup of melanoma patients in the MATINS study, comparing those with low (blue line) and high (red line) baseline IFN-γ levels. The analysis showed a clear survival advantage in patients with low baseline levels, as illustrated in the graph below. These promising findings provide valuable insights for further investigation in future clinical trials. However, with only 10 patients, the results should be interpreted with caution.

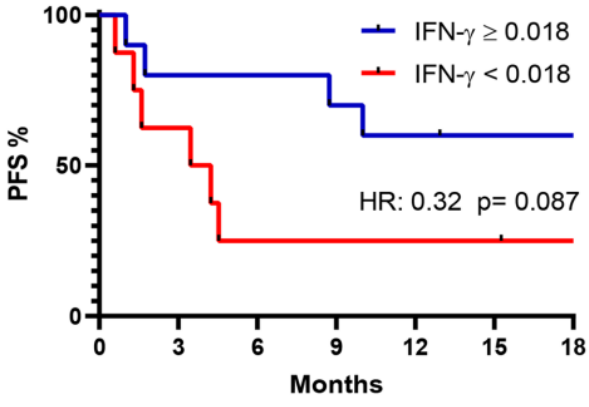
Subgroup of melanoma patients in the MATINS trial



Source: Faron Pharmaceuticals, CMD 2024

To put this into perspective, the graph below illustrates survival outcomes for patients treated with PD-1 inhibitors, stratified by IFN-γ levels. As expected, the PD-1 inhibitors show better outcomes in the high IFN-γ group, as elevated levels of IFN-γ are often a reliable marker of immune activity in tumours. This aligns with the mechanism of action of PD-1 inhibitors, which counteract immune suppression by blocking the PD-1/PD-L1 pathway between cancer cells and immune cells, such as CD8+ T cells. We believe this suggests a promising opportunity for combining BEX with PD-1 inhibitors in IFN-γ low patients, possibly using BEX as an induction therapy.

PFS analysis based on IFN-γ mRNA level expression



Source: Giunta et al., Scientific reports, 2020

Although the MATINS trial did not provide clear evidence of monotherapy efficacy for BEX, it generated important safety and tolerability data, along with meaningful clinical insights for future studies in solid tumours.

Next on the agenda in solid tumours

At the CMD in October 2024, Faron presented the pathway forward for BEX in solid tumours, outlining plans to initiate three additional trials in 2025, as shown in the table below (BEX plus PD-1).

Bexmarilimab solid tumour pipeline

Treatment	Indication(s)	Phase of Development			
		Preclinical	Phase 1	Phase 2	Phase 3
Single-Agent *Bexmarilimab*	Advanced solid tumors **FARON SPONSORED**	MATINS (First in Human, single agent)			
***Bexmarilimab* + PD-1**	PD-1 Blockade Basket trial in Solid Tumors **FARON SPONSORED**	MATINS-02			
	PD-1 resistant NSCLC and Melanoma **INVESTIGATOR INITIATED**	BLAZE			
	Soft Tissue Sarcomas **INVESTIGATOR INITIATED**	BEXAR			
TBC	Lymphomas (DLBCL and TCL) **FARON SPONSORED**	MATINS-03			

Source: Faron Pharmaceuticals, CMD 2024

Of the three studies, Faron will take full responsibility for the MATINS-2 study, a trial aligned with the findings discussed on the previous page, where BEX will be evaluated in combination with a PD-1 inhibitor across a variety of solid tumours. Additionally, two investigator-sponsored trials are in the planning phase: BLAZE, which will focus on a PD-1 combination study in non-small cell lung cancer (NSCLC) and melanoma, and BEXAR, which will evaluate BEX in patients with soft tissue sarcoma. However, it is important to note that investigator-led studies are often poorly executed, with a high likelihood of significant delays and missed timelines.

The MATINS-2 trial will primarily focus on indications and settings where PD-1 inhibitors have not shown significant efficacy. This includes PD-1 resistant patients (cold tumours) in indications such as gastric cancer, ER+ breast cancer, and cholangiocarcinoma. In previous MATINS trial, BEX demonstrated promising monotherapy signals in these indications, achieving disease control (DC) in 25–40% of patients. Additionally, as a fourth direction in the study, Faron consider including an arm of 1L NSCLC patients investigating BEX in combination with a PD-1 inhibitor. Although PD-1 inhibitors are approved and widely used in NSCLC, many patients still do not respond, highlighting the need for new therapeutic strategies. However, given the intense research activity in NSCLC, we look forward to getting further details to better understand BEX's potential in this setting.

The MATINS-2 study design and proposed timeline

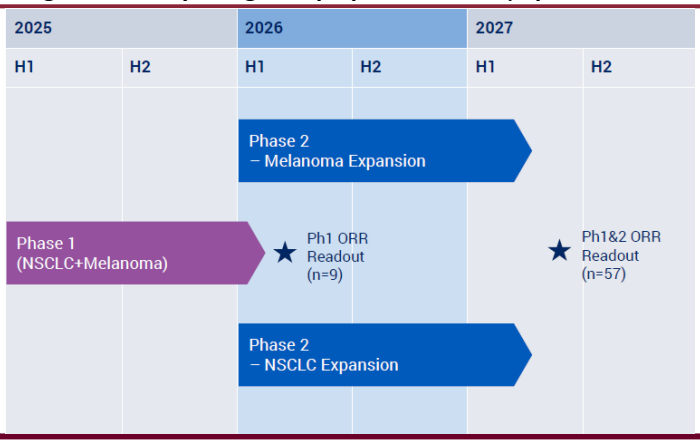
Source: Faron Pharmaceuticals, CMD 2024

The BLAZE study about to start

According to the timeline provided at the CMD, the BLAZE study is investigator-led trial to begin patient recruitment in Q3(25). Conducted at the Royal Marsden Hospital in London, UK, the study will focus on patients demonstrating resistance to PD-1 treatment in the 1L setting for melanoma and NSCLC. As illustrated below, the trial will begin with a Phase I component, and once the recommended dose of BEX is identified, it will expand into a Phase II trial, with possible top-line results in H1 2027. The study will also analyse biomarker data to investigate the role of macrophages in treatment resistance, assessing whether BEX can remodel macrophages from an immunosuppressive to a pro-inflammatory state, thereby enhancing immune-mediated anticancer activity.

While the study appears to have some overlap with the MATINS-2 trial, it presents an interesting opportunity to further evaluate BEX in indications where immunotherapies have shown strong efficacy.

The BLAZE investigator-led study: design and proposed timeline (expected to start in Q3 2025)

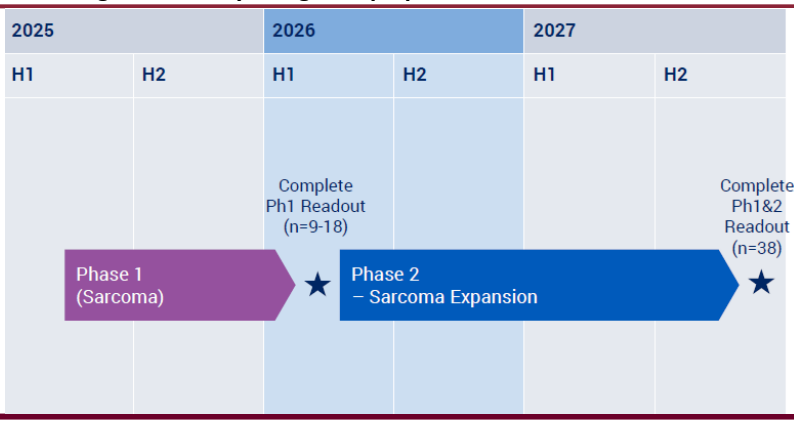


Source: Faron Pharmaceuticals, CMD 2024

Lastly, the BEXAR trial is another investigator-led study, expected to begin patient recruitment before the summer of 2025. This trial will be conducted at Vall d'Hebron Hospital in Barcelona, focusing on patients with soft tissue sarcoma.

Soft tissue sarcoma is a cancer indication where PD-1 inhibitors have thus far demonstrated limited effectiveness, as these tumours are generally considered immunosuppressed 'cold' tumours, characterised by a high abundance of M2-like macrophages. The rationale for the trial is based on BEX's ability to sensitise these refractory patients, followed by the addition of PD-1 inhibitors to enhance treatment efficacy.

The BLAZE investigator-led study: design and proposed timeline



Source: Faron Pharmaceuticals, CMD 2024

We believe the plans for BEX in solid tumours are quite extensive. While the opportunity appears significant, much remains to be demonstrated before its full potential in solid tumours can be assessed. Additionally, competition in this space is intense, with hundreds of clinical trials under way. However, BEX has a unique profile, as it specifically targets macrophages, an area where we see only limited competition.

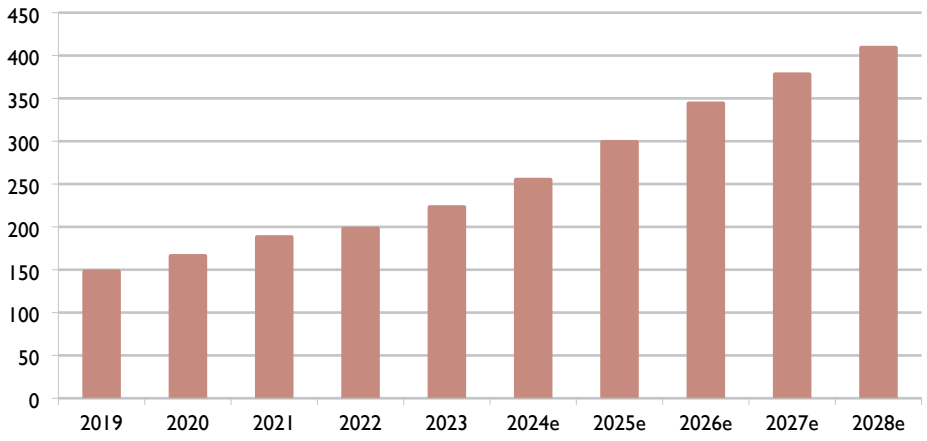
Market dynamics and deal activity

Securing a partner for BEX is central to Faron's strategy following a positive data readout from the ongoing Phase II BEXMAB trial. Oncology remains a top licensing priority for pharmaceutical companies, underpinned by strong market fundamentals. With another patent cliff approaching, we believe interest in later-stage assets will remain robust and favourable, aligning well with BEX's current positioning and Faron's strategic objectives.

Cancer the largest and fastest growing segment

Oncology is by far the largest therapeutic area in the pharmaceutical industry, with global sales in 2024 projected to have reached USD255bn, accounting for about 15% of total global pharmaceutical spending, according to IQVIA. Global pharmaceutical sales are projected to grow by 5–6% annually through to 2028, but oncology drugs are expected to outpace this, with an estimated annual growth rate of 12–13% (IQVIA). This growth in sales is driven primarily by innovation, reflected in a steady stream of new treatment approvals and the expansion of existing therapies. Additional growth drivers include the rising incidence of cancer in an ageing population and increasing demand from emerging markets.

Cancer medicine spending 2019-2028, (USDbn)



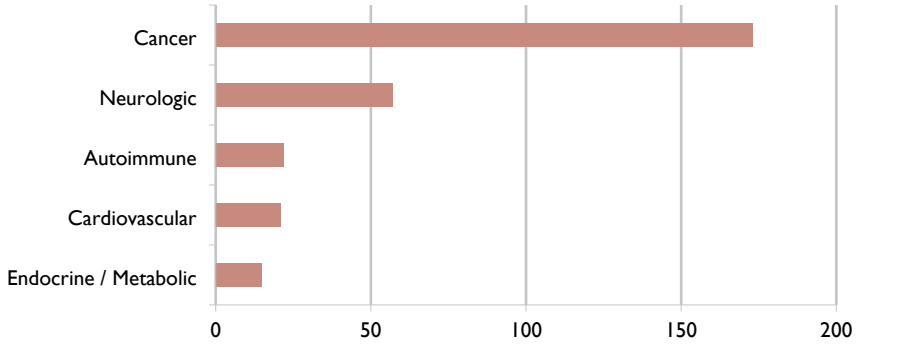
Source: Carnegie Research, IQVIA

Within the oncology field, the US market is the largest and is projected to generate USD106bn in sales in 2024, accounting for 42% of the global oncology market (IQVIA). Driven by higher pricing and characterized by the rapid adoption of new innovations, the US is expected to remain the primary growth driver in the oncology sector, with an anticipated annual growth rate of 15% through 2028, reaching USD187bn (IQVIA).

The overall size of the market, combined with the persistent unmet medical need among cancer patients, underscores why most pharmaceutical and biotech companies remain highly committed to maintaining a strong presence in the oncology therapeutic area. This sustained interest has been reflected in consistently high levels of investment activity over the years, and 2024 was no exception. The table on the next page illustrates this trend, highlighting biopharma R&D partnering investments in the leading therapeutic areas during the year.

Please note: The figures from different sources that we present in this section might not directly be comparable, as definitions of oncology and pharmaceuticals may vary. However, we believe they offer a reliable overview of the underlying trends in the sector.

Deal values of biopharma R&D partnerships in 2024 (USDbn)

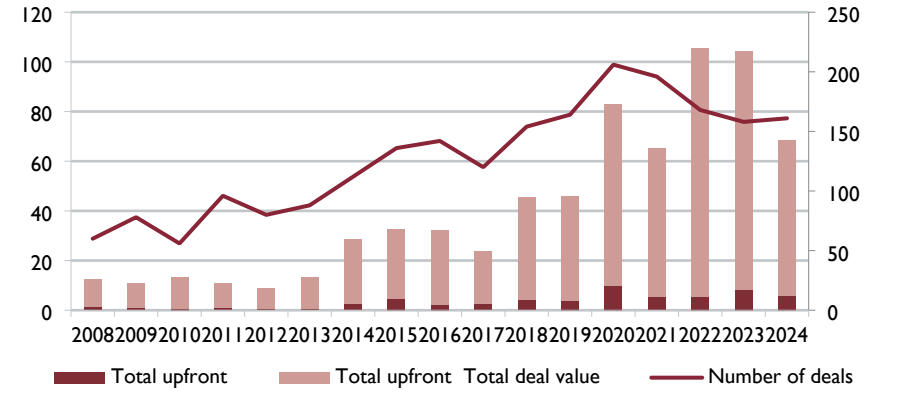


Source: DealForma, Carnegie Research

Slightly higher oncology licensing deal activity in 2024 vs 2023

Licensing activity is particularly important to Faron. Data indicates that total licensing deal values declined in 2024, but the number of deals increased slightly compared to the previous year, according to DealForma. Looking at the broader trend, both the number of licensing deals and total deal values have demonstrated steady growth over time.

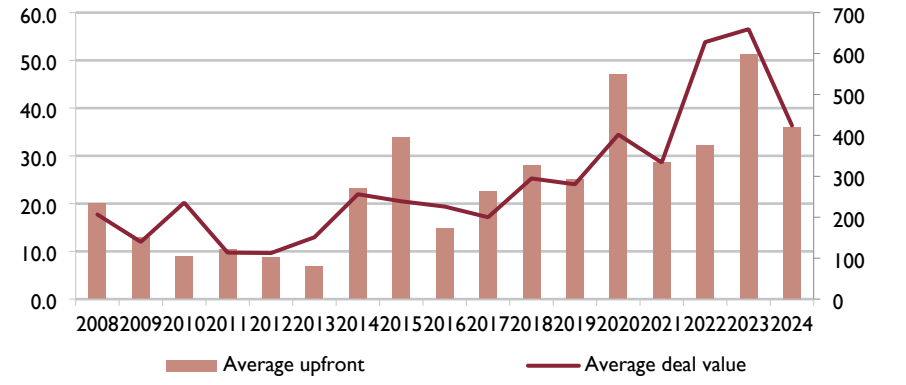
Partnership activity in oncology licensing (2008-2024)



Source: DealForma, Carnegie Research

In the table below, we show the data from the table above as averages to highlight overarching trends over time, reflecting a positive trajectory in both upfront payments and total value.

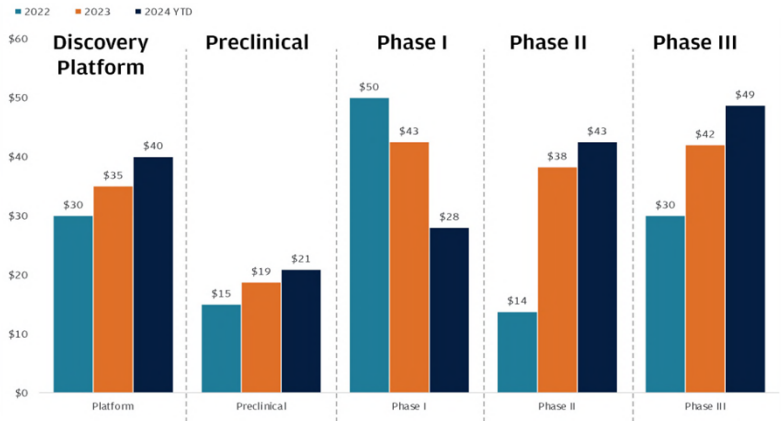
Average upfront payments and total deal value (USDm)



Source: Carnegie Research

The table below provides a more detailed view of upfront payments, presented as median upfront payments from big pharma licensing deals by stage of development between 2022 and 2024, according to DealForma.

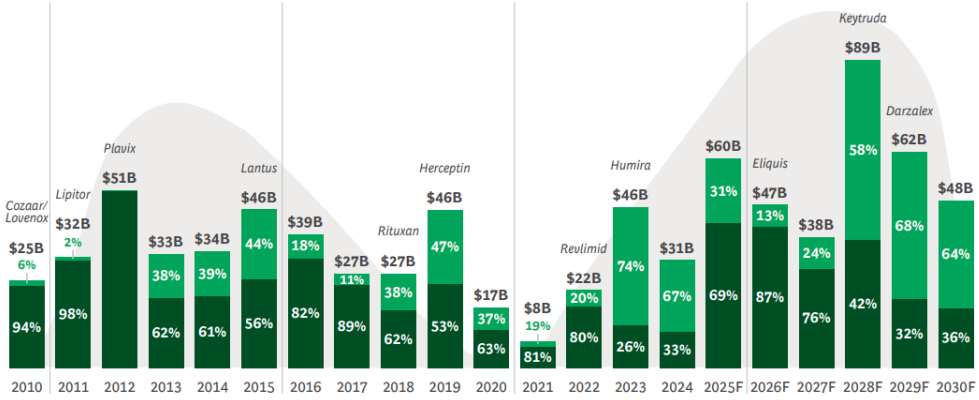
In-licensing by big pharma – median upfront by stage at signing (2022 to Nov 2024)



Source: DealForma, 2025

In addition to these factors, pharmaceutical companies' interest in licensing opportunities over the coming years is being driven by significant upcoming patent expirations. We believe this will intensify demand for late-stage, market-near assets. According to Boston Consulting Group, global revenue at risk from loss of exclusivity exceeds USD300bn between now and YE(30).

Pharma revenue at risk due to loss of exclusivity (2010–30)



Source: Boston Consulting Group, 2025

Relevant licensing deals during past year

To further explore licensing activity, we provide on the next page a list of relevant deals signed over the past year involving clinical-stage assets. As shown, several major oncology licensing deals have been signed during this period. Excluding deals with upfront payment exceeding USD200m, we find a median upfront payment of USD75m and an average of USD97m.

Selection of clinical oncology assets licensed to biopharma during the past year

Company	Licenseer	Date	Project	Dev. Phase	Target	Upfront (USDm)	Total deal value (USDm)
Scorpion Therapeutics	Eli Lilly	Jan 2025	STX-478	I/II	PI3Kα inhibitor	N.D.	2,500
Innocare/Keymed	Prolium Bioscience	Jan 2025	ICP-B02	I/II	CD20xCD3	N.D.	520
Simcere	Abbvie	Jan 2025	SIM0500	I	GPRC5D,BCMA,CD3	N.D.	1,055
Innovent	Roche	Jan 2025	IBI3009	I	DLL-3	80	1,000
CSPC Zhonggi	Beigene	Dec 2024	SYH2039	I	MAT2A inhibitor	150	N.D.
Keros Therapeutics	Takeda	Dec 2024	Elritercept	II	TGF-beta	200	1,300
Relay Therapeutics	Elevar Therapeutics	Dec 2024	RLY-4008	I/II	FGFR2 inhibitor	75	500
Kura Oncology	Kyowa Kirin	Nov 2024	ziftomenib	III	Menin Inhibitor	330	1,500
LaNova Medicines	Merck	Nov 2024	LM-299	I	PD1xVEGF	588	3,300
Baiyu Pharmaceutical	Novartis	Oct 2024	BY1921	I	PARP7	70	1,100
Curon Biopharma	Merck	Aug2024	CN201	I	CD3xCD20	600	1,300
Immuneonco	Instil Bio	Aug 2024	IMM2510/ IMM27M	I	PDL1xVEGF / CTLA4	50	2,000
Orion	Merck	July 2024	Opevesostat	III	CYP11A1	30	1,600
Bioteus	Hansoh Pharma	March 2024	PM1080	I	EGFR/cMet	N.D.	690
Hansoh Pharma	GSK	Dec 2023	HS-20093	I/II	B7-H3 mAb	185	1,700
SystImmune	Bristol Myers Squibb	Dec 2023	BL-B01D1	I	EFGRxHER3	800	8,400

Source: Carnegie Research

The table below lists recent M&A deals focused on oncology companies, which we believe reflects strong market appetite heading into 2025.

Recent oncology M&A activity

Target	Buyer	Date	Dev. Phase	Upfront (USDm)	Total deal value (USDm)
Scorpion Therapeutics	Eli Lilly	Jan 2025	I/II	n.a.	2,500
Poseida Therapeutics	Roche	Jan 2025	I	1,500	1,500
IDRx	Glaxosmithkline	Jan 2025	III	1,000	1,150
Chimerix	Jazz Pharmaceuticals	March 2025	NDA	n.a.	935
Esobiotec	Astrazeneca	March 2025	I/II	425	1,000
Araris Biotech	Taiho Pharmaceuticals	March 2025	Preclinical	400	1,140

Source: Carnegie Research

Political uncertainty on the rise

As described above, we see numerous indicators of strong market conditions for partnering. However, political uncertainty – particularly regarding the US pharmaceutical market, we believe – has increased in recent months. Although the new US administration has so far not introduced any significant surprises for the industry, we argue there remains a clear political agenda focused on drug pricing and tariffs, which may affect pharma and biotech appetite for partnering. Still, we believe the pressure on orphan drugs may be of lesser concern, as policy efforts are more likely to target products addressing larger patient populations.

Financial estimates

We forecast an opportunity for BEX to achieve accelerated approval in 2027, with initial sales beginning in the second-line HR-MDS setting, followed by broader approval, including the first-line setting, a year later. Given the limited competition, we believe BEX has significant potential in HR-MDS and forecast peak sales of USD1.1bn by 2036.

Bexmarilimab sales forecast for MDS

Based on current timelines and assuming a positive outcome from the ongoing BEXMAB study, we estimate Faron to initiate a pivotal Phase III trial in H1(26). As already mentioned, interactions with regulatory authorities indicate potential for an early accelerated approval, at least in the US, contingent on a favourable interim data readout. We believe that the timing of such an interim analysis will to some extent depend on the strength of the Phase II results. Assuming an ORR of 50–60%, we anticipate that an interim readout could occur within one year of dosing the first patient. If positive, we see a pathway for BEX to achieve accelerated approval in the r/r HR MDS setting, with a subsequent launch in H2(27). Our projection is somewhat more conservative than the company's proposed timeline outlined in the table on page 19. We estimate that an approval including the frontline setting could follow about one year later.

Significant addressable market opportunity for BEX

In our modelling of the potential addressable market, we use the incidence of HR-MDS as the key metric. Given the limited survival expectancy associated with more advanced disease, we believe incidence is assumed to closely approximate prevalence. Furthermore, we assume that patients who have previously progressed on a BEX-based treatment regimen are unlikely to be re-treated with the drug in subsequent lines of therapy.

As with most pharmaceuticals, the US market remains the most critical, primarily due to its more flexible pricing environment for innovative therapies. Additionally, the adoption of newly approved treatments tends to be faster in the US, supported by a reimbursement system that typically operates more efficiently than in regions such as Europe. In our model, we estimate the incidence of MDS in the US to be about 16,200 individuals in 2024. This figure is derived from multiple sources, including Surveillance, Epidemiology, and End Results (SEER) data, GlobalData, company disclosures, and peer-reviewed scientific publications. We project that the incidence of MDS will grow in line with expected population growth. Specifically, we have based our assumptions on forecasts from the United States Census Bureau for individuals aged 65 and older, as this demographic is the most relevant for MDS.

HR-MDS patient build - USA

	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040
US MDS sales model																	
Incidence ('000)	16.2	16.4	16.6	16.8	17.0	17.2	17.4	17.6	17.8	18.0	18.2	18.4	18.7	18.9	19.1	19.3	19.6
Growth rate (%)		*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*
HR MDS	8.1	8.2	8.3	8.4	8.5	8.6	8.7	8.8	8.9	9.0	9.1	9.2	9.3	9.4	9.6	9.7	9.8
Share (%)	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*
1L	6.5	6.5	6.6	6.7	6.8	6.9	6.9	7.0	7.1	7.2	7.3	7.4	7.5	7.6	7.6	7.7	7.8
2L (HMA-r/r)	3.2	3.3	3.3	3.4	3.4	3.4	3.5	3.5	3.6	3.6	3.6	3.7	3.7	3.8	3.8	3.9	3.9

Source: Carnegie Research

Based on data from risk stratification models such as IPSS-R and IPSS-M, along with additional sources, we estimate that about 50% of MDS cases are classified as HR-MDS. In our model, we assume that 80% of diagnosed patients initiate first-line (1L) treatment, and about half of these patients subsequently progress to second line (2L) therapy. We model a consistent distribution between HR-MDS and LR-MDS cases, as well as transition rates between 1L and 2L treatment, across all relevant markets.

In Europe, we estimate about 20,900 individuals with MDS in 2024, corresponding to an incidence rate of around five per 100,000 population, broadly in line with our estimate for the US. Epidemiological data for Europe is generally less robust than that available for the US; however, sources such as GlobalData and company disclosures suggest that MDS incidence in Europe is comparable to that of the US. We anticipate that the incidence of MDS in Europe will grow in line with overall population trends. Specifically, our assumption of a 1.1% annual growth rate through to 2040 is based on projections from the European Commission for individuals aged 65 and older.

HR-MDS patient build - Europe

	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040
Europe sales model																	
Incidence ('000)	20.9	21.2	21.4	21.6	21.9	22.1	22.3	22.6	22.8	23.1	23.3	23.6	23.9	24.1	24.4	24.7	24.9
Growth rate (%)		*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*
HR MDS	10.5	10.6	10.7	10.8	10.9	11.1	11.2	11.3	11.4	11.5	11.7	11.8	11.9	12.1	12.2	12.3	12.5
Share (%)	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*
1L	8.4	8.5	8.6	8.7	8.7	8.8	8.9	9.0	9.1	9.2	9.3	9.4	9.5	9.7	9.8	9.9	10.0
2L (HMA-r/r)	4.2	4.2	4.3	4.3	4.4	4.4	4.5	4.5	4.6	4.6	4.7	4.7	4.8	4.8	4.9	4.9	5.0

Source: Carnegie Research

Our best estimate for the Japanese market is an annual MDS incidence of about 7,500 cases. This figure is derived from data provided by Japan's Ministry of Health, Labour and Welfare, as well as company disclosures and GlobalData estimates. According to the Japan Center for Economic Research, Japan's overall population is projected to decline over the next decades. However, this decline is driven primarily by a reduction in the younger population, while the population aged 65 and older, the most relevant for MDS, remains relatively stable over the forecast period.

HR-MDS patient build - Japan

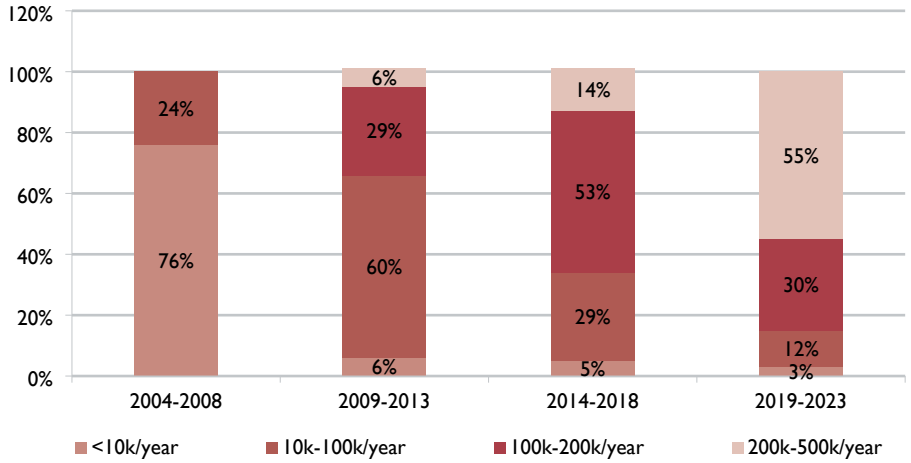
	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040
Japan sales model																	
Incidence ('000)	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5
Growth rate (%)		*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
HR MDS	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8
Share (%)	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*
1L	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0
2L (HMA-r/r)	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5

Source: Carnegie Research

Price assumptions for BEX

Given the limited clinical data available to date, our pricing assumption for BEX is primarily based on reference pricing of comparable oncology therapies. Oncology drug prices have been rising overall, particularly in the US market. According to IQVIA, the median annual cost for new oncology drugs launched in 2023 was USD298,628, with 85% of newly launched oncology therapies priced above USD100,000 per year.

Launch costs distribution of new novel drugs in oncology (USD)



Source: IQVIA - Global oncology trends 2024, Carnegie Research

Orphan drugs are also known for commanding high prices. In 2023, IQVIA estimated the median annual cost for newly launched orphan products in the US at USD273,000. As an orphan oncology drug, we believe there is potential for premium pricing of BEX at launch in the US market. We estimate a net treatment cost of approximately USD180,000 in the US For ex-US markets, our model assumption is somewhat more conservative, with an estimated price of EUR70,000.

As noted above, we have calibrated our pricing assumptions based on reference products, primarily in MDS and AML. Recently launched therapies in the US have typically carried listed annual treatment costs exceeding USD200,000, as Reblozyl (LR-MDS), Rytelo (LR-MDS), and Vanflyta (AML). The targeted drug Tibsovo (r/r HR-MDS) has a list price suggesting cost per month of over USD30,000. As noted above, we have calibrated our pricing assumptions based on reference products, primarily in MDS and AML. Recently launched therapies in the US have typically carried listed annual treatment costs exceeding USD200,000, including Reblozyl (LR-MDS), Rytelo (LR-MDS), and Vanflyta (AML). Additionally, the targeted therapy Tibsovo, approved for r/r HR-MDS, has a list price suggesting a monthly treatment cost of over USD30,000.

However, it is important to note that list prices often differ from net prices, as discounts and rebates are commonly applied. For oncology drugs, we believe it is typical to observe discounts in the range of 10–20% off the list price.

We argue that drug prices are generally significantly lower in markets outside the US, although reliable net price data remain limited. To inform our pricing assumptions for ex-US markets, we have reviewed published studies on international drug pricing and, where available, analysed price comparisons for individual therapies. According to an analysis published in JAMA Oncology (Vokinger et al., 2021), launch prices for oncology drugs between 2009 and 2019 were, on average, about 1.5x higher in the US than in Europe. A separate study published in The Lancet Oncology (Vokinger et al., 2020) found that US prices for oncology drugs are, on average, 2.3x higher than those in Europe, underscoring the substantial disparity in drug pricing between these markets. Data from these studies also suggests that this gap may widen over time, as drug prices in the US tend to increase, while prices in other markets, particularly in Europe and Japan, have shown a tendency to decline. As a result, we model an annual price increase of 2% in the US, while assuming a gradual price decline of 1% per year in ex-US markets.

Penetration assumptions of BEX in MDS

As noted in the previous section, there is a high unmet medical need for patients diagnosed with HR-MDS, and current treatment options remain very limited. The pipeline for new therapies in HR-MDS is relatively limited, with the venetoclax plus AZA combination, currently being evaluated in the Verona trial, representing one of the few promising treatments in late-stage development. In assessing the potential of BEX, we view the outcome of the ongoing Verona trial as a key determinant of the opportunity for the BEX plus AZA combination in treating HR-MDS patients. While strong data from Verona could, in our view, somewhat limit the near-term commercial opportunity for BEX plus AZA, but we expect a subset of patients to remain ineligible for the venetoclax plus AZA regimen due to its significant haematological toxicity.

Over the longer term, should venetoclax gain approval for MDS, we anticipate the potential development and clinical adoption of a triple combination therapy involving BEX, venetoclax, and AZA. Although such a triple combination may be associated with very high costs, we believe it would still receive reimbursement if it demonstrates meaningful survival benefit.

Given the limited treatment options and a sparse pipeline of promising new therapies, we estimate that BEX could achieve significant market penetration among HR-MDS patients. In our model, we assume a 30% penetration rate in both the 1L and 2L settings. This assumption is contingent on the approval of venetoclax, with BEX serving as an alternative in 1L for patient's ineligible for venetoclax, and in the 2L setting for those who progress on the venetoclax plus AZA combination.

We model a five-year sales ramp-up period in the US, with 80% of peak penetration achieved by year three. In ex-US markets, we estimate peak penetration will be reached within six years in Europe and about seven years post-launch in Japan. These assumptions align with the median ramp-up timelines observed for other oncology drug launches, according to GlobalData.

Market exclusivity

BEX is protected by multiple patents extending at least to 2037. In addition, we expect it to benefit from orphan drug exclusivity – seven years in the US and 10 years in both Europe and Japan – as well as biologic data exclusivity, which provides 12 years of protection in the US and 11 years in Europe. In Japan, an applicant for a biosimilar cannot seek marketing authorisation under the PMD Act until the re-examination period for the original drug has expired. For orphan drugs, this re-examination period is extended to a maximum of 10 years, which in practice, we estimate, often delays the entry of biosimilars for up to 11 years. We believe BEX is well-positioned to obtain orphan status for HR-MDS in Japan, where the threshold requires the drug to be intended for use in fewer than 50,000 patients and to address a high unmet medical need.

Sales build in MDS in US, Europe and Japan

Overall, we forecast a non-risk-adjusted peak sales potential of USD1.1bn for BEX in MDS across key pharmaceutical markets. As shown below, we anticipate a launch in Japan in 2029, about a year behind Europe and the US. Please note that EUR sales have been converted to USD.

US sales model for BEX in MDS (USDm)

	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040
US MDS sales model																	
Incidence ('000)	16.2	16.4	16.6	16.8	17.0	17.2	17.4	17.6	17.8	18.0	18.2	18.4	18.7	18.9	19.1	19.3	19.6
Growth rate (%)		*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*
HR MDS	8.1	8.2	8.3	8.4	8.5	8.6	8.7	8.8	8.9	9.0	9.1	9.2	9.3	9.4	9.6	9.7	9.8
Share (%)	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*
1L	6.5	6.5	6.6	6.7	6.8	6.9	6.9	7.0	7.1	7.2	7.3	7.4	7.5	7.6	7.6	7.7	7.8
2L (HMA-r/r)	3.2	3.3	3.3	3.4	3.4	3.4	3.5	3.5	3.6	3.6	3.6	3.7	3.7	3.8	3.8	3.9	3.9
Bexmarilimab																	
1L					0.4	1.0	1.7	1.9	2.1	2.2	2.2	2.2	2.2	2.2	2.1	2.0	1.9
1L penetration (%)					*6%*	*15%*	*24%*	*27%*	*30%*	*30%*	*30%*	*30%*	*30%*	*29%*	*27%*	*26%*	*24%*
2L				0.2	0.5	0.8	1.0	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.0	1.0
2L penetration (%)				*6%*	*15%*	*24%*	*29%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*29%*	*27%*	*26%*
Price ('000)				180	184	187	191	195	199	203	207	211	215	219	224	228	233
Increase/decrease					2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Net sales (USDm)				**36**	**168**	**347**	**508**	**575**	**636**	**657**	**678**	**700**	**722**	**721**	**707**	**693**	**680**

Source: Carnegie Research

European sales model for BEX in MDS (USDm)

	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040
Europe sales model																	
Incidence ('000)	20.9	21.2	21.4	21.6	21.9	22.1	22.3	22.6	22.8	23.1	23.3	23.6	23.9	24.1	24.4	24.7	24.9
Growth rate (%)		*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*
HR MDS	10.5	10.6	10.7	10.8	10.9	11.1	11.2	11.3	11.4	11.5	11.7	11.8	11.9	12.1	12.2	12.3	12.5
Share (%)	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*
1L	8.4	8.5	8.6	8.7	8.7	8.8	8.9	9.0	9.1	9.2	9.3	9.4	9.5	9.7	9.8	9.9	10.0
2L (HMA-r/r)	4.2	4.2	4.3	4.3	4.4	4.4	4.5	4.5	4.6	4.6	4.7	4.7	4.8	4.8	4.9	4.9	5.0
Bexmarilimab																	
1L					0.5	1.5	1.9	2.2	2.6	2.8	2.8	2.8	2.9	2.9	2.8	0.8	0.3
1L penetration (%)					*6%*	*17%*	*21%*	*24%*	*29%*	*30%*	*30%*	*30%*	*30%*	*30%*	*29%*	*9%*	*3%*
2L				0.3	0.4	0.8	1.1	1.2	1.4	1.4	1.4	1.4	1.4	1.4	1.3	0.4	0.1
2L penetration (%)				*6%*	*9%*	*18%*	*24%*	*27%*	*30%*	*30%*	*30%*	*30%*	*30%*	*29%*	*27%*	*8%*	*2%*
Net Price converted to USD ('000)				77	77	76	75	74	74	73	72	71	71	70	69	69	68
Increase/decrease					*0%*	*-1%*	*-1%*	*-1%*	*-1%*	*-1%*	*-1%*	*-1%*	*-1%*	*-1%*	*-1%*	*-1%*	*-1%*
Net sales (USDm)				**20**	**70**	**171**	**221**	**252**	**292**	**303**	**303**	**303**	**303**	**299**	**284**	**85**	**26**

Source: Carnegie Research

Japan sales model for BEX in MDS (USDm)

	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040
Japan sales model																	
Incidence ('000)	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5
Growth rate (%)		*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
HR MDS	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8
Share (%)	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*
1L	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0
2L (HMA-r/r)	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Bexmarilimab																	
1L						0.1	0.3	0.4	0.6	0.8	0.9	0.9	0.9	0.9	0.9	0.8	0.8
1L penetration (%)						*3%*	*9%*	*14%*	*21%*	*26%*	*29%*	*30%*	*30%*	*30%*	*29%*	*27%*	*26%*
2L						0.0	0.1	0.2	0.3	0.4	0.4	0.5	0.5	0.5	0.4	0.4	0.4
2L penetration (%)						*3%*	*9%*	*14%*	*21%*	*26%*	*29%*	*30%*	*30%*	*30%*	*29%*	*27%*	*26%*
Net Price converted to USD ('000)						77	76	75	74	74	73	72	71	71	70	69	69
Increase/decrease						0%	-1%	-1%	-1%	-1%	-1%	-1%	-1%	-1%	-1%	-1%	-1%
Net sales (USDm)				**0**	**0**	**9**	**29**	**48**	**69**	**85**	**93**	**97**	**96**	**95**	**30**	**84**	**79**

Source: Carnegie Research

Assessing the development risk for BEX in MDS

We risk-adjust our sales forecasts for BEX, applying an estimated likelihood of approval (LOA) of 33% for MDS. This estimate is based on an evaluation of historical development risks in the indication, supplemented by clinical results for BEX in MDS to date, which we believe justify a deviation from historical benchmarks. For example, we argue that the promising interim data from the BEXMAB study, presented late last year, has significantly de-risked the Phase II study.

Development risks and probabilities by stage of development

	Phase I	Phase II	Phase III	NDA	Total
Bexmarilimab	100%	70%	50%	95%	33%
Haematologic	50%	28%	60%	90%	8%
IO reference	64%	40%	49%	98%	12%

Source: Clinical Development Success Rates and Contributing Factors 2011–2020, 2021, BIO, Carnegie Research

In our view, a strong top-line readout in April 2025, specifically an ORR of 50–60% or higher, should be considered a de-risking event and would support progression to a pivotal Phase III study. In this scenario, we would raise our LOA for Phase II to about 85%, resulting in a total LOA of 40%. Should the survival data from the BEXMAB trial, expected in H2(25), further demonstrate a clear advantage of the BEX + AZA combination over AZA alone, we would likely increase our Phase II LOA estimate to 100%, bringing the total LOA to 48%.

Solid tumour forecast for BEX

At this stage, we view MDS as the most promising indication for BEX, supported by encouraging clinical data. In solid tumours, the MATINS study has provided valuable insights into dosing and safety; however, given the limited indications of efficacy, we remain uncertain about the optimal setting and combination in which BEX may demonstrate significant potential. Still, we believe the opportunity in solid tumours could be considerable in the right therapeutic context. Rather than modelling estimates by specific indication, we assign an overall potential value for solid tumours, forecasting non-risk-adjusted peak sales of USD1.0bn by 2036 following a potential launch in 2030. These estimates will be refined as the planned studies advance and additional data becomes available, allowing for a more accurate assessment of BEX's potential in solid tumours.

Risk assessment in solid tumours

For the same reasons discussed above, we do not deviate from historical benchmarks in our LOA estimate for solid tumours, and assign an LOA of 10%.

Development risks and probabilities by stage of development

	Phase I	Phase II	Phase III	NDA	Total
Bexmarilimab	100%	23%	43%	95%	10%
Solid tumours	49%	23%	43%	93%	5%
IO reference	64%	40%	49%	98%	12%

Source: Clinical Development Success Rates and Contributing Factors 2011–2020, 2021, BIO, Carnegie Research

Our licensing deal assumptions

Despite increased political uncertainty in the US over the past few months, deal activity in the oncology sector looks robust. We believe that a strong Phase II data readout from the BEXMAB trial could trigger significant partnering interest. In our model, we assume a licensing agreement will be signed in 2026, following the data readout for mOS in H2(25).

We estimate a total licensing deal value for BEX of USD600m, including an upfront payment of USD70m. Additionally, we forecast that Faron would be eligible for a flat royalty rate of 20% on

net sales. At this stage, we risk-adjust the projected deal payments in line with our assessed probability of success for BEX.

We have deliberately adopted a somewhat conservative approach in our assumptions regarding a potential licensing agreement, pending a clearer understanding of BEX's efficacy profile.

Cost forecasts

As BEX continues to advance in development, we expect programme-related costs to gradually increase, particularly as preparations for the Phase III study progress. However, future costs will depend largely on the final study design. Our best estimate is that the trial will include about 300 patients and cost around EUR35m from initiation to completion.

Profit and loss table (2022-2027e)

(EURm)	2022	2023	2024	2025e	2026e	2027e
Revenues	0.0	0.0	0.0	0.0	0.0	10.3
R&D costs	-20.7	-19.5	-11.7	-16.7	-22.0	-22.0
Administrative expenses	-7.5	-9.0	-6.9	-7.1	-7.7	-8.0
Other operating expenses	0.8	0.0	0.0	0.0	0.0	0.0
EBIT	**-27.4**	**-28.6**	**-18.7**	**-23.8**	**-29.7**	**-19.7**
Net financials	-1.3	-2.4	-7.2	-1.6	-2.2	-2.5
Pre-tax profit	**-28.7**	**-30.9**	**-25.9**	**-25.4**	**-31.9**	**-22.2**
Taxes	0.0	0.0	0.0	0.0	0.0	0.0
Net profit	**-28.7**	**-30.9**	**-25.9**	**-25.4**	**-31.9**	**-22.2**

Source: Carnegie Research, company materials

Valuation

We value Faron Pharmaceuticals with a fair value range of EUR2.2–2.8 per share. Our valuation is based on a risk-adjusted cash flow model (rNPV), where each project is assessed over its patent lifespan and then aggregated in a sum-of-the-parts (SOTP) analysis. We have applied a WACC range of 12–16%, with the lower end of our valuation range derived using a WACC of 16%, and the upper end using a WACC of 12%, reflecting varying levels of market risk appetite.

SOTP model valuation

In our SOTP analysis of Faron, we include only projects with a defined path forward, whether driven by the company or a partner, meaning bexmarilimab is the sole asset included in our valuation at this time. Our forecasts are risk-adjusted based on our assessment of development risk, depending on the respective stage of progress. Faron's two additional assets, traumakine and haematokine, appear to have been deprioritised for the time being and are therefore excluded from our valuation.

Bexmarilimab assumptions

As outlined in previous sections of this report, we believe BEX has the potential to receive approval for HR-MDS as early as 2027, with forecast peak sales in this indication reaching USD1.1bn by 2036. We model a partnership deal being secured in 2026, including an upfront payment of USD70m, a total deal value of USD600m, and additional royalty income of 20% on net sales. We assume the partner will be responsible for the further development of BEX. Our estimates for MDS are risk-adjusted, based on a LOA of 33%.

We also see an opportunity for BEX in solid tumours, where we estimate peak sales of USD1.0bn in 2038. Our risk assessment indicates a LOA of 10%.

Sum-of-the-parts Valuation (EURm)

Project	Indication	Likelihood of approval (LOA)	Peak sales (USDm)	Launch date estimate	NPV WACC (16%)	NPV WACC (12%)
Bexmarilimab	MDS	33%	1 100	2027	223	293
	Solid tumours	10%	1 000	2031	26	34
Pipeline valuation					249	328
Net cash position (last reported)					20	20
Group admin costs					-26	-28
NPV					**244**	**320**
Number of shares					112.9	112.9
NPV per share (EUR)					**2.2**	**2.8**

Source: Carnegie Research

Sensitivity analysis – SOTP valuation

Sensitivity analysis - LOA (bexmarilimab) / WACC (EUR per share)

	WACC								
	10%	11%	12%	13%	14%	15%	16%	17%	18%
23%	2.3	2.2	2.0	1.9	1.7	1.6	1.5	1.4	1.3
28%	2.8	2.6	2.4	2.2	2.1	2.0	1.8	1.7	1.6
33%	3.3	3.1	2.8	2.6	2.5	2.3	2.2	2.0	1.9
38%	3.7	3.5	3.2	3.0	2.8	2.6	2.5	2.3	2.2
43%	4.2	3.9	3.6	3.4	3.1	2.9	2.8	2.6	2.4

Source: Carnegie Research

We have also analysed the sensitivity of Faron's valuation to the net price of BEX in relation to its market penetration in the HR-MDS indication.

Sensitivity analysis - BEX price / penetration (WACC 16%)

	Penetration				
	10%	20%	30%	40%	50%
USD120k/EUR50k	1.2	1.5	1.9	2.2	2.5
USD150k/EUR60k	1.2	1.6	2.0	2.4	2.8
USD180k/EUR70k	1.3	1.7	2.2	2.6	3.0
USD210k/EUR80k	1.3	1.8	2.3	2.8	3.3
USD240k/EUR90k	1.4	1.9	2.5	3.0	3.5

Source: Carnegie Research

Sensitivity analysis - BEX price / penetration (WACC 12%)

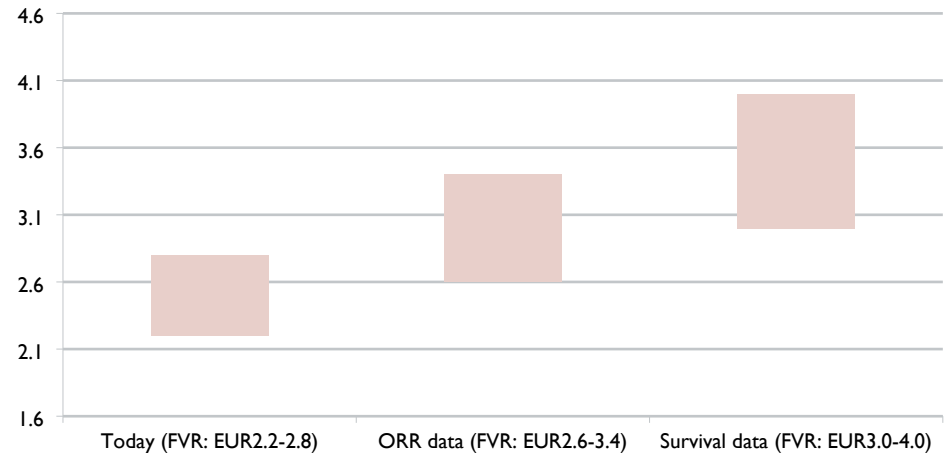
	Penetration				
	10%	20%	30%	40%	50%
USD120k/EUR50k	1.5	2.0	2.4	2.9	3.4
USD150k/EUR60k	1.6	2.1	2.6	3.2	3.7
USD180k/EUR70k	1.6	2.2	2.8	3.4	4.0
USD210k/EUR80k	1.7	2.4	3.0	3.7	4.4
USD240k/EUR90k	1.8	2.5	3.2	4.0	4.7

Source: Carnegie Research

Valuation scenarios – outcomes from the BEXMAB study

The top-line results from the BEXMAB Phase II study are approaching and represent a potential de-risking event. As noted earlier, a positive outcome could lead us to increase our LOA, thereby reducing the risk adjustment applied to our estimated cash flow streams. In the table below, we present various valuation scenarios based solely on different LOA assumptions, reflecting outcomes for positive ORR data and positive survival data, the latter expected to be reported in H2(25).

Fair value range scenarios following data readouts (EUR per share)



Source: Carnegie Research

Risks and considerations

In this section, we outline the key risks associated with Faron Pharmaceuticals' position and the broader sector in which it operates. For Faron specifically, the primary risks we identify relate to clinical development outcomes, competitive dynamics, and the company's ability to secure a partner for late-stage development and commercialisation. The following list is not intended to be exhaustive but highlights the risks we consider most relevant to Faron and its share price performance.

Development risks

The primary risk when investing in pharmaceutical development companies is that clinical results may prove negative, rendering further development unjustifiable. Drug development is inherently high-risk, particularly for first-in-class molecules as bexmarilimab, where clinical uncertainty and unproven mechanisms of action add further complexity. That said, we believe the development risk for bexmarilimab has been partially mitigated by the promising results observed to date.

Partner dependence

Faron is a small company with limited resources and no commercial organisation, and its strategy relies on securing a partner to support late-stage clinical development and commercialisation. We believe the company is well-positioned to attract partnering interest if the BEXMAB study delivers positive results; however, we also recognise that factors such as timing and strategic fit play a crucial role in such decisions. Should a partnership not materialise, Faron would need to finance future pivotal studies and invest in building its own commercial infrastructure.

Need for additional financing

As Faron does not currently generate recurring revenue from approved drugs or partnering income, the company has ongoing capital needs, which typically increase as its projects advance through clinical development. To successfully execute its development plan and strategic objectives, we believe Faron will require additional funding, preferably secured through a partnership. We believe the current financing is sufficient to support operations through 2025.

Competition risks

Oncology is the largest therapeutic area, but also a highly competitive one, with hundreds of clinical projects currently in development. While we view Faron's projects as unique, several other treatments targeting similar patient populations are also in development and could outcompete bexmarilimab prior to its patent expiration or the end of other exclusivity protections.

Regulatory risks

The pharmaceutical market is highly regulated in all major regions. To bring a product to market, extensive clinical testing is required to demonstrate both efficacy and a manageable safety profile. However, once approved, the clinical data package not only supports commercialisation but also helps maintain exclusivity against competition.

Pricing risks

Our valuation is highly dependent on the pricing of BEX. Many healthcare systems have regulated pricing mechanisms for pharmaceutical products, and we view pricing pressure as a recurring political theme aimed at reducing healthcare spending. In the US, where pricing is less regulated, there are also significant risks of downward pressure on drug prices driven by ongoing policy debates and reform efforts.

Sustainability

We find Faron to be committed to conducting its business in a responsible and ethical manner, underpinned by a clear sustainability strategy. Just as innovation drives the development of its medicines, we believe it also informs the company's approach to environmental, social, and governance (ESG) practices.

Faron is committed to enhancing patient access to medicines, being an employer of choice, and prioritizing environmental sustainability, all while operating with the highest standards of quality, integrity, and ethics. Its governance framework includes active board oversight, supported by participation and reporting from leadership and team members across functions and geographies. The company's values incorporate principles of corporate social responsibility and sustainability, guiding its relationships with clients, employees, and the broader communities and environments in which it operates.

The UN Sustainable Development Goals

Source: United Nations

Faron highlights the following strategic ESG priorities:

- Developing treatments for medical conditions with significant unmet needs.
- Conducting itself responsibly and ethically, creating a positive and supportive working environment.
- Acting fairly in its dealings with suppliers and other third parties.
- Minimising the impact on its environment.

Appendix – Management

The management team of Faron Pharmaceuticals consists of the following five members.

Dr Juho Jalkanen – Chief Executive Officer since 2024

Dr Jalkanen joined Faron in 2017 as Vice President, Business Development. In 2018 he became the company's Chief Development Officer. In that role he was responsible for translational and clinical studies as well as market research and valuation of research projects and clinical programmes. He also served as Faron's interim Chief Medical Officer in 2021 and was a member of Faron's Board of Directors from 2013–18.

Dr Jalkanen earned a Master's degree in economics and business administration from the Turku School of Economics and both his MD and PhD degrees from the University of Turku. He is a fully licensed general practitioner and specialist in vascular surgery.

Holdings in the company: 1,089,888 shares and 567,040 stock options, entitling to same number of shares in the company.

Yrjö Wichmann – Chief Financial Officer since 2024

Mr Wichmann served as the company's CFO between 2014 and 2019 and is an accomplished biotech and financial executive with over 20 years' experience in financing and investment banking. Most recently, Mr Wichmann has served as Senior Vice President, Financing & IR at Faron. Before his roles at Faron, Mr Wichmann held several senior positions in the life sciences and biotechnology sector at IP Finland Oy, Biohit Oyj (NASDAQ OMX Helsinki), CapMan Oyj, FibroGen Europe Oyj (NASDAQ) and D. Carnegies & Co AB. He is a member of the Investment Committee at Dasos Timberland Fund I and II and a board member at Nordic Science Investment Oy.

Mr Wichmann holds a Master's in economics from Helsinki University.

Holdings in the company: 98,132 shares and 358,000 stock options, entitling to same number of shares in the company.

Dr Petri Bono – Chief Medical Officer since 2024

Dr Bono, MD, PhD, is a seasoned senior pharmaceuticals executive with a background in oncology and various leadership positions. Previously Dr Bono served as the Chief Medical Officer and member of the group executive team of Terveystalo, the largest private healthcare service provider in Finland. Before Terveystalo he was the Chief Medical Officer at Helsinki University Hospital. In addition to being Associate Professor of Cancer Biology at University of Helsinki, Dr Bono has held various leadership positions at Helsinki University Hospital, including Director and Physician-in-Chief of the Comprehensive Cancer Center. Dr Bono has participated in numerous oncology trials from Phases I to III, including early phase immuno-oncological trials, and has published 102 peer-reviewed papers in international journals including New England Journal of Medicine, Lancet Oncology, JAMA, and Cancer Cell.

Holdings in the company: 4,500 shares and 100,000 stock options, entitling to same number of shares in the company.

Dr Maija Hollmén – Chief Scientific Officer since 2022

Dr Hollmén joined Faron as Chief Scientific Officer in December 2022. Dr Hollmén oversees preclinical and supports clinical development for Faron. Her priority is the further development of bexmarilimab.

Dr Hollmén is an Adjunct Professor of Tumour Immunology on the Faculty of Medicine at the University of Turku in Finland, as well as a Principal Investigator, and earned both her PhD and MSc degrees from the University of Turku.

Dr Hollmén's post-doctoral studies were conducted at ETH Zurich alongside Professor Michael Detmar, focusing on tumour immunology and how cancer cells educate macrophages to support tumour growth. Dr Hollmén returned to Turku and formed her own laboratory to develop strategies to resolve immunosuppressive cells and pathways and, during this time, concentrated on Clever-1.

Holdings in the company: 807,542 shares and 12,000 stock options, entitling to same number of shares in the company.

Vesa Karvonen – General Counsel since 2022

Vesa Karvonen is a legal professional with over 25 years of experience. He holds a Master of Laws degree from the University of Turku, Finland. Previously, he served as Director and Head of Legal at Deloitte Finland (2019–22), Director at Owens Corning (2018–19), and General Counsel at Paroc Group (2002–19).

Holdings in the company: 104,000 shares and 90,000 stock options, entitling to same number of shares in the company.

Appendix – Board of directors

The board of directors of Faron Pharmaceuticals consists of five members.

Tuomo Pätsi – Chairman of the Board of directors since 2024

Mr Pätsi (b. 1964) is a Non-Executive Director of Faron Pharmaceuticals Ltd., a role he has served since joining the Board in March 2023.

Mr. Pätsi has over 30 years' experience working in biotech and pharmaceuticals, with more than 10 years working at Celgene in various senior management roles, including President of European and International Operations and President of the EMEA region and Worldwide Markets (wholly owned subsidiary of Bristol-Myers Squibb). He is an experienced biotech and pharmaceutical executive who until recently was Executive Vice President for Seagen Inc., a US-based cancer-focused biotechnology company.

Before this, he served as Vice President of Europe for Human Genome Science, a speciality pharma organisation in Europe. Earlier in his career, he held roles of increasing responsibility in pharmaceutical companies, including more than 10 years at Amgen Inc. Mr Pätsi began his career as a biomedical research scientist in Finland.

He is a registered pharmacist and holds an MSc in pharmacology from the School of Pharmacy, Helsinki University.

Holdings in the company: 31,765 shares and 130,000 stock options, entitling to same number of shares in the company.

Dr Markku Jalkanen – Member of the Board of directors since 2007

Dr Jalkanen (b. 1954) is a former Chief Executive Officer of Faron Pharmaceuticals Ltd. and was a founding member of the company. He has more than 40 years of experience in biomedical research, biotech development and the biopharmaceutical industry, and has published more than 130 peer-reviewed scientific publications in various highly ranked international journals.

Between 1996 and 2002, Dr Jalkanen was the founding CEO and President of BioTie Therapies Corp, which became the first publicly traded Finnish biotech company to be listed on NASDAQ. BioTie was sold to Acorda Therapeutics in January 2016 for USD363m. Over his career, Dr Jalkanen has held several board memberships for both public and private companies including Inveni Capital Management, Meddia Ltd and Priaxon AG. He is also an adviser for the only active Finnish life sciences fund, Inveni Capital, and a board member of Faron Ventures Oy.

Dr Jalkanen obtained a Master's in medical Biochemistry from the University of Kuopio and subsequently received a PhD in Medical Biochemistry from the University of Turku. He completed a side-laudatur examination in Molecular Biology from the University of Turku and completed his post-doctoral training at Stanford University, California between 1983 and 1986. Dr Jalkanen obtained the position of docent in Biochemistry from University of Helsinki and the same qualification in Molecular and Cell Biology from the University of Turku. He became a professor at the University of Turku in 1992.

Holdings in the company: 3,413,434 shares (directly and with his spouse) and 540,000 stock options, entitling to same number of shares in the company.

John Poulos – Member of the Board of directors since 2017

Mr Poulos (b. 1954) joined the board of Faron as a Non-Executive Director in May 2017. He has extensive experience in the global pharmaceutical industry having spent nearly 40 years at AbbVie and Abbott.

Mr Poulos served as Vice President, Head of Business Development and Acquisitions, for AbbVie from 2013–16. He was also Group Vice President, Head of Pharmaceutical Licensing and Acquisitions, for Abbott from 2005–12. During his career with AbbVie and Abbott, Mr Poulos was instrumental in the negotiation of numerous acquisitions, including Knoll/BASF Pharma (Humira) in 2001 for USD6.9bn, Kos Pharmaceuticals in 2006 for USD3.7bn, Solvay in 2010 for USD6.2bn, and Pharmacyclics (Imbruvica) in 2015 for USD21bn.

Mr Poulos is currently President GNK Advisors Inc., a Pharmaceutical Business Development firm, and is a member of the Board of Memgen, Inc.

Mr Poulos holds a BS in Marketing and MBA in Finance from Indiana University.

Holdings in the company: no shares and 170,000 stock options, entitling to same number of shares in the company.

Dr Marie-Louise Fjällskog – Member of the Board of directors since 2023

Dr Fjällskog (b. 1964) is a Non-Executive Director, joining the board in September 2023. She is an experienced life sciences leader who has held senior leadership positions at large pharmaceutical, biotech and speciality pharma companies.

Dr Fjällskog has extensive professional experience in the pharmaceutical and biopharmaceutical industry, particularly in clinical oncology, translational research, and drug development. She holds an MD degree and a PhD from Uppsala University, Sweden, where she is also an Associate Professor of Oncology. With over 25 years of clinical experience, Dr Fjällskog has made significant contributions to the development of targeted therapies for cancer. She has held key roles in various pharmaceutical companies, such as Sensei Biotherapeutics, Merus, and Infinity Pharmaceuticals, where she led clinical development programs and played instrumental roles in their success, including Sensei's USD152m IPO in 2021. Her extensive expertise and leadership have also earned her a position on the board of Biovica International AB, a biotech company in Sweden and in the US, respectively. She is also on the board of Norwegian company Lytix Biopharma.

In January 2022, Dr Fjällskog assumed the role of Chief Medical Officer at Faron where she led Faron's clinical development programmes, particularly the bexmarilimab programme. Dr Fjällskog stepped down from the CMO role in September 2023.

Holdings in the company: No shares and 210,000 stock options, entitling her to the same number of shares in the company.

Christine Roth – Member of the Board of directors since 2023

Ms Roth (b. 1963) is a Non-Executive Director, joining the Board in September 2023.

Ms Roth is a pharmaceutical executive with over three decades of experience in the industry. She has played key roles in the development and launch of several therapies, including the first immuno-oncology therapy and intentionally designed targeted therapy combinations. Her career includes leadership positions at major pharmaceutical companies, such as Novartis, Bristol-Myers Squibb, GlaxoSmithKline (GSK) and, most recently, Bayer AG, where she serves as the Executive Vice President of the Oncology Strategic Business Unit focusing on precision molecular oncology, next-generation immuno-oncology medicines, and radioligand therapies. At GSK, she was responsible for rebuilding the oncology business, including the integration of assets following the acquisition of Tesaro.

Ms Roth's expertise extends across various therapy areas, including Oncology, Cardiovascular, Metabolic, and Infectious Diseases. She is actively involved in industry associations such as the American Society of Clinical Oncology and the American Society of Hematology.

She holds a bachelor's degree in chemistry from the University of North Carolina at Chapel Hill.

Holdings in the company: 46,075 shares and 60,000 stock options, entitling her to the same number of shares in the company.

Appendix – Scientific advisory board

To support its drug development Faron Pharmaceuticals has set up a scientific advisory board of five members.

Mika Kontro, MD, PhD is an adjunct professor and a consultant in clinical haematology at the Helsinki University Hospital Comprehensive Cancer Center. Dr Mika currently works as K. Albin Johannson Cancer Research Fellow (Finnish Cancer Institute) and as a group leader in Finnish Institute of molecular medicine, FIMM. He has a strong background in running clinical trials and was selected in 2017 for European Hematology Association Clinical Research Training programme (CRTH). He currently chairs the Finnish AML group and is a board member of the Nordic AML Group.

Toni Choueiri, MD is the Jerome and Nancy Kohlberg Chair and Professor of Medicine at Harvard Medical School, Boston, MA, the Director of the Lank Center for Genitourinary (GU) Oncology at Dana-Farber Cancer Institute and co-leader of the Kidney Cancer Program at Dana-Farber/Harvard Cancer Center. He serves at the US National comprehensive cancer network (NCCN) panel. He has more than 800 PubMed indexed publications and is the lead investigator in multiple international phase I-III trials. In a series of NEJM articles on which Dr Choueiri was either first or last author, he has made seminal observations leading to multiple FDA and EMA approvals.

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Financial statements

Profit & loss (EURm)	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
Sales	0	0	0	0	0	0	0	0	0	10
COGS	0	0	0	0	0	0	0	0	0	0
Gross profit	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**10**
Other income & costs	-20	-13	-17	-21	-27	-28	-19	-24	-30	-30
Share in ass. operations and JV	0	0	0	0	0	0	0	0	0	0
EBITDA	**-20**	**-13**	**-17**	**-21**	**-27**	**-28**	**-19**	**-24**	**-30**	**-20**
Depreciation PPE	0	0	0	0	0	0	0	0	0	0
Depreciation lease assets	0	0	0	0	0	0	0	0	0	0
Amortisation development costs	0	0	0	0	0	0	0	0	0	0
Amortisation other intangibles	0	0	0	0	0	0	0	0	0	0
Impairments / writedowns	0	0	0	0	0	0	0	0	0	0
EBITA	**-20**	**-13**	**-17**	**-21**	**-27**	**-29**	**-19**	**-24**	**-30**	**-20**
Amortization acquisition related	0	0	0	0	0	0	0	0	0	0
Impairment acquisition related	0	0	0	0	0	0	0	0	0	0
EBIT	**-20**	**-13**	**-17**	**-21**	**-27**	**-29**	**-19**	**-24**	**-30**	**-20**
Share in ass. operations and JV	0	0	0	0	0	0	0	0	0	0
Net financial items	0	0	0	0	-1	-2	-7	-2	-2	-3
of which interest income/expenses	0	0	0	0	0	0	0	0	0	0
of which interest on lease liabilities	0	na	na	na	na	na	na	na	na	na
of which other items	0	na	na	na	na	na	na	na	na	na
Pre-tax profit	**-20**	**-13**	**-17**	**-21**	**-29**	**-31**	**-26**	**-25**	**-32**	**-22**
Taxes	0	0	0	0	0	0	0	0	0	0
Post-tax minorities interest	0	0	0	0	0	0	0	0	0	0
Discontinued operations	0	0	0	0	0	0	0	0	0	0
Net profit	**-20**	**-13**	**-17**	**-21**	**-29**	**-31**	**-26**	**-25**	**-32**	**-22**
Adjusted EBITDA	-20	-13	-17	-21	-27	-28	-19	-24	-30	-20
Adjusted EBITA	-20	-13	-17	-21	-27	-29	-19	-24	-30	-20
Adjusted EBIT	-20	-13	-17	-21	-27	-29	-19	-24	-30	-20
Adjusted net profit	-20	-13	-17	-21	-29	-31	-26	-25	-32	-22
Sales growth Y/Y	+chg	-chg	na	na	na	na	na	na	na	+chg
EBITDA growth Y/Y	+chg	+chg	-chg	-chg	-chg	-chg	+chg	-chg	-chg	+chg
EBITA growth Y/Y	+chg	+chg	-chg	-chg	-chg	-chg	+chg	-chg	-chg	+chg
EBIT growth Y/Y	+chg	+chg	-chg	-chg	-chg	-chg	+chg	-chg	-chg	+chg
EBITDA margin	na	nm	nm	nm	nm	nm	nm	nm	nm	-189.5%
EBITA margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
EBIT margin	na	nm	nm	nm	nm	nm	nm	nm	nm	-191.4%
Tax rate	0.0%	na	na	na	na	na	na	na	na	na

Cash flow (EURm)	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
EBITDA	-20	-13	-17	-21	-27	-28	-19	-24	-30	-20
Paid taxes	0	0	0	0	0	0	0	0	0	0
Change in NWC	0	1	-1	-2	5	3	-5	0	0	1
Non cash adjustments	0	0	0	1	0	2	0	1	0	0
Discontinued operations	0	0	0	0	0	0	0	0	0	0
Total operating activities	**-21**	**-12**	**-17**	**-22**	**-23**	**-24**	**-23**	**-23**	**-29**	**-18**
Capex tangible assets	0	0	0	0	0	0	0	0	0	0
Capitalised development costs	0	0	0	0	0	0	0	0	0	0
Capex - other intangible assets	0	0	0	0	0	0	0	0	0	0
Acquisitions/divestments	0	0	0	0	0	0	0	0	0	0
Other non-cash adjustments	0	0	0	0	0	0	0	0	0	0
Total investing activities	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Net financial items	0	0	0	0	-1	-2	-7	-2	-2	-3
Lease payments	0	0	0	0	0	0	0	0	0	0
Dividend paid and received	0	0	0	0	0	0	0	0	0	0
Share issues & buybacks	16	14	13	24	13	25	27	43	37	20
Change in bank debt	0	0	1	1	10	-1	0	0	0	0
Other cash flow items	0	0	1	1	0	0	-1	0	0	0
Total financing activities	**16**	**15**	**15**	**26**	**23**	**24**	**26**	**43**	**37**	**20**
Operating cash flow	-21	-12	-17	-22	-23	-24	-23	-23	-29	-18
Free cash flow	-21	-12	-18	-22	-23	-24	-23	-23	-29	-19
Net cash flow	-5	3	-3	3	2	3	10	21	10	4
Change in net IB debt	-5	3	-3	3	-10	1	3	20	8	1
Capex / Sales	10.5%	nm	nm	nm	nm	nm	nm	nm	nm	1.9%
NWC / Sales	-134.2%	nm	nm	nm	nm	nm	nm	nm	nm	-45.2%

Source: Carnegie Research & company data

Financial statements, cont.

Balance sheet (EURm)	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
Acquired intangible assets	0	0	0	0	0	0	0	0	0	0
Other fixed intangible assets	1	1	1	1	1	1	1	1	1	1
Capitalised development	0	0	0	0	0	0	0	0	0	0
Tangible assets	0	0	0	0	0	0	0	0	0	0
Lease assets	0	0	0	0	0	0	0	0	0	0
Other IB assets (1)	0	0	0	0	0	0	0	0	0	0
Other non-IB assets	1	0	0	0	0	0	0	0	1	1
Fixed assets	**1**	**1**	**1**	**1**	**2**	**1**	**1**	**2**	**2**	**2**
Inventories (2)	0	0	0	0	0	0	0	0	0	0
Receivables (2)	0	0	0	0	0	0	0	0	0	0
Prepaid exp. & other NWC items (2)	3	2	3	5	3	2	2	2	3	2
IB current assets (1)	0	0	0	0	0	0	0	0	0	0
Other current assets	0	0	0	0	0	0	0	0	0	0
Cash & cash equivalents (1)	4	7	4	7	7	7	10	28	33	32
Current assets	**7**	**9**	**7**	**12**	**10**	**9**	**11**	**30**	**36**	**34**
Total assets	**8**	**10**	**8**	**13**	**11**	**10**	**13**	**32**	**38**	**37**
Shareholders' equity	0	2	-2	3	-11	-15	-10	8	13	11
Minorities	0	0	0	0	0	0	0	0	0	0
Other equity	0	0	0	0	0	0	0	0	0	0
Total equity	**0**	**2**	**-2**	**3**	**-11**	**-15**	**-10**	**8**	**13**	**11**
Deferred tax	0	0	0	0	0	0	0	0	0	0
LT IB debt (1)	2	2	3	3	11	9	8	8	8	8
Other IB provisions (1)	0	0	0	0	0	0	0	0	0	0
Lease libilities	0	0	0	0	0	0	0	0	0	0
Other non-IB liabilities	0	0	1	0	1	1	4	4	4	5
LT liabilities	**2**	**3**	**4**	**3**	**12**	**11**	**12**	**12**	**12**	**12**
ST IB debt (1)	0	0	0	0	2	3	4	4	4	4
Payables (2)	4	3	2	2	6	9	5	6	7	7
Accrued exp. & other NWC items (2)	0	0	0	0	0	0	0	0	0	0
Other ST non-IB liabilities	2	3	4	4	2	2	1	2	2	3
Liabilities - assets held for sale	0	0	0	0	0	0	0	0	0	0
Current liabilities	**6**	**6**	**6**	**7**	**10**	**15**	**10**	**12**	**13**	**13**
Total equity and liabilities	**8**	**10**	**8**	**13**	**11**	**10**	**13**	**32**	**38**	**37**
Net IB debt (=1)	-2	-4	-1	-3	6	6	3	-16	-21	-20
Net working capital (NWC) (=2)	-1	-1	1	3	-3	-7	-3	-4	-4	-5
Capital employed (CE)	3	4	1	6	2	-2	2	19	24	22
Capital invested (CI)	0	0	2	4	-2	-6	-2	-2	-3	-4
Equity / Total assets	5%	16%	-22%	22%	-102%	-148%	-78%	25%	34%	29%
Net IB debt / EBITDA	0.1	0.3	0.1	0.2	-0.2	-0.2	-0.1	0.7	0.7	1.0

Per share data (EUR)	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
Adj. no. of shares in issue YE (m)	31.03	43.29	46.90	53.23	59.81	68.79	104.6	111.6	111.6	111.6
Diluted no. of Shares YE (m)	31.03	43.29	46.90	53.23	59.81	68.79	104.6	111.6	111.6	111.6
EPS	-0.67	-0.36	-0.38	-0.42	-0.51	-0.48	-0.30	-0.23	-0.29	-0.20
EPS adj.	-0.67	-0.36	-0.38	-0.42	-0.51	-0.48	-0.30	-0.23	-0.29	-0.20
CEPS	-0.67	-0.36	-0.38	-0.42	-0.51	-0.48	-0.30	-0.23	-0.29	-0.20
DPS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
BVPS	0.01	0.04	-0.04	0.05	-0.19	-0.22	-0.09	0.07	0.12	0.10

Performance measures	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
ROE	-785.8%	-1340.3%	14180.8%	-3961.5%	671.5%	232.3%	207.9%	2509.9%	-310.1%	-189.2%
Adj. ROCE pre-tax	-412.9%	-377.9%	-573.5%	-540.1%	-682.7%	63151.0%	-17162.3%	-232.8%	-145.4%	-95.2%
Adj. ROIC after-tax	-4771.1%	20631.5%	-1518.1%	-688.1%	-2433.5%	763.9%	492.0%	1114.2%	1193.7%	629.0%

Valuation	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
FCF yield	-8.2%	-4.6%	-7.0%	-8.8%	-9.1%	-9.5%	-9.2%	-9.1%	-11.7%	-7.4%
Dividend yield YE	na	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Dividend payout ratio	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Dividend + buy backs yield YE	na	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
EV/Sales YE	na	nm	nm	nm	nm	nm	nm	nm	nm	22.41
EV/EBITDA YE	na	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.
EV/EBITA YE	na	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.
EV/EBITA adj. YE	na	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.
EV/EBIT YE	na	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.
P/E YE	na	nm	nm	nm	nm	nm	nm	nm	nm	nm
P/E adj. YE	na	nm	nm	nm	nm	nm	nm	nm	nm	nm
P/BV YE	na	>50	neg.	48.88	neg.	neg.	neg.	32.45	19.56	23.62
Share price YE (EUR)		2.73	2.41	2.68	2.82	3.12	2.54	2.25		

Source: Carnegie Research & company data

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