
Annual and sustainability report
2022
Inspired by caring, powered by science
sobi

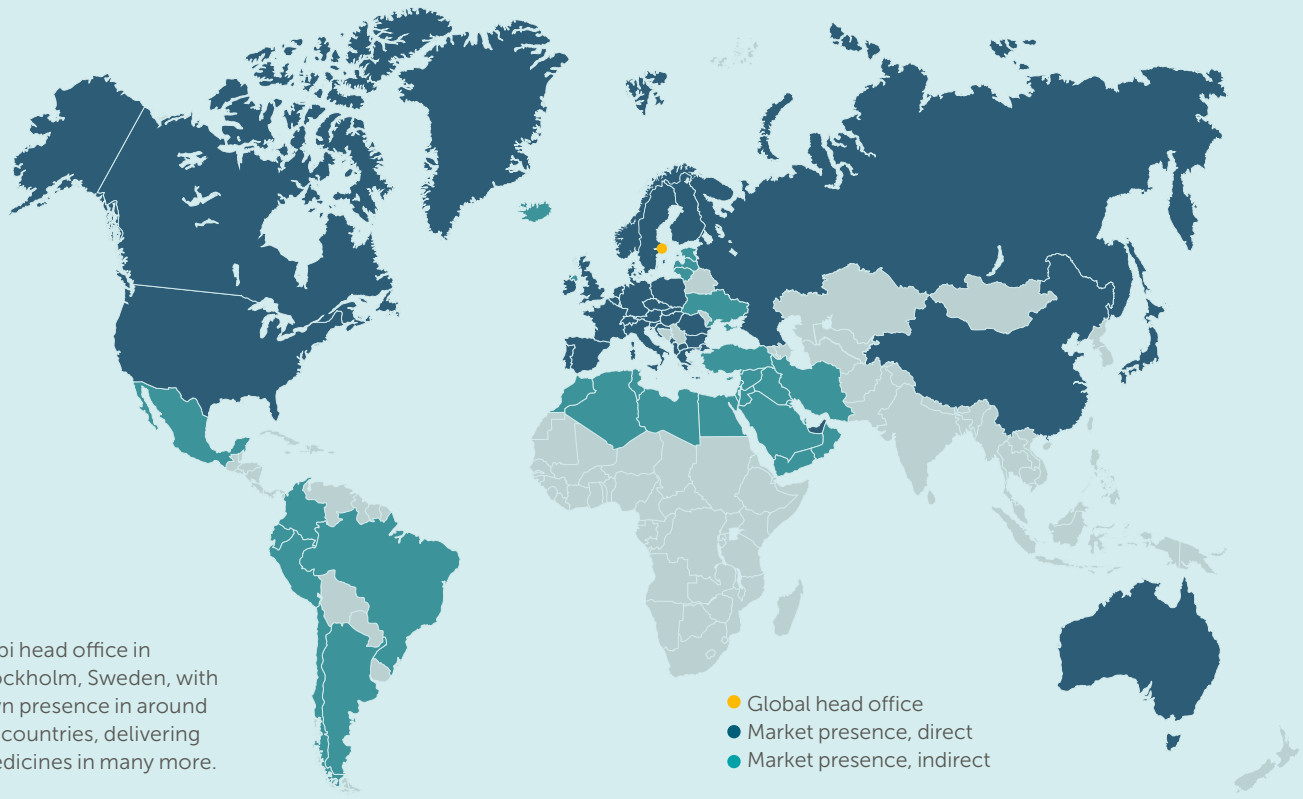
Welcome to Sobi's Annual and sustainability report 2022. The audited Annual report includes pages 32-97. The Sustainability report can be found on pages 22-27 and 119-159 and is Sobi's statutory sustainability report in accordance with the Annual Accounts Act. It is based on GRI Standards 2021. The Sustainability report also includes Sobi's Task Force on Climate-related Financial Disclosures (TCFD) report, and the EU taxonomy disclosures. The Swedish version of this Annual report is the master version. In case of discrepancies between the different language versions, the Swedish version will prevail.

There are more than 7,000 rare diseases

A rare disease is defined as having a prevalence of less than five people in 10,000 in the EU[1] or a condition that affects less than 200,000 people in the US[2]. Rare diseases typically have complex biology and are often life-threatening, however most do not have approved medicines.

1. https://www.ema.europa.eu/en/human-regulatory/overview/orphan-designation-overview.
2. https://www.fda.gov/patients/rare-diseases-fda.

Sobi presence



Sobi head office in Stockholm, Sweden, with own presence in around 30 countries, delivering medicines in many more.

Sobi at a glance

Swedish Orphan Biovitrum AB (publ) (Sobi®) is a specialised international biopharmaceutical company transforming the lives of people with rare and debilitating diseases.

Providing reliable access to innovative medicines in the areas of haematology, immunology and specialty care, Sobi has approximately 1,600 employees across Europe, North America, the Middle East, Asia and Australia.

In 2022, revenue amounted to SEK 18.8 B and operating profit before amortisation and impairment of intangible assets (EBITA) adjusted was SEK 6.6 B. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm.

More about Sobi at sobi.com, LinkedIn and YouTube.

Sobi values

Care: we are who we are because of our dedication, knowledge and passion. Care is the foundation upon which our strategy, our business and our culture are built.

Ownership: it is our duty to act. We therefore encourage entrepreneurship and learn from our experiences.

Urgency: we need to embrace a sense of urgency, while safeguarding our standards, because patients cannot wait.

Partnership: we embrace partnerships and collaboration, both within Sobi and with external partners and stakeholders.

Ambition: we set ourselves ambitious goals and do our utmost to achieve them.

Year in brief

18,790
Total revenue, SEK million

6,605
EBITA adjusted, SEK million

~1,600
Number of employees

8%
Revenue growth at constant exchange rates

35%
EBITA adjusted, margin

Member of
Dow Jones Sustainability Indices
Powered by the S&P Global CSA

In 2022, Sobi for the first time qualified as a constituent of the Dow Jones Sustainability Indices.

Progress on strategic priorities

Grow Immunology and Specialty Care Revenue from Sobi's Immunology disease area decreased by 1 per cent at constant exchange rates to SEK 6.7 B. Revenue from Kineret® rebased during the year following inflated sales in 2021 to treat COVID-19. Gamifant® has reached high adoption in the US and declined mainly due to lower use in adults. Synagis® continued to be an important medicine for Sobi in the US.

Always act responsibly In 2022, a company-wide initiative on diversity, equity and inclusion commenced. Further steps were also taken to map Sobi's supply chain climate impact and deploy the company's Responsible Sourcing Programme.

Lead in Haematology Revenue from Sobi's Haematology disease area increased by 15 per cent at constant exchange rates to SEK 10.8 B. The Haemophilia business stabilised, and Doptelet® achieved record revenue in the US and was launched to treat immune thrombocytopenia in many EU countries and the UK. Aspaveli® was launched to treat paroxysmal nocturnal haemoglobinuria in some EU countries and the UK and Zynlonta® (loncastuximab tesirine) obtained approval in the EU.

Go global Outside the EU and the US, Gamifant became Sobi's first-ever approval in China, and Sobi made its first-ever regulatory submissions in Japan for Doptelet and Empaveli®. Sales were also expanded in several emerging countries.

Capture the value of the pipeline At year-end, Sobi's pipeline consisted of eight medicines or potential new medicines in around 15 projects from phase 2 through registration.

Maintain commitment to patients Sobi continued its support of the World Federation of Hemophilia (WFH) Humanitarian Aid Program, in which Sobi and Sanofi are Founding Visionary Contributors. By the end of 2022, 661 million international units of factor medicine had been donated since 2014.

Guido Oelkers, Chief Executive Officer

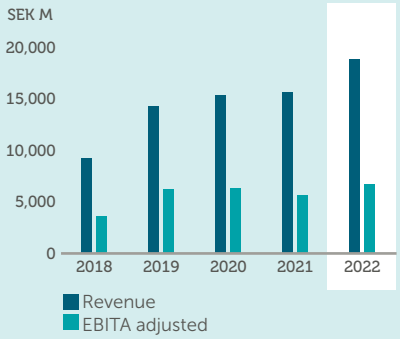
Three items on my radar going into 2023

One
Ensure every eligible person living with a rare and debilitating disease within Sobi's disease areas is given an opportunity to benefit from our approved medicines.

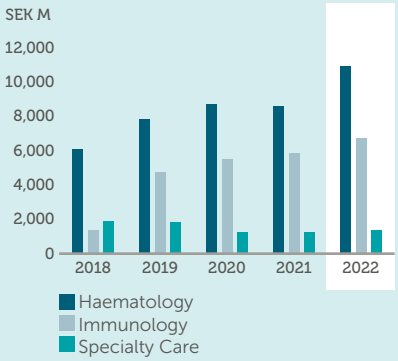
Two
Deliver innovative solutions from our pipeline.

Three
Commitment to our patients, our employees and society.

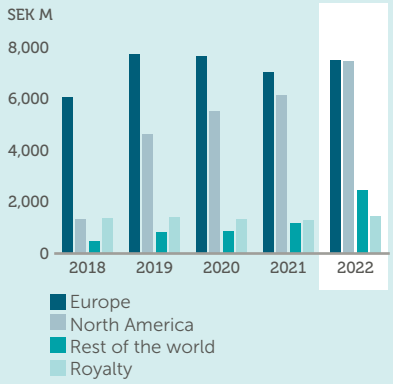
Revenue and EBITA adjusted



Revenue by disease area



Revenue by geographic area



Key figures

SEK M	2018	2019	2020	2021	2022
Total revenue	9,139	14,248	15,261	15,529	18,790
Gross profit	6,723	10,913	12,036	12,045	14,014
Gross margin[i]	74%	77%	79%	78%	75%
Operating costs	3,601	6,430	7,575	8,288	10,201
EBITA[i]	3,571	5,933	6,700	5,575	5,930
EBITA adjusted[i, ii]	3,571	6,145	6,301	5,575	6,605
EBIT (operating profit)	3,122	4,533	4,818	3,733	3,813
Profit for the year	2,418	3,304	3,245	2,679	2,638
Earnings per share, before dilution, SEK	8.97	11.29	11.01	9.08	8.92
Earnings per share, before dilution, SEK adjusted[i, ii, iii]	8.97	11.89	9.66	9.08	10.77
Cash flow from operating activities[iv]	2,090	3,634	4,926	5,470	4,665
Equity per share[i]	33.1	56.4	66.5	75.6	85.6
Equity ratio[i]	53%	37%	42%	48%	51%
Average number of employees (full-time positions)	902	1,335	1,509	1,559	1,556

i. Sobi presents certain financial measures in the Annual and sustainability report that are not defined according to the IFRS, so-called Alternative performance measures. Further information on why these are considered important, and how they are calculated, can be found in Alternative performance measures.

ii. For information about non-recurring items during 2022, please see Note 12 and Alternative performance measures. EBITA 2020 excluding non-recurring item; other operating income related to the reversal of the CVR liability of SEK 399 M. EBITA 2019 excluding non-recurring items; transaction costs related to the acquisition of Dova of SEK 92 M, restructuring costs of SEK 157 M and gain from divestment of SOBI005 of SEK 37 M.

iii. For information about non-recurring items during 2022, please see Note 12 and Alternative performance measures. EPS 2020 excluding the reversal of the CVR liability of SEK 399 M. EPS 2019 excluding impairment of intangible assets of SEK 18 M related to restructuring.

iv. As of 2020, Sobi has reclassified hedging arrangements for financing from cash flow from operating activities to cash flow from financing activities.

From the chairman and CEO

Chairman

Continued growth in 2022 with confidence in the focus on rare diseases

Dear shareholder,
2022 was a good year for Sobi in which we continued to grow and deliver on all our commitments – in terms of strategy execution as well as meeting our financial outlook and other goals set for the year. This performance was delivered despite significant geopolitical and macroeconomic uncertainty and fundamental societal challenges as Sobi reached more people with rare diseases.

Strategy
The board's combined experience and knowledge will support the management team to execute our strategy in a challenging geopolitical operating environment.

In June 2022, the board and management team met to review the current strategy and progress, and to discuss Sobi's future direction. Based on the conclusions from this meeting, the strategy was confirmed, and the board has confidence in the future direction of Sobi and the focus on rare diseases.

Corporate governance
Governance is a vital part of the board's work. Through its meetings and various sub-committees, the board oversees Sobi's business, operations and progress on an ongoing basis, including sustainability which is regularly on the agenda. Our Code of Conduct serves as the basis for Sobi's internal governance structure and adherence is mandatory for all Sobi employees. The Responsible Sourcing Programme and the Partner Code of Conduct serve as the basis for Sobi's external governance of collaborators and suppliers, and cover topics connected to the environment, labour, ethics and human rights.

Sobi is intent on continuing to contribute to the fulfilment of the UN Sustainable Development Goals (SDGs) and the Paris Climate Agreement. It will also continue to report on key performance indicators in line with the UN Global Compact and the Global Reporting Initiative.

Håkan Björklund
Chairman of the Board

"I would like to thank everyone in Sobi as well as many stakeholders outside Sobi for the help and support I have received as chairman"

Board succession
I have served as board member and chairman since 2016, during a time of expansion for Sobi. New medicines have moved the company from a base offering of haemophilia medicines and Kineret into a broader offering of haematology and immunology. Sobi has also grown geographically from its European base to expand in the US and enter new countries in the Middle East, Africa, Asia/Australia and Latin America.

In October 2022, Sobi announced that I will not be available for re-election at the next annual general meeting. The Nomination committee then began the process of proposing a successor. In November 2022, Sobi announced that the Nomination committee proposed that the current board member and deputy chairman Bo Jesper Hansen is elected as chairman of the board at the annual general meeting on 9 May 2023. The early announcement of Bo Jesper Hansen as chair-designate allowed ample time to facilitate the chairman succession and transition.

I would like to thank everyone at Sobi as well as our many external stakeholders for their help and support I have received as chairman. I would also like to extend my very best wishes to Bo Jesper Hansen as Sobi's proposed new chairman, subject to shareholder approval at the annual general meeting.

Håkan Björklund
Chairman

CEO

Guido Oelkers
Chief Executive Officer

Progress across business, strategic priorities and a great place to work

Solid business performance

In 2022, Sobi delivered solid and sustained business performance throughout the year. Despite the prevailing geopolitical uncertainty in the world around us, Sobi advanced positively in many ways – revenue, geographic expansion, efficiency programmes, profitability and pipeline. As a result, we achieved our financial outlook to provide a mid to high single-digit percentage revenue growth and an EBITA adjusted margin at a low 30s percentage of revenue.

Revenue amounted to SEK 18.8 B in 2022 and increased by 21 per cent, or 8 per cent at constant exchange rates. Launch medicines that include Doptelet outside China, Gamifant and Aspaveli combined grew by 37 per cent at constant exchange rates.

The efficiency programmes launched in the first quarter of 2022 included the decision to discontinue contract manufacturing for Pfizer in the first quarter of 2024, the consolidation of our Geneva site into our Basel site, the merger of Research & Development (R&D) and Medical & Scientific Affairs and the restructuring of general and administrative functions. The efficiency programmes are focusing resources into the core areas of our business, will simplify our organisation and adjust our cost base to enable us to continue to achieve sustainable growth and margin improvement in the coming years.

EBITA was SEK 5.9 B, with a margin of 32 per cent in 2022. EBITA included some items that affected comparability, such as restructuring costs. Without these, the EBITA adjusted margin was 35 per cent.

Progress on strategic priorities

Lead in Haematology

Revenue from our Haematology disease area increased by 15 per cent at constant exchange rates to SEK 10.8 B. The Haemophilia business stabilised, and Doptelet achieved record revenue in the US and was launched to treat immune thrombocytopenia in many EU countries and the UK. Aspaveli was launched to treat paroxysmal nocturnal haemoglobinuria in some EU countries and the UK and Zynlonta obtained approval in the EU.

Grow Immunology and Specialty Care

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Go global

Outside the EU and the US, Gamifant became our first-ever approval in China, and we made our first ever regulatory submissions in Japan for Doptelet and Empaveli. Sales were also expanded in several emerging countries.

Capture the value of the pipeline

At year-end, Sobi's pipeline consisted of eight medicines or potential new medicines in around 15 projects from phase 2 through registration.

Sustainability

Our main contribution to sustainable development is to improve the lives of people living with rare diseases. During 2022, we increased access to our medicines to approximately 75,000 full-time equivalent patients, reinforcing our patient-centric approach. We also launched a new employee initiative focusing on diversity, equity and inclusion. Our sustainability efforts were recognised by improved or retained ratings in several sustainability indices and Sobi for the first time qualified as a constituent of the Dow Jones Sustainability Indices, DJSI Europe.

Great place to work

In a post-pandemic, yet continuously ambiguous and volatile world, we have put a particular focus on our way of working and leading for the future launching initiatives to strengthen our culture and we remain committed to an inclusive, sustainable and flexible workplace that fosters growth and development.

Guido Oelkers
Chief Executive Officer

The global market in rare diseases

There are more than 7,000 rare diseases globally of which approximately 95 per cent have no approved medicine. With a tremendous unmet medical need, there is ample opportunity to find and make available medicines that transform the lives of people with rare and debilitating diseases.

Rare and orphan diseases

While many rare diseases are very uncommon, they together affect a significant proportion of the global population. An estimated 300 million people globally have a rare or orphan disease[1].

The EU defines a rare disease as one that impacts fewer than five in 10,000 people. This results in over 6,000 conditions defined as rare that impact around 30 million people, or about one of every 15 EU citizens. In the US, a rare disease impacts less than 200,000 Americans, and approximately 30 million individuals are affected by a rare disease. Japan defines an orphan disease as one that impacts fewer than 50,000 Japanese, which represents a high unmet medical need. In China, an orphan disease framework is under development.

As scientific progress continues, including the available diagnostic tools, the number of conditions categorised as rare or orphan is expected to increase.

Incentives to develop new medicines

Countries have implemented various incentives to support the development of medicines for orphan and rare diseases.

The EU offers a range of incentives to support orphan medicines. This includes access to centralised authorisation procedures resulting in a single opinion and decision valid in all EU member states, protocol assistance, grants and fee reductions. Orphan medicines are granted an additional two years of market exclusivity for a total of ten years. Additional incentives are also available within member states.

In the US, incentives have been developed as part of the Orphan Drug Act. These range from tax credits for qualified clinical studies and exemption from certain user fees such as the Prescription Drug User Fee Act, to a period of seven years of market exclusivity after approval.

The incentives available to support orphan medicines in Japan include a priority review process and subsidies to support development. Laws and programmes supporting rare or orphan diseases also exist in Argentina, Australia, Brazil, Columbia, Mexico, Peru and South Korea.[2, 3]

Expanded options for patients

The world is at a turning point in the care and medicines to help address rare and orphan diseases.

The first medicine that received orphan drug designation from the US Food and Drug Administration was in 1983 to treat primary brain malignancies while the first medicine that received orphan designation from the European Medicines Agency was in 2000 for acute myeloid leukaemia. Despite the long history of orphan designations, 40 per cent of all medicines receiving an orphan designation have been approved in the last five years.[4]

To date, over 2,200 medicines have been granted an orphan designation in the EU. The number of orphan medicines has increased steadily over time with just under 30 per cent of all medicines approved since 2019. In 2021, 52 per cent of all medicines approved in the US were intended to help address rare or orphan diseases with similar numbers expected for 2022.[5] Over 200 medicines have been approved as orphan in Japan since 2004.

Sales from orphan medicines continue to outpace the overall pharmaceutical market. Orphan medicines are expected to reach sales of USD 173 B in 2022, accounting for 16 per cent of the total global prescription medicine sales. This number is projected to surpass USD 250 B and 20 per cent of the total global pharma market by 2025.[6] Medicines within oncology, haematology and immunological conditions contribute around 65 per cent of the total current orphan medicine sales.[7]

Unmet medical needs remain

Despite recent advances in medicines and access, rare diseases continue to represent a huge unmet medical need and a significant public health challenge. Of the over 7,000 estimated rare diseases globally, approximately 95 per cent have no approved medicines to help address them.[8]

Even for diseases where medicines exist, it can take people years to receive an accurate diagnosis of their condition. It is estimated that more 50 per cent of people with a rare disease have not been diagnosed.

A brighter future

The awareness and support available to individuals and families facing the challenges of a rare condition is at an all-time high.

After being established by the European Organisation for Rare Diseases, Rare Disease Day is now recognised in over 100 countries around the world. Over 2,000 patient organisations are focused on providing information and services to people with rare conditions. To support such important initiatives, Sobi actively partners with multiple organisations to raise awareness and advocate on behalf of people and their communities.[9]

Greater awareness and more available medicines mean the world is looking brighter every day for people suffering from rare and orphan diseases.

1. European Journal of Human Genetics volume 28, pages 165-173 (2020) via https://www.nature.com/articles/s41431-019-0508-0.
2. Journal of Rare Diseases, volume 15, article 60, Orphanet 2020.
3. Intractable Rare Dis Res. 2012 Feb; 1(1): 3-9.
4. EMA Community Register of orphan medicinal products (accessed on 07.10.2022) and FDA Orphan Drug Designations and Approvals database (accessed on 24.10. 2022).
5. Advancing Health through Innovation, New Drug Therapy Approvals in 2021, FDA Center for Drug Evaluation and Research.
6. Orphan Drug Report 2022, Evaluate Pharma.
7. Orphan Drug Report 2022, Evaluate Pharma.
8. Journal of Rare Diseases, volume 13, article 196, Orphanet 2018.
9. https://sobi-northamerica.com/our-patients/patient-organizations.

Strategy

Vision:
'To be recognised as a global leader in providing innovative medicines that transform the lives of people with rare and debilitating diseases.'

Mission:
'We are working together to find and make available medicines that transform the lives of people with rare and debilitating diseases. All with the goal of ensuring that every eligible person is given the opportunity to benefit from our medicines.'

Strategy and strategic objectives

Inspired by caring, powered by science, Sobi is dedicated to: 1) Ensure every eligible person living with a rare and debilitating disease within Sobi's disease areas is given an opportunity to benefit from our approved medicines. 2) Deliver innovative solutions from our pipeline. 3) Commitment to our patients, our employees and society.

Sobi has four strategic business priorities – to deliver on its strategy:

Lead in Haematology

Sobi will continue to be a leader in haematology.

In Haemophilia, Sobi continues to increase access to the extended half-life factor replacement medicines Elocta® and Alprolix® – to reach more people with haemophilia A and B in more countries. Efanesoctocog alfa, formerly known as BIVV001, has the potential to change the paradigm for people with haemophilia A and provide future growth.

Outside Haemophilia, Sobi is expanding access to Doptelet by bringing the medicine to more countries and focusing on its use to treat immune thrombocytopenia. With the launches of Aspaveli/Empaveli in the EU, UK and other countries to treat paroxysmal nocturnal haemoglobinuria, Sobi has entered an area of large unmet medical need when existing medicines fail. With the approval of Zynlonta, a new opportunity has been created to expand Sobi's scope in haematology.

Grow Immunology and Specialty Care

Sobi will continue to grow in Immunology and Specialty Care.

In Immunology, Sobi is maximising value to patients and the company through the existing medicines Kineret and Gamifant in both new countries and/or new indications. Sobi will also continue to offer Synagis as new options become available and has the right to 100 per cent of AstraZeneca's half share of US profits and losses for nirsevimab.

In Specialty Care, Sobi is focused on Orfadin®, Tegsedi® and Waylivra® with a few other medicines available in select countries based on specific needs and opportunities.

Go global

Sobi will continue to expand geographically.

In 2022, Sobi made further progress in China, Japan and Australia and commenced a distribution agreement in Latin America. With Gamifant, Sobi obtained its first approval in China. The company's presence in Japan was expanded through an exclusive distribution agreement with Asahi Kasei Pharma Co., Ltd. in anticipation of the upcoming launches for Doptelet and Empaveli, which are Sobi's first two medicines under regulatory review in the country. The progress in China and Japan highlights Sobi's journey towards becoming a more global company.

Capture the value of the pipeline

Sobi will continue to capture value from its pipeline.

Sobi is concentrating on mid and late-stage opportunities that help address unmet medical needs and have significant market potential in the niches they serve. With eight medicines or potential new medicines in around 15 projects from phase 2 through registration, new launches are anticipated to sustain future growth.

Sobi has two strategic sustainability priorities:

Maintain commitment to patients

Sobi will continue to improve access to medicines for people with rare diseases globally by deepening its engagement in the areas of haematology and immunology. It will also continue to apply a truly patient-centric development approach in collaboration with patient communities by investing in the development of new medicines and by expanding its geographical reach. Patient safety is Sobi's most important focus.

Always act responsibly

Sobi expects the highest ethical, environmental and social standards from its employees, collaborators and other stakeholders. Impacts and risks related to Sobi's operations and value chain are assessed and monitored, and improvements to avoid or minimise impact are continuously implemented. Sobi's team is key to delivering on its strategy, and Sobi continues to work to create an inclusive, sustainable and flexible workplace that fosters growth and supports the development of professionals from different backgrounds.

Sobi's strategy has four strategic business priorities:

Business model

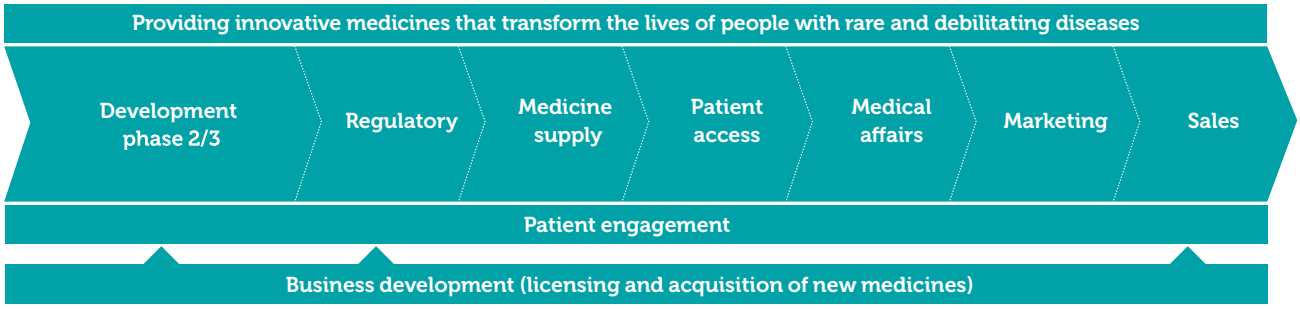
Sobi's platform in rare diseases

The rare disease landscape is unlike any other in medicine. People with rare diseases and their support networks face a disproportionate struggle for knowledge, advocacy and medicines compared to more common diseases. This places a heavy personal and financial burden on individuals and families. The ever-evolving rare disease ecosystem presents inherent scientific, medical and commercial challenges – as well as opportunities.

Sobi keeps pace with these developments and supports rare disease communities by engaging in a continuous dialogue with all stakeholders across the biopharmaceutical value chain. This includes patients and their caregivers, patient organisations, healthcare systems, government authorities, regulatory bodies, payers and business partners.

Sobi's strengths lie in evaluating and developing clinical projects, commercialisation and bringing medicines to people as quickly as possible. Importantly, this is accomplished in close partnership with the patient community – to allow Sobi to co-develop solutions across the entire medicine development value chain that are truly patient led.

Sobi works cross-functionally and engages across the medicine life cycle to develop a solid platform in rare diseases:



Sobi continuously expands its business with the licensing and acquisition of new medicines from other companies with a similar vision and values, but that are focused on research and discovery. This allows Sobi to expedite access to lifesaving medicines and includes medicines in clinical development or under regulatory review. For example, Zynlonta in July 2022, or those already approved and available to patients, such as Tegsedi and Waylivra in 2020 and 2021. The exact timing depends on the specific circumstances, including when a collaborator is looking to license or sell their medicine in specific geographies or indications.

All medicine supply is outsourced to contract manufacturing organisations that supply Sobi with the medicines to be sold. Sobi's own manufacturing in Stockholm, Sweden, producing recombinant factor VIII for Pfizer, will be permanently closed in the first quarter of 2024.

Capital-allocation priorities

As Sobi seeks new medicines to either license or acquire, it applies a solid set of capital-allocation priorities. These include a focus on rare diseases, preferably in haematology or immunology, medicines in late-stage development or already marketed with peak sales potential between USD 150-500 M and with a preference for not diluting the EBITA margin.

Proactive engagement

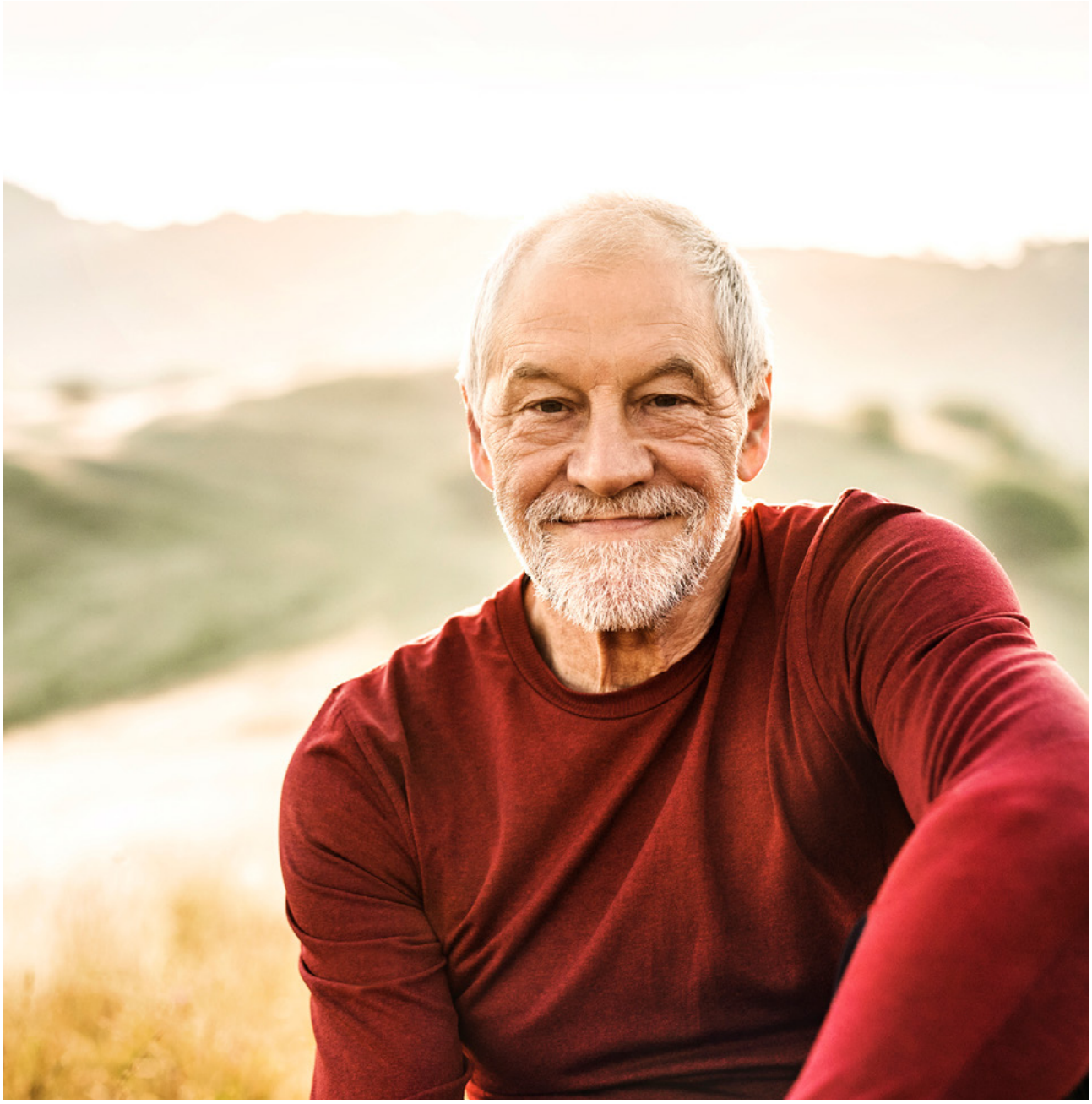
Patient engagement future proofs medicine development activities and connects Sobi to communities. Early, consistent and responsible engagement with patient organisations and networks in clinical development enables Sobi to design clinical studies and create solutions with and for the patient community. By embedding live experience and giving a voice to patients, Sobi helps to ensure that development and future medicines align with patient's preferences and behaviours and address real patient needs.

Sobi's business is supported by designing, collecting and sharing robust insights and evidence from patients. This includes ethnographic research to ensure that diverse unmet medical needs are broadly captured and are considered and reflected across the medicine development value chain. Together with Sobi's clinical development, medical, patient-access and commercial teams working with healthcare stakeholders, these insights increase understanding of the changing needs of various stakeholders that are continuously fed back into the company to improve medicines and systems.

Patient access

Medicine innovation is only of value if it benefits patients and physicians. Another way in which Sobi works with the community is through patient access through established healthcare systems to ensure availability, delivery and distribution in all countries served.

Responsible pricing and reimbursement are essential components in enabling equity and opportunities for better patient care and outcomes. In all



price-setting and subsequent negotiations, Sobi considers the following aspects:

- Unmet medical need
- The benefits the innovation brings to patients
- Benefits for the healthcare system
- Affordability and reliability of access
- The cost required to continue innovation and meet future medical needs

Both patient engagement and patient access are vital to Sobi's goal of ensuring fast and reliable access to medicines for people with rare diseases worldwide. This further underscores Sobi's corporate commitment and contribution to environmental, social and governance principles, such as those that support the SDGs.

Sobi's rare disease platform provides a unique position to improve health on a global scale for several small and often overlooked and underserved patient groups.

Business review

Haematology

58%

of total revenue

Immunology

36%

of total revenue

Specialty Care

7%

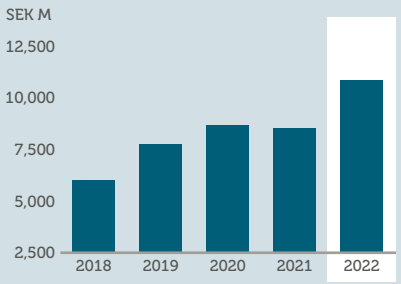
of total revenue

Haematology

10,831
Revenue in SEK M

15%
Change at constant exchange rates

Revenue, Haematology



Haemophilia in general

Revenue in Sobi's Haemophilia business increased by 2 per cent at constant exchange rates to SEK 7,714 M during the year, which accounted for 41 per cent of total revenue. This included a decrease of 4 per cent at constant exchange rates to SEK 1,427 M in royalties from Sanofi from their sales of Eloctate® and Alprolix.

Elocta and Alprolix

Sales of Elocta increased by 5 per cent at constant exchange rates to SEK 4,402 M during the year, which accounted for 23 per cent of total revenue. Sales of Alprolix increased by 1 per cent at constant exchange rates to SEK 1,885 M during the year, which accounted for 10 per cent of total revenue.

Despite competition in the market, both medicines benefited from the confidence of the haemophilia community based on their ability to increase protection, including improving joint health and the long-term outcomes in people with haemophilia.

In July, A-SURE real-world data was presented that showed the efficacy of Elocta in improving key endpoints compared to previous short half-life factor VIII medicines – to further strengthen Elocta's unique body of evidence as an innovative medicine option. Sobi's commitment to broaden access to its medicines was further demonstrated by the launch of Elocta in Algeria and Turkey and approval in Israel.

Based on decades of clinical and real-world evidence, Sobi believes that factor replacement is a fundamental cornerstone in helping to treat and prevent bleeds in people with haemophilia. In July, the phase 3 XTEND-1 data was presented for efanesoctocog alfa, which showed significant efficacy compared to previous factor VIII prophylaxis. With

Sobi's commitment to people with haemophilia was highlighted in the Spanish documentary film 'Un recorrido Hépico. El viaje de la Hemofilia' about a young man named Fabio who cycles 1,300 kilometres to raise awareness about haemophilia B. https://www.youtube.com/watch?v=QGHGgDurckA

the development of this new medicine, in collaboration with Sanofi, Sobi plans to bring factor medicines to the next level and change how haemophilia is treated.

In full alignment with 'Liberate Life', the patient-centric vision in haemophilia, Sobi continued to support the haemophilia community with educational activities aimed at elevating standards of care and offering people with haemophilia the possibility to live a life full of opportunities.

Sobi's commitment to people with haemophilia was also demonstrated in its relentless support, in collaboration with Sanofi, to the World Federation of Hemophilia for initiatives related to access to medicines and education programmes. It also continued to support the Humanitarian Aid Program, which since its creation in 1996 has aimed to improve the level of care in developing countries, including through the donation of medicines.

Doptelet

Sales of Doptelet increased by 91 per cent at constant exchange rates to SEK 2,526 M during the year, which accounted for 13 per cent of total revenue. Sales to the distributor in China increased by 128 per cent at constant exchange rates to SEK 1,102 M.[1]

In the US, Sobi estimates that sales of the thrombopoietin receptor agonist class of medicines to treat immune thrombocytopenia increased by approximately ten per cent during the year. Supported by improved access and formulary coverage and clarity in Sobi's commercial strategy as well as consistent delivery, Doptelet increased its market share significantly with over 1,900 people estimated to be actively receiving the medicine at year-end. In 2022 a new direct-to-patient information campaign and advertisement on connected TV and streaming platforms initiated, which allowed a targeted approach to reach people interested in immune thrombocytopenia.

In Europe, which still accounts for a smaller proportion of sales, ongoing and new launches continued to drive growth. Reimbursement decisions were made in several new countries, including Italy, Spain and the UK, while Doptelet achieved preferred status over oral and injectable competitors in other countries, including Norway. A new patient-awareness campaign 'Find your balance' raised awareness further.

> "Based on decades of clinical and real-world evidence, Sobi believes that factor replacement is a fundamental cornerstone in helping to treat and prevent bleeds in people with haemophilia."

Aspaveli/Empaveli

Sales of Aspaveli/Empaveli amounted to SEK 178 M in their first year of launch, which accounted for 1 per cent of total revenue.

During 2022, Aspaveli/Empaveli was launched in several countries in Europe, including Germany, the UK and Italy, and in Saudi Arabia as the first Sobi country outside Europe. The medicine also obtained approval in new countries, including Canada. Aspaveli/Empaveli is the first and only C3 inhibitor and the first approved medicine to treat paroxysmal nocturnal haemoglobinuria and control both intravascular and extravascular haemolysis for people suffering from this rare blood disorder. The unmet medical need remains large and access to improved medicines is essential for patients. Sobi continues to raise awareness of the unmet medical need, including through initiatives such as ethnographic research and a new solution from Florio aiming to upgrade the standard of care.

Manufacturing

Factor VIII contract manufacturing revenue from Pfizer decreased by 7 per cent to SEK 413 M. Sobi's contract manufacturing will cease in the first quarter of 2024.

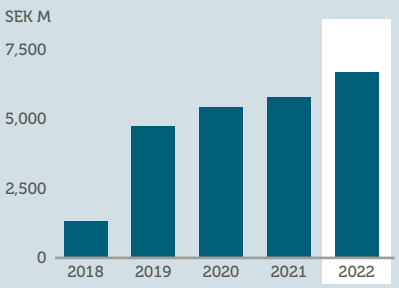
1. Doptelet entered the China National Reimbursement Drug List (NRDL) in 2020 with renewal confirmed from 1 March 2023. NRDL inclusion generally facilitates broader access to the medicine. Doptelet, and any approved avatrombopag generic from 2023, are anticipated to remain on the NRDL until three avatrombopag generics have been approved for sale in China. At this point, a transfer to competitive volume-based procurement is anticipated.

Immunology

6,679
Revenue in SEK M

-1%
Change at constant exchange rates

Revenue, Immunology



Kineret

Sales of Kineret decreased by 11 per cent at constant exchange rates to SEK 2,284 M during the year, which accounted for 12 per cent of total revenue. This performance reflected the lower use of Kineret to treat COVID-19 in 2022 compared to 2021.

Despite the lower use in treating COVID-19 infections, 2022 was another year of good performance for Kineret with underlying sales growth estimated in the single-digit percentages. Growth was mainly driven by the increased use in Still's disease and familial Mediterranean fever in Europe and international countries and the increased use to treat rheumatoid arthritis in the US. There was also growth in the number of approvals in new countries. Currently, more than 20,000 people are treated with Kineret for rare diseases and Kineret is therefore one of Sobi's large-volume medicines. To increase future supplies of Kineret, Sobi is collaborating with its manufacturing supplier, Pfizer. In June 2022, Pfizer began constructing a new biotechnology factory in Zagreb, Croatia. The facility is designed to produce biotechnology medicines, including the active ingredient in Kineret.

Gamifant

Sales of Gamifant decreased by 10 per cent at constant exchange rates to SEK 895 M during the year, which accounted for 5 per cent of total revenue. Gamifant has reached high adoption in the US and declined mainly due to lower use in adults.

Since Gamifant's launch in the US in 2018, Sobi has achieved a high adoption in its approved indication and continued to focus on promoting the benefits of the medicine, which now reaches hundreds of people. Activities include ongoing commercial efforts to amplify educational programmes, particularly with new prescribers, including a tailored approach to help address any unique needs and increased field presence. At the end of the year, new Gamifant real-world data was presented from the REAL-HLH study, which was the first study of treatment patterns and treatment outcomes in a larger cohort of people. Outside the US, Gamifant is approved in the United Arab Emirates and China. Studies are ongoing to assess if more patients can potentially benefit from Gamifant.

Synagis

Sales of Synagis in the US increased by 12 per cent at constant exchange rates to SEK 3,501 M during the year, which accounted for 19 per cent of total revenue. This performance reflected a shift in the seasonality of the respiratory syncytial virus in the US during the 2021-2022 season, which started earlier and lasted longer and benefited sales at the beginning of 2022. Sobi anticipates that the virus is returning to its historical patterns as a winter virus, which therefore saw sales in the latter part of 2022 start later than in 2021.

Synagis remains the only approved medicine in the US for the prevention of serious lower respiratory tract infections caused by the respiratory syncytial virus in high-risk infants, and significantly reduces the risk of hospitalisation. During the year, Sobi continued extensive public awareness and educational activities around the burden of respiratory syncytial virus infections in premature infants.

Geographic expansion – Go global

Main achievements in 2022

Country/region	Achievements and progress
Central and Eastern Europe	
	• Significant expansion of Sobi's Haemophilia disease area, including Elocta and Alprolix.
Turkey	
	• Launch of Haemophilia disease area, including Elocta.
Japan	
	• Doptelet under regulatory review for chronic liver disease. • Empaveli under regulatory review for paroxysmal nocturnal haemoglobinuria. • Distribution agreement with Asahi Kasei Pharma Co.
China	
	• Kineret under regulatory review for familial Mediterranean fever. • Kineret under regulatory review for Still's disease. • Kineret under regulatory review for cryopyrin-associated periodic syndromes. • Gamifant approved and launched for primary haemophagocytic lymphohistiocytosis.
Latin America	
	• Implementation of distribution agreement with Pint Pharma signed in December 2021. • Empaveli launch in the first quarter of 2023.
Australia	
	• Doptelet under regulatory review for chronic liver disease and immune thrombocytopenia. • Empaveli approved for paroxysmal nocturnal haemoglobinuria; reimbursed. • Kineret approved for rheumatoid arthritis, systemic juvenile idiopathic arthritis and cryopyrin-associated periodic syndromes; reimbursed.

Specialty Care

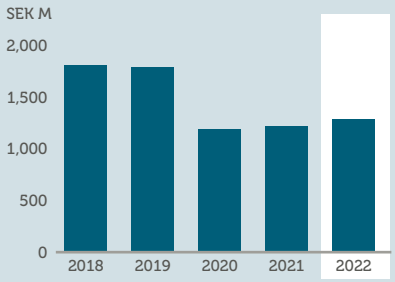
1,280
Revenue in SEK M

-5%
Change at constant exchange rates

Sales in Specialty Care decreased by 5 per cent at constant exchange rates to SEK 1,280 M during the year, which accounted for 7 per cent of total revenue. This included a decrease of 10 per cent at constant exchange rates to SEK 462 M for Orfadin, a decrease by 10 per cent at constant exchange rates to SEK 429 M for Tegsedi and an increase by 19 per cent at constant exchange rates to SEK 152 M for Waylivra.

In 2022, Orfadin was approved in Brazil by ANVISA, the Brazilian health authority, to treat hereditary tyrosinemia type 1. Orfadin is also approved to treat alkaptonuria in the EU and obtained more approvals during the year in selected countries in Latin America and the Middle East. Reimbursement was also obtained in new countries, such as France and Italy. Tegsedi is being distributed in both Europe and the US whereas Waylivra is only being distributed in Europe. Both medicines continued to increase Sobi's presence in rare genetic diseases with new reimbursements, including Bulgaria, Luxembourg and Ireland for Tegsedi, and Spain and the Netherlands for Waylivra.

Revenue, Specialty Care



Florio, a Sobi company, develops next-generation apps and other digital solutions in collaboration with doctors and patients that capture and visualise disease and treatment-related data in real time to enable better decision making and ultimately provide better care.

florio® HAEMO, a solution for people with haemophilia, their caregivers and healthcare professionals, is available in more than 25 countries across Europe and the Middle East. In 2022, Florio launched florio ITP, which is an app for people with immune thrombocytopenia, in a handful of European countries. Roll out to additional countries is planned in 2023.

Florio has also developed my florio ITP, which is a digital diary for patients that is available in the US in partnership with the Platelet Disorder Support Association. Florio continues to develop apps in collaboration with doctors and patients in line with Sobi's pipeline.

Main medicines

Disease area	Medicine / pipeline	Rare disease	Revenue in 2022 / status
Haematology			
Area of medicine concerned with the study of the cause, prognosis, treatment, and prevention of diseases related to blood	Elocta (efmoroctocog alfa)[i]	Haemophilia A, a rare, genetic bleeding disorder caused by the lack of blood clotting factor VIII.	SEK 4,402 M
	Alprolix (eftrenonacog alfa)[i]	Haemophilia B, a rare, genetic bleeding disorder caused by the lack of blood clotting factor IX.	SEK 1,885 M
	Royalties	Royalties on sales by Sanofi of Eloctate and Alprolix.	SEK 1,427 M
	Doptelet (avatrombopag)	Immune thrombocytopenia and chronic liver disease, disorders causing low platelets.	SEK 2,526 M
	Aspaveli/Empaveli (pegcetacoplan)[ii]	Paroxysmal nocturnal haemoglobinuria, a rare blood disorder caused by the destruction of red blood cells.	SEK 178 M
	Zynlonta (loncastuximab tesirine)[iii]	Diffuse large B-cell lymphoma, an aggressive, malignant disease.	n/a (approved in the EU in December 2022)
Main pipeline	efanesoctocog alfa[i]	Haemophilia A.	Approved in the US, phase 3 in the EU
	Aspaveli/Empaveli	Additional indications, including immune-complex membranoproliferative glomerulonephritis and C3 glomerulopathy, two rare kidney diseases, cold agglutinin disease and transplant-associated thrombotic microangiopathy after allogenic haematopoietic stem cell transplantation.	Phase 3, phase 2
	Zynlonta	Additional/earlier indications in diffuse large B-cell lymphoma.	Phase 3, phase 2
Immunology			
Area of medicine concerned with the study of the cause, prognosis, treatment, and prevention of diseases related to the immune system	Kineret (anakinra)	Still's disease, familial Mediterranean fever and other rare, sometimes genetic autoimmune diseases caused by an overactive immune system, and COVID-19 in the EU and the US.	SEK 2,284 M
	Gamifant (emapalumab)	Primary haemophagocytic lymphohistiocytosis, an ultra-rare, rapidly progressive, often-fatal syndrome caused by hyperinflammation.	SEK 895 M
	Synagis (palivizumab)	Prevention of serious lower respiratory tract infections in babies caused by the respiratory syncytial virus.	SEK 3,501 M
Main pipeline	Gamifant	Macrophage activation syndrome caused by underlying rheumatological diseases, including Still's disease.	Phase 3
	Aspaveli/Empaveli	Amyotrophic lateral sclerosis, a neurological disease caused by the degeneration of nerve cells.	Phase 2
	SEL-212[iv]	Chronic refractory gout, an autoinflammatory disease caused by the deposition of urate crystals in synovial fluid and other tissues.	Phase 3
	nirsevimab[v]	Prevention of serious lower respiratory tract infections in babies caused by the respiratory syncytial virus.	Under regulatory review in the US
Specialty Care			
	Orfadin (nitisinone)	Hereditary tyrosinemia type 1, a rare genetic disorder caused by the lack of the enzyme fumarylacetoacetate hydrolase, and alkaptonuria, another rare genetic disorder.	SEK 462 M
	Tegsedi (inotersen)	Polyneuropathy from hereditary transthyretin amyloidosis, a rare genetic disorder caused by the abnormal build-up of the protein amyloid in organs and tissues.	SEK 429 M
	Waylivra (volanesorsen)	Familial chylomicronaemia syndrome, a rare genetic disorder caused by very high levels of blood triglycerides.	SEK 152 M

i. In collaboration with Sanofi.
ii. In collaboration with Apellis Pharmaceuticals, Inc.
iii. In collaboration with ADC Therapeutics SA.
iv. In collaboration with Selecta Biosciences, Inc.
v. Sobi has the right to AstraZeneca PLC's full share of US profits and losses for nirsevimab.

Pipeline

At year-end, Sobi's pipeline consisted of eight medicines or potential new medicines in around 15 projects from phase 2 through registration.

Haematology

Efanesoctocog alfa

Efanesoctocog alfa, a potential new medicine for haemophilia A, is in phase 3 clinical development in collaboration with Sanofi and was recently approved in the US. Regulatory submission in the EU will follow the availability of data from the XTEND-Kids paediatric study, which read out positively in March 2023.

In July 2022, following data readout in March 2022, positive results from the XTEND-1 phase 3 study of efanesoctocog alfa were presented at the International Society of Thrombosis and Haemostasis 2022 Congress. The data demonstrated a clinically meaningful prevention of bleeds and superiority to prior factor prophylaxis based on an intra-patient comparison. Efanesoctocog alfa was well-tolerated and inhibitor development to factor VIII was not detected.

Doptelet

In March 2022, Sobi made a regulatory submission in Japan for Doptelet as a potential medicine for induced thrombocytopenia in chronic liver disease. This achievement marked a milestone as the first regulatory submission acceptance for Sobi in Japan. A regulatory decision is anticipated in the first half of 2023.

Aspaveli/Empaveli

Aspaveli/Empaveli, a medicine to treat paroxysmal nocturnal haemoglobinuria, is in clinical development for use in new indications in collaboration with Apellis Pharmaceuticals, Inc.

Paroxysmal nocturnal haemoglobinuria

In February 2022, Aspaveli was approved in the UK for adults with paroxysmal nocturnal haemoglobinuria who become anaemic after receiving a C5 inhibitor for at least three months. Aspaveli is the first new medicine in Europe to treat PNH with a novel mechanism of action since 2007, which provides greater choice for physicians and their patients. Sobi also made a regulatory submission in Japan with a regulatory decision anticipated in the first half of 2023.

New indications

In October 2022, Sobi dosed the first patient in the CASCADE phase 3 study to evaluate Aspaveli/Empaveli in cold agglutinin disease. The disease is a serious and chronic type of autoimmune haemolytic anaemia characterised by chronic anaemia, profound fatigue, acute haemolytic crises and other potential complications, including an increased risk of life-threatening thromboembolic events such as stroke.

In June 2022, Apellis announced that the first patient had been dosed in the VALIANT phase 3 study evaluating Aspaveli/Empaveli in primary immune-complex membranoproliferative glomerulonephritis and C3 glomerulopathy. These are two rare and debilitating kidney diseases where the excessive accumulation of C3 breakdown by-products in the kidney causes inflammation and organ damage.

Data readout from the new phase 3 studies is anticipated from 2024.

In April 2022, Sobi's collaborator Apellis concluded enrolment into the MERIDIAN phase 2 study to treat amyotrophic lateral sclerosis. Apellis anticipates data from this study, which has potential registrational intent, to be available by mid-2023.

Early in 2022, Sobi announced that a phase 2 study in transplant-associated thrombotic microangiopathy after allogenic haematopoietic stem cell transplantation dosed the first patient. Data readout is anticipated in the second half of 2023.

Zynlonta

Zynlonta, a medicine for certain debilitating diseases in haematology, is in clinical development in collaboration with ADC Therapeutics SA.

In December 2022, the EU approved Zynlonta to treat relapsed or refractory diffuse large B-cell lymphoma, a debilitating disease in haematology.

In September 2022, at the Annual Meeting of the Society of Hematologic Oncology 2022, initial data was presented on Zynlonta from the safety run-in of the ongoing LOTIS-5 phase 3 study. The combination of rituximab, which is an established medicine to treat lymphoma, and Zynlonta demonstrated no new safety signals and showed encouraging antitumour activity, including an overall response rate by central review of 75 per cent of patients, with 40 per cent attaining a complete response. Data readout is anticipated beyond 2024.

In July 2022, Sobi announced an exclusive license agreement with ADC Therapeutics to develop and commercialise Zynlonta for use in haematology and other indications of large unmet medical need in Europe and most international countries. Zynlonta is an antibody-drug conjugate against CD19, which is a protein expressed on the surface of B cells.

Immunology

Kineret

In November 2022, Kineret was authorised in the US in emergency cases to treat COVID-19 in hospitalised adults with pneumonia that require supplemental oxygen (low- or high-flow oxygen) and were at risk of progressing to severe respiratory failure. This followed EU approval in December 2021.

In October 2022, Sobi announced that the second regulatory submission was made for Kineret in China, to treat Still's disease, which is a rare type of inflammatory arthritis that involves fevers, rashes and joint pain. Regulatory decision is anticipated in 2024. This followed an earlier announcement of the first regulatory submission for Kineret in China to treat familial Mediterranean fever, which is a genetic autoimmune disorder that causes recurrent episodes of fever together with abdominal, chest or joint pain. Regulatory decision is anticipated in the second half of 2023. A regulatory submission in cryopyrin-associated periodic syndromes, a group of rare illnesses related to defects in the protein cryopyrin, is planned to be underway in 2023.

Gamifant

Gamifant, a medicine for primary haemophagocytic lymphohistiocytosis, is in clinical development to treat other types of immune disorders of large unmet medical need.

In March 2022, Gamifant was approved in China to treat adult and paediatric (new-born and older) patients with primary haemophagocytic lymphohistiocytosis with a refractory, recurrent or progressive disease or intolerance to conventional medicines. This was the first-ever approval for Sobi in China.

Early in 2022, dosing was initiated in a new phase 3 study, EMERALD. EMERALD is initially evaluating the treatment of macrophage activation syndrome in paediatric and adult patients with underlying rheumatological diseases, including Still's disease, the first cohort. Data readout is anticipated in the first half of 2023.

SEL-212

SEL-212, a potential new medicine to treat chronic refractory gout, is advancing in phase 3 clinical development in collaboration with Selecta Biosciences, Inc.

In March 2023, Selecta and Sobi announced positive top-line results from the DISSOLVE phase 3 programme. Both the DISSOLVE I and the DISSOLVE II phase 3 studies met their primary endpoint with detailed results expected to be presented at an upcoming medical meeting.

In June 2022, Selecta announced that the DISSOLVE phase 3 development programme was on track for completion as the DISSOLVE II phase 3 study achieved enrolment completion at the end of the second quarter of 2022. This followed an announcement in March 2022 that Selecta had closed screening and randomisation in both Russia and Ukraine and proactively activated additional enrolment sites in the US.

Nirsevimab

Nirsevimab, a potential new immunisation for the prevention of respiratory syncytial virus infections in infants, is nearing the completion of development by AstraZeneca and Sanofi.

In November 2022, the companies announced that nirsevimab had been approved in the EU for the prevention of lower respiratory tract infections caused by the respiratory syncytial virus in new-borns and infants during their first RSV season. The approval was based on results from the nirsevimab clinical development programme, including the MELODY phase 3, MEDLEY phase 2/3 and phase 2b studies. The EU approval preceded a regulatory submission acceptance for nirsevimab in the US announced in January 2023.

In May 2022, Sanofi announced results from a prespecified pooled analysis of the pivotal MELODY phase 3 study and the phase 2b study for nirsevimab. This followed an announcement by AstraZeneca in March 2022 of the publication in The New England Journal of Medicine of detailed results from the MELODY phase 3 study, which showed that a single dose of nirsevimab met the primary efficacy endpoint of reducing the incidence of medically attended lower respiratory tract infections caused by the respiratory syncytial virus.

Sobi has the right to AstraZeneca's full share of US profits and losses for nirsevimab.

Pipeline

For a continuously updated pipeline chart, please visit sobi.com (sobi.com/en/pipeline).

Disease area

● Haematology ● Immunology

Phase 2

- Aspaveli/Empaveli (pegcetacoplan) — Transplant-associated thrombotic microangiopathy after allogenic haematopoietic stem cell transplantation
- Zynlonta — Diffuse large B-cell lymphoma (front line)
- Aspaveli/Empaveli (pegcetacoplan) — Amyotrophic lateral scierosis

Phase 3

- efanesoctocog alfa — Haemophilia A
- Aspaveli/Empaveli (pegcetacoplan) — Immune-complex membranoproliferative glomerulonephritis and C3 glomerulopathy.
- Aspaveli/Empaveli (pegcetacoplan) — Cold agglutinin disease
- Zynlonta — Diffuse large B-cell lymphoma (second line)
- Gamifant (emapalumab) — Macrophage activation syndrome in rheumatological diseases
- SEL-212 — Chronic refactory gout
- MEDI18897 (nirsevimab) — Respiratory syncytial virus prevention

Registration

- Doptelet (avatrombopag) — Immune thrombocytopenia (in China)
- Doptelet (avatrombopag) — Chronic liver disease (in Japan)
- Aspaveli/Empaveli (pegcetacoplan) — Paroxysmal nocturnal haemoglobinuria (in Japan)
- Kineret (anakinra) — Familial Mediterranean fever (in China)
- Kineret (anakinra) — Still's disease (in China)

Sustainability

Sobi's mission, in short, is to transform the lives of people with rare and debilitating diseases. This is also the company's main contribution to sustainable development.

Sobi's sustainability strategy is based on a solid materiality assessment and has two main aspects:

Maintain commitment to patients – by supporting the rare disease community, ensuring reliable and secure access to medicines, giving a voice to patients and enabling connectedness. A strong pipeline and expanded access through geographical expansion are key elements of Sobi's commitment, which puts patient safety first by adhering to the highest pharmaceutical standards.

Always act responsibly – through strong business ethics and measures aimed at creating a healthy and well-functioning organisation that has the aim to serve the international community. Sobi shows its commitment by setting ambitions and targets to improve the company by understanding and mitigating its impacts throughout the value chain. It does this by working together with partners to reduce its total environmental footprint, and by striving to make a positive contribution to individuals and societies.

Sobi is a signatory to the ten principles of the UN Global Compact on human rights, labour, environment and anti-corruption. It has integrated the principles into its core business operations and reports its progress to "Advanced level". Sobi's sustainability strategy is based on its commitment to the UN Sustainable Development Goals (SDGs) and the Paris Agreement. A complete description of Sobi's sustainability ambitions and progress can be found in the integrated sustainability report.

Sobi's strategy has four strategic business priorities:

- Lead in Haematology
- Grow Immunology and Specialty Care
- Go global
- Capture the value of the pipeline

... and two strategic sustainability priorities:

Maintain commitment to patients

- Access to treatment
- Patient centricity and engagement
- Patient and product safety
- Ethical marketing and sales
- Transparent and ethical R&D

Always act responsibly

- An inclusive and diverse workplace that grows people
- Safe, healthy and fair working conditions
- Reduction of environmental footprint
- Responsible sourcing
- Compliance and corruption prevention

Commitment to the UN Global Compact. Contribution to the 2030 Agenda, the UN Sustainable Development Goals and the Paris Agreement

Maintain commitment to patients

Sobi's business strategy reflects its ambition and commitment to reach more people in more countries with novel and transformative medicines in areas of high unmet medical need.

Patient access

In 2022, Sobi continued to increase access to medicines. Aspaveli/Empaveli was launched in several countries in Europe, including Germany, the UK and Italy, and in Saudi Arabia as the first Sobi country outside Europe. With Gamifant, Sobi obtained its first approval in China. The company's presence in Japan was expanded through a distribution agreement. Kineret was authorised in the US in emergency cases to treat COVID-19. Orfadin also obtained more approvals during the year in selected Latin American and Middle Eastern countries.

During the year, Sobi increased the number of people it reached to approximately 75,000 measured in full-time equivalent patients. One of Sobi's objectives for 2025 is to reach twice as many patients compared with 2020.

In 2022, Sobi continued to participate in the dialogue on the EU Pharmaceutical Strategy to tackle important challenges for European patients and the health sector and ensure access to affordable medicine. It also advocated for support of people living with rare diseases through collaboration within trade organisations.

Community engagement

Sobi engages with patient organisations and networks in clinical development to design clinical studies and create solutions with and for the patient community. By embedding experience and input from patient communities, Sobi helps to ensure that future medicines help address real patient needs.

The company continued its partnership with the European Patients' Academy on Therapeutic Innovation (EUPATI) and Patient Focused Medicine Development (PFMD) to support the education and involvement of the patient

Support for aid program

As Founding Visionary Contributors, Sobi and Sanofi continued to support the WFH Humanitarian Aid Program in 2022. The companies are donating up to 500 million international units (IU) of factor medicine for humanitarian use to fulfil their 2014 pledge to donate up to an unprecedented 1 billion IU over a ten-year period. Since the initial pledge, over 20,200 people with haemophilia (18,880 in 2021) have been treated with factor medicine donated by Sobi and Sanofi.

By providing a more predictable and reliable flow of medicines, the WFH Humanitarian Aid Program allows people to receive consistent and reliable access to medicines and care. In addition, the educational training for treaters and patients made possible by the Program are critical for developing domestic capacities to improve diagnosis and treatment monitoring and enabling long-term sustainable change. Donations do not provide long-term or sustainable access to treatment, and the ambition is therefore to transform donations to access within regulated healthcare systems.

Over

20,200

people reported treated since programme start

648

surgeries in 2022

Over

32,800

acute bleeds treated in 2022

In total

661 M

IU of factor donated

community in clinical studies. By the end of 2022, it had established four international patient councils to advise on early clinical development.

Sobi supports the rare disease community including bodies such as patient organisations Rare Disease Europe (EURORDIS) and, in the US, the National Organization for Rare Disorders (NORD). Sobi continued to support the haemophilia community through its patient-centric vision in haemophilia 'Liberate Life', and its online resource centre, which is available in 25 local and regional versions.

Focus on patient safety

Providing safe medicines represents Sobi's license to operate. Safety surveillance, pharmacovigilance, is integrated across the life cycle of medicines to allow potential safety risks to be identified and mitigated to minimise or avoid harm. Sobi's global safety organisation focuses on the detection, assessment, understanding and the prevention of adverse effects, and the correct management of safety information is subject to regular employee training.

Pipeline focused on unmet medical need

In 2022, Sobi's pipeline was expanded to include more new medicines and studies in multiple indications and countries, which makes more medicines available to more people. To realise the potential of the portfolio, the R&D budget was relatively stable at 12 per cent of revenue for 2022 (13 per cent in 2021).

At year-end, Sobi's pipeline consisted of eight medicines or potential new medicines in around 15 projects from phase 2 through registration. Several medicines in the pipeline either have novel mechanisms of action or are unique in their disease. Orphan drug regulations can shorten time to patient.

Sobi's development strategy also includes exploring innovative approaches that help optimise outcomes. Florio, a Sobi company, develops the next generation of digital solutions in collaboration with doctors and patients. Florio solutions capture and visualise disease and treatment-related data in real time to enable better decision-making and care for both paediatric and adult patients. florio HAEMO, a solution for people with haemophilia, their caregivers and healthcare professionals, is available in more than 25 countries across Europe and the Middle East and during 2022, florio ITP, a solution for people with immune thrombocytopenia, was launched in some European countries.

Medical advancements

Sobi regularly participates in scientific meetings to share medical advancements to enhance the practice of medicine. In 2022, Sobi participated in events such as the WFH World Congress, the International Society on Thrombosis and Haemostasis, ISTH, and the 64th American Society of Hematology Annual Meeting and Exposition.

Sobi is a long-term supporter of the WFH and the European Haemophilia Consortium (EHC). Sobi's annual support to the WFH Corporate Partner Program continues to enable country development programmes, educational resources, training for healthcare professionals, capacity building and training for patients, and patient organisations as well as support for the World Bleeding Disorder Registry. The company's EHC sponsorship enables capacity building across Europe, including youth leadership and the activation of the youth community in Europe.

~15

projects from phase 2 through registration

8

medicines or potential new medicines in development

Always act responsibly

Sobi aims to always act ethically and expects the highest standards of ethical behaviour from its employees. The company offers a healthy workplace with continuous professional development opportunities.

Caring for employees

Sobi's workforce is key to its ability to deliver on its strategy. The company is committed to an inclusive, sustainable and flexible workplace that fosters growth, develops professionals from different backgrounds and that provides a supportive culture. Sobi works to enable its people to achieve their full potential, recognises effort and rewards impact.

Diversity, equity and inclusion (DEI)

During the year, a company-wide DEI initiative was commenced with an external and internal mapping of best practice. A work group leads the initiative with a wide representation from different functions, geographies and cultural backgrounds. The initiative is sponsored by the senior management team. Targets and activities will be set in 2023.

Global employee engagement survey

The results from the 2022 employee survey were slightly lower, in parts presumably due to the societal effects of COVID-19 and the extended company bid process in 2021. The response rate continued to be high and there were positive signs from work-life balance initiatives and around employee workload.

Leadership

A global leadership competency model was established during 2022 that identified the desired qualities of Sobi leaders. This model will be further developed in 2023 and will fuel Sobi's people management processes.

Dedication to ethics and zero tolerance for corruption

The Sobi Code of Conduct and the Sobi values are tools to support the company's ambition to always act responsibly. Sobi's Code is available to internal as well as external stakeholders, and the whistle-blower hotline has been extended to include external parties.

Sobi's compliance programme aims to foster a culture of ethical decision-making as well as to prevent non-compliant behaviour from taking place. During the year, a new global operating procedure governing compliance monitoring and self-inspections was implemented. Furthermore, an updated global Investigations policy was launched in accordance with the EU Whistleblowing Directive.

The Corporate compliance committee consisting of the CEO, CFO, General Counsel and Chief Compliance Officer has oversight of compliance investigations. This ensures both non-retaliation against whistle-blowers and organisational fairness in the application of sanctions. In 2022, 12 cases were reported and investigated.

Expansion into new countries and the introduction of new employees into the company require the continuous revision of policies, systems and training. This ensures high standards are maintained, and that all new employees receive the proper training as part of their induction programmes. Training on Code of Conduct and anti-corruption and anti-bribery are mandatory every second year. In 2022, 97 per cent (95 per cent in 2021) of eligible Sobi employees completed the Code of Conduct training and 96 per cent (96 per cent in 2021) completed the anti-corruption and anti-bribery training.

83%

renewable energy in Sobi operations

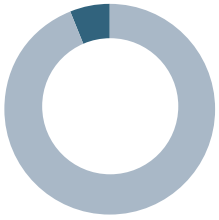
97%

completed Code of Conduct training

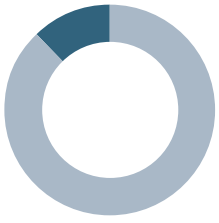
Proportion of suppliers with implemented practices

Calculated as share of contract manufacturers reporting in EcoVadis who have implemented these principles.

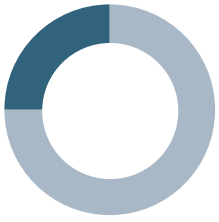
Actions on energy consumption & GHGs



Use of renewable energy



Audit or assessment of suppliers on CSR issues



Support for Ukraine

To help address the immediate humanitarian needs in Ukraine, Sobi donated SEK 1 M to the Red Cross in Sweden in 2022 to support relief efforts in Ukraine.

Responsible sourcing

As Sobi's supply chain is outsourced, it relies on sustainable and dependable suppliers to produce, pack and distribute medicines. Therefore, a large part of Sobi's sustainability impact occurs outside its own operations.

Sobi is part of the Pharmaceutical Supply Chain Initiative (PSCI), a non-profit business membership organisation driving excellence in safety, environmental and social outcomes for the entire global pharmaceutical and healthcare supply chain. The PSCI brings together members to define, establish and promote responsible supply chain practices, human rights, environmental sustainability and responsible business.

Sobi also uses the EcoVadis sustainability reporting platform to monitor and drive the performance and progress of its supply chain partners in terms of the environment, labour and human rights, ethics and sustainable procurement.

Supplier status and progress is followed up in Sobi's regular business review meetings with each supplier, and improvement targets are set, based on the company's sustainability priorities.

Reducing the environmental footprint

Direct and indirect emissions from Sobi's own operations (scope 1 and scope 2) are limited. Sobi tracks its emissions in a common reporting platform that includes all global operations and entities.

All electricity consumed at Sobi's Stockholm manufacturing facility originates from certified renewable energy sources.

By reducing energy consumption, increasing efficiency and switching to renewable energy, Sobi aims to achieve net zero emissions from its sites and car fleet no later than in 2030. In 2022, Sobi completed a mapping of its other indirect (scope 3) emission categories and quantified all relevant categories through a mix of supplier specific data and spend-based emission factors for the first time. Sobi's mapping shows categories 1, 4 and 6 to be the main contributors to scope 3 emissions and scope 3 by far stand for the majority of emissions connected to Sobi. Further information in section Indirect greenhouse gas emissions.

As a part of its Responsible Sourcing Programme, Sobi integrates follow-up on suppliers' progress on climate goals in all relevant supplier categories.

Sobi's GHG emissions in tonnes CO_2

Scope 1	Direct emissions from Sobi's own operations	787
Scope 2	Indirect emissions from Sobi's own operations	563
Total emissions Scope 1 & 2:		1,351
Scope 3	Other indirect emissions that occur in Sobi's value chain	703,174

The Sobi Responsible Sourcing Programme is based on three pillars

One

Alignment of values and principles

Sobi ensures alignment with partners through its Partner Code of Conduct, which is a document that suppliers must adhere to as part of their Sobi contract.

Two

Supplier risk assessment and qualification

Sobi evaluates prospective and current partners and performs due diligence and screening for compliance with management, labour, human rights and environmental standards. The company customises its approach, depending on the geographic and supplier category risk profile as well as the strategic importance of the supplier.

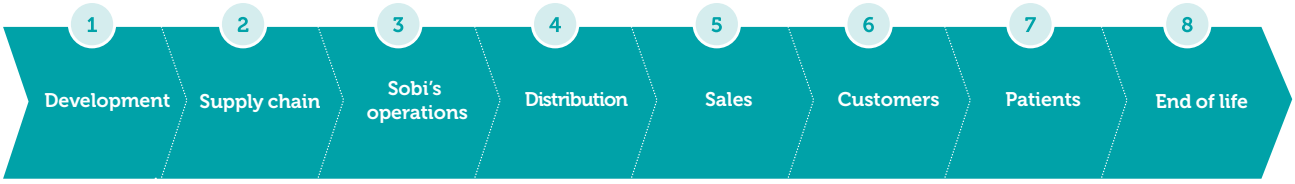
Three

Performance management and monitoring

Sobi strives to reduce complexity by using common platforms to drive supplier performance. These also allow targets, activities and progress to be shared more effectively between suppliers and customers within the pharmaceutical industry.

Sustainability value chain

Sobi applies a value chain perspective to understand its actual and potential impacts and ability to influence. This analysis helps define how best to contribute positively and minimize negative impacts, and it shapes Sobi's sustainability strategy.



1. Development

All development activities are conducted by or together with external partners. Sobi's best ability to influence lies in the choice of partners, making strict and well-functioning due diligence processes critical. The patient community is Sobi's most important stakeholder and understanding and meeting patients' needs is critical. Sobi puts great emphasis on involving patients in the design of studies and co-creation of solutions.

2. Supply chain

Sobi's medicine supply chain is almost entirely outsourced to external partners, with manufacturing in several steps from active pharmaceutical ingredient to ready and packed medicine. Within these long-term relationships, Sobi can monitor and influence environmental and social impacts connected to these companies' manufacturing processes and operations.

3. Sobi's operations

Except for a small manufacturing unit in Sweden, Sobi's operations are dedicated to developing, commercialising and bringing medicines to people across the world. Environmental impacts of operations are limited, well mapped and actively managed. As an employer, Sobi can make a positive difference for its employees and strives to create a healthy, safe and fair work environment.

"Respect and support for the rights, safety and well-being of patients is at the core of Sobi's processes."

4. Distribution

Sobi delivers medicine to all continents, with the help of its transport and logistics partners. This causes an impact, primarily connected to consumption of energy and emissions. Through the choice of partners, and an active relationship management, Sobi's ability to influence is high.

5. Sales

Sobi's commercial teams work with healthcare stakeholders in all markets with Sobi presence. The pharmaceutical industry is exposed to several types of compliance risks and therefore a highly regulated sector. Through strong compliance processes, Sobi has a high ability to prevent potential negative impact. Sobi contributes positively through providing new knowledge for healthcare professionals and patient organisations.

6. Customers

Healthcare providers and organisations are the link between Sobi and patients. These organisations have a need for responsible and reliable partners that help them to reduce their environmental footprint while fulfilling their responsibilities to patients and society. Sobi's responsibility is to contribute to this.

7. Patients

Sobi has the ability to provide a large positive impact for patients. Respect and support for the rights, safety and well-being of patients is at the core of Sobi's processes both in direct collaboration with patients and patient organisations as well as in all other stakeholder interactions.

8. End of life

Unused medicine, packaging or medical devices generates waste. Sobi has a large possibility to influence returns management, packaging efficiencies and information to end users on proper disposal.

Details of how Sobi contributes and manages impact can be found in the Sustainability report. Sobi's business priorities are detailed in the section Business model.

Share info

Swedish Orphan Biovitrum AB (publ) is listed on Nasdaq Stockholm under the symbol SOBI.

In 2022, the share price increased by 16.5 per cent to SEK 215.70. The highest closing price was SEK 245.50 on 25 August and the lowest was SEK 176.25 on 25 January. Sobi's market capitalisation at year-end 2022 was SEK 66.8 B.

Turnover and trading locations

The Sobi share is traded on Nasdaq Stockholm and several trading platforms. In 2022, trading on Nasdaq Stockholm accounted for ~45 per cent of the total turnover.

The average daily turnover in Sobi shares was 513,536 in trading on Nasdaq Stockholm and 1,144,353 in total. 133.5 million shares were traded during 2022 on Nasdaq Stockholm and 297.5 million shares in total, corresponding to a value of approximately SEK 28 B and SEK 62.3 B, respectively.

Share capital

On 31 December 2022, the total number of shares amounted to 309,804,782. Excluding treasury shares, the number of shares was 296,015,059. All issued shares are ordinary shares with a par value each of SEK 0.55 and carry one vote per share.

Incentive programmes

Sobi has launched several share-based incentive programmes for senior executives and employees. Currently, there are three active share programmes, all vesting within three years. The programmes represent a total maximum of 3,001,220 shares, or 1.0 per cent of the total number of shares in the company. During the year, 365,622 shares were used for allotment under one performance-based long-term share programme. For the CEO, senior executives and pre-selected key employees the programmes consist by half of share options. During the year, 491,835 options were allotted under the programme. The programmes represent a total maximum of 5,699,055 share options.[1]

Shareholders

On 31 December 2022, the number of shareholders was 21,914. The largest shareholder, Investor AB, held 34.7 per cent of the shares. Swedish legal entities, including institutions and private individuals, held 63.4 per cent of the shares. Shares held by Sobi at year-end totalled 13,789,723 shares.

Dividend

The board proposes that no dividend be paid for 2022. For more information about Sobi's dividend policy, please refer to the corporate governance report.

1. More options are granted than shares as options are valued through Black-Scholes model which includes several parameters, including volatility, type of option, underlying share price, time, strike price and risk-free interest rate. In addition, options have no value below the strike price.

Largest shareholders on 31 December 2022[i]

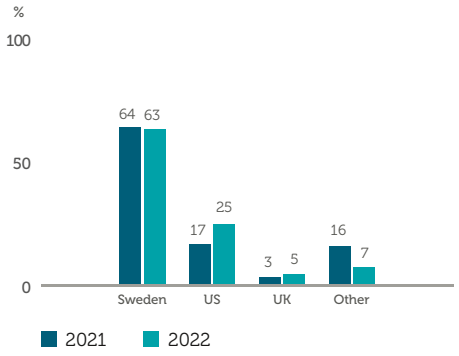
Shareholder	Number of shares	Share capital, per cent	Share votes, per cent
Investor AB	107,594,165	34.7	34.7
AstraZeneca PLC	30,661,512	9.9	9.9
Fjärde AP-fonden	20,107,765	6.5	6.5
State Street Bank and Trust Co. (nominee)	15,815,684	5.1	5.1
Swedish Orphan Biovitrum AB (publ)	13,789,723	4.5	4.5
J.P. Morgan Chase Bank NA (nominee)	12,160,973	3.9	3.9
Northern Trust Company, London branch (nominee)	7,656,644	2.5	2.5
Swedbank Robur Fonder	6,088,150	2.0	2.0
Handelsbanken Fonder	6,053,900	2.0	2.0
BNY Mellon SA/NV (nominee)	5,997,569	1.9	1.9
BNY Mellon NA (nominee)	4,715,645	1.5	1.5
CBNY-Norges Bank	4,504,567	1.5	1.5
Folksam	2,945,489	1.0	1.0
Livförsäkringsbolaget Skandia, ömsesidigt	2,215,731	0.7	0.7
BNPP NYB PB clearance (nominee)	2,144,077	0.7	0.7
Nordea Investment Funds	2,116,065	0.7	0.7
SEB Investment Management	2,029,478	0.7	0.7
Brown Brothers Harriman & Co	1,850,186	0.6	0.6
HSBC Bank PLC (nominee)	1,803,387	0.6	0.6
Länsförsäkringar fondförvaltning AB	1,709,782	0.6	0.6
Top-20 shareholders	251,960,492	81.3	81.3
Other	57,844,290	18.7	18.7
Total	**309,804,782**	**100**	**100**

i. The shareholders are presented as they appear in the shareholder register held by Euroclear Sweden AB. The list may therefore not show shareholders whose shares have been registered in the name of a nominee, through the trust department of a bank or similar institution. Euroclear is the source for all shareholder information in this section.

Shareholder categories

31 December 2022	Per cent of capital
Foreign shareholders	36.6
Swedish shareholders	63.4
whereof	
Institutions	60.6
Individuals	2.8

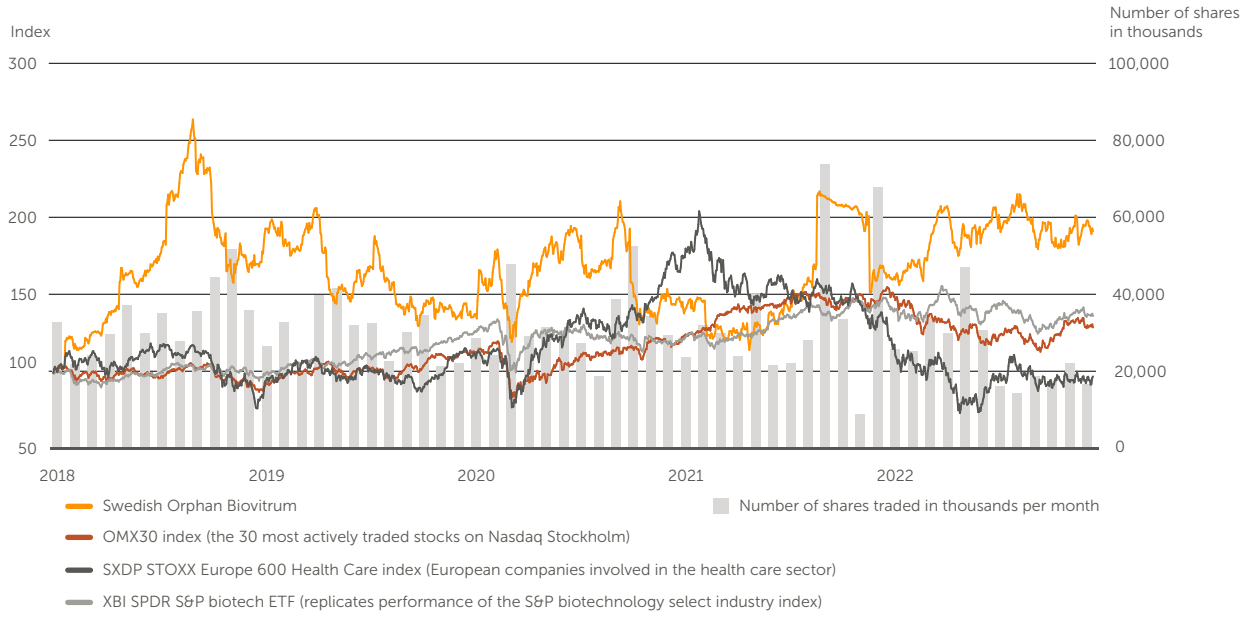
Shareholding by country



Key data per share

SEK	2018	2019	2020	2021	2022
Earnings/loss per share	8.97	11.29	11.01	9.08	8.92
Equity per share	33.1	56.4	66.5	75.6	85.6
Last price paid, 31 December	193.0	154.5	166.1	185.1	215.7
P/E ratio	21.5	13.7	15.1	20.4	24.2
Number of shares, 31 December	273,322,117	299,977,839	303,815,511	307,114,495	309,804,782

Sobi share price and trading volume 2018–2022



Data from Bloomberg.

Five-year summary

	2018	2019	2020	2021	2022
Income statement, SEK M					
Total revenue	9,139	14,248	15,261	15,529	18,790
Gross profit	6,723	10,913	12,036	12,045	14,014
EBITDA[i]	3,607	6,121	6,841	5,740	6,231
EBITA[i]	3,571	5,933	6,700	5,575	5,930
EBITA adjusted[i, ii]	3,571	6,145	6,301	5,575	6,605
EBIT (operating profit)	3,122	4,533	4,818	3,733	3,813
Profit for the year	2,418	3,304	3,245	2,679	2,638
Capital, SEK M					
Total assets	17,183	45,658	48,283	48,661	52,496
Capital employed[i]	9,048	33,560	34,777	34,109	35,626
Equity	9,040	16,930	20,206	23,203	26,525
Cash and cash equivalents	2,999	737	404	1,045	1,361
Net debt (+)/net cash (–)[i]	-2,999	15,404	13,748	9,500	7,406
Cash flow, SEK M					
Cash flow from operating activities before changes in working capital[iii]	2,341	5,300	5,367	4,356	5,472
Cash flow from financing activities[iii]	2,090	3,634	4,926	5,470	4,665
Cash flow from investing activities	-575	-21,686	-3,964	-367	-1,477
Cash flow from financing activities[iii]	-1	15,780	-1,282	-4,474	-2,991
Change in cash and cash equivalents	1,514	-2,271	-320	629	197
Key figures, %					
Gross margin[i]	74	77	79	78	75
EBITA margin[i]	39	42	44	36	32
EBITA margin adjusted[i, ii]	39	43	41	36	35
Return on capital employed[i]	34.5	13.5	13.9	10.9	10.7
Return on equity[i]	30.7	25.4	17.5	12.3	10.6
Equity ratio[i]	53	37	42	48	51
Debt/equity ratio[i]	90	170	139	110	98
Share ratio, SEK					
Earnings per share	8.97	11.29	11.01	9.08	8.92
Equity per share[i]	33.1	56.4	66.5	75.6	85.6
Cash flow per share[i]	5.6	-7.8	-1.1	2.1	0.7
Cash flow from operating activities per share[i]	7.8	12.4	16.7	18.5	15.8

i. Sobi presents certain financial measures in the Annual and sustainability report that are not defined according to the IFRS, so-called Alternative performance measures. These have been noted in the table above and further information on why these are considered important, and how they are calculated, can be found in Alternative performance measures at the end of this report.

ii. For further information regarding items affecting comparability (IAC) during 2022, please see Note 12 and Alternative performance measures. Year 2020 excluding non-recurring item; other operating income related to the reversal of the CVR liability of SEK 399 M. Year 2019 excluding non-recurring items; transaction costs related to the acquisition of Dova of SEK 92 M, restructuring costs of SEK 157 M and gain from divestment of SOBI005 of SEK 37 M.

iii. As of 2020, Sobi changed the form of presentation for the cash flow statement and reclassified hedging arrangements for financing from cash flow from operating activities to cash flow from financing activities.

Contents

Directors' report

The board of directors and CEO of Swedish Orphan Biovitrum AB (publ.), corporate organisation number 556038-9321, submit the following Annual report and consolidated financial statements for the 2022 financial year.

Highlights 2022

Financial highlights

- Total revenue amounted to SEK 18,790 M (15,529), an increase of 21 per cent and 8 per cent at constant exchange rates (CER).
- Revenue in Haematology amounted to SEK 10,831 M (8,536), an increase of 27 per cent and 15 per cent at CER.
- Revenue in Immunology amounted to SEK 6,679 M (5,780), an increase of 16 per cent and a decrease of 1 per cent at CER.
- The gross margin was 75 per cent (78).
- Operating profit was SEK 3,813 M (3,733), an increase of 2 per cent.
- EBITA was SEK 5,930 M (5,575), an increase of 6 per cent.
- EBITA adjusted was SEK 6,605 M (5,575) and excludes IAC of SEK 675 M. The EBITA adjusted margin was 35 per cent (36). See Alternative performance measures for further information.
- Profit for the year totalled SEK 2,638 M (2,679), representing earnings per share before dilution of SEK 8.92 (9.08). Please see Note 25 and Alternative performance measures for earnings per share adjusted.
- Cash flow from operating activities was SEK 4,665 M (5,470), a decrease of 15 per cent.

Business highlights

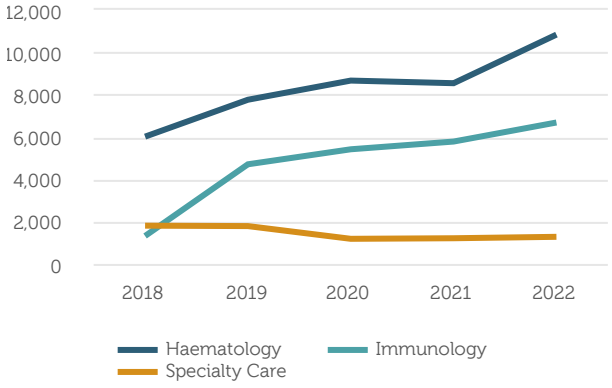
- Gamifant was approved in China for the treatment of HLH.
- The FDA granted Breakthrough Therapy designation to efanesoctocog alfa for haemophilia A which was then approved in 2023.
- Sobi signed an exclusive licence agreement with ADC Therapeutics to develop and commercialise Zynlonta for use in haematology and other indications of large unmet medical need in Europe and most international markets.
- Zynlonta was approved in the EU for the treatment of relapsed or refractory diffuse large B-cell lymphoma.
- Kineret was granted Emergency Use Authorisation by the FDA for the treatment of COVID-19 related pneumonia.
- During the year, Sobi announced that its contract with Pfizer for manufacture of the drug substance for ReFacto AF®/Xyntha® will now expire in the first quarter of 2024, instead of the end of 2025. Manufacture will be transferred to Pfizer, ensuring continued patient access. A process to reduce manufacturing began in the second half of 2022 and the final volumes are expected to be delivered to Pfizer in early 2024.

SEK M	2022	2021
Total revenue	18,790	15,529
Gross profit	14,014	12,045
Gross margin[i]	75 %	78 %
EBITA[i]	5,930	5,575
EBITA adjusted[i, ii]	6,605	5,575
EBITA margin[i]	32 %	36 %
Adjusted EBITA margin[i, ii]	35 %	36 %
Profit for the year	2,638	2,679
Earnings per share, before dilution, SEK	8.92	9.08
Earnings per share, before dilution, SEK adjusted[i, ii]	10.77	9.08

i. See Alternative performance measures.

ii. For IAC please see Note 12 and Alternative performance measures.

Five-year revenue trend



Sobi's operations

Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare and debilitating diseases. Providing reliable access to innovative medicines in the areas of haematology, immunology and specialty care, Sobi has approximately 1,600 employees across Europe, North America, the Middle East, Asia and Australia.

In 2022, revenue was generated by:

- Haemotology, through sales of the medicines Elocta, Alprolix, Doptelet and Aspaveli/Empaveli. Revenue is also derived from manufacture of the drug substance for ReFacto AF/Xyntha for Pfizer, and royalties on Sanofi's sales of Eloctate and Alprolix.
- Immunology, through sales of the medicines Kineret, Gamifant and Synagis.
- Specialty Care, through sales of the medicines Orfadin, Tegsedi, Waylivra and other medicines.

Total revenue by disease area

SEK M	2022	2021	Change
Elocta	4,402	3,960	11%
Alprolix	1,885	1,764	7%
Royalty	1,427	1,251	14%
Doptelet	2,526	1,116	126%
Aspaveli/Empaveli	178	1	>200%
Manufacturing	413	445	-7%
Haematology	**10,831**	**8,536**	**27%**
Kineret	2,284	2,290	–%
Synagis	3,501	2,650	32%
Gamifant	895	840	6%
Immunology	**6,679**	**5,780**	**16%**
Orfadin	462	459	1%
Tegsedi	429	427	1%
Waylivra	152	121	26%
Other Specialty Care	237	207	15%
Specialty Care	**1,280**	**1,213**	**6%**
Total	**18,790**	**15,529**	**21%**

Total revenue

Total revenue amounted to SEK 18,790 M (15,529), an increase of 21 per cent and 8 per cent at CER.

Revenue by disease area

Haematology

Revenue for Haematology amounted to SEK 10,831 M (8,536), an increase of 27 per cent and 15 per cent at CER.

Sales of Elocta amounted to SEK 4,402 M (3,960), an increase of 11 per cent and 5 per cent at CER. The performance benefited from continued growth in patients and consumption per patient. This was somewhat offset by unfavourable price developments and retroactive adjustments.

Sales of Alprolix amounted to SEK 1,885 M (1,764), an increase of 7 per cent and 1 per cent at CER. Growth in patients and consumption per patient were slightly offset by unfavourable price developments and retroactive adjustments.

Royalty revenue amounted to SEK 1,427 M (1,251), derived from Sanofi's sales of Eloctate and Alprolix.

Sales of Doptelet amounted to SEK 2,526 M (1,116), an increase of 126 per cent and 91 per cent at CER. including sales to the partner in China of SEK 1,102 M (404), up 173 per cent and 128 per cent at CER. In addition to China, growth was driven by increased uptake in the US and ongoing launches in Europe.

Doptelet entered the China NRDL in 2020 with renewal confirmed from 1 March 2023. Doptelet, and any approved avatrombopag generic from 2023, are anticipated to remain on the National Reimbursement Drug List (NRDL) until three avatrombopag generics have been approved for sale in China. At this point, a transfer to competitive volume-based procurement is anticipated.

Aspaveli/Empaveli sales were SEK 178 M (1) driven by ongoing launches. The number of patients reached ~100 at year-end.

Manufacturing revenue for ReFacto AF/Xyntha amounted to SEK 413 M (445), a decrease of 7 per cent.

Immunology

Revenue for Immunology totalled SEK 6,679 M (5,780), an increase of 16 per cent and a decrease of 1 per cent at CER.

Sales of Kineret remained unchanged SEK 2,284 M (2,290), a decrease of 11 per cent at CER. The decrease is mainly explained by reduced sales in COVID-19.

Sales of Synagis amounted to SEK 3,501 M (2,650), an increase of 32 per cent and 12 per cent at CER. This is mainly a reflection of increased use, positive price developments and a favourable comparative basis in the first quarter of 2022. This is a result of lower levels of RSV infections in the first quarter of 2021 due to COVID-19 related restrictions.

Sales of Gamifant amounted to SEK 895 M (840), an increase of 6 per cent and a decrease of 10 per cent at CER. Gamifant has reached high adoption in the US and declined mainly due to lower use in adults.

Specialty Care

Revenue for Specialty Care amounted to SEK 1,280 M (1,213), an increase of 6 per cent and a decrease of 5 per cent at CER, reflecting continued generic competition to Orfadin and fewer people treated with Tegsedi.

Total revenue by region

SEK M	2022	2021	Change
Europe	7,484	7,011	7%
North America	7,441	6,120	22%
Rest of the world	2,438	1,147	113%
Other[i]	1,427	1,251	14%
Total	**18,790**	**15,529**	**21%**

i. Refers to royalty on Sobi's haemophilia medicines that are not attributable to a specific region according to the split above. All royalties refer to Sanofi's sales of Eloctate and Alprolix.

Items affecting comparability (IAC)

In the first half of 2022, Sobi took steps to restructure its business through certain efficiency programmes for which total costs of SEK 569 M were recognised over the same period. The programmes refer to the discontinuation of contract manufacturing for Pfizer, the consolidation of a legacy site in Geneva into Basel and the restructure of selling and administrative and R&D functions to appropriately support the business.

Due to the sanctions against Russia, a provision was made for expected credit losses towards customers in Russia, amounting to SEK 106 M at the end of the year. Total IAC for the year amounted to SEK 675 M (-), please see Note 12 and Alternative performance measures for further information.

Gross profit

Gross profit totalled SEK 14,014 M (12,045), representing a gross margin of 75 per cent (78). The margin reduction was driven by an unfavourable business mix, primarily attributable to significant sales of Doptelet to the partner in China. Gross profit also includes IAC of SEK 363 M linked to the termination of contract manufacturing for Pfizer. The gross margin excluding IAC was 77 per cent (78).

Operating expenses

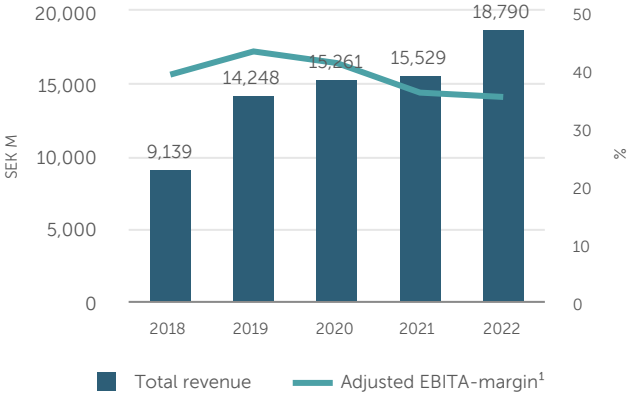
Operating expenses amounted to SEK 10,201 M (8,312), an increase of 23 per cent.

Sales and administrative expenses amounted to SEK 7,847 M (6,294) and included IAC of SEK 210 M and amortisation of SEK 2,117 M (1,841). Excluding IAC and depreciation, the increase was 24 per cent, reflecting launch preparations and activities for Aspaveli/Empaveli, Doptelet and Zynlonta.

Research & development costs amounted to SEK 2,354 M (1,994) and included IAC of SEK 102 M. Excluding IAC, the increase was 13 per cent. The increase was mainly driven by the development programmes for Aspaveli/Empaveli and efanesoctocog alfa, as well as development costs for Zynlonta.

Other operating income and expenses amounted to SEK -1 M (-24).

Total revenue and adjusted EBITA margin[1]



1. See Alternative performance measures.

Operating profit

EBITA amounted to SEK 5,930 M (5,575), corresponding to a margin of 32 per cent (36). For EBITA adjusted see Alternative performance measures. Operating profit (EBIT) totalled SEK 3,813 M (3,733), an increase of 2 per cent. Amortisation and impairment of intangible assets amounted to SEK 2,117 M (1,841).

Net financial items

Net financial items amounted to SEK -492 M (-438). The increase mainly reflected higher interest rates on loans.

Income tax

Recognised income tax amounted to SEK -683 M (-616) of which SEK -628 M (-659) pertained to current tax and SEK -55 M (43) to deferred tax. The effective tax rate was 20.6 per cent (18.7). The lower rate in 2021 was mainly related to capitalisation of losses from prior years. See also Notes 15 and 20.

Profit

Profit for the year totalled SEK 2,638 M (2,679). Earnings per share before dilution amounted to SEK 8.92 (9.08).

Cash flow

Cash flow from operations before changes in working capital was SEK 5,472 M (4,356). Working capital had an impact of SEK-807 M (1,114) on cash flow, reflecting increased receivables driven by Synagis due to a later start of the US RSV season compared with 2021 and the timing of receivables payment. Retroactive rebate payments attributable to Europe and phasing of rebate payments for Synagis, following the US labeller transition to Sobi during the fourth quarter of 2021, also had a negative impact on working capital. This was partially offset by the timing of inventory purchases. Cash flow from operating activities therefore amounted to SEK 4,665 M (5,470).

Cash flow from investing activities was SEK -1,477 M (-367). 2022 included an upfront payment of SEK -588 M to ADC Therapeutics for Zynlonta, a milestone payment of SEK -479 M to Apellis for Aspaveli/Empaveli, a milestone payment of SEK -115 M to Eisai for Doptelet and a milestone payment of SEK -106 M to Selecta for SEL-212.

Cash flow from financing activities was SEK -2,991 M (-4,474). During the year, loan repayments were possible due to the strong cash flow from operating activities.

The regulatory submission acceptance of nirsevimab in the US in January 2023 triggered a milestone payment of USD 175 M to AstraZeneca in February 2023.

Five-year summary

SEK M	2022	2021	2020	2019	2018
Total revenue	18,790	15,529	15,261	14,248	9,139
Cost of goods sold	-4,776	-3,484	-3,225	-3,335	-2,415
Research and development costs	-2,354	-1,994	-1,594	-1,495	-1,090
Operating profit	3,813	3,733	4,818	4,533	3,122
Net financial items	-492	-438	-601	-286	-40
Profit for the year	2,638	2,679	3,245	3,304	2,418
Earnings per share, before dilution, SEK	8.92	9.08	11.01	11.29	8.97
Earnings per share after dilution, SEK	8.84	9.03	10.90	11.22	8.93
Number of shares, 000s	309,805	307,114	303,816	299,978	273,322
Equity/assets ratio[i]	51%	48%	42%	37%	53%

i. See Alternative performance measures.

Financial position

On 31 December 2022, cash and cash equivalents and current investments amounted to SEK 1,361 M (1,045).

On 31 December 2022, undrawn committed credit facilities amounted to SEK 5,440 M (4,336). Drawn credit facilities and issued commercial certificates totalled SEK 8,796 M (10,597). During the year Sobi established a commercial paper programme of up to SEK 4,000 M and a back-up facility of SEK 2,000 M. Please see Note 3 for more information about the maturity structure. On 31 December 2022, net debt was SEK 7,406 M (9,500). Net debt was mainly reduced by strong cash flow during the year.

Swedish Orphan Biovitrum AB (publ) and subsidiaries, ("the Group" or "Group") also has other non-interest-bearing financial liabilities that are recognised at discounted value and therefore generated interest expense, these liabilities are not included in net debt/net cash. For contractual obligations related to these liabilities, please see Note 28.

Equity

On 31 December 2022, consolidated equity amounted to SEK 26,525 M (23,203).

Parent Company

Swedish Orphan Biovitrum AB (publ) ("the Parent Company" or "Parent Company") is a specialised international biopharmaceutical company transforming the lives of people with rare and debilitating diseases.

Operating revenue amounted to SEK 13,381 M (12,401) and operating profit totalled SEK 2,761 M (4,383). The year-on-year cost increase reflected launch preparations and activities for Aspaveli/Empaveli, Doptelet and Zynlonta, restructuring costs, increased development costs and depreciation.

Profit for the year totalled SEK 2,451 M (1,790) and included reversal of a write-down of SEK 1,000 M for the value of shares in the subsidiary Swedish Orphan Biovitrum International AB following the progress of the launch of Gamifant.

Cash flow from investing activities amounted to SEK -1,289 M (-288), including an upfront payment of SEK -588 M to ADC Therapeutics for Zynlonta, a milestone payment of SEK -479 M to Apellis for Aspaveli/Empaveli and a milestone payment of SEK -106 M to Selecta for SEL-212.

On 31 December 2022, cash and cash equivalents amounted to SEK 1,146 M (878) and equity to SEK 21,627 M (19,069).

Pipeline

Sobi is concentrating on mid and late-stage opportunities that help address unmet medical needs and have significant market potential in the niches they serve. There are eight medicines or potential new medicines in around 15 projects from phase 2 through registration. In support of already marketed medicines, Sobi is conducting phase 4 studies to gather further evidence about their best use and potential expansion of patient benefits. Please refer to the section Pipeline for further information.

Pipeline events during the year

Haematology

Efanesoctocog alfa

Efanesoctocog alfa, a potential new medicine for haemophilia A, is in phase 3 clinical development in collaboration with Sanofi and was recently approved in the US.

Aspaveli/Empaveli

In February 2022, Aspaveli was approved in the UK for adults with paroxysmal nocturnal haemoglobinuria who become anaemic after receiving a C5 inhibitor for at least three months.

Doptelet

In March 2022, Sobi made a regulatory submission in Japan for Doptelet as a potential medicine for induced thrombocytopenia in chronic liver disease.

Zynlonta

In July 2022, Sobi announced an exclusive license agreement with ADC Therapeutics to develop and commercialise Zynlonta for use in haematology and other indications of large unmet medical need in Europe and most international countries. In December 2022, the EU approved Zynlonta for the treatment of relapsed or refractory diffuse large B-cell lymphoma, a debilitating disease in haematology.

Immunology

Kineret
In November 2022, Kineret was authorised by FDA for emergency use in the US for the treatment of COVID-19 in hospitalised adults with pneumonia who require supplemental oxygen (low- or high-flow oxygen) and were at risk of progressing to severe respiratory failure.

Gamifant
In March 2022, Gamifant was approved in China to treat adult and paediatric (new-born and older) patients with primary haemophagocytic lymphohistiocytosis with a refractory, recurrent or progressive disease or intolerance to conventional medicines.

Nirsevimab
In November 2022, it was announced that nirsevimab had been approved in the EU for the prevention of lower respiratory tract infections caused by the respiratory syncytial virus in new-borns and infants during their first RSV season. The approval was based on results from the nirsevimab clinical development programme, including the MELODY phase 3, MEDLEY phase 2/3 and phase 2b studies. The EU approval preceded a regulatory submission acceptance for nirsevimab in the US announced in January 2023.

Other information

Changes in management
In 2022, Anders Ullman replaced Ravi Rao, who stepped down and left Sobi, as new Head of Research & Development and Chief Medical Officer. In addition, Anne Marie De Jonge Schuermans has left Sobi, and Christine Wesström was appointed Head of Technical Operations and Pablo de Mora was appointed Head of Global Marketing and Access. Both are new members of the Executive committee.

In 2023, Lena Bjurner was appointed Head of Human Resources. Anders Ullman will retire during 2023 and will then be replaced by Anton Hoos as Head of Research & Development and Medical Affairs, Chief Medical Officer.

On 31 December 2022, the Executive committee consisted of:

Chief Executive Officer: Guido Oelkers
Chief Financial Officer: Henrik Stenqvist
Head of North America: Duane H. Barnes
Head of Europe: Sofiane Fahmy
General Counsel & Head of Legal Affairs and Head of Human Resources: Torbjörn Hallberg
Head of Strategic Transformation Operations: Mahmood Ladha
Head of Communication and Investor Relations: Thomas Kudsk Larsen
Head of Global Marketing & Access: Pablo de Mora
Head of International: Norbert Oppitz
Head of Strategy & Corporate Development: Daniel Rankin
Senior Scientific & Medical Advisor: Armin Reininger
Head of Research & Development and Medical Affairs, Chief Medical Officer: Anders Ullman
Head of Technical Operations: Christine Wesström

For more information about the Executive committee, please refer to pages 116-118.

Sustainability report
In accordance with the Chapter 6, Section 11 of the Swedish Annual Accounts Act, Sobi has elected to prepare a statutory sustainability report that is separate from the Annual report, which can be found on pages 22-27 and 119-159. The Sustainability report has been prepared accordance with GRI Standards 2021.

Corporate governance report
Under the Swedish Annual Accounts Act, Sobi is required to prepare a corporate governance report. In accordance with chapter 6, Section 8 of the Swedish Annual Accounts Act, Sobi has elected to prepare a corporate governance report that is separate from the Annual report. The corporate governance report can be found on pages 103-111 and 113-118.

Environmental permits

Sobi's production facility in Stockholm, Sweden, holds a permit for environmentally hazardous activities allowing the facility to produce a maximum of 1,000 tonnes of pharmaceuticals via industrial-scale chemical or biological reaction, including intermediates, per calendar year. Compliance with the permit conditions is disclosed in an environmental report to the local regulator. The conditions are mainly related to effluents and include a requirement to adjust the pH of the process water. Sobi has been granted REACH authorisation for the use of Triton X-100 at the production site. In Solna, Sweden, the company conducts activities that are notifiable under the conditions for facilities that professionally produce organic or inorganic compounds via chemical or biological reactions in test, pilot or laboratory scale, or other non-industrial scale. The company also has a permit for handling flammable products.

In 2022, no breaches of the conditions were reported by either of the facilities. While adaptation to current regulations has not, to date, had any adverse impact on Sobi's competitiveness or operations, the company cannot predict the impact of future regulations.

Share capital and ownership

On 31 December 2022, Sobi's share capital amounted to SEK 169,997,000, distributed between 309,804,782 shares, with a par value of SEK 0.55. On 31 December 2022, the total number of shares

outstanding, excluding treasury shares, was 296,015,059, each carrying one vote.

On 31 December 2022, Investor AB was Sobi's largest single shareholder with a total of 107,594,165 shares, representing 34.7 per cent of the votes and 34.7 per cent of the capital.

Share conversions

The annual general meeting (AGM) on 10 May 2022 authorised Sobi's board to resolve on an issue of C shares, and to repurchase all C shares issued in order to hedge long-term incentive programmes. The AGM also resolved to approve the board's proposed transfer of shares.

On 31 December 2022, Sobi held 13,789,723 shares in treasury (of which 1,830,525 ordinary shares were acquired during the year) with a par value of SEK 0.55, totalling SEK 7.6 M. The shares represent about 4.5 per cent of the total share capital. The shares were acquired by converting C shares for the purpose of allotment to the employees covered by Sobi's share-based incentive programmes. In 2022, 365,622 shares were allotted to employees and 491,835 options were allotted, in accordance with the terms of the programmes. The par value of these shares was about SEK 0.55, totalling SEK 0.5 M, and representing about 0.5 per cent of the total share capital. Please see Note 10 for more information about Sobi's outstanding share-based incentive programmes at the end of 2022.

All C shares issued in 2022 were converted to ordinary shares during the year. For more detailed information about the total number of shares in the company, the number of different classes of shares and the votes carried by the company's shares, please refer to Note 25 and the section Share info.

The board's proposed guidelines for senior executives

The 2020 AGM resolved on remuneration guidelines for the company's senior executives that apply until the 2024 AGM. In accordance with the EU's Shareholder Rights Directive (SRD II), a remuneration policy for 2022 will be presented to the 2023 AGM for adoption and be available on sobi.com three weeks prior to the meeting. For a complete version of the current guidelines, please refer to Note 10.

Proposed appropriation of profit

The following funds are at the disposal of the AGM:

SEK K	
Share premium reserve	9,418,774
Retained earnings	8,787,171
Profit for the year	2,450,755
Total	**20,656,700**

The board proposes that no dividends be paid for the 2022 financial year.

The board proposes that the share premium reserve, retained earnings and profit for the year, SEK 20,656,700 K, be carried forward.

The war in Ukraine

There are still uncertainties regarding how and to what extent Sobi's operations will be affected by the war in Ukraine. Sobi maintains an office in Moscow, Russia with ~45 employees. Sales in Russia corresponded to 1 per cent of total revenue for the year. At the end of the year, the net exposure in accounts receivables towards customers in Russia amounted to SEK 128 M, including a provision of SEK 106 M for expected credit losses. Sobi continues to follow the situation closely in order to comply with any rules and regulations implemented by governmental bodies at international level and to assess the potential and actual risks stemming from the situation.

Events after the reporting period

Efanesoctocog alfa

Efanesoctocog alfa, a new class of high-sustained factor VIII therapy for haemophilia A, was approved in the US.

Sobi and Sanofi announced positive topline results from pivotal XTEND-Kids phase 3 study of efanesoctocog alfa in children under 12 years of age with haemophilia A.

Nirsevimab

The regulatory submission acceptance of nirsevimab in the US in January 2023 triggered a milestone payment of USD 175 M to AstraZeneca in February 2023.

SEL-212

Sobi and Selecta announced positive topline results from the DISSOLVE phase 3 program of SEL-212 in chronic refractory gout.

Financial outlook for 2023

Sobi will continue to expand its presence in haematology, immunology and specialty care through ongoing launches, new medicines and geographic markets and anticipates sustained sales growth:

- Revenue is anticipated to grow by a low-to-mid single-digit percentage at CER

As Sobi continues to invest in launches and advance the pipeline of new medicines and emphasise the long-term value of the business, Sobi anticipates keeping a favourable EBITA adjusted margin:

- EBITA adjusted margin is anticipated to be at a low 30s percentage of revenue

The outlook continues to exclude any elements of Sobi's right to the full share of US profits and losses for nirsevimab.

Risk management

The aim of Sobi's risk management is to support the operations and create profitable business opportunities combined with good risk control. The risk management process contributes with structures and systems to proactively identify and manage risks that could have a negative impact on Sobi's ability to achieve its targets. Effective risk assessment aligns Sobi's business opportunities and value creation with the expectations of its shareholders and other stakeholders for sustainable, long-term value growth and control.

Sobi's risk management process is integrated, bottom-up and comprises the entire operations. Each operating unit works actively to identify and manage risks in order to achieve targets and deliver on strategies. Identified risks are analysed, managed and reported to Sobi's risk management function. Sobi's risk management function aggregates and consolidates these risks and presents a Group-wide risk map to the Executive committee and the board. Sobi's risk management process is described in the Sobi Group risk management policy and the Sobi Group risk management instructions.

This section lists the principal risks that could have a significant effect on the financial situation, results of operations, and/or reputation. It is outlined why effective management of these risks is important and relevant to the business, and how risks are managed. These risks are not listed in any particular order of priority.

The COVID-19 pandemic has had, and will likely continue to have, an impact on business, financial situation and results of operations. Sobi expects the COVID-19 pandemic to affect certain risks, such as risks related to demand for medicines, government priorities and healthcare systems, and so forth.

The conflict in Ukraine has affected Sobi's access to markets in Russia and Ukraine, as well as Sobi's ability to reach people.

The sustainability risks have been integrated with the existing risk management process for some time. But in 2022, for the first time, Sobi used scenario analysis, a key recommendation of the TCFD, to divide potential impacts into transitional and physical risks and opportunities. The findings of the analysis have been integrated with the overall risk assessment conclusions. An annual workflow has been established where climate and sustainability risks will be fed into the overall risk management process. For more information, please refer to climate-related risks and opportunities in the Sustainability report.

Pipeline

Risk area	Description	Management response
Development pipeline	Sobi is dependent on a few key medicines, and any event that adversely affects leading medicines could affect the business and financial position. The development of a new medicine is a complex, capital-intensive and overall risky process involving significant resources. A medicine could fail or be delayed at any stage of the process for a number of reasons, which may affect growth, revenue or profit.	A strong pipeline that enables the extension of existing medicines into new indications, and further expansion of the pipeline. Strengthen the pipeline through licensing and acquisition of medicines. Sobi is focused on late-stage development projects that address unmet medical needs and are deemed to have significant market potential.
Medicine approval	Prior to launch, a medicine must meet the strict quality, safety and efficacy requirements expected by regulators. Failure could lead to a delayed or cancelled launch and have a material adverse effect on the business and financial position.	Quality management systems in place. Monitoring of changes in the regulatory environment, including revised processes, timelines and guidance. Close management of clinical studies to ensure the evidence is aligned with regulators' demands.

Commercialisation

Risk area	Description	Management response
Market authorisation	Sobi's medicines are commercialised through marketing authorisation rights and the loss of, or inability to obtain or maintain, such rights could affect the business and financial results.	Strong focus to obtain and maintain marketing authorisation, especially for newly acquired medicines.
Pricing and competitive pressure	Sobi operates in a highly competitive market and marketing authorisation does not guarantee that the medicines will be granted pricing or reimbursement in the national or regional healthcare systems. In many countries, there is also pressure from governments and other healthcare payers on provider prices. A decline may lead to a reduction in revenue, cash flow and profit.	Value-based pricing model demonstrating the value and health economics of medicines. Close monitoring of changes in healthcare systems in relevant markets.
Market access	Sobi's ability to market medicines successfully depends, in part, upon the acceptance of, and access to, the medicines not only by people, but also by independent third parties, including public health insurers, doctors and pharmacists in the jurisdictions in which the company operates. Failure to access people and third parties may lead to lower demand for Sobi's medicines and affect the financial results.	Close collaboration with stakeholders throughout the entire development process to anticipate market needs and demands. The European Pharmaceutical Strategy, a collaboration on unmet medical needs and evidence generation. Sobi also advocates for support for people living with rare diseases by collaborating with trade organisations to promote knowledge sharing.

Business execution

Risk area	Description	Management response
Supply chain	Sobi relies on third parties to manufacture and distribute the medicines, which increases the risk that insufficient quantities of the medicines will be available at an acceptable cost or quality, on time or at all. As a result, current and anticipated future dependence upon others for the manufacture and distribution of the medicines may affect the business, results and financial position.	Good relationships with supplier networks, close monitoring and maintenance of stock levels, and clear expectations with well-developed forecasts create opportunities for securing access and delivery. Contingency plans including dual sourcing and multiple suppliers, where possible. Responsible sourcing programme.
IT and cybersecurity	An IT-system breakdown or cybersecurity incident could lead to a significant business disruption. This could also include disruptions to distributors, suppliers and other business partners. If a security breach were to result in a loss of data or damage, or inappropriate disclosure of confidential or proprietary information, Sobi could be held liable and the reputation could be harmed. This could have a material adverse effect on the business and financial position.	A stable IT environment, with reliable protection and robust infrastructure. Group-wide cybersecurity framework in place, including disaster and data recovery plans and strategies to secure critical systems and processes. Recurring cybersecurity training for employees.
Workforce	Sobi may be unable to recruit and retain key personnel, including skilled and qualified scientific, technical and commercial employees. The loss of any key personnel or the inability to attract, recruit and retain the highly skilled employees required for Sobi's activities may have a material adverse effect on the business and financial position.	Good working conditions, including development opportunities, well-being and job satisfaction. Leadership and competitive terms of employment. Ongoing strengthening of culture and brand including activities improving diversity, equity and inclusion.

Finance and taxation

Risk area	Description	Management response
Financials	Financial risks refer to fluctuations in exchange rates, interest rates, refinancing, liquidity and credit obligations. Negative impacts could affect the business and financial position.	Financial risk management is presented in Note 3.
Impairment of assets	Licensing and acquisition create intangible assets a material balance-sheet item. Impairment of intangible assets may adversely affect the financial position and results of operations. The future development of the macroeconomic environment, unsuccessful acquisitions or other factors could lead to significant impairment losses in the future, which could have a material adverse effect on the business and financial position.	Significant accounting judgements, and the estimates and assumptions entailing a considerable risk of material adjustment to carrying amounts, are presented in Note 4.
Tax	Sobi is subject to complex tax laws and operations include cross-border transactions. Changes in tax laws or challenges to the tax position could adversely affect the business, results and financial position.	Sobi pays corporate tax in a responsible way, implying that taxes are paid when profit is earned in accordance with international transfer pricing rules. Strong tax-compliance processes with strong collaboration between the Group Tax function and subsidiaries and external tax counsel when needed.

Legal, regulatory and compliance

Risk area	Description	Management response
Patient safety	Patient safety is very important and Sobi monitors the safety profiles of all medicines. Failure to do so could have a material adverse effect on reputation, business and financial results, and lead to liability claims.	All clinical studies are conducted and reported in accordance with the applicable regulatory requirements and good clinical practice. Compliance with the European Medicines Agency's policy on publication of clinical data for medicinal products for human use. Robust processes and systems in place to manage patient safety and efficacy trends. These include a worldwide service for adverse reactions reporting. Regular training for employees in patient safety.
Litigation and other claims	Sobi may occasionally be involved in litigation, including for example product liability claims or commercial disputes. Such events could lead to considerable costs for damages, legal fees and temporary or permanent bans on the marketing of certain medicines, and this could have a material adverse effect on the business and financial position.	Combined internal and external counsel management.
IP protection	Sobi's business depends on intellectual property and the ability to protect such intellectual property from third-party infringement. Sobi may be unable to protect intellectual property rights, trade secrets and unpatented property know-how, which could affect the business and financial position.	Active management of IP rights and IP litigation in all markets.
Regulatory compliance regarding business ethics, information security and data privacy	Failure to comply with applicable laws, rules and regulations, including anti-bribery, anti-corruption, information security or privacy legislation, may result in civil and/or criminal law cases and/or regulatory sanctions, fines or penalties, and affect reputation, business or financial results. Since Sobi's business relies on third parties for a large portion of the manufacturing and supply of medicines, this also includes all third parties.	Zero tolerance for unethical behaviour. Established compliance framework and governance systems owned by senior management. Extensive and recurring training for all employees. Whistleblowing system for internal and external parties. Third-party risk management and Responsible Sourcing Programme.
Regulatory compliance regarding sustainability including environmental, climate, health and safety	Any failure to comply with applicable laws, rules and regulations, including any failure with Sobi's business ambitions may result in regulatory sanctions, fines or penalties, and affect reputation, the business and financial results. Since Sobi's business relies on third parties for a large portion of the manufacturing and supply of medicines this also includes all third parties.	Sobi's board has overall responsibility for Sobi's sustainability performance. Climate change has been identified as a material issue. Plans and progress are reported to the board on a regular basis, together with the outcomes of sustainability risk assessments and adverse events. A more detailed description of sustainability risk management can be found in the Sustainability report, including the TCFD report.

Consolidated statement of comprehensive income

SEK M	Note	2022	2021
	1-4		
Total revenue	5	18,790	15,529
Cost of goods sold		-4,776	-3,484
Gross profit		**14,014**	**12,045**
Sales and administrative expenses		-7,847	-6,294
Research and development expenses		-2,354	-1,994
Other operating income	7	34	32
Other operating expenses	8	-35	-56
Operating profit	6, 9, 10, 11, 12, 16, 17, 29	**3,813**	**3,733**
Financial income	13	5	16
Financial expenses	14	-497	-454
Net financial items		**-492**	**-438**
Profit before tax		**3,321**	**3,295**
Income tax	15	-683	-616
Profit for the year[i]		**2,638**	**2,679**
Other comprehensive income[ii]	25		
Items that cannot be reclassified into profit or loss			
Remeasurement of defined-benefit pension plans and similar plans (net of tax)		60	17
Remeasurement of equity instruments (net of tax)		-76	11
Other comprehensive income that cannot be reclassified into profit or loss (net of tax)		**-16**	**28**
Items that may be reclassified to profit or loss			
Translation differences		880	464
Net investment hedges (net of tax)		-363	-242
Cash flow hedges (net of tax)		-85	-63
Other comprehensive income that may be reclassified to profit or loss (net of tax)		**432**	**159**
Other comprehensive income for the year		**416**	**187**
Total comprehensive income for the year[i, ii]		**3,054**	**2,866**
Earnings per share, SEK	25		
Earnings per share before dilution		8.92	9.08
Earnings per share before dilution, adjusted[iii]		10.77	9.08
Earnings per share after dilution		8.84	9.03
Earnings per share after dilution, adjusted[iii]		10.66	9.03

i. All attributable to Parent Company shareholders.

ii. Under amendments to IAS 1, all non-owner changes in equity are to be presented in the consolidated statement of comprehensive income. Translation differences are entirely related to the consolidated net assets of subsidiaries in foreign currency.

iii. Alternative performance measures, see at the end of this report.

Consolidated balance sheet

SEK M	Note	31-12-2022	31-12-2021
ASSETS	1-4		
Non-current assets			
Intangible assets	16	40,013	38,424
Tangible assets	17	274	493
Financial assets	19	121	199
Deferred tax assets	20	877	767
Total non-current assets		**41,285**	**39,883**
Current assets			
Inventories	21	3,332	3,424
Accounts receivable	22	5,249	3,439
Other receivables	22	558	345
Prepaid expenses and accrued income	23	710	525
Cash and cash equivalents	24	1,361	1,045
Total current assets	26	**11,210**	**8,778**
TOTAL ASSETS		**52,496**	**48,661**
EQUITY AND LIABILITIES			
Equity			
Share capital		170	169
Other contributed capital		10,211	9,945
Other reserves	25	351	-66
Retained earnings		13,155	10,476
Profit for the year		2,638	2,679
Equity attributable to Parent Company shareholders		**26,525**	**23,203**
LIABILITIES			
Non-current liabilities			
Borrowings	27	2,971	8,777
Deferred tax liabilities	20	3,797	3,605
Lease liabilities	9	200	247
Compensations post-employment benefits	29	87	148
Other provisions	30	159	86
Other liabilities, non-interest-bearing	28	3,899	3,834
Total non-current liabilities	26	**11,114**	**16,697**
Current liabilities			
Borrowings	27	5,796	1,768
Accounts payable		1,252	558
Tax liabilities		23	40
Lease liabilities	9	134	114
Other provisions	30	499	267
Other liabilities, non-interest-bearing	28	1,900	1,314
Accrued expenses and deferred income	31	5,253	4,700
Total current liabilities	26	**14,857**	**8,761**
TOTAL EQUITY AND LIABILITIES		**52,496**	**48,661**

Related to pledged assets and contingent liabilities, please see Note 32.

Consolidated statement of changes in equity

SEK M	Share capital	Other contributed capital	Other reserves[i]	Retained earnings and profit for the year	Total equity
Opening equity, 1 January 2021	**167**	**9,816**	**-253**	**10,476**	**20,206**
Comprehensive income					
Profit for the year	—	—	—	2,679	2,679
Other comprehensive income					
Remeasurement of defined-benefit pension plans and similar plans (net of tax)	—	—	17	—	17
Remeasurement of equity instruments (net of tax)	—	—	11	—	11
Other comprehensive income that cannot be reclassified into profit or loss (net of tax)	**—**	**—**	**28**	**—**	**28**
Translation differences	—	—	464	—	464
Net investment hedges (net after tax)	—	—	-242	—	-242
Cash flow hedges (net of tax)	—	—	-63	—	-63
Other comprehensive income that may be reclassified to profit or loss (net of tax)	**—**	**—**	**159**	**—**	**159**
Other comprehensive income	**—**	**—**	**187**	**—**	**187**
Total comprehensive income	**—**	**—**	**187**	**2,679**	**2,866**
Shareholder transactions					
Issue of shares	2	-2	—	—	—
Share-based compensation to employees	—	134	—	—	134
Tax adjustments for share programmes[ii]	—	-3	—	—	-3
Total shareholder transactions	**2**	**129**	**—**	**—**	**131**
Closing equity, 31 December 2021	**169**	**9,945**	**-66**	**13,155**	**23,203**

Opening equity, 1 January 2022	**169**	**9,945**	**-66**	**13,155**	**23,203**
Comprehensive income					
Profit for the year	—	—	—	2,638	2,638
Other comprehensive income					
Remeasurement of defined-benefit pension plans and similar plans (net of tax)	—	—	60	—	60
Remeasurement of equity instruments (net of tax)	—	—	-76		-76
Other comprehensive income that cannot be reclassified into profit or loss (net of tax)	—	—	**-16**	**—**	**-16**
Translation differences	—	—	880	—	880
Net investment hedges (net after tax)	—	—	-363		-363
Cash flow hedges (net of tax)	—	—	-85		-85
Other comprehensive income that may be reclassified to profit or loss (net of tax)	**—**	**—**	**432**	**—**	**432**
Other comprehensive income	**—**	**—**	**416**	**—**	**416**
Total comprehensive income	**—**	**—**	**416**	**2,638**	**3,054**
Shareholder transactions					
Issue of shares	1	-1	—	—	—
Share-based compensation to employees	—	261	—	—	261
Tax adjustments for share programmes[ii]	—	6	—	—	6
Total shareholder transactions	**1**	**266**	**—**	**—**	**268**
Closing equity, 31 December 2022	**170**	**10,211**	**351**	**15,793**	**26,525**

i. For a specification of Other reserves, please see Note 25.

ii. The change relates to the difference between the market value and recognised IFRS 2 costs.

Consolidated cash flow statement

SEK M	Note	2022	2021
Cash flow from operating activities			
Profit before tax		3,321	3,295
Non-cash items			
Depreciation/amortisation and impairment		2,419	2,006
Other non-cash items[i]		741	529
Cash items			
Interest received		5	0
Interest paid		-309	-324
Payment to pension funds		-32	-26
Income tax paid		-673	-1,124
Cash flow from operating activities before changes in working capital		**5,472**	**4,356**
Cash flow from changes in working capital			
Changes in inventories		413	-318
Changes in operating receivables		-1,982	452
Changes in operating liabilities		763	980
Cash flow from operating activities		**4,665**	**5,470**
Investing activities			
Investments in intangible assets[ii]	16	-1,405	-323
Investments in tangible assets	17	-72	-47
Disposal of tangible assets	17	—	3
Cash flow from investing activities		**-1,477**	**-367**
Financing activities			
Borrowings	27	13,675	14,193
Repayment of borrowings		-16,094	-18,191
Hedging arrangements for financing		-438	-351
Repayment of leasing		-133	-125
Cash flow from financing activities		**-2,991**	**-4,474**
Change in cash and cash equivalents		**197**	**629**
Cash and cash equivalents at beginning of year		**1,045**	**404**
Exchange difference in cash and cash equivalents		**119**	**12**
Cash and cash equivalents at year-end		**1,361**	**1,045**

i. 2022 refers mainly to restructuring costs, provision for expected credit losses in Russia, expensed interest costs and IFRS 2 costs on share-based compensation to employees.

ii. 2022 investments refers mainly to milestone payments linked to Aspaveli/Empaveli of SEK 477 M, Doptelet of SEK 115 M and SEL-212 of SEK 106 M and an upfront payment to ADC Therapeutics for Zynlonta of SEK 588 M.

Parent Company income statement

SEK M	Note	2022	2021
	1-4		
Total revenue	5	13,381	12,401
Cost of goods sold		-3,609	-2,933
Gross profit		**9,772**	**9,468**
Selling and administration expenses		-5,775	-4,179
Research and development expenses		-1,601	-1,256
Other operating income	7	428	353
Other operating expenses	8	-63	-3
Operating profit	6, 9, 10, 11, 12, 16, 17	**2,761**	**4,383**
Result from participation in Group companies	18	1,000	–
Financial income	13	489	336
Financial expenses	14	-931	-728
Net financial items		**558**	**-392**
Profit after financial items		**3,318**	**3,991**
Group contributions, net		-260	-1,113
Excess depreciation		-218	-600
Appropriations		**-478**	**-1,713**
Profit before tax		**2,840**	**2,278**
Income tax	15	-389	-488
Profit for the year		**2,451**	**1,790**

Parent Company statement of comprehensive income

SEK M	2022	2021
Profit for the year	2,451	1,790
Items that cannot be reclassified into profit or loss		
Remeasurement of equity instruments (net of tax)	-76	11
Items that may be reclassified to profit or loss		
Cash flow hedges (net of tax)	-85	-63
Other comprehensive income for the year	**-161**	**-52**
Total comprehensive income for the year	**2,290**	**1,738**

Parent Company balance sheet

SEK M	Note	31-12-2022	31-12-2021
ASSETS	1-4		
Non-current assets			
Intangible assets	16		
Licenses and patents		18	1
Product and marketing rights		10,394	9,634
Capitalised costs		370	261
Ongoing development work		312	211
Total intangible assets		**11,094**	**10,107**
Tangible fixed assets	17		
Plant and machinery		23	30
Equipment, tools, fixtures and fittings		13	35
Other non-current assets		1	1
Ongoing new construction		8	23
Total tangible fixed assets		**44**	**89**
Financial assets			
Participations in Group companies	18	8,676	7,676
Receivables from Group companies		13,318	14,298
Other financial assets	19	112	190
Deferred tax assets	20	125	27
Total financial assets		**22,231**	**22,192**
Total non-current assets		**33,369**	**32,387**
Current assets			
Inventories	21	2,703	2,536
Accounts receivable	22	995	1,126
Other receivables	22	462	292
Receivables from Group companies		5,508	4,308
Prepaid expenses and accrued income	23	611	455
Cash and cash equivalents	24	1,146	878
Total current assets		**11,426**	**9,595**
TOTAL ASSETS		**44,794**	**41,982**

SEK M	Note	31-12-2022	31-12-2021
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital		170	169
Statutory reserve		800	800
Total restricted equity		**970**	**969**
Unrestricted equity			
Share premium reserve		9,419	9,153
Retained earnings		8,787	7,157
Profit for the year		2,451	1,790
Total unrestricted equity		**20,657**	**18,100**
Total equity		**21,627**	**19,069**
Untaxed reserves			
Excess depreciation		3,909	3,691
Total untaxed reserves		**3,909**	**3,691**
LIABILITIES			
Non-current liabilities			
Borrowings	27	2,971	8,777
Other provisions	30	247	79
Other liabilities, non-interest-bearing	28	3,372	2,818
Total non-current liabilities		**6,591**	**11,674**
Current liabilities			
Borrowings	27	5,796	1,768
Accounts payable		958	359
Liabilities to Group companies		3,292	3,229
Other provisions	30	210	104
Other liabilities, non-interest-bearing	28	797	896
Accrued expenses and deferred income	31	1,614	1,192
Total current liabilities		**12,667**	**7,548**
TOTAL EQUITY AND LIABILITIES		**44,794**	**41,982**

Related to pledged assets and contingent liabilities, please see Note 32.

Parent Company statement of changes in equity

	Restricted equity		Unrestricted equity		
SEK M	Share capital	Other contributed capital	Other reserves	Retained earnings and profit for the year[i]	Total equity
Opening equity, 1 January 2021	**167**	**800**	**9,024**	**7,209**	**17,200**
Profit for the year	—	—	—	1,790	1,790
Other comprehensive income	—	—	—	-52	-52
Total comprehensive income	—	—	—	**1,738**	**1,738**
Shareholder transactions					
Issue of shares	2	—	-2	—	—
Share-based compensation to employees	—	—	134	—	134
Tax adjustments for share programmes[ii]	—	—	-3	—	-3
Total shareholder transactions	**2**	—	**129**	—	**131**
Closing equity, 31 December 2021	**169**	**800**	**9,153**	**8,948**	**19,069**
Opening equity, 1 January 2022	**169**	**800**	**9,153**	**8,948**	**19,070**
Profit for the year	—	—	—	2,451	2,451
Other comprehensive income	—	—	—	-161	-161
Total comprehensive income	—	—	—	**2,290**	**2,290**
Shareholder transactions					
Issue of shares	1	—	-1	—	—
Share-based compensation to employees	—	—	261	—	261
Tax adjustments for share programmes[ii]	—	—	6	—	6
Total shareholder transactions	**1**	—	**266**	—	**267**
Closing equity, 31 December 2022	**170**	**800**	**9,419**	**11,238**	**21,627**

i. See specification of other comprehensive income.

ii. The change relates to the difference between the market value and recognised IFRS 2 costs.

At year-end, Sobi's share capital amounted to SEK 169,997 K distributed between 309,804,782 ordinary shares with a par value of SEK 0,55 and one voting right. At the balance sheet date, Sobi held 13,789,723 ordinary shares in treasury, corresponding to 4.5 per cent of the total number of shares.

The table below shows a breakdown of Other comprehensive income and how each component has changed during the year.

Other comprehensive income	Cash flow hedges	Equity instruments	Total
Opening equity, 1 January 2021	**68**	**9**	**77**
Gain/loss from remeasurement of hedging instruments recognised in equity	-81	—	-81
Tax on gain/loss from remeasurement of hedging instruments recognised in equity	18	—	18
Transferred to profit or loss	1	—	1
Tax on transferred to profit or loss	0	—	0
Gain/loss from remeasurement of equity instruments recognised in equity	—	14	14
Tax effect on equity instruments	—	-3	-3
Closing equity, 31 December 2021	**6**	**20**	**25**
Opening equity, 1 January 2022	**6**	**20**	**25**
Gain/loss on remeasurement of hedging instruments recognised in equity	-151	—	-151
Tax on gain/loss from remeasurement of hedging instruments recognised in equity	31	—	31
Transferred to profit or loss	45	—	45
Tax on transferred to profit or loss	-9	—	-9
Gain/loss from remeasurement of equity instruments recognised in equity	—	-81	-81
Tax effect on equity instruments	—	5	5
Closing equity, 31 December 2022	**-78**	**-56**	**-134**

Parent Company cash flow statement

SEK M	Note	2022	2021
Cash flow from operating activities			
Profit after financial items		3,318	3,991
Non-cash items			
Depreciation/amortisation and impairment		559	385
Other non-cash items		-111	392
Cash items			
Interest received		496	273
Interest paid		-325	-406
Income tax paid		-489	-960
Cash flow from operating activities before changes in working capital		**3,449**	**3,675**
Cash flow from changes in working capital			
Changes in inventories		-205	-9
Changes in operating receivables		243	942
Changes in operating liabilities		1,944	2,250
Cash flow from operating activities		**5,430**	**6,858**
Investing activities			
Investments in intangible assets[i]	16	-1,277	-261
Investments in tangible assets	17	-12	-30
Disposal of tangible assets	16	—	3
Cash flow from investing activities		**-1,289**	**-288**
Financing activities	27		
Borrowings		13,675	14,193
Repayment of borrowings		-16,094	-18,191
Group contributions		-1,113	-1,584
Hedging arrangements for financing		-440	-351
Cash flow from financing activities		**-3,972**	**-5,933**
Change in cash and cash equivalents		**169**	**638**
Cash and cash equivalents at beginning of year		**878**	**240**
Exchange difference in cash and cash equivalents		**99**	**0**
Cash and cash equivalents at year-end		**1,146**	**878**

i. 2022 investments refer mainly to milestone payments linked to Aspaveli/Empaveli of SEK 477 M and SEL-212 of SEK 106 M and an upfront payment to ADC Therapeutics for Zynlonta of SEK 588 M.

Notes

1 General information

Swedish Orphan Biovitrum AB (publ), corporate registration number 556038-9321 and its subsidiaries, ("the Group or "Group") is a specialised international biopharmaceutical company transforming the lives of people with rare and debilitating diseases.

The Parent Company is a limited liability company headquartered in Stockholm, Sweden. The address of the head office is Tomtebodavägen 23A, Solna, Sweden.

Sobi has been listed on Nasdaq Stockholm since 15 September 2006 and on the OMX Stockholm Large Cap segment since 2 January 2014.

The annual report of the Parent Company and the consolidated financial statements were authorised for issue by the board of directors on 28 March 2023. The income statement and the balance sheet of the Parent Company and the consolidated statement of comprehensive income and the balance sheet of the Group are subject to adoption at the AGM on 9 May 2023.

2 Accounting policies

Basis of preparation of the financial statements

The consolidated financial statements have been prepared in accordance with the Swedish Annual Accounts Act, RFR 1 Supplementary Rules for Groups, and International Financial Reporting Standards (IFRS) and interpretations from IFRS Interpretations Committee (IFRS IC) as adopted by the EU.

The consolidated financial statements have been prepared using the cost method, except for financial assets and liabilities, including derivative instruments, which are measured at fair value through profit or loss, and other comprehensive income (for hedges and equity instruments, which are not held for trading). The most significant accounting policies applied for the preparation of these consolidated financial statements are presented below. These policies have been consistently applied to all years presented, unless otherwise stated.

All amounts reported in the financial statements, comments, statements, tables and notes are presented in SEK M (millions of Swedish kronor) unless otherwise stated. All amounts are rounded to the nearest million kronor. All values in parentheses () are comparative figures for the year-earlier period, unless otherwise stated.

Within the Group, assets and liabilities are classified as either current or non-current. Current receivables and liabilities fall due within one year of the balance sheet date. Non-current receivables and liabilities essentially consist of amounts expected to be settled later than one year from the balance sheet date.

New and revised accounting policies 2022

The new or revised standards and interpretations applied since 1 January 2022 have had no material effect on the consolidated financial statements.

New or revised accounting policies that will come into effect after 2022

As of 1 January 2023, the amendments to IAS 1 Presentation of Financial Statements will be applied. The amendments require entities to disclose their material accounting policy information, instead of significant accounting policies. At the same time, International Accounting Standards Board Practice Statement 2: *Making Materiality Judgements* has been updated to provide guidance on how to make materiality judgements when preparing general purpose financial statements in accordance with IFRS Standards. The amendments will affect Sobi's accounting policy disclosures in the 2023 Annual report but will not have any impact on the consolidated financial statements.

The forthcoming amendment to IAS 12 concerning deferred tax related to right-of-use assets and lease liabilities will only impact the disclosure requirements in Note.

No other new or revised standards and interpretations that are not yet effective have been adopted in advance and are not expected to have any material effect on the consolidated financial statements.

Change in the external reporting

As of 1 January 2022, Sobi reports provisions as a separate item on the balance sheet. Long-term provisions have previously included post-employment benefits, which are now reported as a separate item on the balance sheet. Short-term provisions have previously been reported as part of accrued expenses and deferred income and amounted to SEK 267 M at the beginning of the year. The comparative period has been recalculated to reflect this change. See also Note 30.

Consolidated financial statements

Subsidiaries

Subsidiaries are all companies in which the Parent Company holds a controlling influence, directly or indirectly. A controlling influence exists if the Parent Company, directly or indirectly has control over a company, is exposed to, or has the rights to variable returns from its involvement in the company, and the ability to affect those returns through its controlling influence. Subsidiaries are consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date on which that control ceases. When preparing Sobi's consolidated financial statements, intra-Group transactions and unrealised gains and losses on transactions between Group companies are eliminated.

The consolidated financial statements are prepared using the acquisition method. A business combination is therefore considered a transaction in which the Group acquires the subsidiary's assets and assumes its liabilities directly. The identifiable assets and acquired liabilities are measured at fair value at the acquisition date.

Transaction costs arising from acquisitions are recognised as administrative expenses in the income statement. Contingent considerations are recognised as financial liabilities and measured at fair value at the acquisition date. Sobi holds contingent considerations which Sobi classifies as non-contingent in the case that the milestone for the condition has been met but not settled and/or that the condition for the milestone is very likely to be achieved. Contingent considerations are remeasured at fair value on each reporting date where the interest component is recognised as a financial expense on the income statement and the remaining change of the remeasurement is recognised as other operating income/expense.

The difference between the fair value of the consideration and the fair value of the Group's share of acquired assets, liabilities and contingent liabilities is recognised as goodwill. In step acquisitions, goodwill is determined at the acquisition date when the controlling influence is obtained, and not in connection with previous acquisitions. To determine goodwill in step acquisitions, the previous holding of equity interests in the acquired company is included, adjusted to fair value, and any gains or losses arising from the remeasurement are recognised in profit or loss. In every acquisition, the Group determines whether non-controlling interests in the acquiree are measured at fair value, or at the

holding's proportionate share of the acquiree's net assets. Goodwill is not amortised according to plan, but tested annually and when there is an indication of impairment. If the aggregated fair value of the acquiree's identifiable assets, liabilities and contingent liabilities exceeds the cost, any excess (negative goodwill) is recognised immediately in the income statement. Any losses are considered an indication that the transferred asset may be impaired

Segments
Sobi's operations are organised into three segments: Haematology, Immunology and Specialty Care. Operating segments are presented in a manner consistent with the internal reporting submitted to the chief operating decision-maker. The chief operating decision-maker is the function responsible for resource allocation and assessment of the operating segment's performance. Sobi's chief operating decision-maker is the Group's CEO. Internal reporting to the CEO uses three segments that represents Sobi's three segments. The accounting policies applied by the segments are consistent with the Group's. Please see Note 5.

Foreign currency
Functional and reporting currency
Items included in the financial statements for each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (functional currency). The consolidated financial statements are presented in Swedish krona (SEK), which is the Parent Company's functional currency and the Group's presentation currency.

Transactions and balance-sheet items
Transactions in foreign currency are translated into the functional currency using the exchange rate prevailing on the transaction date, or on the date when the items are remeasured. Exchange differences arising from the settlement of such transactions, and from the translation of monetary assets and liabilities denominated in foreign currency at the closing day rate, are recognised in profit or loss. Exceptions are when the transactions are hedges that meet all hedge accounting criteria since these exchange differences are recognised in other comprehensive income.

Exchange differences relating to operating items are recognised in operating profit, while other items are recognised as financial income or expense.

Exchange differences for non-monetary financial assets measured at fair value, such as shares that are classified as financial assets measured at fair value through other comprehensive income, are reported in other comprehensive income.

Group companies
Assets and liabilities in foreign Group companies are translated from the functional currency to the Group's reporting currency, at the exchange rate at the balance sheet date. Income and expenses are translated at the average exchange rate. Exchange rate differences that arise when translating foreign Group companies are reported in other comprehensive income and accumulated in a separate item in equity, called translation differences.

Exchange differences that arise on financial instruments used to hedge the net assets of foreign Group companies are reported as a separate part of other comprehensive income. Upon divestment, both accumulated exchange differences on the foreign Group company and on the financial instrument used to hedge the net assets of the Group company are reported as part of the capital gain.

Goodwill and fair value adjustments arising on the acquisition of a foreign operation are treated as assets and liabilities of the operation and translated to the Group's reporting currency using the closing day rate.

Total revenue
Total revenue comprises sales of proprietary medicines, medicines for which Sobi holds the distribution and/or licensing agreements, royalty revenue, revenue from manufacturing, revenue from profit sharing arrangement and other revenue. Intra-Group sales are eliminated. Sobi has no customer contracts where the performance obligations extend beyond 12 months after the balance sheet date. Revenue is recognised as follows:

Product sales
Revenue from sales of medicines is recognised when Sobi has satisfied its performance obligations, which means that the customer has taken control over the medicine. In practice, this arises when the goods have been delivered from Sobi's consignment stock to the customer. The performance obligations associated with contracts between Sobi and its customers consist mainly of distinct goods that are transferred to the customer against payment. The medicines are not customised and can be used by the customers in the condition they are delivered. The medicines are thus considered distinct and separately identifiable. Upon delivery, the customer normally assumes responsibility for the goods, depending on the shipping terms, and the obligation to pay becomes unconditional. Standard payment terms vary between 30 and 90 days and are recognised as accounts receivable.

The price of the goods is identified in contract and are variable to some extent as deductions are made for agreed discounts and pharmaceutical taxes. Where the deductions cannot be estimated reliably, an assessment is made, and the amounts are reserved on the balance sheet.

Returns are based on historical data for returns and include product and quality warranties for any defective goods and returns related to expired goods. For returns related to damages during transportation, provided that Sobi has arranged the transport, the insurance company is required to pay compensation.

Royalty revenue
Sobi is entitled to royalties on pre-sold goods, as per agreement. Revenue is recognised over time on a monthly basis and based on forecasts, which are based on estimates, of underlying sales at the licensee, with quarterly reconciliation and invoicing. Accrued royalty revenue, which is also classified as contract assets under IFRS 15, is recognised on the balance sheet under prepaid expenses and accrued income. The payment terms are normally 45 days after the end of the quarter.

Contract manufacturing
Contract manufacturing revenue is recognised when the goods have been delivered to the customer, meaning control of the goods has been transferred to the customer. The revenue is based on a volume-based price step, which is based on the customer's estimated annual volume. The annual volume is updated by the customer, quarterly. The payment terms are 90 days.

Revenue from profit-sharing arrangement
Revenue from profit sharing arrangement consists of revenue from agreements where the counterparty is not considered a customer according to IFRS 15 but where Sobi has the rights and obligations to the counterparty's underlying revenue and expenses.

In connection with the acquisition of the rights to Synagis in the US from AstraZeneca in 2019, Sobi obtained the rights to 100 per cent of AstraZeneca's half share of profit and losses for nirsevimab in the US market.

Revenue and expenses from the profit-sharing arrangement for nirsevimab is recognised gross in the period in which the underlying revenue and expenses occur at the collaboration partner. Revenue is recognised net, with deduction for related estimated rebates, fees and returns. Revenue is recognised within total revenue as revenue from profit-sharing arrangement. Geographically, revenue is recognised in the US. Arrangement-related expenses are cost of goods sold including royalty expenses, selling and administrative expenses and research & development expenses and these are recognised on each line within operating expenses.

Settlement of revenue and expenses linked to the agreement is done regularly after deduction of Sobi's share of the expenses, with a 60-day payment term. Sobi has the right to postpone the settlement according to the agreement against future settlements whereby an interest is charged on the unsettled amount which is recognised as a financial expense in the income statement.

Sobi will start recognising revenue and expenses linked to the agreement during 2023. In 2022 no revenue or expenses linked to the agreement were recognised. Please see Note 4 for information about significant estimates, assumptions and judgements linked to the agreement.

Other revenue

Other revenue can include revenue from licensing agreements, such as milestone payments and service fees.

Milestone payments refer to partial payments received from partners triggered by the fulfilment of a specific part of a partnering agreement, such as regulatory approval of a jointly developed medicine. This type of revenue is recognised when the contracted event has occurred and there is reasonable assurance that payment will be collected. Due to various contract formulations, the initial licence fee can be recognised in two ways: either as incurred or allocated over its estimated useful life. During 2022 and 2021 no milestone payments were received.

Service fees comprise consideration for sales and marketing services related to some partner medicines during a contractual term. Revenue is recognised over time.

Other operating income/expenses

Other operating income/expenses are income and expenses arising from activities outside Sobi's ordinary operations. These items include exchange-rate effects on operating receivables and liabilities. Accumulated gains or losses arising on the cash-flow hedge reserve in equity are reclassified to other operating income/expenses in the period in which the hedged item affects profit or loss. For more information, please see Notes 7, 8 and 25.

Current and deferred tax

Taxes in the statement of comprehensive income comprise current and deferred tax. Current tax refers to tax payable/received attributable to current/prior years. Deferred tax refers to tax attributable to future years and is calculated on the basis of temporary differences between the carrying amount and tax bases of assets and liabilities. Deferred tax is measured using the applicable/substantively enacted tax rates and tax rules for the period in which the reversal/realisation is expected to occur.

Deferred tax is not recognised for temporary differences in consolidated goodwill, nor for temporary differences attributable to participations in subsidiaries, since it is unlikely that such a reversal will take place in the foreseeable future. In the consolidated financial statements, untaxed reserves are divided into deferred tax liabilities and equity. Deferred tax assets relating to deductible temporary differences and tax loss carry-forwards are recognised to the extent it is probable that future taxable profits are available, against which these can be utilised. Tax is recognised under Income tax in the statement of comprehensive income except for those items recognised in other comprehensive income or equity. See also Notes 15 and 20.

Intangible assets

Goodwill

Goodwill is measured at cost less any accumulated impairment losses. Goodwill is allocated to cash-generating units and tested annually for impairment and when there is any indication that the acquired goodwill is impaired. Impairment loss for goodwill is not reversed.

Product and marketing rights

Product and marketing rights, and any associated development projects, which are acquired separately are measured at cost including any costs directly attributable to the acquisition. In the event that contingent considerations are dependent on future events linked to the achievement of certain regulatory and commercial milestones, product and marketing rights are initially recognised at the fair value of the consideration paid and future consideration plus transaction costs. Fair value is determined by totalling the payment obligations in connection with the acquisition. The future considerations are probability-weighted and discounted to present value at the acquisition date, and a corresponding amount is recognised as a separate financial liability. Refer also to the Financial instruments section – liabilities measured at amortised cost and Note 4.

Product and marketing rights acquired in a business combination are measured at acquisition-date fair value. Product and marketing rights have a limited life and are measured at cost less any accumulated amortisation and any subsequent accumulated impairment losses. Amortisation is carried out to allocate the cost over their estimated life, normally 5-20 years. Straight-line amortisation is used to allocate the cost over their useful lives, based on the expected commercial useful lives of each product and marketing right. Amortisation expense is classified as selling costs. See also Notes 4 and 16.

Licences and patents

The costs and amortisation of licences are treated in the same way as product and marketing rights above. Patent costs are expensed as incurred.

Research & development costs

Costs for development projects are recognised as intangible assets if Sobi can demonstrate that it is technically possible to complete and profitably commercialise the results, and only if the costs of the project can be measured reliably. In practice, this means that the costs cannot be capitalised until the relevant authority/institution has granted approval. Acquired development projects are capitalised at the acquisition date and recognised in accordance with product and marketing rights above. When a development project has received approval, it is reclassified to product and marketing rights. See above for amortisations. Other research & development costs that do not meet the relevant recognition criteria of IAS 38 are recognised as an expense when incurred.

Capitalised costs

Software and IT projects in progress

Acquired software licences are capitalised on the basis of the costs arising when the relevant software is acquired and available for use. These costs are amortised over the estimated useful life of the software.

Costs associated with developing or maintaining software are recognised as an expense when they are incurred. Costs directly associated with identifiable software developed specifically for Sobi that are controlled by Sobi and will probably generate economic benefits exceeding costs beyond one year, are recognised as intangible assets. Direct costs include expenses for employees working on software development and a reasonable proportion of overhead costs.

Costs to enhance the performance of software or extend its useful life (development costs) beyond the original plan are capitalised and added to the initial cost of the software. Amortisation according to plan for software recognised as an asset is performed using the straight-line method over its useful life up to a maximum of three years.

Costs for future manufacturing

Costs for future manufacturing of Sobi's medicines are capitalised if they meet the criteria for capitalisation under IAS 38 and are classified as intangible assets. Costs that are capitalised are costs that are directly attributable to the development of new production lines. Amortisation commences when the asset is brought into actual use.

Amortisation of capitalised costs

Amortisation of capitalised costs is charged to selling and administrative expenses. For more information, please see Note 6.

Tangible assets

Tangible assets are recognised as assets on the balance sheet if it is expected that future economic benefits will accrue to Sobi, and the cost of the asset can be measured reliably.

All tangible assets are measured at cost less depreciation. The cost includes costs directly attributable to the acquisition of the asset. Additional costs are added to the carrying amount of the asset or recognised as a separate asset, depending on which is appropriate, only when it is probable that the future economic rewards associated with the asset will accrue to the Group and the cost of the asset can be measured reliably. All other forms of repair and maintenance are recognised as expenses in profit or loss as incurred.

Depreciation of tangible assets

Tangible assets are depreciated according to plan over their estimated useful life. They are depreciated on a straight-line basis over their estimated useful life less residual value. The following depreciation periods are applied:

Plant and machinery

- Laboratory equipment and other investments 3-7 years
- Other major investments, such as property refurbishment 5-20 years

Equipment, tools, fixtures and fittings

- Servers and other large computer hardware 3-5 years
- Furniture, fixtures and fittings 5-10 years

The residual value and useful life of the assets are assessed at each balance sheet date and adjusted if necessary. An asset's carrying amount is immediately depreciated to its recoverable amount if the carrying amount of the asset exceeds its estimated recoverable amount. The gain or loss arising on the disposal or retirement of tangible assets is the difference between the proceeds and the carrying amount less direct selling costs. The profit/loss item is recognised as other operating income or other operating expense.

Impairment of intangible and tangible assets

Goodwill, which has an indeterminable useful life, and intangible assets not yet available for use are not depreciated but tested annually for impairment and when there is any indication that the value of an asset may be impaired.

Product and marketing rights and other assets that are depreciated/amortised are tested for impairment whenever events and circumstances indicate that the carrying amount may not be recoverable. An asset is impaired if its carrying amount exceeds its recoverable amount. An impairment is therefore the difference between the carrying amount and the recoverable amount where the recoverable amount is defined as the higher of an asset's net realisable value and value-in-use. When determining the value-in-use, the future cash flows expected to be generated by the asset are discounted using a rate equivalent to Sobi's weighted average cost of capital (WACC).

When assessing goodwill impairment, this is grouped at the lowest levels for which there are separately identifiable cash flows – cash-generating units. Any impairment of goodwill is not reversed. Impairment testing of goodwill, product and marketing rights and development projects is described in Note 16.

An impairment loss for an asset other than goodwill is reversed if there has been a change in the estimates used to determine the asset's recoverable amount. A reversal must not exceed the carrying amount that would have been determined, less depreciation, had no impairment loss been recognised.

Cash-generating units

Goodwill acquired in a business combination is allocated to the Group's cash-generating units. A cash-generating unit is defined as the lowest level within the Group at which the goodwill in question is monitored for internal management purposes, see also Note 16.

Leases

Most of Sobi's leased assets comprise properties and vehicles. The right-of-use asset and corresponding lease liability are recognised on the balance sheet when the leased asset is made available for use. Short-term and low-value leases are excepted, which in all material respects comprise copying machines, printers and computers. Variable lease payments other than those that depend on an index or rate are recognised as an expense in the period in which they occur.

The lease liability is initially recognised at the present value of the Group's fixed payments less any lease incentives receivable, and variable lease payments that depend on an index or rate that have not been paid on the commencement date. Options to extend and terminate are included in the payments if it is reasonably certain that these will be used. The lease payments are discounted using the interest rate implicit in the lease if that rate can be readily determined, otherwise Sobi's incremental borrowing rate is used. The lease liability is subsequently remeasured to reflect changes in the lease term, which are treated as adjustments to the right-of-use asset.

The right-of-use asset is initially measured at cost and includes the present value of the lease liability, including lease payments made on or before the commencement date and initial direct costs. Restoration costs are included in the asset if a corresponding provision for restoration costs is identified. The right-of-use asset is depreciated on a straight-line basis over the shorter of the useful life of the asset and the lease term. The following periods of useful life are applied:

- Properties 2-10 years
- Vehicles 36-48 months

In the cash flow statement, payments attributable to the lease liability are reported under financing activities while payments for short-term leases, low-value asset leases and variable lease payments not included in the measurement of the lease liability are recognised under operating activities. For more information, please see Note 9.

Financial instruments

A financial instrument is a contract that gives rise to a financial asset in one company, and a financial liability or equity instrument in another.

Classification of financial instruments

The Group classifies its financial instruments into the following categories:

1. Assets measured at amortised cost
2. Assets measured at fair value through profit or loss
3. Assets measured at fair value through other comprehensive income
4. Liabilities measured at amortised cost
5. Liabilities measured at fair value through profit or loss

The classification depends on the purpose for which the instruments were acquired and the type of financial instrument. The recognition of equity instruments that are not held for trading depends on whether Sobi, at the acquisition date, has made an irrevocable election to measure equity instruments at fair value through other comprehensive income. The classification of the instruments is determined at initial recognition, and they are only reclassified if the business model for the instruments is changed.

Assets expected to mature or be sold within 12 months, and liabilities with no unconditional right to defer settlement of the liability for at least 12 months after the balance sheet date, are classified as current assets or current liabilities. Other assets and liabilities are classified as fixed assets or non-current liabilities.

Financial instruments not measured at fair value through profit or loss are measured at fair value on the transaction date, including transaction costs on the balance sheet. Financial instruments measured at fair value through profit or loss are initially measured at fair value, while related transaction costs are recognised in profit or loss.

Financial instruments measured at fair value through other comprehensive income are measured at fair value on the balance sheet, including transaction costs, at the transaction date.

Financial instruments recognised as assets on the balance sheet include equity instruments, endowment policies, accounts receivable, derivatives, and cash and cash equivalents. Financial liabilities mainly include borrowings, considerations, accounts payable, derivatives and other liabilities.

1. Assets measured at amortised cost

Assets are classified in this category if both of the following criteria are met:

- The objective of the business model is to hold the financial asset to collect the contractual cash flows.
- The contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

The Group's assets in this category consist of accounts and other receivables, and cash and cash equivalents. These are measured at amortised cost less any impairment.

The maturities of accounts receivable are mainly short, which is why they are recognised initially at nominal value without discounting. Impairment of accounts receivable in the Group is based on an individual assessment and a model for expected future losses, which have been calculated using historical losses and forward-looking estimates. Any impairments are recognised in operating expenses.

2. Assets measured at fair value through profit or loss

Financial assets measured at fair value through profit or loss are financial assets that are not measured at amortised cost. This category includes the Group's endowment policies and derivatives that are not included in an effective cash flow hedge or net investment hedge.

3. Assets measured at fair value through other comprehensive income

Financial assets measured at fair value through other comprehensive income are derivatives that meet hedge accounting requirements (cash flow hedges and net investments) and equity instruments in the form of quoted shares. In cases where Sobi has elected to present value changes in equity instruments in other comprehensive income, there is no subsequent reclassification of changes in fair value through profit or loss on derecognition. Any dividends on equity instruments are recognised as income in the statement of profit or loss when the right to receive payment has been determined.

4. Liabilities measured at amortised cost

This category includes financial liabilities such as borrowings, accounts payable and lease liabilities, as well as liabilities related to contingent and non-contingent considerations tied to licensing and collaboration agreements for the development and commercialisation of product and marketing rights. Liabilities in this category are measured at amortised cost using the effective interest method. See above, under the heading Subsidiaries, for Sobi's classification of a contingent consideration as non-contingent.

Borrowings are initially measured at fair value, net after transaction costs. Borrowings are subsequently measured at amortised cost and any difference between the amount received and the repayment amount is recognised in profit or loss over the term of the loan, using the effective interest method. Borrowings are classified as current liabilities unless there is an unconditional right to defer settlement of the liability until 12 months after the balance sheet date.

Liabilities related to contingent considerations are initially measured at the fair value of future obligations with a corresponding amount recognised as an intangible asset. Contingent considerations are usually linked to future payments dependent upon the achievement of certain regulatory and commercial milestones. The fair value of contingent considerations is initially determined by probability-weighting and discounting potential future payments. The liability is subsequently measured at amortised cost using the effective interest method, whereby the interest expense is recognised as a financial expense in the income statement allocated over the expected obligation period.

A change in value attributable to exchange rate effects is reported as financial income/expense in the income statement, provided that they are not included in an effective hedge. A change in the liability as a result of a changed assumption regarding future payments is reported with a corresponding change in associated intangible asset.

Liabilities tied to contingent considerations are classified as current liabilities, non-interest bearing when the related milestone payment is payable, or expected to be payable, within 12 months of the balance sheet date, see also Notes 4, 26 and 28, and above under the heading of product and marketing rights and Note 16.

5. Liabilities measured at fair value through profit or loss
This category includes liabilities not measured at amortised cost. The liabilities are measured both initially and in subsequent periods at fair value on the balance sheet. This category includes derivatives and contingent considerations related to business combinations, where changes in the value of such liabilities are recognised in profit or loss. The components of the change in value relating to interest and exchange rate effects are recognised in net financial items while other changes in fair value are recognised in profit or loss. Changes in the fair value of derivatives that are not included in an effective cash flow hedge or net investment hedge are recognised in profit or loss. Changes in the fair value of derivatives that are included in an effective cash flow hedge or net investment hedge are recognised in other comprehensive income.

Derivatives
Derivatives are used for hedging and not for speculation. Sobi differentiates between derivatives included in an effective hedging relationship and other derivatives held for trading. Derivatives are measured at fair value on the balance sheet, both initially and in subsequent remeasurements, and recognised as either an asset or a liability, depending on whether their fair value is positive or negative. Derivatives that do not meet the criteria for hedge accounting are recognised in profit or loss. Derivatives held to manage financial risks are recognised in net financial items, while derivatives held to manage risks in the operating result are recognised in other operating income/expenses.

Hedge accounting
The Group applies hedge accounting for currency risk and uses derivative instruments and loans in these hedging relationships. The method for recognising the resulting gains or losses from the remeasurement of loans or derivatives in hedge accounting depends on whether the instrument has been identified as a hedging instrument in a cash flow hedge, fair value hedge or net investment hedge.

Cash flow hedges
The effective portion of changes in fair value of a derivative instrument identified as a cash flow hedge is recognised in other comprehensive income. The gain or loss relating to the ineffective portion is recognised immediately in profit or loss. Accumulated gains or losses in equity are reclassified to profit or loss in the periods in which the hedged item affects the results. If a hedging instrument expires or is sold, or when a hedge no longer meets the criteria for hedge accounting and there are accumulated gains or losses from hedging in equity, these gains or losses remain in equity and are transferred to the income statement when the hedged item is recognised in profit or loss. If a loan is designated as a hedging instrument for foreign-exchange risk, the effective portion of the remeasurement effects pertaining to exchange rate fluctuations is recognised in the same way as for derivatives, while other parts of the loan are recognised as a loan not included in a hedging relationship.

Net investment hedges
A net investment is hedged with financial liabilities denominated in foreign currency. The accounting is similar to cash flow hedges.

Inventories
Inventories are measured at the lower of cost and net realisable value. Cost is calculated using the first in, first out principle (FIFO). Net realisable value is the expected selling price in the ordinary course of business less selling costs. Obsolescence risk and confirmed obsolescence have been taken into account in the measurement.

Cash and equivalents
The cash and cash equivalents comprise cash, cash at bank accounts and investments with a maturity of less than three months from the acquisition date that are subject to an insignificant risk of changes in value.

Equity
Ordinary shares are classified as equity. Transaction costs directly attributable to the issue of new shares or options are recognised in equity, net after tax, as a deduction from the proceeds.

Provisions
A provision is recognised on the balance sheet when Sobi has a legal or constructive obligation as a result of a past event, it is probable that an outflow of resources will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation. If the outflow of resources is expected to take place at a point far in the future, the expected future cash flow is discounted, and the provision is recognised at its present value. The provisions are mainly related to restructuring, personnel, legal disputes and share-based payments.

Restructuring
A restructuring provision, for a substantially change in the way that Sobi works is, recognised when a detailed and formal restructuring plan has been established and publicly announced, at which point clear expectations are created that the plan will be implemented. Future operating costs are not provided for. Restructuring provision often include termination benefits, which can be either voluntary or involuntary. In those cases, in which a service obligation is tied to the benefit, costs are distributed over the period in which the services are carried out. Salaries relating to periods following the termination of duty to work are expensed when the decision is communicated.

Provision for personnel
Mainly comprise endowment policies and termination benefits.

Endowment policies are recognised gross on the balance sheet as a financial asset and a provision. For more information, see Direct pensions.

A provision for costs in connection with termination of personnel is recognised only if Sobi is demonstrably obliged to terminate employment before the normal period of service has ended or when benefits are provided as an incentive to encourage voluntary termination, e.g. early retirement packages. In cases where Sobi terminates employment, a detailed plan is prepared that, at a minimum, contains information about the workplace, positions and approximate number of individuals concerned, as well as the compensation for each employee category or position and the schedule for the plan's implementation.

Share-based payments
Refers to cash-settled share-based incentive programmes and social contributions for all share-based incentive programmes. The provision is based on the current periods best estimate of the possible future payment The uncertainty of outflow refers to the fair value of the underlying financial instrument during the vesting period and the fulfilment of the performance conditions.

Contingent liabilities
Contingent liabilities are recognised when there is a possible obligation arising from past events and whose existence is confirmed by only one or more uncertain future events, or when there is a commitment that is not recognised as a liability or a provision because it is unlikely that an outflow of resources will be required.

Employee benefits

Short-term benefits
Short-term employee benefits are calculated without discounting and recognised as an expense when an employee renders service. An accrued expense for estimated bonus payments is recognised when the Group has a legal or constructive obligation to make such payments as a result of services rendered by employees and a reliable estimate of the obligation can be made.

Pension obligations
Pensions and other benefits after the termination of employment are classified as either defined-contribution or defined-benefit plans. Most of the Group's employees are covered by a defined-contribution pension plan. There are defined-benefit plans in France, Italy, Norway, Switzerland and Sweden.

A defined-contribution pension plan is a pension plan according to which the Group pays fixed contributions to a separate legal entity. The Group's commitments are limited to the contributions it has undertaken to pay. The contributions payable to defined-contribution plans are expensed in the period in which the services are rendered. Prepayments are recognised as an asset to the extent that the prepayment will lead to a cash refund or reduction in future payments for the Group.

A defined-benefit pension plan is a pension plan that promises a specified pension payment on retirement that is normally based on one or several factors, such as the employee's age, tenure of service, earnings history and salary.

The liability for defined-benefit pension plans is recognised on the balance sheet as the present value of the obligations under the plan at the balance sheet date less the fair value of the plan assets. The defined-benefit pension obligation is calculated at least annually by independent actuaries using the Projected Unit Credit Method. The present value of the defined-benefit obligation is determined by discounting estimated future cash flows using the interest rate for high-grade corporate bonds and mortgage bonds issued in the same currency in which the benefits will be paid, and with maturities comparable with the current pension liability. Special payroll tax is included in the present value of the obligation. Actuarial gains and losses due to experience-based adjustments and changes to actuarial assumptions are recognised in other comprehensive income in the period in which they occur. Past service costs are recognised immediately as an operating expense within selling and administrative expenses and research & development expenses depending on the function in which the insured is/was employed. Interest expense less expected return on plan assets is recognised as a financial expense.

Direct pensions
For some senior executives, their pension plan has been supplemented with direct pension promises. In these cases, the Parent Company, over time, has taken out endowment policies pledged to the employee as collateral for the agreement. Endowment policies taken out by the Parent Company are classified as a financial asset on the balance sheet, since they are a long-term holding, and measured at fair value, while the pension obligation to the employee is recognised under provisions. A provision for special payroll tax is also recognised for the endowment policies. Premiums paid into the endowment policies are not deductible. However, the payment to the beneficiary is deductible.

Long-term incentive programmes
Outstanding share programmes and share option programmes are recognised according to IFRS 2 Share-based Payment.

The fair value of allotted share programmes is estimated on the issue date using a generally accepted modelling technique, the Monte Carlo simulation model, and taking market conditions and performance obligations into account. Performance obligations in the form of a revenue component exist for the programmes that include the CEO, senior executives and managers.

Fair value at the date of allotment is recognised as a personnel cost in profit or loss, allocated over the vesting period, and corresponding adjustments are made in equity. At the end of every quarter, the Group reviews its assessments of how many shares are expected to be vested based on the service condition. The shares are delivered to the employee at the end of the programmes, under the framework of the programmes.

The fair value of the allotted share option programmes is estimated on the issue date using the Black-Scholes model, taking market conditions and performance obligations into account. Performance obligations exist, as described above, for share programmes. Fair value at the date of allotment is recognised as a personnel cost in profit or loss, allocated over the vesting period, and corresponding adjustments are made in equity. The amount recognised as an expense is continuously adjusted to reflect the actual number of share options vested. The social security contributions are remeasured at every balance sheet date until settlement takes place and allocated using the same principles as the cost of the shares.

The Group also has long-term cash-based incentive programmes, which are not classified as share-based payments, which include employees in Canada, China, Japan and US. Since awards under these programmes are contingent upon continued employment in Sobi, the costs are recognised continuously over the vesting period. A liability is calculated on each balance sheet date based on the market value, renewed assessments of target fulfilment and how much has been vested. The net of these effects is recognised as a personnel cost in the consolidated statement of profit or loss. The social security contributions are remeasured at every balance sheet date until settlement takes place and allocated using the same principles as the cost of the shares.

See also Note 10 for a more detailed description of the long-term incentive programmes.

The Parent Company's accounting policies
The Parent Company, Swedish Orphan Biovitrum AB (publ), has prepared its annual report in accordance with the Swedish Annual Accounts Act (1995:1554) and the Swedish Financial Reporting Board's recommendation RFR 2 Accounting for Legal Entities. The statements issued by the Financial Reporting Board regarding listed companies are also applied. According to RFR 2, the Parent Company is to prepare its annual financial statements using all of the IFRS and statements adopted by the EU as far as possible within the framework of the Swedish Annual Accounts Act, the Pension Obligations Vesting Act, and with consideration for the relationship between accounting and taxation. The recommendation sets out the exemptions, and amendments to, IFRS that must be made.

The Parent Company has assets and liabilities that are measured at historical cost, except for some financial assets and liabilities that are measured at fair value. The Parent Company applies the same accounting policies as the Group with the following exceptions:

Change in the external reporting
As of 1 January 2022, short-term provisions are recognised as a separate item on the balance sheet. Previously, it was reported as part of accrued expenses and deferred income and amounted to SEK 104 M at the beginning of the year. The comparative period has been recalculated to reflect this change. Please see Note 30.

Employee benefits/defined-benefit plans
In the calculation of defined-benefit pension plans, the Parent Company complies with the Swedish Pension Obligations Vesting Act, which is a prerequisite for tax deductibility. The most significant differences compared with the requirements under IAS 19 are how the discount rate is established, that the calculation of the defined-benefit obligation is based on current salary levels without assumptions regarding future salary increases, and that all actuarial gains and losses are recognised in other comprehensive income as they arise. Please see Note 29 for more information.

Leases
Leases are recognised in accordance with the exemption in RFR 2, whereby the right-of-use asset and lease liability are not recognised on the balance sheet. Costs under the lease are recognised in the income statement on a straight-line basis over the term of the lease. Lease incentives received are recognised as an integral part of the total lease expense, over the term of the lease.

Group contributions
The Parent Company applies the alternative approach and, consequently, reports all Group contributions received/provided as appropriations.

Taxes
Untaxed reserves including deferred tax liabilities are recognised for legal entities.

Subsidiaries
Investments in subsidiaries are recognised in accordance with the cost model. The value of subsidiaries is tested when there is an indication of a decline in value. Dividends received from subsidiaries are recognised as revenue. Transaction costs associated with an acquisition are recognised as part of the cost of acquisition. Contingent considerations are recognised as part of the cost if it is probable, they will be realised. If the initial assessment needs to be revised in subsequent periods, the cost must be adjusted.

Internal receivables
The Parent Company uses a method to test for impairment on internal receivables and loans based on the model used by the Group for external accounts receivable.

3 Financial risk management

Financial risks and risk management
Through its operations, Sobi is exposed to various kinds of risks that may impact Sobi's earnings, cash flow and financial position. The risks can be divided into operational risk and financial risk. Financial risk refers to a potentially negative impact resulting from changes in the financial risk factors. Below is a description of the financial risk factors deemed most significant for Sobi, and how they are managed. Operational risks are described in a separate section of the Directors' report.

Financial risk is managed at central level by Sobi's treasury function, which in addition to being responsible for the Group's financing, ensures that solutions are in place for liquidity management and payments, continuously monitoring financial risk and supporting the business operations in treasury related issues.

The Treasury policy, which is adopted by the board, establishes the division of responsibilities and control of treasury matters between the board, CEO, CFO and the treasury function. The board has appointed an Audit committee to monitor the structure of the Treasury policy and, if necessary, propose changes to the board. The main objectives of the Treasury policy are to maintain a low level of financial risk and to manage risk safely.

Financial risk factors

Currency risk – transaction risk
Transaction risk arises when sales and purchasing transactions are denominated in different currencies and is defined as the risk that changes in foreign exchange rates will negatively affect Sobi's profitability or cash flow. Sobi has chosen to split transaction risk into two sub-groups: operational transaction risk and financial transaction risk with the following definitions:

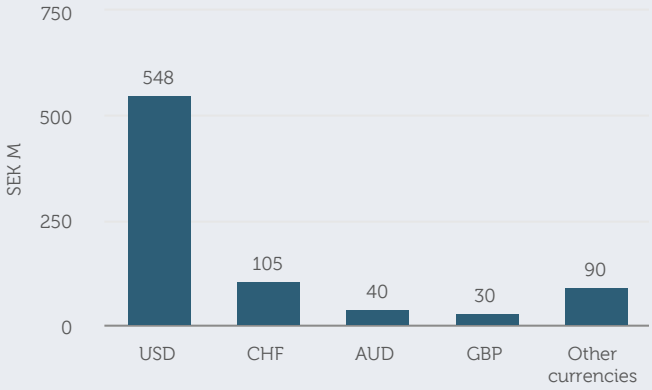
- Operational transaction risk: negative impact from committed transactions, such as foreign denominated payables and receivables, derived from operational activities where future currency revaluations of such items are posted to the operational result.
- Financial transaction risk: negative impact from committed transactions, such as committed foreign denominated loans and receivables derived from financial activities where future currency revaluations of such items are posted to the finance net.

This risk is limited in the subsidiaries as their operational and financial transactions are mainly denominated in their local currencies. This risk is significant for the Parent Company, since Sobi has considerable flows of foreign currencies, primarily EUR and USD.

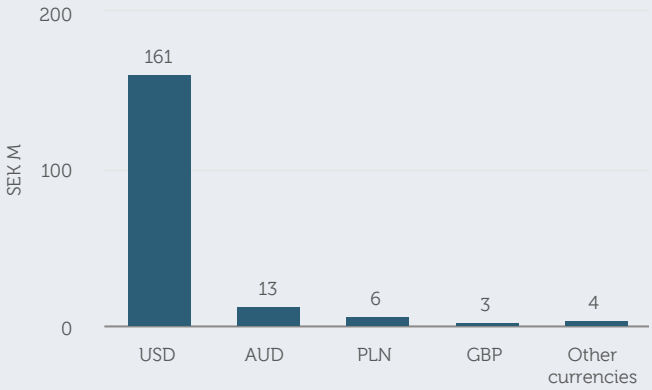
Financial instruments, such as foreign exchange transactions including derivatives, are used to manage the transaction exposure. Sobi also applies hedge accounting and uses cash-flow hedges to reduce some of the transaction risk in EUR and USD. These flows are primarily related to the Elocta, Alprolix and Synagis medicines.

The currencies with the largest net exposures, including derivatives, are shown in the diagram below.

Operational net transaction exposure, absolute values on the balance date



Financial net transaction exposure, absolute values on the balance date



On the balance sheet date, if the SEK had appreciated 5 per cent against other currencies, the operating result and the finance net would have been impacted by SEK -26 M (-52) and SEK -9 M (-5). At year-end there are sometimes large balances in operational exposure due to internal invoicing which is managed during the following days when the total exposure is known. In 2022, the actual impact was SEK 33 M (2) on the operating result and SEK -11 M (16) on the finance net.

Reasonable change

Impact of 5 per cent appreciation of SEK

Operating profit	2022	2021
USD	-27	-62
CHF	5	9
AUD	-2	-1
GBP	1	1
Other currencies	-3	1
Total	**-26**	**-52**

Net financial items	2022	2021
USD	-8	-2
AUD	-1	-1
PLN	0	0
GBP	0	0
Other currencies	0	-2
Total	**-9**	**-5**

Currency risk – translation risk

Translation risk is the risk that fluctuations in exchange rates will have a negative impact on equity when the Group's net assets denominated in foreign currency are translated into SEK. The changes in equity are considered acceptable and not managed with currency derivatives. The risk is partly managed by limiting the size of the net assets by raising foreign currency loans.

The most significant currencies for Sobi are CHF, EUR and USD. If the SEK had appreciated by 5 per cent against other currencies, Group equity and net financial assets and liabilities would have been impacted as shown in the tables below.

Impact of 5 per cent appreciation of SEK

2022	Equity	Financial assets and -liabilities
CHF	-225	-4
EUR	57	56
USD	73	475
Other currencies	-24	-20
Total	**-119**	**507**

2021	Equity	Financial assets and -liabilities
CHF	-198	4
EUR	92	81
USD	51	436
Other currencies	-17	-16
Total	**-72**	**505**

Liquidity risk

Liquidity risk is the risk that Sobi is unable to raise financing on acceptable terms or meet its payment obligations due to factors beyond Sobi's control. How the liquidity risk should be managed is described in the Treasury policy. Both short-term and long-term forecasts of the Group's liquidity are regularly compiled to ensure that sufficient cash and undrawn credit facilities are available to meet the needs of the day-to-day operations.

According to the policy, Sobi shall also maintain an appropriate liquidity reserve. The liquidity reserve comprises bank balances, current investments and undrawn committed credit facilities. On 31 December 2022, Sobi's undrawn committed credit facilities totalled SEK 7,532 M (4,336), of which SEK 2,093 M (0) was reserved for outstanding commercial papers and checks, with a net available of SEK 5,440 M (4,336). On 31 December 2022, drawn credit facilities amounted to SEK 6,728 M (10,597). See the distribution in the table below.

Credit facilities, maturity structure

Group	2023	2024	2025	Total
Credit facilities, undrawn	2,417	5,116	0	7,532
Credit facilities, drawn	3,728	3,000	0	6,728
Credit facilities, total	**6,145**	**8,116**	**0**	**14,260**

The following table shows the contractual, undiscounted cash flows including interest from the Group's financial liabilities, divided according to the time remaining until the contractual maturity date or, if there is no such date, the expected balance sheet date.

Maturity analysis

Group	Less than 1 year	Between 1-2 years	Between 2-5 years	More than 5 years
On 31 December 2022				
Derivatives[i]	21	—	—	—
Borrowings	6,050	3,104	—	—
Accounts payable	1,252	—	—	—
Lease liabilities	143	97	107	10
Contingent considerations	52	3,131	1,205	16,616
Non-contingent considerations	1,195	574	—	—
Total	**8,713**	**6,906**	**1,312**	**16,626**

Group	Less than 1 year	Between 1-2 years	Between 2-5 years	More than 5 years
On 31 December 2021				
Derivatives[i]	10	—	—	—
Borrowings	1,953	5,260	3,792	—
Accounts payable	558	—	—	—
Lease liabilities	118	111	152	12
Contingent considerations	—	2,744	823	11,974
Non-contingent considerations	692	565	497	—
Total	**3,331**	**8,681**	**5,264**	**11,986**

i. Included in Other liabilities, non-interest bearing on the balance sheet.

The liabilities in the table are presented at nominal value according to an assessment of the contracts on 31 December 2022. For recognised liabilities on the balance sheet, please see Note 26.

Interest rate risk

Interest rate risk is the risk that Sobi would be adversely affected by changes in interest rates, both on profits through changes in general interest rates and on instruments with fixed interest rates through changes in market values. Changes in market values are considered acceptable since Sobi's general principle is to minimise the volatility of its earnings. Sobi's exposure to interest rate risk mainly occurs through external loans and cash.

Sobi's financing sources primarily consist of equity, cash flow from operating activities, and borrowings. Interest-bearing debt exposes the Group to interest rate risk. Loans are normally raised with a fixed-rate period of three months and at year-end, Sobi's average remaining fixed-rate period was one month.

Interest-rate sensitivity is measured by assuming a constant interest-rate change of 1 percentage point. On 31 December 2022 such a change would have had an annual impact of SEK 81 M (100) on net financial items. On 31 December 2022 Sobi's interest-bearing liabilities amounted to SEK 8,768 M (10,545). The loans raised carry variable interest, which is deemed most favourable for Sobi. There were no fixed-income derivatives outstanding at the balance sheet date.

Credit risk

Credit risk refers to the risk of loss if a counterparty is unable to meet its obligations. Credit risk can be divided into credit risk in the form of accounts receivable, and financial credit risk.

Sobi's credit risk is mainly related to accounts receivable. On the balance sheet date, these amounted to SEK 5,249 M (3,439) of which SEK 1,058 M (607) was overdue. Please see Note 22 for information about overdue receivables. Sobi's customers are mainly large distributors with low credit risk, hospitals and government administrations, which means that these are largely funded by the government of each respective country. If Sobi deems that a receivable will not be paid, a provision is made for an expected credit loss in accordance with the principles described in Note 2. On 31 December 2022, these amounted to SEK -174 M (-71). Sobi has received securities only for a limited volume of its accounts receivable.

Credit rating reports are obtained for both distribution agreements and larger individual transactions, when the customer is not previously known or when other circumstances give rise to uncertainty regarding creditworthiness. The credit ratings must be obtained from a nationally recognised statistical rating organisation. A credit limit is set for every customer, and continuously monitored and evaluated.

In the Treasury policy, Sobi has established principles that limit Sobi's maximum exposure to financial credit risk on a per counterparty basis. To further limit financial credit risk, financial transactions are primarily conducted with counterparts with a high credit rating. Any surplus liquidity may be invested in instruments with a low level of credit risk and a high level of liquidity. Investments are only permitted in instruments issued by the Swedish Government and municipalities, or by banks, financial institutions and companies with a minimum credit rating of A from Standard & Poor's (S&P) or an equivalent rating from another rating agency. A high level of liquidity means that investments can be converted into cash at any given time.

Capital structure

Sobi manages its capital structure and leverage to generate good shareholder returns and value for other stakeholders, and to keep cost of capital at a reasonable level. The capital structure can be adapted by, for example, paying dividends to shareholders, repaying capital to shareholders, issuing new shares or repaying debts.

Sobi mainly uses leverage as a measure of Sobi's capital structure, which is calculated using net debt/EBITDA adjusted. The aim is to keep leverage at a level that is appropriate for Sobi's operations, and that enables relevant acquisitions and investments.

On the balance sheet date, Sobi's debt/equity ratio was:

Group	2022	2021
Net debt	7,406	9,500
EBITDA adjusted[i]	6,758	5,740
Leverage	1.10	1.66

i. See also the Directors' report, section Items affecting comparability (IAC) for more information.

Hedge accounting

Sobi uses currency derivatives and loans in foreign currency as hedging instruments to manage currency risk in future cash flows, and loans in foreign currency to limit the Group's net assets and currency exposure in equity. Hedge accounting is applied to hedging relationships that meet the qualifying criteria and where Sobi considers hedge accounting appropriate.

There is an economic relationship in Sobi's cash flow hedges and hedges of net investments, since these relate to foreign-exchange risk and hedging instruments, and the hedged items are in the same currency. Sobi assesses hedge effectiveness at each hedge's inception, and at every balance sheet date. Sobi applies a hedge ratio of 1:1 if the underlying conditions are identical.

Sources of ineffectiveness:

- Difference or change in the hedging instrument's settlement date and timing of the most probable cash flow in a cash flow hedge
- Changes to the hedged item's amount
- A significant change in the derivative counterparty credit risk

The following table presents Sobi's hedging relationships at the end of 2022 and their effects on profit or loss during the year. In 2022, Sobi's total ineffectiveness was SEK 0 M (0).

Cash flow hedges 2022

Currency	Nominal value, SEK M	Hedging - instrument	Hedged item	Hedged risk	Maturity interval
EUR	115	Borrowings	Highest probable inflows of EUR	Foreign-exchange risk (spot)	2023

Cash flow hedges 2021

Currency	Nominal value, SEK M	Hedging - instrument	Hedged item	Hedged risk	Maturity interval
EUR	225	Borrowings	Highest probable inflows of EUR	Foreign--exchange risk (spot)	2022-2023

Net investment hedges 2022

Currency	Nominal value, SEK M	Hedging - instrument	Hedged item	Hedged risk
USD	326	Contingent considerations	Net assets in USD	Foreign-exchange risk (spot)
USD	0	Non-contingent considerations	Net assets in USD	Foreign-exchange risk (spot)

Net investment hedges 2021

Currency	Nominal value, SEK M	Hedging - instrument	Hedged item	Hedged risk
USD	312	Contingent considerations	Net assets in USD	Foreign-exchange risk (spot)
USD	64	Non-contingent considerations	Net assets in USD	Foreign-exchange risk (spot)

During 2022 one net investment hedge was discontinued. During 2021 no hedging relationships were discontinued prospectively. The change in the hedging reserve is presented in Note 25.

4 Significant accounting judgements, estimates and assumptions

Sobi makes estimates and assumptions about the future, and accounting judgements. Significant accounting judgements, estimates and assumptions entailing a considerable risk of material adjustments in the carrying amounts of assets and liabilities in the upcoming financial year are presented below. For significant accounting judgements regarding fair value, please see Note 26.

Accounting judgements

Revenue

When revenue is recognised, each agreement is interpreted separately and Sobi makes an assessment of any obligations. Revenue is recognised when control has been transferred to the buyer, depending on the shipping terms. Revenue is calculated as invoiced gross revenue according to agreement less variable consideration corresponding to actual and estimated discounts to public and private customers, and pharmaceutical taxes. Since actual and final conditions for discounts and pharmaceutical taxes on sales in the current period are not always known at the balance sheet date, some of the deductions from gross revenue are based on estimates. On 31 December 2022 sales-related accruals amounted to SEK 3,131 M (3,053). Please see Notes 5 and 31.

In addition, the likelihood of future economic rewards accruing to Sobi is assessed on the basis of several factors, including a customer's payment history and credit rating. If Sobi judges that a receivable will not be paid, a provision for credit loss is made in accordance with the principles described in Note 2.

Acquisitions

Business and asset acquisitions

For acquisitions, Sobi determines whether the transaction is a business combination or an asset acquisition. The assessment is made in accordance with IFRS 3. Each acquisition is considered separately and, in some cases, Sobi applies the concentration test to simplify the determination of whether the transaction is an asset acquisition. At the end of 2022 Sobi had not completed any business acquisitions considered an asset acquisition.

Intangible assets

Upon the acquisition of intangible assets that include terms for consideration that are contingent upon the outcome of a future event, usually linked to the achievement of certain regulatory and commercial milestones, assessments and assumptions are made to determine the initial acquisition value (fair value of consideration paid and any additional consideration). The value of future considerations is determined by totalling the payment obligations in connection with the acquisition, which are probability-weighted and discounted to present value at the acquisition date, and a corresponding amount is recognised as a separate financial liability. Please see Note 28 and under the heading of Financial liabilities.

Estimates and assumptions

Intangible assets

Sobi's intangible assets are essentially attributable to goodwill, product and marketing rights, and related development projects. Sobi's goodwill is derived from the acquisition of Swedish Orphan, Dova and Gamifant.

Goodwill

Sobi conducts regular goodwill impairment testing, in accordance with the principle described in Note 2. The recoverable amount of cash-generating units is determined by calculating their value-in-use. This calculation requires certain assumptions to be made. See Note 16. On 31 December 2022 Sobi's goodwill amounted to SEK 7,007 M (6,288). Testing carried out during the year showed no indication of impairment.

Product and marketing rights

Certain assumptions are needed to assess the value of product and marketing rights, and related development projects. These are described in Note 16. Changes in these assumptions could have a material adverse effect on the carrying amount of the asset. On 31 December 2022 Sobi's product and marketing rights amounted to SEK 32,188 M (31,559).

Sales forecast assumptions have a major impact on future value and are based on assumptions of underlying growth, future development and expanded applications for the medicine. For development projects, assumptions about positive outcomes in clinical studies are a prerequisite for future value. These assumptions are probability weighted.

Product and marketing rights that are amortised are tested for impairment whenever events and circumstances indicate that the carrying amount may not be recoverable. During the year, no such events or circumstances occurred. Product and marketing rights that have not yet been amortised are tested for impairment, at least annually, in accordance with the principle described in Note 2.

For product and marketing rights that are amortised, the amortisation period ranges from 5-20 years and is adapted to the expected commercial useful life of each right. Sobi has assessed that these amortisations are attributable to the selling costs, since the intangible assets that are classified as product and marketing rights primarily pertain to marketing rights, which means that Sobi can market or sell the medicines. Right of use is consumed over the asset's useful life, which corresponds to the related medicine's estimated useful life in the market.

Research & development costs

Sobi conducts research & development in internal projects and jointly with external partners. In cases where Sobi carries out projects with an external partner and both parties share certain costs, the costs are estimated when the project commences. This cost is then used as a basis for settlement with the external partner. The calculation is assessed and updated regularly. In some collaboration agreements, Sobi agrees to pay considerations. This consideration is balanced and recognised as licences and patents, or product and marketing rights. Amortisation does not commence until the project has reached commercialisation phase and meets the requirements of IAS 38 Intangible Assets. Evaluation of the project's progress and impairment testing are carried out as described under the heading of product and marketing rights. In 2022, there were no impairment losses related to the clinical programmes.

Costs for internal development and payments for projects and substances under agreement with third parties are expensed as incurred if they do not meet the requirements of IAS 38. Regulatory frameworks and uncertainty usually mean that the criteria are not met. However, in cases where the requirements are met, intangible assets are capitalised and amortised according to plan. Capitalisation commences when Sobi can demonstrate that it is technically feasible and profitable to commercialise the results.

Profit-sharing arrangement

Nirsevimab

In connection with the acquisition of the rights to Synagis in the US from AstraZeneca in 2019, Sobi obtained the rights to 100 per cent of AstraZeneca's half share of profit and losses for nirsevimab in the US market. AstraZeneca is responsible for the development of nirsevimab and Sanofi is responsible for the commercialisation.

Revenue and expenses linked to the agreement is recognised in the period when the underlying revenue and expenses occurs at the cooperation partner in accordance with the principles described in Note 2. This is based on assumptions and estimates about when the underlying sales take place and the expenses arise at AstraZeneca and Sanofi, which are settled quarterly with the cooperation partner. AstraZeneca is entitled to incrementally increasing single-digit to mid-to-low double-digit percentage royalty on annual profit-sharing based on certain tiered levels. This expense is recognised together with other cost of goods sold linked to the agreement as expense from profit-sharing arrangements within cost of goods sold and is based on assumptions about forecasts of future sales, which are reconciled quarterly in accordance with above.

Invoicing and settlement between the companies take place on a net basis, i.e., with a deduction for Sobi's share of the expenses as noted above. If the expenses exceed revenue, Sobi is invoiced by the counterparty.

The validation of the regulatory submission for nirsevimab in the US in January 2023 triggered a milestone payment of USD 175 M (SEK 1,811 M) which was paid to AstraZeneca on 21 February 2023. The agreement includes additional potential milestone payments of total USD 180 M (SEK 1,826 M). Furthermore, Sobi shall reimburse AstraZeneca for contractual historical expenses. Milestone settled, potential milestones and historical research & development expenses are recognised as part of the asset value as of 21 February 2023 as Sobi has not exercised its unconditional right to withdraw from the agreement. Recognition of the acquisition value of the asset and liabilities linked to the agreement is done in accordance with the principles described for intangible assets and financial liabilities linked to contingent considerations in Note 2 and below.

Furthermore, Sobi is entitled to a payment from AstraZeneca of EUR 65 M (SEK 723 M) upon regulatory approval of nirsevimab in the US. Sobi has assessed to handle this settlement as a reduction of the purchase price of the asset and thus initially recognised it as a receivable with a corresponding deduction of the acquisition value of the asset, similar to the principles for contingent considerations described in note 2 and below.

At the acquisition of Synagis and the profit-share for nirsevimab, Sobi made the assessment that one intangible asset was acquired whereby the additional acquisition value linked to nirsevimab is recognised together with the acquisition value for Synagis.

Taxes

When preparing the financial statements, Sobi calculates the income tax for each tax jurisdiction in which Sobi operates, and deferred tax attributable to temporary differences, please see Note 2.

Deferred tax assets mainly attributable to loss carry-forwards and temporary differences are recognised if the tax assets are expected to be realised through future taxable profits in the various tax jurisdictions.

At the end of 2022, Sobi recognised deferred tax assets of SEK 877 M (767) and deferred tax liabilities of SEK 3,797 M (3,605). Additionally, there were non-capitalised tax loss carry-forwards of SEK 2,762 M (2,716) at the end of 2022. Changes in estimates of future taxable income and expense, as well as changes in tax rates, could have either a positive or negative effect on earnings when determining the value of deferred tax. Please see Note 20 for more information about deferred taxes.

Financial liabilities

Contingent considerations

Sobi has financial liabilities linked to contingent considerations attributable to business combinations and intangible assets acquired. As described in Note 2, Sobi classifies certain contingent considerations as non-contingent. At the end of 2022 recognised liability for contingent and non-contingent considerations amounted to SEK 3,406 M (2,818) and to SEK 1,748 M respectively. Total obligation amounted to SEK 21,005 M (15,540 and SEK 1,770 M (1,754) respectively. The contingent obligations are normally linked to future payments upon the achievement of certain regulatory and commercial milestones. Recognised liability is based on assumptions and estimates of the future potential payments, which are probability-weighted and discounted. Sobi uses historical data for clinical and regulatory advancement to assess the probability that regulatory obligations will be achieved. Commercial milestones are usually tied to the achievement of various sales levels for the medicine. Sobi makes assumptions, which are probability-weighted, about the achievement of these levels based on sales revenue forecasts. The assumptions may change over time, as circumstances change due to new facts, which could lead to a significant change in the value of a recognised liability and its corresponding intangible asset. For more information about accounting policies for financial liabilities related to contingent considerations, please see Note 2. Also please refer to Note 28 for more information about financial liabilities linked to contingent considerations.

5 Segment information and revenue

Segment information

Sobi's activities are organised in three segments – Haematology, Immunology and Specialty Care.

Haematology segment: revenue is derived from sales of Elocta, Alprolix, Doptelet and Aspaveli/Empaveli. Revenue is also derived from royalties on Sanofi's sales of Eloctate and Alprolix and manufacturing of the medicine substance for ReFacto AF/Xyntha for Pfizer.

Immunology segment: revenue is derived from sales of Kineret, Synagis and Gamifant.

Specialty Care segment: revenue is derived from sales of Orfadin, Tegsedi, Waylivra and other medicines in Specialty Care.

The *Group – other* category mainly relates to costs for central functions such as finance, legal, communication, HR and other items that cannot be allocated per segment.

Revenue, EBITA and EBITA adjusted for each segment comprise their contribution to the Group's revenue, EBITA and EBITA adjusted. No sales are conducted between the segments. The segments' assets are measured in the same way as in the financial statements. These assets are distributed on the basis of the segment's operations and the asset's physical location.

Group 2022	Haematology	Immunology	Specialty Care	Group – other	Total
Revenue and EBITA per segment					
Revenue	10,831	6,679	1,280	–	18,790
EBITA	4,111	2,304	287	-774	5,930
EBITA adjusted[i]	4,475	2,410	287	-568	6,605
Depreciation	-857	-1,041	-162	-57	-2,117
Financial expenses	–	–	–	-497	-497
Financial income	–	–	–	5	5
Profit/loss after financial items	**3,254**	**1,263**	**125**	**-1,323**	**3,321**
Non-current assets					
Goodwill	5,706	1,301	–	–	7,007
Other intangible assets	15,040	17,436	384	146	33,006
Total intangible assets	**20,746**	**18,737**	**384**	**146**	**40,013**

Group 2021	Haematology	Immunology	Specialty Care	Group – other	Total
Revenue and EBITA per segment					
Revenue	8,536	5,780	1,213	–	15,529
EBITA	3,698	2,054	388	-566	5,575
EBITA adjusted	3,698	2,054	388	-566	5,575
Depreciation	-627	-1,008	-158	-48	-1,841
Financial expenses	–	–	–	-454	-454
Financial income	–	–	–	16	16
Profit/loss after financial items	**3,071**	**1,047**	**230**	**-1,053**	**3,295**
Non-current assets					
Goodwill	5,121	1,168	–	–	6,288
Other intangible assets	13,755	17,716	544	121	32,135
Total intangible assets	**18,875**	**18,884**	**544**	**121**	**38,424**

i. Items affecting comparability in 2022, please see Note 12 and Alternative performance measures.

Group	2022	2021
Haematology		
Elocta	4,402	3,960
Alprolix	1,885	1,764
Royalty	1,427	1,251
Doptelet	2,526	1,116
Aspaveli/Empaveli	178	1
Manufacturing	413	445
Total	**10,831**	**8,536**
Immunology		
Kineret	2,284	2,290
Synagis	3,501	2,650
Gamifant	895	840
Total	**6,679**	**5,780**
Specialty Care		
Orfadin	462	459
Tegsedi	429	427
Waylivra	152	121
Other Specialty Care	237	207
Total	**1,280**	**1,213**
Total revenue	**18,790**	**15,529**

Group	2022	2021
Revenue – Gross to net[i]		
Product sales, gross	23,693	19,195
Contractual discounts	-1,994	-1,778
Statutory discounts	-4,543	-3,418
Tender-based discounts	-115	-74
Product returns	-64	-43
Cash discounts	-42	-64
Total discounts	**-6,758**	**-5,378**
Product sales, net	**16,935**	**13,817**
Manufacturing	413	445
Royalty	1,427	1,251
Service fees	15	16
Total revenue	**18,790**	**15,529**

i. Operating revenue less mandatory and contractual price reductions.

Parent Company	2022	2021
Revenue – Gross to net[i]		
Product sales, gross	12,470	11,595
Contractual discounts	-690	-769
Statutory discounts	-254	-136
Cash discounts	-1	-1
Total discounts	**-945**	**-906**
Product sales, net	**11,525**	**10,689**
Manufacturing	413	445
Royalty	1,427	1,251
Service fees	15	16
Total revenue	**13,381**	**12,401**

i. Operating revenue less mandatory and contractual price reductions.

	Group		Parent Company	
	2022	2021	2022	2021
Total contract assets[i]				
Accounts receivable	5,249	3,439	995	1,126
Accrued royalty[ii]	334	321	334	321
Total	**5,583**	**3,760**	**1,330**	**1,448**

i. For maturity structure and the year's change, please see Note 22.

ii. Included in prepaid expenses and accrued income on the balance sheet.

Total contract liabilities

The table below shows the share of revenue recognised in relation to contract liabilities during the financial year, and the share of revenue recognised in relation to performance obligations satisfied in a prior financial year.

Group	Accrued contractual and tender-based discounts	Accrued refunds based on government and regulatory price changes	Accrued product returns	Accrued co-financing	Accrued cash and other discounts	Total
Opening balance, 1 January 2021	**561**	**1,509**	**56**	**28**	**5**	**2,158**
Reserves for current year	1,012	3,200	66	107	7	4,393
Adjusted reserves for prior years	54	-407	-18	0	—	-371
Payments	-994	-2,174	-23	-104	-8	-3,303
Translation differences	25	142	7	3	0	177
Closing balance, 31 December 2021	**658**	**2,270**	**88**	**34**	**4**	**3,053**
Opening balance, 1 January 2022	**658**	**2,270**	**88**	**34**	**4**	**3,053**
Reserves for current year	1,247	4,043	67	189	47	5,593
Adjusted reserves for prior years	-41	-273	-3	-1	3	-315
Payments	-1,271	-4,002	-34	-186	-43	-5,537
Translation differences	60	258	14	4	1	336
Closing balance, 31 December 2022	**653**	**2,296**	**131**	**39**	**12**	**3,131**

Revenue and assets by segment and geographic area

Group 2022	Haematology		Immunology		Specialty Care		Group – other	Total	
	Revenue	Non-current assets	Revenue	Non-current assets	Revenue	Non-current assets	Non-current assets	Revenue	Non-current assets
Europe[i]	6,180	9,873	677	7,562	627	384	146	7,484	17,965
North America[ii]	1,241	10,873	5,699	11,175	501	—	—	7,441	22,048
Rest of the world	1,982	—	304	—	152	—	—	2,438	—
Other[iii]	1,427	—	—	—	—	—	—	1,427	—
Total[iv, v]	**10,831**	**20,746**	**6,679**	**18,737**	**1,280**	**384**	**146**	**18,790**	**40,013**

Group 2021	Haematology		Immunology		Specialty Care		Group – other	Total	
	Revenue	Non-current assets	Revenue	Non-current assets	Revenue	Non-current assets	Non-current assets	Revenue	Non-current assets
Europe[i]	5,743	8,996	627	7,011	641	544	121	7,011	16,671
North America[ii]	1,079	9,879	4,600	11,873	441	—	—	6,120	21,753
Rest of the world	463	—	553	—	131	—	—	1,147	—
Other[iii]	1,251	—	—	—	—	—	—	1,251	—
Total[iv, v]	**8,536**	**18,875**	**5,780**	**18,884**	**1,213**	**544**	**121**	**15,529**	**38,424**

i. Sales revenue from external customers in France amounted to SEK 1,631 M (1,805), in Germany to SEK 1,601 M (1,233) and in Sweden to SEK 667 M (678).

ii. Sales revenue from external customers in the US amounted to SEK 7,364 M (6,054).

iii. Other pertains to royalty derived from haemophilia medicines that are not attributable to a specific region according to the distribution above. All royalty pertains to Sanofi's sales of Eloctate and Alprolix.

iv. Total sales revenue from external customers in other countries amounted to SEK 6,100 M (4,508).

v. Sobi's largest customer accounted for approximately 24 per cent (17) of sales. The customer was reported under all segments; Haematology, Immunology and Specialty Care. See also Note 22 for further information.

Parent Company	2022	2021
Revenue by geographic area[i]		
Europe[ii]	6,494	5,837
North America	4,294	4,313
Rest of the world	1,165	1,000
Other[iii]	1,427	1,251
Total	**13,381**	**12,401**

i. The geographic distribution is based on where the customer is located.

ii. Revenue in Sweden amounted to SEK 667 M (678).

iii. Other pertains to royalty derived from haemophilia medicines that are not attributable to a specific region according to the distribution above. All royalty pertains to Sanofi's sales of Eloctate and Alprolix.

6 Depreciation/amortisation and impairment of assets

Group	2022	2021
Depreciation/amortisation according to plan by type of asset		
Licences and patents	18	8
Product and marketing rights	2,016	1,758
Capitalised costs	83	75
Plant and machinery	16	15
Equipment, tools, fixtures and fittings	18	25
Right-of-use assets	117	114
Other non-current assets	4	4
Total	**2,273**	**2,000**
Impairment by type of asset		
Plant and machinery	10	7
Right-of-use assets	136	–
Total	**146**	**7**
Total depreciation/amortisation and impairment by type of asset	**2,419**	**2,006**
Depreciation/amortisation according to plan by type of function		
Cost of goods sold	28	34
Selling and administrative expenses	2,222	1,949
Development costs	24	17
Total	**2,273**	**2,000**
Impairment by type of function		
Cost of goods sold	133	–
Selling and administrative expenses	3	–
Development costs	9	7
Total	**146**	**7**
Total depreciation/amortisation and impairment by type of function	**2,419**	**2,006**

Parent Company	2022	2021
Depreciation/amortisation according to plan by type of asset		
Licences and patents	10	1
Product and marketing rights	434	282
Capitalised costs	83	75
Plant and machinery	14	12
Equipment, tools, fixtures and fittings	8	14
Other non-current assets	1	1
Total	**550**	**385**
Impairment by type of asset		
Plant and machinery	9	–
Total	**9**	**–**
Total depreciation/amortisation and impairment by type of asset	**559**	**385**
Depreciation/amortisation according to plan by type of function		
Cost of goods sold	13	10
Selling and administrative expenses	537	375
Development costs	–	0
Total	**550**	**385**
Impairment by type of function		
Cost of goods sold	9	–
Total	**9**	**–**
Total depreciation/amortisation and impairment by type of function	**559**	**385**

Please see Note 16 and 17 for further information.

7 Other operating income

Group	2022	2021
Exchange-rate gains[i]	**–**	**2**
Other	**34**	**30**
Total	**34**	**32**

Parent Company	2022	2021
Expenses re-invoiced to Group companies	400	350
Other	28	3
Total	**428**	**353**

i. Exchange-rate effects are offset against other operating income or other operating expense. In 2022, exchange rate effects generated a loss of SEK –33 M (2). For the Parent Company, exchange rate effects generated a loss of SEK –62 M (–2), please see Note 8.

8 Other operating expenses

Group	2022	2021
Exchange-rate losses[i]	33	–
Scrapping/disposal of non-current assets[ii]	0	56
Other	2	–
Total	**35**	**56**

Parent Company	2022	2021
Exchange-rate losses[i]	62	2
Scrapping/disposal of non-current assets	0	1
Total	**63**	**3**

i. Exchange-rate effects are offset against other operating income or other operating expense. In 2022, exchange rate effects generated a loss of SEK –33 M (2). For the Parent Company, exchange rate effects generated a loss of SEK –62 M (–2), please see Note 7.

ii. Prior year's disposals mainly pertain to disposal of the opt-in right to the early-stage development projects, NI-1701 and NI-1801 for more information please see Note 16.

9 Leases

Sobi holds leases for various types of objects, mainly properties and vehicles. The term of property leases is normally between two and ten years, while vehicle leases are normally between 36 and 48 months. Options to extend or terminate are included in the lease contracts for several of Sobi's properties and are accounted for in the Group's assessment of whether it is reasonably certain to exercise these options. Most contracts also include clauses related to the indexation of future rental costs, which are continuously accounted for. Service components are not included in capitalised amounts, in accordance with IFRS 16. The same applies to other variable costs, such as electricity and heating, where the costs are based on the actual use of the properties.

Sobi signed an agreement with Pfizer in 2021 for the production of Kineret. Under the agreement, Sobi will compensate Pfizer for its investment in a production facility up to completion of the facility, and thereafter compensate for the remaining investment over a ten-year period. In total, Sobi expects to pay approximately EUR 90 M (around SEK 960 M) over the life of the contract. The contract is treated by the Group as a lease contract. At the end of the year, Sobi had paid SEK 123 M to Pfizer, which appears on the balance sheet as a prepaid cost until the facility begins production.

Sobi also has several leases that are short-term or low value. The Group applies the exemption for short-term and low-value leases, which essentially comprise copying machines, printers and computers.

Sobi recognises right-of-use assets under a lease contract as tangible assets on the balance sheet, see below for the recognised amounts and activities for the period.

Group Right-of-use assets	Properties	Cars	Total
On 1 January 2021	**373**	**36**	**409**
Addition	33	25	58
Depreciation and impairment	-92	-22	-114
Divestments and disposals	-1	-4	-5
Translation differences	9	1	10
On 31 December 2021	**322**	**37**	**359**
Addition	51	34	85
Depreciation and impairment[i]	-227	-26	-253
Divestments and disposals	-2	-4	-5
Translation differences	8	4	12
On 31 December 2022	**152**	**45**	**198**

i. 2022 includes impairment of right-of-use assets of SEK 124 M following the discontinuation of contract manufacturing for Pfizer and SEK 12 M following the decision to consolidate the Geneva site into Basel.

Sobi recognises lease liabilities under separate headings on the balance sheet – non-current liabilities and current liabilities. See the table for amounts recognised and activities for the period.

Group Lease liabilities	2022	2021
On 1 January	**361**	**419**
Addition	90	57
Divestments and disposals	-6	-3
Accumulated interest	6	6
Payments	-133	-125
Translation differences	17	7
On 31 December	**333**	**361**
Non-current	200	247
Current	134	114

For maturity analysis of lease liabilities, please refer to Note 3.

The following amounts were recognised in profit or loss:

Group	2022	2021
Depreciation and impairment of right-of-use assets[i]	253	114
Interest expense on lease liabilities	7	6
Costs attributable to short-term leases	4	7
Costs attributable to low-value leases	1	1
Costs attributable to variable lease payments not included in the measurement of the lease liability	16	12
Total amount recognised in profit or loss	**281**	**140**
Amounts recognised in the cash flow statement		
Repayment of lease liability	-133	-125
Short-term leases	-4	-7
Low-value leases	-1	-1
Variable lease payments not included in the measurement of the lease liability	-16	-12
Total cash flow	**-154**	**-145**

i. 2022 includes impairment of right-of-use assets of SEK 124 M following the discontinuation of contract manufacturing for Pfizer and SEK 12 M following the decision to consolidate the Geneva site into Basel.

During the year, the Group did not derive any benefits from right-of-use assets in a sublease, nor any gains or losses from sale and leaseback transactions.

The Parent Company, which prepares its accounts in accordance with RFR 2, applies the exemption to recognising assets and liabilities for assets as a legal entity. See the table below for lease payments.

Future rental and minimum lease payments

Contracted future rental payments for premises related to non-terminable contracts falling due:

	Parent Company	
	2022	2021
Within 1 year	69	60
Between 1-5 years	146	173
Later than 5 years	–	–
Total	**215**	**233**
Rental payments for the year	62	62

Other contracted future minimum lease payments related to non-terminable contracts falling due:

	Parent Company	
	2022	2021
Within 1 year	2	2
Between 1-5 years	2	2
Later than 5 years	—	—
Total	**4**	**4**
Lease payments for the year	2	3

10 Employees, personnel costs and remuneration of board members and senior executives

Number of employees[i]

Group	2022	of whom women, %	of whom men, %	2021	of whom women, %	of whom men, %
Australia	4	50%	50%	2	50%	50%
Belgium	17	59%	41%	16	60%	40%
Central and Eastern Europe	57	58%	42%	35	49%	51%
Denmark	8	88%	13%	12	75%	25%
Finland	7	71%	29%	7	71%	29%
France	68	62%	38%	65	60%	40%
United Arab Emirates	36	19%	81%	37	27%	73%
Greece	11	55%	45%	9	56%	44%
Italy	56	57%	43%	69	51%	49%
Japan	24	33%	67%	13	38%	62%
Canada	18	61%	39%	15	40%	60%
China	18	83%	17%	19	79%	21%
Netherlands	8	38%	63%	9	42%	58%
Norway	5	80%	20%	4	75%	25%
Portugal	8	75%	25%	5	60%	40%
Russia	43	70%	30%	35	69%	31%
Switzerland	153	56%	44%	143	59%	41%
Spain	47	68%	32%	49	61%	39%
UK	75	57%	43%	80	46%	54%
Sweden	355	62%	38%	399	62%	38%
Germany	95	65%	35%	86	63%	37%
US	430	58%	42%	441	58%	42%
Austria	13	62%	38%	10	60%	40%
Total	**1,556**	**59%**	**41%**	**1,559**	**58%**	**42%**

i. On 31 December 2022, the number of full-time employees was 1,556, while the number of employees at the same date was 1,605.

Gender composition of the board and management

The information in the table does not include employee representatives. The information refers to conditions at the balance sheet date.

Group	2022	2021
Board		
Men	4	4
Women	3	4
Total	**7**	**8**
CEO and other senior executives		
Men	12	11
Women	1	1
Total	**13**	**12**

Salaries, other remuneration and social security costs

Group and Parent Company	2022 Salaries and remuneration	2022 Social security costs	2021 Salaries and remuneration	2021 Social security costs
Parent Company	541	258	500	247
(of which pension expense)		*(88)*		*(75)*
Subsidiaries	2,540	336	1,981	300
(of which pension expense)		*(100)*		*(101)*
Group, total	**3,081**	**594**	**2,481**	**548**
(of which pension expense)		*(188)*		*(176)*

Salaries and other remuneration divided between board members, the CEO and other employees

Group and Parent Company	2022 Board and CEO	2022 Other employees	2021 Board and CEO	2021 Other employees
Parent Company				
Salaries and other remuneration	50	491	45	455
(of which bonus)i	*(33)*	*(137)*	*(29)*	*(138)*
Subsidiaries				
Salaries and other remuneration	—	2,540	—	1,981
(of which bonus)i	*(—)*	*(816)*	*(—)*	*(596)*
Group, total	**50**	**3,031**	**45**	**2,436**
(of which bonus)	*(33)*	*(953)*	*(29)*	*(734)*

i. Bonus includes the Company´s IFRS-2 costs of the share programmes and are not to be equated with employee benefits.

Guidelines and remuneration 2022

The 2020 AGM resolved on remuneration guidelines for Sobi's senior executives as set forth below, which will apply until the 2024 AGM.

The members of the Executive committee of Sobi fall within the provisions of these guidelines. The guidelines also cover any remuneration of board members, except fees resolved by the AGM[1]. The guidelines are forward-looking, i.e. they are applicable to remuneration agreed, and amendments to remuneration already agreed, following adoption of the guidelines by the 2020 AGM. These guidelines do not apply to any remuneration decided or approved by the AGM.

Remuneration of the Executive committee is designed on a total remuneration approach. The position of total remuneration should be market-competitive relative to competitors in each local market. The market comparisons should be made against a set of peer-group companies with comparable sizes, industries and complexity. The remuneration guidelines shall enable international hiring and support diversity within the Executive committee. Employment contracts governed by rules other than Swedish may be duly adjusted to ensure compliance with mandatory rules or established market practice, taking into account, to the extent possible, the overall purpose of these guidelines.

1. Any remuneration of board members, except fees adopted by the AGM, may only consist of consultancy fees.

Remuneration and other benefits to the board, CEO and other senior executives[i], KSEK

2022	Base salary/ fees	Bonus[iv]	Pension expense	Other benefits	Share programmes[v]	Total
Chairman of the board						
Håkan Björklund	1,760					1,760
Other board members						
Bo Jesper Hansen	667					667
Annette Clancy	648					648
Matthew Gantz	673					673
Helena Saxon	788					788
Staffan Schüberg	677					677
Filippa Stenberg	647					647
Elisabeth Svanberg[ii]	181					181
Executive committee, 2022						
Guido Oelkers, Chief Executive Officer	11,449	8,228	3,105	—	24,488	47,270
Other senior executives (11-12 people)[iii, iv]	59,164	33,780	7,680	2,913	43,885	147,422
Total	**76,654**	**42,008**	**10,785**	**2,913**	**68,373**	**200,733**

i. Other senior executives refer to Sobi's Executive committee, which consisted of 12 people in addition to the CEO on 31 December 2022. The remuneration of all members of the Executive committee during the year is included in the table. For information about changes in management, see the Directors' report. The table shows Sobi's costs (excluding social security contributions). For more information about board fees, see the corporate governance report.

ii. At the AGM on 10 May 2022, Elisabeth Svanberg stepped down from her position as board member, while Bo Jesper Hansen was appointed new board member.

iii. Anders Ullman resigned from the board on 31 December 2021 and was a member of the Executive committee from 1 January 2022.

iv. Henrik Stenqvist was appointed deputy CEO in 2018. Since he did not serve as deputy CEO during the 2021 financial year, his remuneration is presented with other senior executives.

v. Reflects the IFRS-2 costs of the share programmes which are reported within the group's operating profit and are not to be equated with employee benefits.

Remuneration and other benefits to the board, CEO and other senior executives[1], KSEK

2021	Base salary/ fees	Bonus	Pension expense	Other benefits	Share programmes[vii]	Total
Chairman of the board						
Håkan Björklund	1,663					1,663
Other board members						
Annette Clancy	587					587
Matthew Gantz	570					570
Lennart Johansson[ii]	217					217
Helena Saxon	720					720
Filippa Stenberg[ii]	413					413
Staffan Schûberg	620					620
Elisabeth Svanberg	570					570
Anders Ullman[ii, iii]	420					420
Executive committee, 2021						
Guido Oelkers, Chief Executive Officer	10,120	10,403	2,880		18,734	42,137
Other senior executives (10-11 people)[iv, v, vi]	48,639	24,240	6,530	3,775	40,397	123,581
Total	**64,539**	**34,643**	**9,410**	**3,775**	**59,131**	**171,498**

i. Other senior executives refer to Sobi's Executive committee, which consisted of eleven people in addition to the CEO on 31 December 2021. Additional people were included in management during the year. The remuneration of all members of the Executive committee during the year is included in the table. For information about changes in management, see the Directors' report. The table shows the Sobi's costs (excluding social security contributions). For more information about board fees, see the corporate governance report.

ii. At the AGM on 4 May 2021, Lennart Johansson stepped down from his position as board member, while Filippa Stenberg and Anders Ullman were appointed new board members.

iii. During the year, the board member invoiced consulting fees of SEK 600 K, in addition to board fees, for business strategic work initiatives that do not pertain to board work.

iv. In addition to standard variable pay, a non-recurring payment of SEK 1,618 K was made to the CEO, and SEK 1,321 K to other executives for extraordinary efforts.

v. Base salary, variable remuneration, pension and other benefits include severance pay in accordance with an agreement of SEK 4,104 K to former senior executives.

vi. Henrik Stenqvist was appointed deputy CEO in 2018. Since he did not serve as deputy CEO during the 2021 financial year, his remuneration is presented with other senior executives.

vii. Reflects the IFRS-2 costs of the share programmes which are reported within the group's operating profit and are not to be equated with employee benefits.

Types of remuneration

Remuneration can consist of fixed base salary, variable pay, pension benefits and other benefits. Additionally, the AGM may, irrespective of these guidelines, resolve on, among other things, share-related or share price-related remuneration. The components are presented below.

Base salary

The fixed base salary of the Executive committee shall be based on competence, responsibility and performance. Sobi uses an international evaluation system to evaluate the scope and responsibility of the position.

Variable pay

The annual short-term incentive plan shall be based on the achievement of predetermined and measurable annual financial (75 per cent) and non-financial objectives (25 per cent). The annual financial objectives shall be related to targets promoting growth and profitability annual revenues and EBITA[1]. The annual financial objectives are recommended by the Compensation & Benefits committee and approved by the board. The annual non-financial objectives are related to strategic and business development goals as defined and approved according to the grandparent-manager principle.

The objectives are determined for the promotion of Sobi's business strategy, long-term development, including its sustainability, value creation and financial growth and shall be designed in a way that encourages compliant behaviour. The maximum annual short-term Incentive may vary but shall not amount to more than 100 per cent of the annual gross base salary. The extent to which the criteria for awarding annual short-term incentive have been met shall be evaluated and determined by the board upon the recommendation of the Compensation & Benefits committee.

Further variable pay may also be paid out in extraordinary circumstances, provided that such an arrangement is of a one-time nature and is agreed on an individual basis for management recruitment or retention purposes or as compensation for extraordinary efforts beyond the individual's ordinary assignment. Such compensation shall be in line with market practice and may, for example, include a one-time cash payment, retention bonus or severance payment in case of a change of control, or similar. The compensation shall not exceed the amount of the gross base salary for three years and shall not be paid more than once a year per individual. Resolutions on such compensation shall be made by the board based on a proposal from the Compensation & Benefits committee.

Long-term incentives

Long-term share-related incentive plans have been implemented in Sobi. Such plans are proposed by the board and presented to the AGM for approval and are therefore excluded from these guidelines. The performance criteria used to assess the outcome of the long-term share-related incentive plan for the Executive committee are distinctly linked to the business strategy and thereby to Sobi's long-term value creation.

Pension and benefits

Sobi's preferred type of pension plan is defined-contribution[2]. If the operating environment requires the establishment of a defined-benefit pension plan under mandatory collective agreement provisions, law, or other regulations, such a plan may be established. The defined-benefit level should, in such cases, be limited to the mandatory level.

1. Earnings before interest, tax and amortisation and impairment of intangible assets.

2. A defined-contribution pension plan determines a percentage level of the employee's annual gross base salary as the contribution paid into the pension plan for each employee.

The pension premiums or allowance for pension shall not amount to more than 40 per cent of the executive's pensionable salary, which may include a capped level of the variable pay to the extent required by mandatory collective agreement provisions.

Other benefits may include, for example, life insurance, health insurance, medical insurance and company cars. Premiums and other costs relating to such benefits shall be based on market practice but amount to no more than 20 per cent of the annual gross base salary.

Senior executives who are expatriates to or from Sweden may receive additional remuneration and other benefits, such as a support package including relocation and tax filing support as well as tax equalisation, to the extent reasonable in light of the special circumstances associated with the expat arrangement, taking into account, to the extent possible, the overall purpose of these guidelines. Such benefits may not exceed 40 per cent of the total annual gross base salary.

Termination of employment
The notice period may not exceed twelve months. Fixed base salary during the notice period and severance pay, including payments for any restrictions on competition, shall in total not exceed an amount equivalent to the gross base salary for two years.

Consultancy fees to board members
Board members elected by the AGM may receive consultancy fees for services provided to Sobi. Such services must contribute to Sobi's business strategy and long-term interests, including its sustainability, and may not relate to regular board work. Any consultancy fee shall be based on market terms and may not exceed the annual remuneration of each board member for their board assignment. The above applies correspondingly to services performed by a wholly owned company of a member of the board.

Salary and employment terms for employees
In the preparation of the board's proposal for these remuneration guidelines, salary and employment conditions for employees of Sobi have been taken into account. Information on the employees' total remuneration, the components of the remuneration and increase and growth rate over time, have been included in the Compensation & Benefits committee's and the board's basis for decisions when evaluating whether the guidelines and the limitations set out herein are reasonable.

Decision process to determine, review and implement the guidelines
The board has established a Compensation & Benefits committee. The committee's tasks include preparing the board's decision to propose guidelines for remuneration to the Executive committee. The board shall prepare a proposal for new guidelines at least every fourth year and present it to the AGM. The guidelines shall be in force until new guidelines are adopted by the AGM. The Compensation & Benefits committee shall also monitor and evaluate programmes for variable remuneration for the Executive committee, the application of these guidelines as well as the current remuneration structures and compensation levels in Sobi. The members of the Compensation & Benefits committee are independent of Sobi and the Executive committee. The CEO and other members of the Executive committee do not participate in the board's processing of and resolutions regarding remuneration-related matters in so far as they are affected by such matters.

Deviation from the guidelines
The board may temporarily resolve to derogate from these guidelines, in whole or in part, if in a specific case there is special cause for the derogation and a derogation is necessary to serve Sobi's long-term interests, including its sustainability, or to ensure Sobi's financial viability. As set out above, the Compensation & Benefits committee's tasks include preparing the board's resolutions in remuneration-related matters. This includes any resolutions to derogate from these guidelines.

Senior executives' employment terms and remuneration
Sobi aims to offer market-based terms, which enables Sobi to recruit and retain highly qualified personnel. Remuneration of elected board members is paid in accordance with a resolution adopted by the 2022 AGM. No pensions are paid to board members. The CEO's remuneration is reviewed and proposed by the chairman of the board together with the Compensation & Benefits committee and approved by the board. Remuneration of other members of the Executive committee is proposed by the CEO and approved by the Compensation & Benefits committee. Remuneration of the CEO and other senior executives consists of base salary, variable pay in the short and long term, other benefits and pensions. Other senior executives refer to those individuals who together with the CEO form the Executive committee.

Base salary
The base salary is based on the individual executive's area of responsibility, expertise and performance. The base salary is reviewed every year.

Short-term variable pay
For the CEO, short-term variable pay in 2022 was capped at 100 per cent of annual gross salary. Variable pay was based on financial and non-financial targets set by the board. For other senior executives, short-term variable pay was capped at 60 per cent of base salary and based on financial and non-financial targets.

Retirement benefits
The CEO is entitled to a defined-contribution pension solution amounting to 30 per cent of base salary. The retirement age is 65 years. Other senior executives employed in Sweden are covered by the ITP plan with a retirement age of 65. They are also covered by a supplementary defined-contribution pension obligation of 27 per cent of pensionable salary up to 50 income base amounts, including ITP.

Incentive programmes
At the balance sheet date, Sobi had three active share programmes. To participate in the share programmes, employees must be permanently employed. Furthermore, Sobi has five active cash-based programmes, of which three relate to employees in the US and Canada, and two relate to employees in China and Japan. All programmes have a three-year term.

Long-term incentive programmes
The aim of the long-term incentive programmes has been to create a long-term commitment to Sobi, to provide the participants with an opportunity to share Sobi's long-term success and value creation, and to enable Sobi to attract and retain senior executives and senior managers. Sobi's long-term incentive programmes are described below.
The 2019-2022 AGMs approved the introduction of long-term incentive programmes for the CEO, senior executives and managers, one programme for other employees, and share options for the CEO, senior executives and selected key employees. The share programmes are structured on the same principles, and they all have a three-year vesting period.

The management programmes include the CEO, senior executives and managers. They require no personal investment in Sobi shares and performance shares are only allotted if the programme criteria have been met. The number of performance shares varies between the organisational levels. The performance targets for the management programmes are that the share price increases by a certain percentage over a three-year period, and that actual annual revenues during the vesting period meet or exceed the annual revenue budget.

In addition to the performance shares, the management programmes for the CEO, senior executives and selected key employees consist by half of share options. The employees eligible and how the performance targets are formulated differ between the programmes.

The programmes for other employees require a personal investment in Sobi shares (investment shares) in order to be allotted free shares on a matching basis. A requirement for all programmes is that the employee must be permanently employed throughout the entire vesting period and, in the case of investment shares, that these are retained throughout the entire vesting period.

In addition to the above, there are cash-based programmes for employees in North America and Asia.

Management programme 2019 (paid in 2022)

For the performance shares that vested on 28 May 2022, the board determined that 55.38 per cent of the performance obligations and other vesting requirements had been met. To achieve the maximum 60 per cent allotment of the performance shares, the performance target was a 50 per cent increase in the share price, adjusted for any dividends. The performance outcome is 0 if the share price is below 15 per cent, with a linear allotment of performance shares for 15-50 per cent. The performance target was achieved with 25.63 per cent. For a maximum allotment of the remaining 40 per cent of the performance shares, actual annual revenue during the vesting period must meet or exceed the budget for the annual revenue, which was achieved for 2019, 2020, and 2021. Therefore, 339,844 shares with a market value of SEK 75 M were allotted under the programme.

For the share options that vested on 28 May 2022, the board determined that the performance criteria for actual average annual revenue for 2019-2021 had been met. From that date, 1,361,540 share options could be exercised at the price of SEK 180,65 until 28 May 2024, whereof 491,835 options have been allotted during the year.

All-employee programme 2019 (paid in 2022)

The 2019 all-employee programme vested on 28 May 2022. Programme participants were allotted two matching shares for each investment share. To qualify for the allotment of matching shares, participants must have retained the investment shares that they acquired. 25,778 shares with a market value of SEK 5,7 M were allotted under the programme.

Cash-based programmes 2019 and 2020 (expired 2022)

For the 2019 and 2020 long-term cash-based programmes for employees in the US and Canada that expired in 2022, the board determined that the outcome of the final year was 104 per cent. The programmes consisted of two components: a time-based component (50 per cent) and a performance-based component (50 per cent) based on two performance targets. The first performance target (50 per cent) was that the share price must increase by at least 10 per cent per year over a four-year period for the 2019 programme and a three-year period for the 2020 programme. The other performance target (50 per cent) was that annual revenue in North America must be at least 95 per cent per year in relation to the budget over a four-year period for the 2019 programme and a three-year period for the 2020 programme. A quarter of the programme vested annually over a four-year period for the 2019 programme and a three-year period for the 2020 programme.

2020-2022 management programmes

Participants in these management programmes are allotted performance shares provided that certain performance targets are achieved. The maximum possible allotment of shares in the management programmes is 649,356 (2020), 1,181,232 (2021) and 1,038,684 (2022).

To achieve a maximum 60 per cent allotment of the maximum number of performance shares, a certain share price performance must be achieved. For the 2020 management programme, a 15-50 per cent increase in the share price is required, adjusted for any dividends. The performance outcome is 0 if the share price is below 15 per cent, with a linear allotment of performance shares for 15-50 per cent. For the 2021 and 2022 management programmes, a 10-40 per cent increase in the share price is required, adjusted for any allotments. The performance outcome is 0 if the share price is below 10 per cent, with a linear allotment of performance shares for 10-40 per cent.

For a maximum allotment of the remaining 40 per cent of the performance shares, actual annual revenue during the vesting period must meet or exceed the budget for the annual revenue. This performance target was achieved for 2020, 2021 and 2022.

In addition to performance shares, the CEO and a maximum of 15 members of Sobi's Executive committee, as well as a maximum of 15 selected key individuals in the Group, have a possibility to receive share options. The vesting period is three years, followed by a two-year exercise period. A requirement for the share options is that the Group's average revenue meets or exceeds the Group's target for average revenue in the budget determined by the board during the vesting period. The exercise price corresponds to 105 per cent of the volume-weighted average price for the Sobi share when the programmes were launched. The maximum value per share that can be obtained by exercising the share options is capped at three times the exercise price. Should the share value exceed this level, the conditions must be recalculated.

Management programmes

Share programme	Performance target	Weigh	Target	Result
2019	Share price performance	60%	15-50	25.63%
2020	Share price performance	60%	15-50	NA
2021-2022	Share price performance	60%	10-40	NA
	Budget – annual revenue	40%	≥100%	NA

2020-2022 all-employee programmes

Participation in the programmes for other employees requires a personal investment in Sobi shares. The maximum possible allotment of shares in the all-employee programmes is 40,930 (2020), 50,014 (2021) and 41,004 (2022).

Participants in the all-employee programmes are allotted two matching shares for every investment share. To qualify for the allotment of matching shares, programme participants must retain their acquired investment shares throughout the entire vesting period.

During the rollout of the 2020 and 2021 share programmes, a number of employees were insiders and not therefore eligible to participate in the programmes. In view of the legal obstacles to participating in the programmes, the board decided to establish long-term three-year cash-based incentive programmes for insiders each year.

Share-options

Main terms and conditions for the share-option programmes[i]

Share-option programme	Number of participants	Performance period	Award date	Exercise period	Exercise price[ii] (SEK)	Option value at grant date	Weighted average share price at grant date
2019	27	2019-2021	28/5/2019	2022-05-28 2024-05-28	180.65	38.33	172.05
2020	24	2020-2022	28/5/2020	2023-05-29 2025-05-29	213.86	45.09	203.68
2021	28	2021-2023	1/6/2021	2024-06-02 2026-06-02	153.01	31.59	145.72
2022	27	2022-2024	30/5/2022	2025-05-31 2027-05-31	217.91	56.38	207.54

i. Volatility is measured as the standard deviation of the expected return on the share price, based on a statistical analysis of daily share prices for Sobi's ordinary share over the past three years. Risk-free interest rate: ten-year treasury bills or a comparable financial investment with the lowest possible risk.

ii. The exercise price corresponds to 105 per cent of the volume-weighted average price for Sobi's share when launching the programmes.

Exercise of the warrants is dependent on the achievement of performance conditions (the actual average turnover achieves or exceeds the budget over a three-year period).

No dividend yields included in assumptions.

Development of option programmes during 2022

	Numbers of shares								
Share-option programme	Opening	New programme	Allotted	Forfeited	Closing	Of which redeemable at year-end	Of which executive committee at the end of the period	Weighted average share price during the redemption period	Weighted average remaining agreed term
2019	1,454,718	—	-491,835	-93,178	869,705	869,705	558,254	215.51	1.4
2020	1,363,514	—	—	-65,425	1,298,089	—	795,735	—	2.4
2021	2,062,909	—	—	-79,943	1,982,966	—	1,280,134	—	3.4
2022	—	1,548,295	—	—	1,548,295	—	1,052,077	—	4.4
Total	**4,881,141**	**1,548,295**	**-491,835**	**-238,546**	**5,699,055**	**869,705**	**3,686,200**		

Development of option programmes during 2021

	Numbers of shares								
Development of option programmes during 2021	Opening	New programme	Allotted	Forfeited	Closing	Of which redeemable at year-end	Of which executive committee at the end of the period	Weighted average share price during the redemption period	Weighted average remaining agreed term
2019	1,454,718	—	—	—	1,454,718	—	799,251	—	2.4
2020	1,363,514	—	—	—	1,363,514	—	920,298	—	3.4
2021	—	2,062,909	—	—	2,062,909	—	1,301,001	—	4.4
Total	**2,818,232**	**2,062,909**	**—**	**—**	**4,881,141**	**—**	**3,020,550**		

2020-2022 Cash-based programmes, North America

The long-term cash-based programmes for all employees in the US and Canada consist of two components: a time-based component (50 per cent) and a performance-based component (50 per cent) which is based on two performance targets. The first performance target (50 per cent) is a share price increase of 10 per cent per year over the three-year period. The other performance target (50 per cent) is that annual revenues in North America must be at least 95 per cent in relation to the budget over the three-year period. Any pay-out of a third of the programme is made annually over a three-year period. The outcome for 2022 was 104 per cent.

2021-2022 Cash-based programmes, Asia

The programmes cover a number of employees in China and Japan and consist of two components: a time-based component (50 per cent) and a performance-based component (50 per cent) which is based on two performance targets. The first performance target (60 per cent) is that the share price must increase by 10-40 per cent over a three-year period, adjusted for any dividends. The performance outcome is 0 if the share price is below 10 per cent, with a linear payment for 10-40 per cent. The other performance target (40 per cent) is that the actual annual revenue during the three-year period must meet or exceed the budget for the annual revenue. This performance target was achieved for the years 2021 and 2022.

Costs for share-related compensation (excluding social costs)	2022	2021
Share programme 2019	12,072	26,821
Share programme 2020	29,599	31,788
Share programme 2021	31,838	22,807
Share programme 2022	37,680	—
Share-option programmes	61,710	49,988
(Whereof costs related to senior executives)	*(68,373)*	*(59,131)*
Total	**172,899**	**131,404**

Social security costs amounted to SEK 17 M (10).

Development of share programmes in 2022

	Number of shares				
2022 PROGRAMMES	Opening	New programme	Forfeited	Allotted	Closing
2019 Management	695,974		-356,130	-339,844	—
2019 Employee	30,128		-4,350	-25,778	—
2020 Management	721,905		-72,549		649,356
2020 Employee	45,196		-4,266		40,930
2021 Management	1,320,760		-139,528		1,181,232
2021 Employee	54,222		-4,208		50,014
2022 Management	—	1,085,266	-46,582		1,038,684
2022 Employee	—	41,738	-734		41,004
Total	**2,868,185**	**1,127,004**	**-628,347**	**-365,622**	**3,001,220**

Development of share programmes in 2021

	Number of shares				
2021 PROGRAMMES	Opening	New programmes	Forfeited	Allotted	Closing
2018 Management	677,876		-453,727	-224,149	—
2018 All-Employee	38,084		-6,414	-31,670	—
2019 Management	742,951		-46,977		695,974
2019 All-Employee	38,998		-8,870		30,128
2020 Management	794,110		-72,205		721,905
2020 All-Employee	51,446		-6,250		45,196
2021 Management	—	1,351,930	-31,170		1,320,760
2021 All-Employee	—	55,864	-1,642		54,222
Total	**2,343,465**	**1,407,794**	**-627,255**	**-255,819**	**2,868,185**

Expensing of the 2020-2022 share-based programmes is calculated using the following parameters and the Monte Carlo simulation model:

	Start date	End date	Outstanding number of matching shares	Outstanding number of performance shares	Service in months	Grant date fair value of matching share	Fair value per grant date of performance share[i]	Fair value of performance share[ii]	Expected personnel turnover, %
2020 Share Programme: all-employee	28 May 2020	28 May 2023	40,930	e/t	36	200.49	e/t	e/t	7
2020 Share Programme: management	28 May 2020	28 May 2023	e/t	649,356	36	e/t	85.77	203.68	7
2021 Share Programme: all-employee	1 June 2021	1 June 2024	50,014	e/t	36	175.25	e/t	e/t	7
2021 Share Programme: management	1 June 2021	1 June 2024	e/t	1,181,232	36	e/t	72.24	143.85	7
2022 Share Programme: all-employee	30 May 2022	30 June 2025	41,004	e/t	36	232.90	e/t	e/t	10
2022 Share Programme: management	30 May 2022	30 June 2025	e/t	1,038,684	36	e/t	107.58	210.40	10

i. Fair value of performance shares linked to share-price performance, see above.

ii. Fair value of performance shares linked to revenue, see above.

Volatility measured as the standard deviation of the expected return on the share price is based on a statistical analysis of daily share prices for Sobi's ordinary share over the past three years.

11 Remuneration of auditors

Group	2022	2021
EY		
Auditing assignments[i]	10	8
Audit activities in addition to the auditing - assignment	0	2
Other services	0	0
Total	**10**	**10**
Other auditors		
Auditing assignments[i]	0	0
Total other auditors	**0**	**0**
Total	**11**	**10**

Parent Company	2022	2021
EY		
Auditing assignments[i]	4	3
Audit activities in addition to the auditing - assignment	0	1
Other services	0	0
Total	**4**	**5**

i. Audit assignment refers to the statutory audit in order to submit an auditor's report and provide audit advice.

12 Costs according to type of cost

Group	2022	2021
Raw materials and consumables	4,007	3,028
Other external costs	4,618	3,509
Employee benefit costs	3,932	3,227
Depreciation/amortisation and impairment	2,419	2,006
Other operating expenses	35	56
Total	**15,011**	**11,828**

Parent Company	2022	2021
Raw materials and consumables	2,913	2,538
Other external costs	6,687	4,678
Employee benefit costs	827	767
Depreciation/amortisation and impairment	559	385
Other operating expenses	63	3
Total	**11,048**	**8,371**

The above costs correspond to: cost of goods sold, selling and administrative expenses, research & development expenses and other operating expenses in the income statement classified as expense by function.

Items affecting comparability per function

Group	2022	2021
Cost of goods sold[i]	363	–
Selling and administrative expenses[ii, iii, iv]	210	–
Research and development expenses[ii, iv]	102	–
Total	**675**	**–**

i. Full-year restructuring costs were SEK 363 M including impairment and accelerated depreciation of tangible assets of SEK 136 M following the decision to discontinue contract manufacturing for Pfizer. The process of downsizing the manufacturing facility started in the second half of 2022 with the last volumes anticipated to be delivered to Pfizer in the beginning of 2024.

ii. Full year refers to external expenses and restructuring costs of SEK 134 M related to structural efficiency programmes, whereof SEK 77 M were allocated to selling and administrative expenses and SEK 57 M were allocated to R&D expenses.

iii. Refers to provision for expected credit losses in Russia of SEK 106 M.

iv. Full-year restructuring costs were SEK 72 M including impairment of tangible assets of SEK 12 M following the decision in the first quarter to consolidate the Geneva site into Basel. SEK 27 M were allocated to selling and administrative expenses and SEK 45 M were allocated to R&D expenses.

13 Financial income

Group	2022	2021
Interest income	5	0
Exchange-rate gains[i]	–	16
Total	**5**	**16**

Parent Company	2022	2021
Interest income, Group companies	485	336
Interest income, other	4	0
Exchange-rate gains[i]	–	–
Total	**489**	**336**

i. Exchange rate gains and losses are presented on a net basis. In 2022, these were recognised as a loss in the Group and in the Parent Company. In 2021, the corresponding item was recognised as a gain in the Group and a loss in the Parent Company. See also Note 14.

14 Financial expenses

Group	2022	2021
Interest expense, borrowings	327	284
Interest expense, other[i]	131	135
Exchange-rate losses[ii]	11	–
Financing costs	27	35
Other	1	0
Total	**497**	**454**

Parent Company	2022	2021
Interest expense, Group companies	15	18
Interest expense, borrowings	327	284
Interest expense, other[i]	90	88
Exchange-rate losses[ii]	470	302
Financing costs	27	35
Other	1	1
Total	**931**	**728**

i. Includes interest expense linked to liabilities for consideration, please see Note 26 and 28.

ii. Exchange rate gains and losses are presented on a net basis. In 2022, these were recognised as a loss in the Group and in the Parent Company. In 2021, the corresponding item was recognised as a gain in the Group and a loss in the Parent Company. See also Note 13.

15 Income tax

Tax expense (-) / tax income (+) in earnings

Group	2022	2021
Current tax		
Current tax on profit for the year[i]	-651	-655
Adjustment of tax prior years	23	-4
Total current tax recognised	**-628**	**-659**
Deferred tax		
Excess depreciation	-313	-396
Inventories	54	95
Acquired product and marketing rights	180	178
Other intangible assets	-4	11
Tax loss carry-forwards	-28	107
Net investment hedges	-94	-63
Pharmaceutical tax	-21	14
Interest limitations	29	60
Expected credit losses	21	0
Restructuring reserve	59	—
Other	63	37
Total deferred tax recognised	**-55**	**43**
Total tax recognised	**-683**	**-616**

Parent Company	2022	2021
Current tax		
Current tax on profit for the year[i]	-475	-486
Adjustment of tax prior years	0	-5
Total current tax recognised	**-475**	**-491**
Deferred tax		
Expected credit losses	22	-2
Restructuring reserve	59	—
Other	5	5
Total deferred tax recognised	**86**	**3**
Total tax recognised	**-389**	**-488**

i. In addition to tax recognised in earnings, current tax income of SEK 22 M (17) was recognised in other comprehensive income, attributable to exchange rate effects on the Parent Company's liabilities in other comprehensive income. Additionally, current tax income of SEK 0 M (-6) was recognised directly in equity, attributable to the Parent Company's long-term incentive programme. Deferred tax income of SEK 11 M (-0) was recognised directly in equity, please see Note 20 for other deferred tax items.

Reconciliation of effective tax

Group	2022	2021
Profit before tax	3,321	3,295
Tax at applicable tax rate for the Parent Company[i]	-684	-679
Tax effect, non-deductible/non-taxable items		
Capitalised tax loss carry-forwards	-22	162
Non-capitalised tax loss carry-forwards	75	-11
Difference foreign tax rates	-23	-49
Non-deductible expenses	-27	-31
Adjustment of tax prior years	0	-4
Other	-3	-4
Total effective tax recognised	**-683**	**-616**

Parent Company	2022	2021
Profit before tax	2,840	2,278
Current tax on profit for the year[i]	-585	-469
Tax effect, non-deductible/non-taxable items		
Reversal write-down of shares in subsidiaries	206	—
Controlled foreign company taxation	-5	0
Non-deductible expenses	-6	-19
Adjustment of tax prior years	0	0
Other	2	—
Total effective tax recognised	**-389**	**-488**

i. The current tax rate for the Parent Company is 20.6 per cent (20.6). Deferred tax was valued using the applicable tax rate for the period in which reversal/resolution is expected to occur.

Non-capitalised tax loss carry-forwards

Group	2022	2021
Tax loss carry-forwards for which no deferred tax asset was recognised	2,762	2,716
Potential tax benefit	509	509

Of non-capitalised tax loss carry-forwards, SEK 1,678 M will expire within the next 7 years, while other tax losses may be carried forward indefinitely. No deferred tax assets were recognised as it is considered uncertain whether the tax loss carry-forwards attributable to subsidiaries and prior years have any tax value for the Group.

16 Intangible assets and impairment testing

Group	Goodwill	Licenses and patents	Product and -marketing rights	Capitalised costs[iv]	Ongoing development work[iv]	Total
1 January-31 December 2021						
Opening cost	**5,873**	**570**	**37,867**	**429**	**284**	**45,023**
Investments	—	—	184	21	76	281
Disposals[i]	—	—	—	0	-53	-53
Reclassifications	—	0	—	97	-96	1
Translation differences	415	2	938	3	—	1,358
Closing cost	**6,288**	**573**	**38,989**	**549**	**211**	**46,610**
Opening accumulated amortisation and impairment	**—**	**-505**	**-5,560**	**-167**	**—**	**-6,232**
Amortisation	—	-8	-1,758	-75	—	-1,841
Disposals	—	—	—	0	—	0
Reclassifications	—	0	—	0	—	0
Translation differences	—	-1	-112	0	—	-113
Closing accumulated amortisation and impairment	**—**	**-514**	**-7,430**	**-243**	**—**	**-8,187**
Closing carrying amount	**6,288**	**59**	**31,559**	**307**	**211**	**38,424**
1 January-31 December 2022						
Opening cost	**6,288**	**573**	**38,989**	**549**	**211**	**46,610**
Investments[ii]	—	—	1,415	12	304	1,732
Disposals	—	-1	-2	-75	—	-78
Reclassifications	—	36	5	194	-203	32
Other changes in closing cost[iii]	—	—	-227	—	—	-227
Translation differences	719	5	1,736	7	—	2,468
Closing cost	**7,007**	**613**	**41,917**	**688**	**312**	**50,537**
Opening accumulated amortisation and impairment	**—**	**-514**	**-7,430**	**-243**	**—**	**-8,187**
Depreciation	—	-18	-2,016	-83	—	-2,117
Disposals	—	1	2	75	—	78
Reclassifications	—	-8	—	-2	—	-10
Translation differences	—	-3	-285	0	—	-288
Closing accumulated amortisation and impairment	**—**	**-542**	**-9,729**	**-253**	**—**	**-10,524**
Closing carrying amount	**7,007**	**71**	**32,188**	**435**	**312**	**40,013**

i. The preceding year's disposals, in an amount SEK –53 M, mainly pertain to disposal of the opt-in right to the early-stage development projects (NI-1701 and NI-1801), which were originally included in the acquisition of Novimmune in 2019.

ii. This year's investments mainly pertain to Zynlonta, SEK 1,415 M and efanesoctocog alfa, SEK 160 M, related to the agreement with Sanofi to reconstruct and validate Sanofi's production facility for adaptation ahead of production of the active substance for efanesoctocog alfa.

iii. Other changes in closing cost, refers to an adjustment as the estimated development costs for efanesoctocog alfa have been reduced by approximately USD 40 M. See also under the heading efanesoctocog alfa.

iv. Capitalised costs comprise IT projects and expenses for transferring the manufacture of an active substance. Items reported under capitalised costs are amortised according to plan.

Specification of major intangible assets

Group	2022	Amortisation rate, years	Remaining amortisation period, years
Synagis/nirsevimab	11,175	20	16
Doptelet	6,488	15	12
Gamifant	4,111	20	16
Aspaveli	3,069	20	19
efanesoctocog alfa[i]	1,697	—	—
SEL-212[i]	1,776	—	—
Zynlonta[i]	1,415	—	—
Alprolix	1,133	20	12
Elocta	1,135	20	13
Orfadin	346	15	2
Other – launched	348	3-15	—
Other – not yet launched[i]	312	—	—
Total[ii]	**33,005**		

i. Amortisation has not yet started.

ii. Closing carrying amount, excluding goodwill.

Parent Company	Licenses and patents	Product and marketing rights	Capitalised costs[iii]	Ongoing development work[iii]	Total
1 January-31 December 2021					
Opening cost	**40**	**11,442**	**404**	**230**	**12,116**
Investments	—	184	—	76	261
Disposals	—	—	0	—	0
Reclassifications	—	—	96	-96	—
Closing cost	**40**	**11,626**	**499**	**211**	**12,376**
Opening accumulated amortisation and impairment	**-38**	**-1,709**	**-163**	**—**	**-1,911**
Amortisation	-1	-282	-75	—	-359
Disposals	—	—	0	—	0
Closing accumulated amortisation and impairment	**-39**	**-1,992**	**-238**	**—**	**-2,269**
Closing carrying amount	**1**	**9,634**	**261**	**211**	**10,107**
1 January-31 December 2022					
Opening cost	**40**	**11,626**	**499**	**211**	**12,376**
Investments[i]	—	1,415	—	304	1,719
Disposals	-1	—	-75	—	-76
Reclassifications	36	5	194	-203	32
Other changes in closing cost[ii]	—	-227	—	—	-227
Closing cost	**75**	**12,820**	**618**	**312**	**13,824**
Opening accumulated amortisation and impairment	**-39**	**-1,992**	**-238**	**—**	**-2,269**
Amortisation	-10	-434	-83	—	-527
Disposals	1	—	75	—	76
Reclassifications	-8	—	-2	—	-10
Closing accumulated amortisation and impairment	**-56**	**-2,426**	**-248**	**—**	**-2,730**
Closing carrying amount	**18**	**10,394**	**370**	**312**	**11,094**

i. This year's investments mainly pertain to Zynlonta of SEK 1,415 M and efanesoctocog alfa of SEK 160 M, related to the agreement with Sanofi to reconstruct and validate Sanofi's production facility for adaptation ahead of production of the active substance for efanesoctocog alfa.

ii. Other changes in closing cost refer to an adjustment as the estimated development costs for efanesoctocog alfa have been reduced by approximately USD 40 M. See also the heading See also under the heading efanesoctocog alfa.

iii. Capitalised costs comprise IT projects and expenses for transferring the manufacture of an active substance. Items reported under capitalised costs are amortised according to plan.

Impairment testing of intangible assets

Goodwill

The assessment of the value of the Group's goodwill is based on value-in-use of the smallest cash-generating unit. Sobi has three separate cash-generating units – Haematology, Immunology and Specialty Care – to which goodwill is allocated. On 31 December 2022 Sobi's goodwill amounted to SEK 7,007 M (6,288). Please see Note 5 for allocation of goodwill to cash-generating units.

The cash flows are based on financial plans established by management and cover a five-year period. The financial plans have been established on the basis of past performance, experiences and market expectations. The plans include assumptions about current development and coming medicine launches. The financial plans also include assumptions of price trends, sales performance and cost trends. Cash flows beyond the five-year period have been extrapolated using an estimated growth rate of 2 per cent.

There is no indication of goodwill impairment at Group level.

The following table shows the growth rate and discount rate used before and after tax:

Parameter, %	2022	2021
Growth rate beyond the initial five-year period	2	2
Discount rate before tax	10.1	10.0
Discount rate after tax	8.0	8.0

Assumptions regarding Sobi's WACC[1]:

- Risk-free interest rate: ten-year treasury bills or comparable financial investment with the lowest possible risk.
- Market risk premium: 6.8 per cent (6.8).
- Beta coefficient: Sobi's beta coefficient is 1.26 (1.26).
- Interest expense: according to Sobi's borrowing cost.
- Tax rate: according to the tax rate in Sweden, except where income is taxed in another country.

Sobi has conducted a sensitivity analysis for the following parameters in the impairment testing of goodwill: discount rate, gross margin, sales volume and perpetual growth rate. The sensitivity analysis indicates that there are good margins in the calculation and no reasonable change to key parameters would lead to an impairment.

Product and marketing rights

Product and marketing rights are tested for impairment whenever events and circumstances indicate that the carrying amount may not be recoverable. The assessment of the value of product and marketing rights is based on the value-in-use of each individual asset. The value-in-use is based on cash flows that are expected to be generated over the remaining life of the asset. When discounting future cash flows, the discount rate is used as described in the table. When product and marketing rights are tested for impairment, a number of assumptions are made. These refer to forecasts of future sales revenue, costs attributable to each individual medicine, the life of the medicine and the discount rate.

Development projects related to product or marketing rights are tested annually for impairment. Key parameters are future cash flows from the individual asset, the probability of achieving positive outcomes in clinical studies and assumptions about the best commercial outcomes. Future cash flows are estimated with regard to the long and short-term development of the project and adjusted for the probability of commercialisation. The earlier in the chain of development the project is, the higher the risk. As it passes through the defined phases of development, the probability of reaching the market increases.

The assessed likelihood of a project passing through the relevant development phase successfully is assessed on the basis of the project's scientific potential to demonstrate positive results in the individual phase of the development process. Assumptions are made using the parameters with the greatest impact on the project's potential to develop into a medicine with maximum commercial potential, and on the basis of what is reasonable to assume about the project's scientific profile using the information that is currently available. The forecast period is based on the medicine's estimated market life.

Sobi has conducted a sensitivity analysis for the following parameters in the impairment testing of development projects: discount rate, gross margin, sales volume and perpetual growth rate. The sensitivity analysis indicates that there are good margins in the calculation and no reasonable change to key parameters would lead to an impairment.

Impairment

There were no impairment losses in 2022 or 2021.

Contractual commitments related to intangible assets

Sobi has undertaken to pay additional consideration under certain acquisition, licensing and collaboration agreements. These consist of contingent and non-contingent payments. Contingent payments (also known as milestone payments) are conditional upon the achievement of certain pre-defined targets.

Agreement with Sanofi

The collaboration agreement with Sanofi mainly concerns Elocta and Alprolix, and the potential future follow-up medicines efanesoctocog alfa and BIVV002.

Sobi and Sanofi receive royalties in the range of 12-17 per cent on each other's sales of Elocta/Eloctate and Alprolix in the respective company's territory. Sobi also receives royalties based on 50 per cent of net profit in Sanofi's territory, where sales are conducted through a third party.

Sobi's right for development and commercialisation of the programme for efanesoctocog alfa means that Sobi holds the commercialisation rights in Europe, North Africa, Russia and certain countries in the Middle East (Sobi's territory). Sanofi holds the commercialisation rights for North America (Sanofi's North American territory) and for the rest of the world excluding Sobi's territory (Sanofi's direct territory and Sanofi's distribution territory). In the event of a future approval and takeover of the right, Sobi will be obligated to reimburse Sanofi for 50 per cent of the development and production costs. Sobi will reimburse Sanofi for 100 per cent of the development costs that only benefit Sobi's territory.

1. Risk-free interest rate plus Beta multiplied by a risk premium. The risk-free rate is an average of 10-year Treasury bill over the past five years. Beta is the correlation between Sobi's share and the stock exchange index. Risk premium is calculated as an average over five years of the market expectations of growth and return. A tax of 20.6 per cent has been used.

Efanesoctocog alfa

In the event that marketing authorisation is granted by the European Commission, Sobi shall make a one-time payment corresponding to 50 per cent of the total development costs, at exercise of the opt-in right, an estimated USD 250 M less USD 50 M which has already been paid. On 31 December 2022, the value of BIV001, which is recognised as an intangible asset, was SEK 1,641 M (1,868). During the year the asset value was adjusted by SEK 227 M as the estimated development costs have been reduced by approximately USD 40 M. For liabilities related to efanesoctocog alfa, please see Note 28, liability to Sanofi.

Other agreements

Doptelet

On 12 November 2019, Sobi acquired all of the outstanding shares in Dova Pharmaceuticals. Through the acquisition, Sobi received access to Dova's medicine Doptelet. After the acquisition, Sobi's commitments in relation to Doptelet were as follows:

Under a contract with Eisai Inc., Sobi will pay up to USD 135 M based on annual net sales of Doptelet, calculated per calendar year. Approximately USD 118 M (approximately SEK 1.2 billion) was outstanding at year-end. This obligation is recognised as a financial liability on Sobi's balance sheet. Please see Note 28, liability to Eisai.

Sobi will pay royalty to Astella Inc. based on net sales of Doptelet.

Synagis and nirsevimab

On 23 January 2019, Sobi completed the acquisition of the rights to Synagis in the US from AstraZeneca, as well as the rights to 50 per cent of future earnings and losses from the potential new medicine nirsevimab in the US market. The upfront consideration was approximately USD 1,500 M (SEK 13.5 billion). In addition to this, Sobi paid a total of USD 60 M (SEK 525 M) in 2019-2021.

Provided that some terms related to sales of Synagis are met, an additional consideration of up to USD 470 M (approximately SEK 4.9 billion) may be payable as of 2026.

In January 2023, AstraZeneca and Sanofi announced the US regulatory submission acceptance. Following this, Sobi has paid a milestone payment of USD 175 M (SEK 1,811 M) during 2023. Further, Sobi will pay additional contractual payments for R&D expenses to AstraZeneca.

The agreement also includes potential net payments corresponding to about USD 110 M (approx. SEK 1.1 billion) on the achievement of other profit and development-related milestones for nirsevimab. In this case, these will be paid with start in 2023. At the end of 2022, Sobi had not reported any asset or liability linked to these potential future milestone payments as Sobi had an unconditional right to withdraw from the agreement until the application for approval is submitted to the FDA.

SEL-212

On 28 July 2020, Sobi concluded the strategic licensing agreement for SEL-212 with Selecta Biosciences, Inc. Sobi is responsible for development as well as regulatory and commercial activities in all markets outside China, while Selecta will conduct the phase 3 study on behalf of Sobi.

Sobi has paid USD 115 M (SEK 1,083 M) to Selecta, including a payment of USD 75 M for the licence fee, USD 25 M for shares in Selecta Biosciences, Inc., and milestone payments of USD 15 M. Provided that certain regulatory and commercial milestones are met, Selecta will be entitled to receive additional potential milestone payments of up to USD 615 M (approximately SEK 6.4 billion). The liability is presented under Other liabilities, non-interest bearing, please see Note 28, liability to Selecta. Selecta will also be entitled to incremental double-digit royalty on future sales.

Aspavelli

On 27 October 2020, Sobi and Apellis entered into a collaboration for global development and ex-US commercialisation of systemic pegcetacoplan in rare diseases with an urgent need for new medicines.

Sobi has paid USD 300 M (SEK 2,657 M) to Apellis, including an upfront payment of USD 250 M and a milestone payment of USD 50 M. Provided that certain regulatory and commercial milestones are met, Apellis will be entitled to receive additional potential milestone payments of up to USD 865 M (approximately SEK 9.0 billion). The liability is presented under Other liabilities, non-interest bearing, please see Note 28, liability to Apellis. Apellis will also be entitled to incremental double-digit royalties on future sales.

Sobi will pay USD 80 M to Apellis over a four-year period as compensation for R&D in accordance with the original development plan. USD 35 M (approximately SEK 365 M) was outstanding at year-end. These costs will be recognised as expenses in the period in which they occur.

Zynlonta

On 8 July 2022, Sobi entered into an exclusive license agreement with ADC Therapeutics SA to develop and commercialise Zynlonta. Under the terms of the agreement, Sobi has been granted rights to develop and commercialise Zynlonta for all haematologic and solid tumour indications outside of the United States, greater China, Singapore and Japan.

Sobi has paid an upfront payment of USD 55 M (SEK 588 M) to ADC Therapeutics. Provided that certain regulatory and commercial milestones are met, ADC Therapeutics will be entitled to receive additional potential milestone payments of up to USD 383 M (approximately SEK 5.2 billion). The consideration of SEK 1,415 M for the acquired intangible assets comprises the up-front payment combined with the liability (probability-weighted and discounted value) for future payments of potential milestone payments. The liability is presented under Other liabilities, non-interest bearing, please see Note 28, liability to ADC Therapeutics. ADC Therapeutics will also be entitled to royalties from mid-teens to mid-twenties per cent of net sales.

Sobi will contribute 25 per cent of the direct development costs up to a cap of USD 10 M per year. These costs will be recognised as expenses in the period in which they occur.

17 Tangible assets

Group	Plant and machinery	Equipment, tools, fixtures and fittings	Right-of-use assets	Other non-current assets	Ongoing new constructions	Total
1 January-31 December 2021						
Opening cost	**444**	**203**	**620**	**20**	**9**	**1,295**
Investments	0	9	58	1	54	122
Divestments and disposals	-20	-3	-24	—	—	-46
Reclassifications	5	31	—	4	-40	-1
Translation differences	1	2	12	1	—	17
Closing cost	**430**	**243**	**665**	**25**	**23**	**1,386**
Opening accumulated depreciation and impairment	**-386**	**-154**	**-210**	**-11**	**—**	**-761**
Depreciation	-15	-25	-114	-4	—	-159
Impairment	-7	—	—	—	—	-7
Divestments and disposals	17	1	19	—	—	37
Reclassifications	0	2	0	-1	—	1
Translation differences	-1	-1	-2	-1	—	-4
Closing accumulated depreciation and impairment	**-392**	**-177**	**-307**	**-17**	**—**	**-893**
Closing carrying amount	**39**	**66**	**359**	**8**	**23**	**493**

1 January-31 December 2022						
Opening cost	**430**	**243**	**665**	**25**	**23**	**1,386**
Investments	1	5	93	0	12	111
Divestments and disposals	-25	-10	-45	-8	—	-87
Reclassifications	16	-22	17	0	-27	-16
Translation differences	2	8	31	2	—	43
Closing cost	**424**	**224**	**761**	**20**	**8**	**1,436**
Opening accumulated depreciation and impairment	**-392**	**-177**	**-307**	**-17**	**—**	**-893**
Depreciation	-16	-18	-117	-4	—	-156
Impairment[i]	-10	—	-136	—	—	-146
Divestments and disposals	20	9	40	8	—	76
Reclassifications	—	8	-24	—	—	-17
Translation differences	-2	-5	-19	-1	—	-27
Closing accumulated depreciation and impairment	**-400**	**-184**	**-564**	**-15**	**—**	**-1,162**
Closing carrying amount	**24**	**40**	**198**	**5**	**8**	**274**

i. Current year includes impairment of right-of-use assets of SEK 124 M following the discontinuation of contract manufacturing for Pfizer and SEK 12 M following the decision to consolidate the Geneva site into Basel.

For further information about leases, please see Note 9.

Parent Company	Plant and machinery	Equipment, tools, fixtures and fittings	Other non-current assets	Ongoing new constructions	Total
1 January-31 December 2021					
Opening cost	**409**	**131**	**5**	**9**	**554**
Investments	—	—	—	54	54
Divestments and disposals	-20	0	—	—	-20
Reclassifications	5	36	—	-40	—
Closing cost	**394**	**166**	**5**	**23**	**588**
Opening accumulated depreciation and impairment	**-369**	**-118**	**-4**	**—**	**-491**
Depreciation	-12	-14	-1	—	-26
Divestments and disposals	17	0	—	—	17
Closing accumulated depreciation and impairment	**-364**	**-131**	**-4**	**—**	**-500**
Closing carrying amount	**30**	**35**	**1**	**23**	**89**

1 January-31 December 2022					
Opening cost	**394**	**166**	**5**	**23**	**588**
Investments	—	—	—	12	12
Divestments and disposals	-7	-2	—	—	-9
Reclassifications	16	-22	—	-27	-32
Closing cost	**404**	**142**	**5**	**8**	**559**
Opening accumulated depreciation and impairment	**-364**	**-131**	**-4**	**—**	**-500**
Depreciation	-14	-8	-1	—	-22
Impairment	-9	—	—	—	-9
Divestments and disposals	6	2	—	—	8
Reclassifications	—	8	—	—	8
Closing accumulated depreciation and impairment	**-381**	**-130**	**-5**	**—**	**-515**
Closing carrying amount	**23**	**13**	**1**	**8**	**44**

18 Participations in Group companies

Parent Company	2022	2021
Cost		
Opening balance	8,853	8,853
Closing balance	**8,853**	**8,853**
Accumulated impairment		
Opening balance	-1,177	-1,177
Reversal of impairment[i]	1,000	—
Closing balance	**-177**	**-1,177**
Closing carrying amount	**8,676**	**7,676**

i. Refers to a reversal of a write-down for the value of the shares in the subsidiary Swedish Orphan Biovitrum International AB following the progress of the launch of Gamifant.

Specification of Parent Company and Group holdings of participations in Group companies

Subsidiary/Corp. Reg. No./Registered office	No. of participations	Participations, %[i]	Carrying amount[ii]
Swedish Orphan Biovitrum International AB, 556329-5624, Stockholm, Sweden	100	100	4,248,584
Swedish Orphan Biovitrum A/S, 19179079, Copenhagen, Denmark			
Swedish Orphan Biovitrum SARL, 490259405, Paris, France			
Swedish Orphan Biovitrum s.r.o, 28171276, Prague, Czech Republic			
Oy Swedish Orphan Biovitrum AB, 1024811, Turku, Finland			
Swedish Orphan Biovitrum s.r.l., 5288990962, Milan, Italy			
OOO Swedish Orphan Biovitrum, 5087746194520, Moscow, Russia			
Swedish Orphan Biovitrum AS, 976313682, Trollåsen, Norway			
Swedish Orphan Biovitrum S.L., B84710623, Madrid, Spain			
Swedish Orphan Biovitrum Ltd, 4369760, Cambridgeshire, UK			
Swedish Orphan Biovitrum GmbH, HRB 226770, Martinsried, Germany			
Swedish Orphan Biovitrum AG, 284.917.678, Basel, Switzerland			
Florio GMBH, HRB 249347, Munich, Germany			
Sobi Pharma (Guangzhou) Company Limited, 91440101MA5D2D0A6G, Guangzhou, China			
Sobi Pharma (Shanghai) Company Limited, 41000002202107120056, Shanghai, China			
Swedish Orphan Biovitrum Unipessoal Lda, 980 670 152, Lisbon, Portugal			
Swedish Orphan Biovitrum Japan Co., Ltd, 0100 01 210061, Tokyo, Japan			
Swedish Orphan Biovitrum Pty Ltd, 645,396,532, Sydney, Australia			
Swedish Orphan Biovitrum (The Netherlands) B.V., 84642281, Amsterdam, Netherlands			
SOBI Middle East FZ-LLC, 91193, Dubai, United Arab Emirates	1,000	100	132
Arexis AB, 556573-5130, Stockholm, Sweden	1,000	100	225,137
Swedish Orphan Biovitrum s.r.o, 28171276, Prague, Czech Republic[iii]	1	1	8
BVBA Swedish Orphan Biovitrum, 0536.217.087, Brussels, Belgium	100	100	166
Swedish Orphan Biovitrum GmbH, 416986, Vienna, Austria	100	100	313
Swedish Orphan Biovitrum (SOBI) Canada, Inc. 949375-1, Oakville, Canada	10,000	100	65
Sobi Single Member I.K.E, 142300401000, Athens, Greece	20,000	100	195
Sobi US Holding Corp., 7626060, Delaware, US[iv]	1,000	100	4,201,336
Sobi, Inc EIN 68-0682244, Delaware, US			
AKaRx, Inc., 20-1990243, Delaware, US			
Dova Pharmaceuticals Ireland Limited, 610709, Dublin, Ireland			
Total			**8,675,935**

i. The participation refers to the ownership of capital, which also corresponds to the proportion of the votes.

ii. Carrying amount stated in KSEK.

iii.The remaining portion owned by Swedish Orphan Biovitrum International AB.

iv. During the year, an internal restructuring was carried out in the US sub-group and Dova Pharmaceuticals Inc., was merged into Sobi, Inc.

19 Financial assets

Group	2022	2021
Equity instruments[i]	64	145
Endowment policy	48	45
Deposits	4	4
Other financial receivables	5	5
Total	**121**	**199**

Group	2022	2021
Change in financial assets		
Opening balance	199	179
Equity instruments[i]	-81	14
Endowment policy	3	1
Deposit	0	2
Other financial receivables	0	4
Closing balance	**121**	**199**

i. Equity instruments refers to the holding in Selecta Bioscience, Inc. The holding is measured at fair value through other comprehensive income.

Parent Company	2022	2021
Equity instruments[i]	64	145
Endowment policy	48	45
Total	**112**	**190**

Parent Company	2022	2021
Change in financial assets		
Opening balance	190	176
Equity instruments[i]	-81	14
Endowment policy	3	1
Closing balance	**112**	**190**

i. See comment for the Group.

20 Deferred tax assets and deferred tax liabilities

Group 2022	Deferred tax assets	Deferred tax liabilities	Net
Excess depreciation	—	-2,526	-2,526
Inventories	819	—	819
Acquired product and marketing rights	—	-1,914	-1,914
Other intangible assets	59	—	59
Tax loss carry-forwards	273	—	273
Pharmaceutical tax	26	—	26
Interest limitations	102	—	102
Expected credit losses	34	—	34
Restructuring provision	59	—	59
Other	170	-22	148
Total	**1,542**	**-4,462**	**-2,920**
Offsetting	-665	665	—
Tax assets/liabilities, net	**877**	**-3,797**	**-2,920**

Group 2021	Deferred tax assets	Deferred tax -liabilities	Net
Excess depreciation	—	-2,213	-2,213
Inventories	696	—	696
Acquired product and marketing rights	—	-1,836	-1,836
Other intangible assets	61	—	61
Tax loss carry-forwards	256	—	256
Pharmaceutical tax	44	—	44
Interest limitations	63	—	63
Expected credit losses	13	—	13
Other	94	-18	76
Total	**1,229**	**-4,067**	**-2,838**
Offsetting	-462	462	—
Tax assets/liabilities, net	**767**	**-3,605**	**-2,838**

Parent Company 2022	Deferred tax assets	Deferred tax liabilities	Net
Restructuring provision	59	—	59
Excess depreciation	4	—	4
Provision for pensions	12	—	12
Long-term incentive programmes	21	—	21
Expected credit losses	29	—	29
Other	—	0	0
Total	**125**	**0**	**125**
Offsetting	0	0	—
Tax assets/liabilities, net	**125**	**—**	**125**

Parent Company 2021	Deferred tax assets	Deferred tax -liabilities	Net
Excess depreciation	5	—	5
Provision for pensions	11	—	11
Long-term incentive programmes	10	—	10
Expected credit losses	7	—	7
Other	—	-5	-5
Total	**33**	**-5**	**27**
Offsetting	-5	5	—
Tax assets/liabilities, net	**27**	**—**	**27**

Change in deferred tax

Group 2022	Amount at beginning of year	Recognised in profit or loss	Recognised in other comprehensive income	Recognised directly in equity	Amount at year-end
Excess depreciation	-2,213	-313	—	—	-2,526
Inventories	696	54	69	—	819
Acquired product and marketing rights	-1,836	180	-258	—	-1,914
Other intangible assets	61	-4	2	—	59
Tax loss carry-forwards	256	-28	45	—	273
Restructuring provision	—	59	—	—	59
Pharmaceutical tax	44	-21	2	—	26
Net investment hedges	—	-94	94	—	—
Interest limitations	63	29	10	—	102
Expected credit losses	13	21	0	—	34
Other	76	63	3	6	148
Total	**-2,838**	**-55**	**-32**	**6**	**-2,920**

Group 2021	Amount at beginning of year	Recognised in profit or loss	Recognised in other comprehensive income	Recognised directly in equity	Amount at year-end
Excess depreciation	-1,817	-396	—	—	-2,213
Inventories	562	95	39	—	696
Acquired product and marketing rights	-1,859	178	-154	—	-1,836
Other intangible assets	50	11	1	—	61
Tax loss carry-forwards	130	107	20	—	256
Pharmaceutical tax	30	14	1	—	44
Net investment hedges	—	-63	63	—	—
Interest limitations	—	60	3	—	63
Expected credit losses	13	0	0	—	13
Other	39	38	-3	3	76
Total	**-2,853**	**44**	**-32**	**3**	**-2,838**

21 Inventories

Group	2022	2021
Raw materials and consumables	64	147
Work in progress	1,895	1,973
Finished goods and goods for resale	1,373	1,304
Total	**3,332**	**3,424**

The cost of inventories is included in cost of goods sold as expenses and amounted to SEK 2,703 M (1,934). Recognised inventories include a provision of SEK 524 M (442) for obsolete inventory. During the year, an impairment loss of M 254 SEK (49) was recognised for inventories.

Parent Company	2022	2021
Raw materials and consumables	64	62
Work in progress	1,788	1,735
Finished goods and goods for resale	851	739
Total	**2,703**	**2,536**

The cost of inventories is included in cost of goods sold as expenses and amounted to SEK 1,868 M (1,611). Recognised inventories include a provision of SEK 524 M (429) for obsolete inventory. During the year, an impairment loss of M 254 SEK (23) was recognised for inventories.

22 Accounts receivable and other receivables

Group	2022	2021
Accounts receivable	5,422	3,509
Less: Provision for credit losses	-174	-71
Accounts receivable, net	**5,249**	**3,439**
Tax assets	51	26
Other receivables	507	319
Total other receivables	**558**	**345**
Total accounts receivable and other receivables	**5,807**	**3,783**

Parent Company	2022	2021
Accounts receivable	1,111	1,135
Less: Provision for credit losses	-116	-8
Accounts receivable, net	**995**	**1,126**
Tax assets	35	22
Other receivables	427	270
Total other receivables	**462**	**292**
Total accounts receivable and other receivables	**1,458**	**1,419**

Sobi's largest customers are primarily large distributors, hospitals and government authorities. The large customer base has a wide geographic spread, with no specific concentration of receivables. Please see Note 5 for further information.

The Group's exposure to expected credit losses is continuously monitored by country and type of counterparty. If Sobi judges that a receivable will not be paid, a provision is made for an expected credit loss in accordance with the principles described in Note 2. This Note also contains information about customers' payment terms.

On 31 December 2022, the Group's overdue receivables amounted to SEK 1,058 M (607) of which SEK 174 M (71) is included in the provision for credit losses. Actual credit losses of SEK 0.6 M (6.1) were charged to profit for the year, of which SEK 0.4 M (5.9) was attributable to the Parent Company.

Changes in the provision for credit losses are as follows:

Expected credit losses

Group	2022	2021
At beginning of year	-71	-71
Provision for credit losses[i]	-112	-11
Reversed provisions	9	12
At year-end	**-174**	**-71**

Parent Company	2022	2021
At beginning of year	-8	-16
Provision for credit losses[i]	-109	—
Reversed provisions	1	8
At year-end	**-116**	**-8**

i. Provision for credit losses of SEK 106 M refers to Russia.

Maturity structure

Group	2022	2021
Not past due	4,190	2,832
Past due 1-30 days	632	374
Past due 31-90 days	361	145
Past due 91-120 days	16	12
Past due >121 days	50	75
Total	**5,249**	**3,439**

Parent Company	2022	2021
Not past due	851	835
Past due 1-30 days	103	187
Past due 31-90 days	12	71
Past due 91-120 days	4	6
Past due >121 days	25	28
Total	**995**	**1,126**

Recognised amounts per currency for accounts and other receivables

Group	2022	2021
CHF	73	81
EUR	1,819	1,115
GBP	185	126
SEK	648	669
USD	2,922	1,637
Other currencies	160	155
Total	**5,807**	**3,783**

Parent Company	2022	2021
CHF	66	76
EUR	517	499
SEK	693	668
USD	37	43
Other currencies	145	132
Total	**1,458**	**1,419**

23 Prepaid expenses and accrued income

Group	2022	2021
Accrued royalty revenue[i]	334	321
Prepaid expenses production facility[ii]	123	7
Other prepaid expenses	254	197
Total	**710**	**525**

Parent Company	2022	2021
Accrued royalty revenue[i]	334	321
Prepaid expenses production facility[ii]	123	7
Other prepaid expenses	154	126
Total	**611**	**455**

i. These are classified as contract assets under IFRS 15.

ii. Refers to payments to Pfizer for a production facility construction for Kineret manufacturing, for further information please see Note 9.

24 Cash and cash equivalents

	2022		2021	
Group	Fair value	Carrying amount	Fair value	Carrying amount
Cash and cash equivalents	1,361	1,361	1,045	1,045
Total	**1,361**	**1,361**	**1,045**	**1,045**

	2022		2021	
Parent Company	Fair value	Carrying amount	Fair value	Carrying amount
Cash and cash equivalents	1,146	1,146	878	878
Total	**1,146**	**1,146**	**878**	**878**

Cash and cash equivalents refer to funds held in bank accounts.

25 Equity

The table below shows a breakdown of the balance sheet Other reserves and how each component has changed during the year.

Other reserves	Translation differences	Cash flow hedges	Net investment hedges	Equity investments	Defined-benefit pension plans and similar plans	Total
Opening balance, 1 January 2021	**-544**	**26**	**288**	**9**	**-32**	**-253**
Translation differences	464	—	—	—	—	464
Hedging instruments						
Gain/loss from remeasurement of hedging instruments recognised in equity[i]	—	-81	-305	—	—	-386
Tax on gain/loss from remeasurement of hedging instruments recognised in equity	—	18	63	—	—	81
Transferred to profit or loss	—	1	—	—	—	1
Tax on transferred to profit or loss	—	0	—	—	—	—
Gain/loss from remeasurement of equity instruments recognised in equity	—	—	—	14	—	14
Tax effect on equity instruments	—	—	—	-3	—	-3
Gain/loss from remeasurement of defined-benefit pension plans and similar plans	—	—	—	—	20	20
Tax on gain/loss from remeasurement of defined-benefit -pension plans and similar plans	—	—	—	—	-3	-3
Closing balance, 31 December 2021	**-80**	**-36**	**46**	**20**	**-15**	**-66**
Opening balance, 1 January 2022	**-80**	**-36**	**46**	**20**	**-15**	**-66**
Translation differences	880	—	—	—	—	880
Hedging instruments						
Gain/loss from remeasurement of hedging instruments recognised in equity[i]	—	-151	-457	—	—	-609
Tax on gain/loss from remeasurement of hedging instruments recognised in equity	—	31	94	—	—	125
Transferred to profit or loss	—	45	—	—	—	45
Tax on transferred to profit or loss	—	-9	—	—	—	-9
Gain/loss from remeasurement of equity instruments recognised in equity	—	—	—	-81	—	-81
Tax effect on equity instruments	—	—	—	5	—	5
Gain/loss from remeasurement of defined-benefit pension plans and similar plans	—	—	—	—	70	70
Tax on gain/loss from remeasurement of defined-benefit -pension plans and similar plans	—	—	—	—	-10	-10
Closing balance, 31 December 2022	**800**	**-121**	**-317**	**-56**	**45**	**351**

i. The translation differences consists of SEK -22 M (27) from hedging effects where a hedging relationship no longer exists.

At year-end, Sobi's share capital was SEK 170 M, distributed between 309,804,782 shares with a par value of SEK 0.55. All shares issued at the balance sheet date were ordinary shares. Ordinary shares carry one vote per share. Sobi held 13,789,723 shares in treasury at the balance sheet date. The own shares item corresponds to 4.5 per cent of the total number of shares in Sobi.

Earnings per share

Earnings per share before dilution are calculated by dividing earnings attributable to Parent Company shareholders by the weighted average number of ordinary shares outstanding during the period, excluding treasury shares.

To calculate earnings per share after dilution, the weighted average number of ordinary shares outstanding is adjusted for the dilutive effect of all potential ordinary shares.

	2022	2021
Earnings attributable to Parent Company shareholders (SEK M)	2,638	2,679
Earnings per share (SEK per share)	8.92	9.08
Earnings per share, adjusted (SEK per share)[i, ii]	10.77	9.08
Earnings per share after dilution (SEK per share)	8.84	9.03
Earnings per share after dilution, adjusted (SEK per share)[i, ii]	10.66	9.03
Number of ordinary shares	309,804,782	307,114,495
Number of ordinary shares (treasury)	13,789,723	11,959,198
Number of ordinary shares (excluding treasury shares)	296,015,059	295,155,297
Number of ordinary shares after dilution	312,648,912	308,862,835
Average number of ordinary shares (excluding treasury shares)	295,604,246	295,051,119
Average number of ordinary shares after dilution (excluding treasury shares)	298,448,376	296,799,459

i. See Alternative performance measures.

ii. For Items affecting comparability, please see Note 12 and Alternative performance measures.

26 Financial assets and liabilities per category

Group	Assets measured at amortised cost	Assets measured at fair value through profit or loss	Assets measured at fair value through other comprehensive income	Total
31 December 2022				
Assets on the balance sheet				
Accounts receivable	5,249	—	—	5,249
Endowment policy	—	48	—	48
Derivatives[i]	—	8	—	8
Equity instruments[ii]	—	—	64	64
Cash and cash equivalents	1,361	—	—	1,361
Total	**6,610**	**56**	**64**	**6,730**
31 December 2021				
Assets on the balance sheet				
Accounts receivable	3,439	—	—	3,439
Endowment policy	—	45	—	45
Derivatives[i]	—	11	—	11
Equity instruments[ii]	—	—	145	145
Cash and cash equivalents	1,045	—	—	1,045
Total	**4,484**	**56**	**145**	**4,685**

i. Of the 2022 derivatives, SEK 8 M (11) was measured at fair value through profit or loss, and SEK 0 M (0) was included in cash-flow hedges. The derivatives are classified as Other liabilities on the balance sheet.

ii. Equity instruments relates to the shares in Selecta Biosciences, Inc. The shares are measured at fair value through other comprehensive income.

Group	Liabilities measured at amortised cost	Liabilities measured at fair value through profit or loss	Total
31 December 2022			
Liabilities on the balance sheet			
Borrowings	8,767	—	8,767
Lease liabilities	333	—	333
Derivatives[i]	—	21	21
Accounts payable	1,252	—	1,252
Contingent considerations[ii]	3,406	—	3,406
Non-contingent considerations[ii]	1,748	—	1,748
Total	**15,507**	**21**	**15,528**
31 December 2021			
Liabilities on the balance sheet			
Borrowings	10,545	—	10,545
Lease liabilities	361	—	361
Derivatives[i]	—	10	10
Accounts payable	558	—	558
Contingent considerations[ii]	2,818	—	2,818
Non-contingent considerations[ii]	1,707	—	1,707
Total	**15,989**	**10**	**15,999**

i. Of the 2022 derivatives, SEK 21 M (10) was measured at fair value through profit or loss, and SEK 0 M (0) was included in cash-flow hedges. The derivatives are classified as other liabilities on the balance sheet.

ii. Liabilities are reported per counterparty in Note 28.

Please see Note 2 for more information about what is included in the various categories.

Financial instruments measured at fair value

The following table shows financial instruments measured at fair value, based on their classification in the fair value hierarchy. The different levels are defined as follows:

- Level 1: quoted prices in active markets for identical assets or liabilities.
- Level 2: observable data for the asset or liability other than the quoted prices included in Level 1.
- Level 3: inputs for the asset or liability that are not based on observable market data.

Liabilities related to considerations were SEK 5,154 M (4,525) at the end of the year. These are measured at amortised cost using the effective interest method. Fair value for these liabilities was SEK 4,612 M at the end of the year. All other financial instruments on the balance sheet had reported values that are in all material aspects equivalent to fair value on 31 December 2022.

On 31 December 2022	Level 1	Level 2	Level 3	Total
Financial assets measured at fair value through profit or loss				
Derivatives held for trading	—	-13	—	-13
Endowment policy[i]	—	—	48	48
Equity instruments	64	—	—	64
Total	**64**	**-13**	**48**	**99**

On 31 December 2021	Level 1	Level 2	Level 3	Total
Financial assets measured at fair value through profit or loss				
Derivatives held for trading	—	1	—	1
Endowment policy[i]	—	—	45	45
Equity instruments	145	—	—	145
Total	**145**	**1**	**45**	**191**

i. Endowment policies are reported gross with the corresponding liability, which is reported as a provision, please see Note 30.

All derivatives are measured at fair value based on market data. On 31 December 2022, the net value of derivatives recognised on the balance sheet was SEK -13 M (1).

27 Borrowings

At the balance sheet date, Sobi had credit facilities totalling EUR 805 M and SEK 5,000 M. During the year, a revolving credit facility of EUR 335 M matured. Furthermore, a commercial paper programme of up to SEK 4,000 M was established, together with a related revolving credit facility of SEK 2,000 M. In addition to the above, Sobi has two overdraft facilities of SEK 250 M and USD 5 M. Sobi has customary covenants in its facility agreements and was fully compliant with those in 2022. For further information about the maturity structure, please see Note 3.

Group and Parent Company	2022	2021
Non-current liabilities to banks and credit institutions	2,971	8,777
Current liabilities to banks and credit institutions	3,728	1,768
Commercial papers	2,067	–
Total	**8,767**	**10,545**

Specification per currency, translated to SEK M

Group and Parent Company	2022	2021
Currency		
EUR	3,435	3,426
SEK	5,332	4,004
USD	–	3,116
Total	**8,767**	**10,545**

28 Other liabilities, non-interest bearing, current and non-current

Group	2022	2021
Non-current		
Liability to Sanofi	1,346	1,337
Liability to Eisai	527	1,015
Liability to Selecta	1,028	873
Liability to Apellis	684	608
Liability to ADC Therapeutics	313	–
Other	–	1
Total	**3,899**	**3,834**
Current		
Liability to Eisai	678	113
Liability to Selecta	–	90
Liability to Apellis	34	452
Liability to ADC Therapeutics	520	–
Derivatives	21	10
VAT	361	264
Other	286	384
Total	**1,900**	**1,314**

Parent Company	2022	2021
Non-current		
Liability to Sanofi	1,346	1,337
Liability to Selecta	1,028	873
Liability to Apellis	684	608
Liability to ADC Therapeutics	313	–
Total	**3,372**	**2,818**
Current		
Liability to Selecta	–	90
Liability to Apellis	34	452
Liability to ADC Therapeutics	520	–
Derivatives	21	10
Other	222	344
Total	**797**	**896**

Sanofi

In 2019, Sobi entered into a contract with Sanofi for efanesoctocog alfa where Sobi, conditional upon marketing authorisation from the European Medicines Agency, will make a one-time payment corresponding to 50 per cent of the total development costs. These were originally estimated to be USD 280-290 M, with deduction for USD 50 M already paid. In 2022, the estimated development costs have decreased by approximately USD 40 million to USD 250 M. As a result of this, the debt has decreased by SEK 253 M, of which SEK 26 M relates to interest, which has been reported as a reduction in interest costs, the other SEK 227 M has been reported as a reduction in the associated intangible asset, please see Note 16. On 31 December 2022, the remaining obligation was recognised as a non-interest bearing non-current liability of SEK 1,346 M (1,337) on the balance sheet.

Eisai

Under a contract with Eisai, Sobi has at the balance sheet date, a remaining obligation to pay up to USD 118 M based on annual net sales of Doptelet, calculated per calendar year. In 2022, Sobi paid USD 13 M. On 31 December 2022, the obligation was recognised as a non-interest-bearing non-current liability of SEK 527 M (1,015) and a non-interest-bearing current liability of SEK 678 M (113) on the balance sheet.

Selecta

In 2020, Sobi entered into a strategic licensing agreement for the potential new medicine SEL-212 with Selecta Biosciences, Inc. Provided that certain regulatory and commercial milestones are met, Selecta is, at the balance sheet date, entitled to receive potential additional milestone payments of up to USD 615 M. During 2022 Sobi paid USD 10 M. On 31 December 2022, the obligations were recognised as a non-interest-bearing non-current liability of SEK 1,028 M (873) and non-interest-bearing current liability of SEK — M (90) on the balance sheet.

Apellis

In 2020, Sobi and Apellis entered into a collaboration for global development and ex-US commercialisation of systemic pegcetacoplan for rare diseases with an urgent need for new medicines. Provided that certain regulatory and commercial milestones are met, Apellis is, at the balance sheet date, entitled to receive potential additional milestone payments of up to USD 865 M. During 2022 Sobi paid USD 50 M. On 31 December 2022, the obligations were recognised as a non-interest-bearing non-current liability of SEK 684 M (608) and a non-interest-bearing current liability of SEK 34 M (452) on the balance sheet.

ADC Therapeutics

In 2022, Sobi entered into an exclusive licensing agreement with ADC Therapeutics SA to develop and commercialise Zynlonta. Relating to this Sobi made an upfront payment of USD 55 M. Provided that certain regulatory and commercial milestones are met, ADC Therapeutics is, at the balance sheet date, entitled to receive potential additional milestone payments of up to USD 383 M. During 2022 Sobi paid no milestones. On 31 December 2022, the obligations were recognised as a non-interest-bearing non-current liability of SEK 313 M (—) and a non-interest-bearing current liability of SEK 520 M (—) on the balance sheet.

29 Post-employment benefits

Group employees have various forms of pension benefits, either defined-contribution or defined-benefit plans. Most of Sobi's employees are covered by defined-contribution plans.

SEK M	2022	2021
Present value of funded obligations	438	431
Fair value of plan assets	-366	-299
Deficit in funded plans	72	132
Present value of unfunded obligations	10	11
Net	**82**	**143**

SEK M	2022	2021
Recognised assets[i]	5	5
Recognised obligations	87	148
Net	**82**	**143**

i. Plans with a net surplus, i.e. where plan assets exceed the defined benefit obligations, are reported as an asset and included in financial fixed assets.

Switzerland

The Swiss pension plans are funded and covered by the Swiss Federal Act on Swiss Federal Occupational Old Age, Survivors and Disability Pension Act (BVG). The pension plans are administrated by two separate legal entities and funded by regular contributions from the employees and Sobi. The final benefit is contribution-based with certain minimum guarantees. Due to these minimum guarantees, these plans are considered defined-benefit according to IFRS, even though many of their characteristics are otherwise similar to a defined-contribution plan. If the plans are underfunded, they can be adjusted using various measures, such as raising contributions for employees and companies, lowering interest rates on the pension obligations, reducing future benefits and disallowing early withdrawals of pension funds. On 31 December 2022, the recognised liability was SEK 70 M (127) and the plans covered 152 (149) employees, of whom all were active.

Sweden

Sweden has both defined-benefit and defined-contribution plans based on collective agreement between the parties in the Swedish labour market.

For white-collar employees in Sweden, the ITP 2 plan's defined-benefit pension obligations for retirement, family pensions and disability pensions are insured through Alecta. According to the Financial Reporting Board's statement UFR 10 Accounting for ITP 2 Plans Financed by Insurance with Alecta, this is a multi-employer defined-benefit plan. For the 2022 financial year, Sobi did not have access to the information required to recognise these obligations as a defined-benefit plan. The ITP 2 pension plan is therefore recognised as a defined-contribution plan. The premium for the defined-benefit retirement and family pension is calculated individually, and is based on factors including salary, previously earned pension and expected remaining period of service. In 2023, expected contributions for ITP 2 plans insured through Alecta amounted to SEK 13 M (18). Sobi's share of the total plan contributions and the total number of active members in the plan is immaterial. The collective funding ratio is the market value of Alecta's assets as a percentage of the insurance obligations calculated according to Alecta's actuarial methods and assumptions, which are not consistent with IAS 19. The collective funding ratio is normally allowed to vary between 125 and 175 per cent. If Alecta's collective funding ratio falls below 125 per cent or exceeds 175 per cent, measures should be taken to create the right conditions for the ratio to return to the normal range. If the ratio is low, an appropriate measure could be to raise the agreed price for new policies and extensions of existing benefits. If the ratio is high, premium reductions could be introduced. At the end of 2022, Alecta's surplus in the form of the collective funding ratio was 172 per cent (172).

The occupational pension premium for a certain number of current and former executives exceeds a certain level, which is why a direct pension is used for that portion of the premium that is not deductible. Sobi secures the direct pension by taking out an endowment policy that is pledged to the senior executive.

There is a net surplus in the Swedish pension plan at the end of the year of SEK 5 M (5) which is recognised as a financial asset.

Other

On 31 December 2022, the liability recognised for other defined-benefit pension plans was SEK 17 M (16). Other pension obligations are attributable to France, Italy and Norway.

Changes in defined-benefit obligations during the year

1 January-31 December 2022	Present value of obligations	Fair value of plan assets	Total
At beginning of the year	442	-299	143
Amounts in profit or loss			
Service cost current year	37	—	37
Service cost previous years	-10	—	-10
Interest expense	6	—	6
Interest income	—	-5	-5
Amounts in cash flow			
Contributions from employees	15	-15	0
Contributions into plans from employer	—	-32	-32
Payments from the plans	-27	31	4
Pension payments directly from the employer	-3	—	-3
Amounts in other comprehensive income			
Remeasurement			
Return on plan assets, excl. amounts included in interest expenses	—	-9	-9
Changed financial assumptions	-79	0	-80
Experience-based assumptions	13	0	13
Other			
Translation differences	57	-36	20
At year-end	**448**	**-365**	**82**

1 January-31 December 2021	Present value of obligations	Fair value of plan assets	Total
At beginning of the year	364	-220	144
Amounts in profit or loss			
Service cost current year	35		35
Interest expense	1		1
Interest income		-1	-1
Amounts in cash flow			
Contributions from employees	11	-11	0
Contributions into plans from employer	-1	-25	-26
Payments from the plans	19	-19	0
Amounts in other comprehensive income			
Remeasurement			
Return on plan assets, excl. amounts included in interest expenses	—	-2	-2
Changed demographic assumptions	-32	0	-32
Changed financial assumptions	-9	0	-9
Experience-based assumptions	28	-6	22
Other			
Translation differences	26	-15	11
At year-end	**442**	**-299**	**143**

Actuarial assumptions at end of the year

Average for pension plans	2022	2021
Discount rate, %	2.2	0.6
Expected annual salary increase, %	2.4	2.2
Pension increases	0.3	0.1
Retirement age	65	65
Remaining life expectancy after retirement age, male, years	20.9	20.9
Remaining life expectancy after retirement age, female, years	23.2	24.9

Distribution by plan assets

	2022	Whereof quoted %	2021	Whereof quoted %
Equity funds	124	100	113	100
Interest-bearing securities	136	100	105	100
Properties	78	—	57	—
Other funds	—	—	8	—
Other	27	—	16	—
Total	**365**	**71**	**299**	**73**

Sensitivity analysis

	2022	2021
Pension obligation under current assumptions	448	442
Discount rate -0.5%	468	477
Discount rate +0.5%	429	409
Salary decrease -0.5%	441	432
Salary increase +0.5%	454	450
Life expectancy after retirement -1 year	443	432
Life expectancy after retirement +1 year	452	450

The above sensitivity analyses are based on a change in one assumption, with all other assumptions remaining constant. In practice, this is highly unlikely to occur and some of the changes in the assumptions may be correlated. When calculating the sensitivity of the defined-benefit obligations to significant actuarial assumptions, the same method (present value of the defined-benefit obligation applying the projected unit credit method at the end of the reporting period) was applied as when calculating the pension liability recognised on the balance sheet.

Other information

For the 2023 financial year, contributions to plans for post-employment benefits are expected to be SEK 31 M (25). The weighted average duration of the obligation is an estimated 14.6 years (17.1).

Risks

Through its defined-benefit pension plans, the Group is exposed to a number of risks. The most significant risks are described in the following table:

Type of risk	
Life expectancy assumptions	Most of the pension obligations entail that the employees covered by the plan will receive life-long benefits and, accordingly, the longer life expectancy assumptions will result in higher pension liabilities.
Inflation	Some of the plan's pension obligations are linked to inflation. Higher inflation leads to higher liabilities (although, in most cases, a ceiling has been set for the level of inflation to protect the plan against exceptional increases in inflation). Most of the plan assets are either unaffected by inflation (fixed-rate bonds) or weakly correlated with inflation (shares), which means that an increase in inflation will also increase the deficit.
Discount rate	A decrease in the interest rate on corporate bonds will increase the liabilities of the plans, although this will partially be offset by an increase in the value of the bond holding.
Asset volatility	The pension liability is calculated using discount rates derived from corporate bonds. A deficit exists if the discount rate does not reflect the expected return on plan assets. The plan assets include shares, which are eventually expected to exceed the interest on corporate bonds, but also entail volatility and risk in the short term.

30 Other provisions

Group	Restructuring	Personnel	Legal disputes	Share-based payments	Other	Total
Opening balance, 1 January 2021	**—**	**48**	**61**	**104**	**35**	**247**
Provisions current year	—	25	—	154	9	187
Adjustment provisions previous year	—	0	—	-6	—	-6
Utilised provisions/payments during the year	—	-19	—	-77	—	-96
Translation differences	—	0	9	11	0	21
Closing balance, 31 December 2021	**—**	**54**	**70**	**186**	**44**	**353**
Non-current other provisions	—	49	—	—	37	**86**
Current other provisions	—	5	70	186	7	**267**
Opening balance, 1 January 2022	**—**	**54**	**70**	**186**	**44**	**353**
Provisions current year	280	28	—	268	3	579
Adjustment provisions previous year	—	—	-28	-6	-10	-44
Utilised provisions/payments during the year	-53	-23	—	-183	0	-259
Translation differences	3	1	1	23	1	29
Closing balance, 31 December 2022	**230**	**60**	**43**	**287**	**38**	**658**
Non-current other provisions	69	52	—	1	38	**159**
Current other provisions	161	8	43	286	0	**499**

Restructuring
Provision for restructuring refers to the efficiency programmes that were carried out during the year to restructure the business. The programmes refer to the discontinuation of contract manufacturing for Pfizer, the consolidation of a legacy site in Geneva into Basel and restructuring of selling and administrative and R&D functions to appropriately support the business. Remaining long-term provision of SEK 69 M is expected to be paid within 1-3 years.

Provision for personnel
Provision for personnel refers mainly to endowment policy and termination benefits.

Legal disputes
Sobi is involved in several, a not-uncommon situation for pharmaceutical companies, ongoing disputes which at the end of the year had not been closed.

Shared-based payments
Refers to provision for cash-based share programmes and social security costs for the share-based programmes.

Other
Refers mainly to a provision to restore the production facility, rented for contract manufacturing for Pfizer, to an acceptable condition with consideration for the operations conducted in accordance with the rental agreement.

Parent Company	Restructuring	Personnel	Legal disputes	Share-based payments	Other	Total
Opening balance, 1 January 2021	**—**	**44**	**61**	**28**	**34**	**167**
Provisions current year	—	1	—	13	0	14
Utilised provisions/payments during the year	—	—	—	-7	—	-7
Translation differences	—	—	9	—	—	9
Closing balance, 31 December 2021	**—**	**45**	**70**	**34**	**34**	**183**
Non-current other provisions	—	45	—	0	34	**79**
Current other provisions	—	—	70	34	—	**104**
Opening balance, 1 January 2022	**—**	**45**	**70**	**34**	**34**	**183**
Provisions current year	313	3	—	27	0	342
Adjustment provisions previous year	—	—	-28	—	—	-28
Utilised provisions/payments during the year	-25	—	—	-16	—	-41
Translation differences	—	—	1	—	—	1
Closing balance, 31 December 2022	**288**	**48**	**43**	**45**	**34**	**457**
Non-current other provisions	164	48	—	1	34	**247**
Current other provisions	123	—	43	44	—	**210**

The provision for restructuring in the Parent Company includes a provision for rent following the discontinuation of contract manufacturing for Pfizer, which at the end of the year amounted to SEK 115 M. In the Group, this has been recognised as an impairment of right-of-use assets according to IFRS 16, please see Note 9. For more information about the various types of provisions, please refer to the comments for the Group.

Expected timing of payment, SEK M	Non-current other provisions	
Group	**2022**	**2021**
Between 1-3 years	159	72
Between 4-5 years	—	5
Later than 5 years	0	9
Total	**159**	**86**

Expected timing of payment, SEK M	Non-current other provisions	
Parent Company	**2022**	**2021**
Between 1-3 years	247	66
Between 4-5 years	—	5
Later than 5 years	—	9
Total	**247**	**79**

31 Accrued expenses and deferred income

Group	2022	2021
Sales-related	3,131	3,053
Employee-related	623	468
Royalty	253	223
Research and development	274	163
Co-Promotion	177	246
Inventory-related	182	172
Other	613	374
Total	**5,253**	**4,700**

Parent Company	2022	2021
Sales-related	327	275
Employee-related	179	211
Royalty	213	197
Research and development	254	144
Co-Promotion	177	245
Inventory-related	171	49
Other	294	69
Total	**1,614**	**1,192**

32 Pledged assets and contingent liabilities

Group	2022	2021
Pledged assets		
Endowment policy	48	45
Other pledged assets	—	3
Total	**48**	**48**

Parent Company	2022	2021
Pledged assets		
Endowment policy	48	45
Total	**48**	**45**

Parent Company	2022	2021
Contingent liabilities		
Guarantee commitment	78	88
Total	**78**	**88**

Guarantee commitments relate to general guarantees for subsidiaries up to a specified amount for certain types of commitments, such as rental and credit card payment.

33 Related-party transactions

Apart from that stated in the Notes on remuneration of senior executives and intra-Group transactions, there were no related-party transactions.

Please see Note 5 for internal transactions between the Group's subsidiaries.

34 Proposed appropriation of profit

The following funds are at the disposal of the AGM:

SEK K	
Share premium reserve	9,418,774
Retained earnings	8,787,171
Profit for the year	2,450,755
Total	**20,656,700**

The board proposes that no dividends be paid for the 2022 financial year.

The board proposes that the share premium reserve, retained earnings and profit for the year, totalling SEK 20,656,700 K, be carried forward.

35 Events after the balance sheet date

Efanesoctocog alfa

FDA approved once-weekly efanesoctocog alfa, a new class of high-sustained factor VIII therapy for haemophilia A.

Sobi and Sanofi announced positive top-line results from pivotal XTEND-Kids phase 3 study of efanesoctocog alfa in children under 12 years of age with haemophilia A.

Nirsevimab

The regulatory submission acceptance of nirsevimab in the US in January 2023 triggered a milestone payment of USD 175 M to AstraZeneca in February 2023.

SEL-212

Sobi and Selecta announced positive topline results from the DISSOLVE phase 3 program of SEL-212 in chronic refractory gout.

The board and CEO confirm that the consolidated financial statements have been prepared in accordance with IFRS, as adopted by the EU, and provide a true and fair view of the Group's financial position and results. The Annual report has been prepared in accordance with generally accepted accounting principles and provides a true and fair view of the Parent Company's financial position and results.

The directors' report for the Group and the Parent Company provides a true and fair view of the development of the Group and the Parent Company's operations, financial position and results and describes the material risks and uncertainties faced by the Parent Company and the companies in the Group. The income statements and balance sheets will be presented to the AGM on 9 May 2023 for adoption.

Stockholm, 28 March 2023

Håkan Björklund
Chairman

Bo Jesper Hansen
Deputy chairman

Annette Clancy
Board member

Matthew Gantz
Board member

Helena Saxon
Board member

Staffan Schüberg
Board member

Filippa Stenberg
Board member

Pia Axelson
Employee representative

Erika Husing
Employee representative

Guido Oelkers
Chief Executive Officer

Our auditor's report was submitted on 31 March 2023
Ernst & Young AB

Jonatan Hansson
Authorised Public Accountant

Auditor's report

To the general meeting of the shareholders of Swedish Orphan Biovitrum AB (publ), corporate identity number 556038-9321

Report on the annual accounts and consolidated accounts

Opinions

We have audited the annual accounts and consolidated accounts of Swedish Orphan Biovitrum AB (publ) for the year 2022. The annual accounts and consolidated accounts are included on pages 32-97 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the Parent Company as of 31 December 2022, and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the Group as of 31 December 2022, and their financial performance and cash flow for the year then ended in accordance with IFRS, as adopted by the EU, and the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the statement of comprehensive income and balance sheet for the Group and the income statement and balance sheet for the Parent Company.

Our opinions in this report on the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the Parent Company's Audit committee in accordance with the Audit Regulation (537/2014) Article 11.

Basis for opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the section Auditor's Responsibilities. We are independent of the Parent Company and the Group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its Parent Company or its controlled companies within the EU.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Key audit matters

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters. For each matter below, our description of how our audit addressed the matter is provided in that context.

We have fulfilled the responsibilities described in the Auditor's responsibilities for the audit of the financial statements section of our report, including in relation to these matters. Accordingly, our audit included the performance of procedures designed to respond to our assessment of the risks of material misstatement of the financial statements. The results of our audit procedures, including the procedures performed to address the matters below, provide the basis for our audit opinion on the accompanying financial statements.

Revenue – Estimate of unsettled pharmaceutical taxes and discounts

Description	How our audit addressed this key audit matter
The Group (below referred to as the company) operates in a number of countries where sales to customers take place under various commercial and governmental contracts and regulations where pharmaceutical taxes and discounts exist as conditions for certain products. Net sales are reported after deductions from pharmaceutical taxes and discounts. Therefore, an estimate of the unsettled revenue adjustments for pharmaceutical taxes and discounts needs to be made at year end. The unsettled revenue adjustments recorded on 31 December 2022, are based on the company's best assessment of the expected outcome of future settlement of the commitments at year end. The assessment is complex and often requires access to both internal and external market and sales data that may be limited at the time of assessment. Refer to Note 2, 4 and 5 in the Annual report for a detailed description of the revenue adjustments and the liabilities reported. Due to the significant amount that the revenue adjustments represent in relation to the company's comprehensive income for the period and the complex assessments, revenue adjustments are a key audit matter in our audit.	We have in our audit obtained an understanding of the company's process to identify and assess the unsettled revenue adjustments. We have also evaluated the company's previous accuracy in preparing forecasts, on a sample basis tested the company's calculation of liabilities for the revenue adjustment against agreements or regulation and assessed the reasonableness of the assumptions and data that the company used in its assessment. In certain countries we have also been supported by our internal specialists in our audit. We have also assessed the disclosures in the Annual report.

Valuation of product and marketing rights and goodwill

Description	How our audit addressed this key audit matter
On 31 December 2022, the majority of (75% or SEK 39,195 million) the Group's (below referred to as the company) total assets consist of product- and marketing rights as well as goodwill (hereafter referred to as "the assets"). The company performs an impairment test of the assets on an annual basis and when events or changes in conditions indicate that the carrying amount of the assets may exceed the recoverable amount. Testing of impairment for the assets involve a number of significant assumptions and assessments, among other assessing the value in use through identifying cash generating units, estimating expected future cash flows including the growth rate and calculating WACC used to discount future cash flows. The company's process for assessing impairment requirements also includes the use of the management's and the board of directors' business plans and forecasts. For additional information refer to the Group's accounting principles in Note 2, significant assessments and assumptions in Note 4 as well as information about the product and marketing rights and goodwill in Note 16 We focused on this area as the book value of the assets are significant and the impairment test is sensitive to changes in assumptions. Therefore, we considered this a key audit matter in our audit.	Our audit was conducted together with our valuation specialists and included but was not limited to the following audit procedures: • Obtained an understanding of the company's process and models used for identifying indicators of impairment • Evaluation of methods used by management when performing the impairment test including the sensitivity analysis and • Review of the assessments made by the company when testing the impairment with our focus on assumptions for which the result of impairment testing is most sensitive to by comparison to historical outcome and accuracy in previous forecasts, evaluation of the company's own sensitivity analysis and performing our own sensitivity analysis. We have also assessed the disclosures in the Annual report.

Contingent considerations

Description	How our audit addressed this key audit matter
During previous years and the current year, the Parent Company and the Group (below referred to as the company) have made for the company significant business and asset acquisitions. In most of the acquisitions there are contingent considerations that are determined based on future events that are often linked to the fulfilment of certain future regulatory and commercial milestones linked to the acquired assets. On 31 December 2022, the reported liabilities for contingent consideration amounted to SEK 5,154 M and SEK 3,948 M in the Group and the Parent Company respectively. In Note 2, the principles for initial recognition and valuation and subsequent valuation of contingent considerations are described. The company continuously evaluates the assumptions for the contingent considerations, which affects the valuation of the liabilities. The values of the Company's liabilities for contingent considerations are disclosed in Notes 3, 4, 16, 26, and 28. Key assumptions used to determine the values are described in Notes 4 and 28. As described in Note 4, management is required to make assessments and develop own assumptions in order to estimate the value of the contingent considerations. Since the value of the contingent considerations constitutes a significant part of the company's liabilities and is linked to significant future commitments for the company, valuation of liabilities for contingent considerations constitutes a key audit matter in our audit.	Our audit has included, among other things, the following audit procedures: • Obtained an understanding of the company's process for valuing contingent considerations, • Review of material agreements including conditions for contingent considerations, • Review of management's assessments and assumptions used to support the valuation of contingent considerations with a focus on the assumptions for which the valuation is most sensitive and • Tested the Company's calculations for arithmetical correctness and consistency with reported values. We have also assessed the disclosures in the Annual report.

Other Information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 1-21, 28-31,, 113-118, 161-170. The other information also consists of the remuneration report that we obtained before the date of the auditor's report. The board of directors and the managing director are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the board of directors and the managing director
The board of directors and the managing director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The board of directors and the managing director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts, the board of directors and the managing director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the board of directors and the managing director intends to liquidate the company, to cease operations, or has no realistic alternative but to do so.

The Audit committee shall, without prejudice to the board of directors' responsibilities and tasks in general, among other things oversee the company's financial reporting process.

Auditor's responsibility
Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit.

We also:

- Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the board of directors and the managing director.
- Conclude on the appropriateness of the board of directors' and the managing director's use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.

We must inform the board of directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

We must also provide the board of directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, actions taken to eliminate threats or related safeguards applied.

From the matters communicated with the board of directors, we determine those matters that were of most significance in the audit of the annual accounts and consolidated accounts, including the most important assessed risks for material misstatement, and are therefore the key audit matters. We describe these matters in the auditor's report unless law or regulation precludes disclosure about the matter.

Report on other legal and regulatory requirements

Report on the audit of the administration and the proposed appropriations of the company's profit or loss

Opinions
In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the board of directors and the managing director of Swedish Orphan Biovitrum AB (publ) for the year 2022 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the board of directors and the managing director be discharged from liability for the financial year.

Basis for opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the section Auditor's responsibilities. We are independent of the Parent Company and the Group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Responsibilities of the board of directors and the managing director

The board of directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The board of directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The managing director shall manage the ongoing administration according to the board of directors' guidelines and instructions and among other matters take measures that are necessary to fulfil the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the board of directors or the managing director in any material respect:

- Has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- In any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional scepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the board of directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

The auditor's examination of the ESEF report

Opinion

In addition to our audit of the annual accounts and consolidated accounts, we have also examined that the board of directors and the managing director have prepared the annual accounts and consolidated accounts in a format that enables uniform electronic reporting (the ESEF report) pursuant to Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528) for Swedish Orphan Biovitrum AB (publ) for the financial year 2022.

Our examination and our opinion relate only to the statutory requirements.

In our opinion, the ESEF report has been prepared in a format that, in all material respects, enables uniform electronic reporting.

Basis for opinion

We have performed the examination in accordance with FAR's recommendation RevR 18 Examination of the ESEF report. Our responsibility under this recommendation is described in more detail in the section Auditors' responsibility. We are independent of Swedish Orphan Biovitrum AB (publ) in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Responsibilities of the board of directors and the managing director

The board of directors and the managing director are responsible for the preparation of the ESEF report in accordance with Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), and for such internal control that the board of directors and the managing director determine is necessary to prepare the ESEF report without material misstatements, whether due to fraud or error.

Auditor's responsibility

Our responsibility is to obtain reasonable assurance whether the ESEF report is in all material respects prepared in a format that meets the requirements of Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), based on the procedures performed.

RevR 18 requires us to plan and execute procedures to achieve reasonable assurance that the ESEF report is prepared in a format that meets these requirements.

Reasonable assurance is a high level of assurance, but it is not a guarantee that an engagement carried out according to RevR 18 and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the ESEF report.

The audit firm applies ISQC 1 Quality Control for Firms that Perform Audits and Reviews of Financial Statements, and other Assurance and Related Services Engagements and accordingly maintains a comprehensive system of quality control, including documented policies and procedures regarding compliance with professional ethical requirements, professional standards and legal and regulatory requirements.

The examination involves obtaining evidence, through various procedures, that the ESEF report has been prepared in a format that enables uniform electronic reporting of the annual and consolidated accounts. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement in the report, whether due to fraud or error. In carrying out this risk assessment, and in order to design audit procedures that are appropriate in the circumstances, the auditor considers those elements of internal control that are relevant to the preparation of the ESEF report by the board of directors and the managing director, but not for the purpose of expressing an opinion on the effectiveness of those internal controls. The examination also includes an evaluation of the appropriateness and reasonableness of assumptions made by the board of directors and the managing director.

The procedures mainly include a validation that the ESEF report has been prepared in a valid XHMTL format and a reconciliation of the ESEF report with the audited annual accounts and consolidated accounts.

Furthermore, the procedures also include an assessment of whether the consolidated statement of financial performance, financial position, changes in equity, cash flow and disclosures in the ESEF report have been marked with iXBRL in accordance with what follows from the ESEF regulation.

Ernst & Young AB, Box 7850, 103 99 Stockholm with Jonatan Hansson as auditor in charge was appointed auditor of Swedish Orphan Biovitrum AB (publ) by the general meeting of the shareholders on 10 May 2022 and have been the company's auditor since 8 May 2014.

Stockholm, 31 March 2023
Ernst & Young AB

Jonatan Hansson
Authorised Public Accountant

Corporate governance report

Swedish Orphan Biovitrum AB (publ) is a Swedish public limited liability company with its registered office in Stockholm, Sweden. Sobi is listed on Nasdaq Stockholm. This report for the 2022 financial year has been audited. Sobi is an international biopharmaceutical company focused on rare diseases with in-house capabilities that stretch from R&D and biologics manufacturing to distribution and commercialisation.

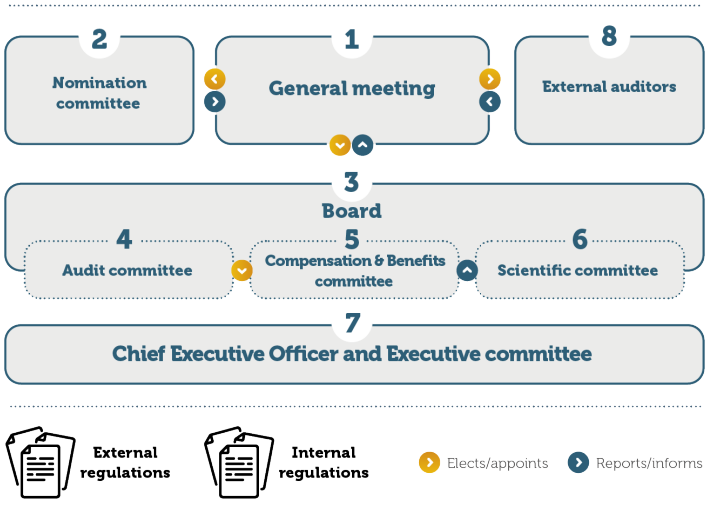
In addition to Swedish legislation and other regulations, the Group's corporate governance is based on the Swedish Corporate Governance Code and the Nasdaq Stockholm Nordic Main Market Rulebook for Issuers of Shares. Sobi complies with the Swedish Corporate Governance Code without any deviations and has not breached the Nordic Main Market Rulebook for Issuers of Shares or standards of good practice for listed companies. The Swedish Corporate Governance Code is available at www.bolagsstyrning.se and the Nordic Main Market Rulebook for Issuers of Shares is available at www.nasdaqomxnordic.com.

This corporate governance report summarises how corporate governance is organised and how it was carried out in 2022. The report has been prepared in accordance with the Swedish Annual Accounts Act (1995:1554) and the Swedish Corporate Governance Code. The illustration below provides an overview of Sobi's corporate governance structure, which is then described in more detail in this report.

In addition to the external regulations set out above, there are also a number of internal regulations in place to support Sobi's corporate governance, such as the Articles of Association, Rules of Procedure for the board and its committees, CEO instructions and Sobi's governing documents with Sobi's Code of Conduct as a portal document.

1. General meeting

Sobi's highest decision-making body is the general meeting through which shareholders have the right to make decisions on Sobi's affairs. The AGM must be held within six months of the end of the financial year, and extraordinary general meetings may be held if the board deems it necessary,



or at the request of Sobi's auditors or shareholders holding at least 10 per cent of all shares in the company. The AGM adopts the income statement and balance sheet, resolves on the appropriation of profits and elects board members, the chair and auditors.

Sobi does not apply any special arrangements with regard to the function of the general meeting, either on the basis of provisions in the Articles of Association or, to the extent they are known to the company, shareholder agreements.

The Articles of Association state that the AGM is to be held in Stockholm or Solna. At present, Sobi has not found that the composition of the shareholder base calls for any special measures to enable shareholders to follow the AGM remotely. Notice of the AGM is published in The Official Swedish Gazette (Post- och Inrikes Tidningar) and on the company's website. When this has been done, an announcement to this effect is published in Svenska Dagbladet.

2022 AGM

The AGM was held on 10 May 2022 in Stockholm. Due to the coronavirus, the shareholders were able to exercise their voting rights at the meeting also by postal voting in accordance with the regulations in Sobi's Articles of Association. The meeting was attended by 300 shareholders (328) in person, by postal voting or by proxy. They represented 64.0 per cent (64.3) of the total number of votes. Lawyer Eva Hägg was elected to chair the meeting.

The complete minutes and information from the 2022 AGM are available at sobi.com.

Resolutions 2022 AGM

The following resolutions were inter alia adopted by the 2022 AGM:

- Re-election of six board members
- Election of one new board member
- Re-election of the chair
- Re-election of Ernst & Young AB as auditor
- Remuneration of the board members and auditors
- Approval of the board's remuneration report for 2021
- Discharge from liability for the board and CEO for the 2021 financial year
- Introduction of long-term incentive programmes

2023 AGM

The AGM will be held on Tuesday, 9 May 2023. For more information about the AGM, please refer to page 161.

Shareholders, share capital, the share and voting rights

At year-end, Sobi had a total of 21,914 (24,685) shareholders. Investor AB was the largest shareholder, with 34.7 per cent (35.0) of the share capital and 34.7 per cent (35.0) of the votes. The 15 largest shareholders accounted jointly for 74.5 per cent (73.4) of the share capital and 74.5 per cent (73.4) of the votes. No shareholders other than Investor AB have a direct or indirect shareholding that represents one-tenth or more of the votes for all shares in the company. Sobi's Articles of Association do not contain any restrictions on how many votes each shareholder may cast at a general meeting.

Nor do they contain any specific provisions on the appointment and dismissal of board members or amendments to the Articles of Association.

Conversion of shares and authorisations for the board

In order to secure commitments under long-term incentive programmes, the AGM on 10 May 2022 adopted (i) a private placement of redeemable and convertible C shares, (ii) authorisation for Sobi's board to make decisions regarding the repurchase of issued C shares, and (iii) the transfer of Sobi's own shares to participants in the programme.

The AGM also resolved to transfer a maximum of 593,859 of Sobi's own shares in order to cover some expenses, mainly social security contributions, which may arise due to the 2019 Incentive Programme. The AGM also resolved to authorise the board to make decisions regarding the issue of shares and/or convertibles and/or warrants.

On 31 December 2022, Sobi held 13,789,723 shares in treasury. In 2022, all previously issued C shares were converted into ordinary shares. For more information about the total number of shares in the company, the different classes of shares and the votes carried by the company's shares, please refer to the section Share info.

Dividend policy

One of Sobi's most important objectives is to create long-term shareholder value. Sobi's board bases its evaluation of potential future dividends on several factors, including:

- The company's sustainable earnings trend
- The company's expansion potential and access to capital
- The company's operational risk
- The dividend's impact on liquidity in terms of cash flow

The board proposes that no dividend be paid for 2022. Sobi deploys capital in support of its business model; continuously looking for opportunities to augment its business and pipeline. As Sobi seeks new medicines to either license or acquire, the company applies a solid set of capital-allocation priorities. They include a focus on rare diseases, preferably in haematology or immunology, medicines in late-stage development or already marketed with peak sales potential between USD 150-500 M and with a preference for not diluting the EBITA margin.

2. Nomination committee

The Nomination committee represents Sobi's shareholders and is tasked with preparing the AGM's resolutions on election and remuneration matters.

According to the instructions and statutes adopted by the AGM on 9 May 2019, the Nomination committee shall consist of four members: the chair of the board and one representative from each of the three largest shareholders in terms of votes in the company on the last banking day of August, based on ownership statistics from Euroclear Sweden AB, who wish to appoint a representative. The Nomination committee observes the rules on the independence of board members according to the Swedish Corporate Governance Code. The names of the members of the Nomination committee prior to the 2023 AGM were published on the company's website on 10 October 2022.

In the period up to the 2023 AGM, the Nomination committee has the following composition: Petra Hedengran (Investor AB) and chair of the Nomination committee, Lennart Francke (Swedbank Robur Fonder AB), Thomas Ehlin (Fourth Swedish National Pension Fund) and Håkan Björklund, chairman of the board of Sobi. Prior to the 2023 AGM, the Nomination committee held six minuted meetings. As a basis for its work, the Nomination committee has taken note of the chairman's account of the board's work. The Nomination committee has prepared proposals for the AGM regarding the election of board members, remuneration of board and committee members, appointment of auditor, auditor fees and chair of the AGM.

3. Board/chair of the board

Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare and debilitating diseases. The portfolio contains both medicines and projects at various stages of development. It is therefore crucial that board members have relevant experience from marketing and research in the pharmaceutical industry, as well as solid financial expertise. The board is responsible for the Group's organisation and management. The board also decides on overall objectives, strategies, the financial structure, policies, appointment of the CEO, remuneration of the Executive committee, acquisitions, divestments and major investments. The board produces annual and interim reports and proposes dividends to the AGM.

Nomination committee prior to the 2023 AGM

Name/Representing	Votes 31 Dec. 2022, %	Votes 31 Dec. 2021, %
Petra Hedengran, chair of the Nomination committee, Investor AB	34.7	35
Lennart Francke, Swedbank Robur Fonder AB	1.9	1.4
Thomas Ehlin, Fourth Swedish National Pension Fund (AP4)	6.5	6.7
Håkan Björklund, chairman of Swedish Orphan Biovitrum AB (publ)	0.0	0.0
Total	**43.1**	**43.1**

The board's work is based on its charter, the CEO instructions and the principles for the division of work between the CEO, chair of the board, board members and committees established by the board. The board charter and the CEO instructions are revised and updated once a year.

Composition of the board

The company's board shall comprise a minimum of three and a maximum of 12 members. The Nomination committee represents the shareholders and is responsible for preparing the AGM's decisions on matters related to election and remuneration and, when applicable, procedural matters for the next Nomination

committee. The Nomination committee has applied rule 4.1 of the Swedish Corporate Governance Code as a diversity policy. The objective of the policy is that the board shall have an appropriate composition with regard to the company's business, stage of development and situation in general, characterised by versatility and breadth in respect of the competence, experience and background of members elected by the AGM, and that efforts shall be made to achieve an even gender distribution. As set out in the Nomination committee's motivated opinion to the 2022 AGM, the Nomination committee has taken into account the importance of a well-functioning composition of the board in terms of diversity, including gender, nationality, professional experience and experience of sustainability work, and strives to achieve and maintain an equal gender balance. The current composition of the board is the result of the Nomination committee's work prior to the 2022 AGM.

The 2022 AGM adopted the Nomination committee's proposal that the board, as of the 2022 AGM and until 31 December 2022, has consisted of seven elected members (six re-elected and one newly elected by the 2022 AGM) as well as two employee representatives appointed by the trade union organisations (plus two deputies for the employee representatives). Three of the elected board members are women.

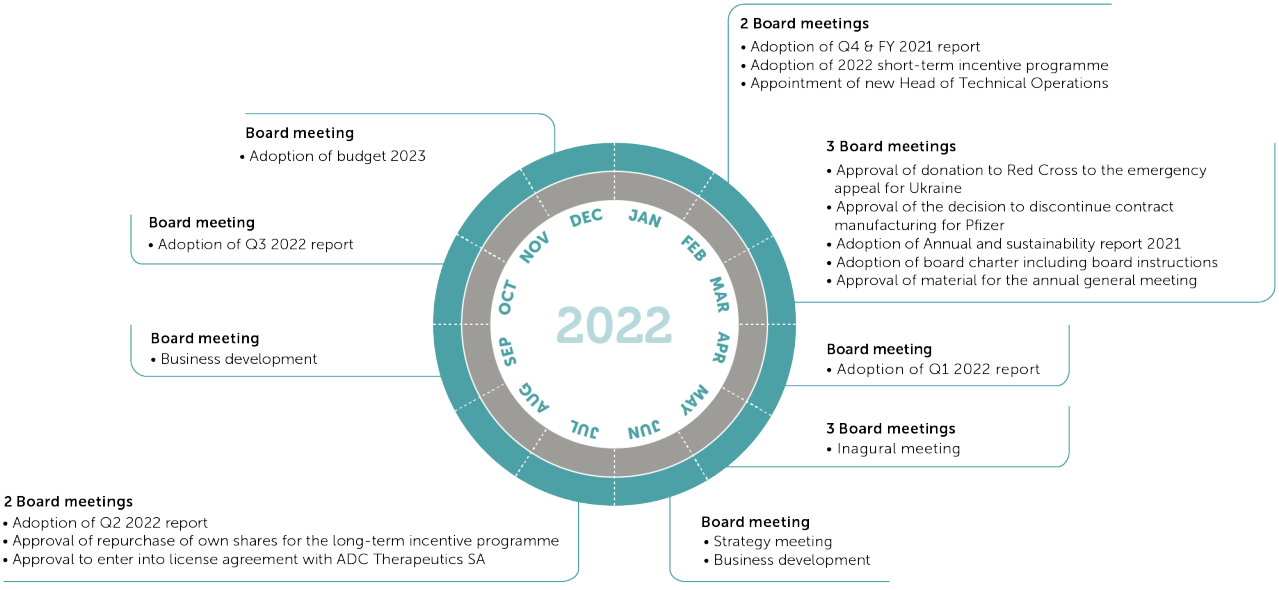
For more information about the board, see pages 113-115.

Independence

Sobi meets the Swedish Corporate Governance Code's independence requirements in that a majority of the AGM-elected board members are independent of the company and its management, and that at least two of them are independent of major shareholders. The table on page 108 shows the independence of board members on the publication date of this report.

Chair of the board

In addition to leading the board's work, the chair of the board's duties include monitoring the company's performance and ensuring that any important matters are addressed if required, in addition to those already on the agenda. The chair shall consult with the CEO on strategic matters, participate in important external relationships and represent the company in ownership issues. The chair is also responsible for ensuring that the board's work is regularly evaluated and that new board members receive adequate training.



Number of meetings

In addition to the statutory board meeting, the board shall meet at least four times per year, generally in connection with the publication of interim and annual reports and the AGM. Additional meetings or teleconferences are convened as necessary. The board conducts an in-depth strategic review of operations during at least one of the board meetings each year. For 2023, the board has scheduled a total of nine ordinary meetings in addition to the statutory board meeting.

Board work in 2022

In 2022, the board held a total of 15 meetings, of which nine were scheduled in addition to the statutory meeting, and five were extra meetings. Sobi's CEO and President attends board meetings, as does Sobi's General Counsel, who has served as secretary at the meetings. Other Sobi employees have attended in a reporting capacity. The number of extra board meetings was motivated by discussions related to business development projects. The matters addressed are shown in the illustration on previous page. The board members' attendance at board meetings is presented in the table on the following page.

Board fees

At the AGM on 10 May 2022, the board resolved that for the period until the next AGM, a fee of SEK 550 K would be paid to each of the elected board members except for the chairman, who would be paid a fee of SEK 1,675 K, and the deputy chairman, who would be paid a fee of SEK 900 K.

Fees for the Audit committee's work would be SEK 185 K for the chair and SEK 110 K for each of the other members. Fees for the Compensation & Benefits committee's work would be SEK 120 K for the chairman and SEK 70 K for each of the other members. Fees for the Scientific committee's work would be SEK 120 K for the chair and SEK 70 K for each of the other members. In 2022, board fees of SEK 6,041 K were paid, including remuneration for committee work.

It was further resolved that for each physical board meeting, a fee of SEK 20 K would be paid to board members residing in Europe but outside the Nordic region, and 3,500 USD to board members residing outside Europe.

The board members' remuneration for committee meetings is presented in the table below.

Evaluation of the board's work

The board conducts an annual evaluation of its work. The evaluation covers working methods and climate, and the main focus of the board's work. This evaluation also focuses on access to, and the need for, specific skills on the board. The evaluation is used as a tool for developing the board's work and serves as input for the Nomination committee's work. Every year, the chair initiates and leads the evaluation of the board's work. In 2022, the evaluation took the form of individual discussions between the chairman and individual board members. The chairman presented the results of the evaluation for the Nomination committee.

4. Audit committee

The Audit committee's main task is to address issues related to the company's accounting, auditing and financial reporting, and matters related to internal governance and control. The Audit committee consisted of three members, all who are independent of management:

- Helena Saxon (chair)
- Staffan Schüberg
- Filippa Stenberg

Sobi's CFO serves as secretary of the committee but is not a member. Sobi's CEO attended all meetings but is not formally a member. The committee held six meetings during the year. Sobi's auditor attended five of the meetings. The committee reports regularly to the board about its work. The board members' attendance and remuneration for committee meetings is presented in the table below.

		Remuneration (KSEK)						Attendance[i]			
	Indepen-dence	Fees	Audit committee	Compen-sation & Benefits committee	Scientific committee	Other[v]	Total	Board	Audit committee	Compen-sation & Benefits committee	Scientific committee
Håkan Björklund	x	1,642	–	118	–	–	1,760	15/15	–	8/9	–
Bo Jesper Hansen	x	600	–	–	47	20	667	8/8	–	–	1/1
Annette Clancy	x	538	–	–	80	30	648	12/15	–	–	1/1
Matthew Gantz	x	538	–	68	–	66	673	15/15	–	9/9	–
Helena Saxon	iii	538	182	68	–	–	788	15/15	6/6	9/9	–
Staffan Schüberg	x	538	108	–	–	30	677	12/15	6/6	–	–
Filippa Stenberg	iii	538	108	–	–	–	647	15/15	6/6	–	–
Elisabeth Svanberg[ii]	x	171	–	–	–	10	181	7/7	–	–	–
Pia Axelson	iv	–	–	–	–	–	–	15/15	–	–	–
Erika Husing	iv	–	–	–	–	–	–	15/15	–	–	–
Linda Larsson	iv	–	–	–	–	–	–	11/11	–	–	–
Katy Mazibuko	iv	–	–	–	–	–	–	11/11	–	–	–

i. The figures in the table show the totals for attendance/meetings. In 2022, the board held a total of 15 meetings, of which nine were scheduled in addition to the statutory meeting and five were extra meetings. The Audit committee held six meetings, the Compensation & Benefits committee held nine meetings, and the Scientific committee held one meeting.

ii. At the AGM on 10 May 2021, Elisabeth Svanberg stepped down from her position as board member, while Bo Jesper Hansen was appointed new ordinary member of the board.

iii. Board member does not qualify as independent in relation to major shareholders.

iv. Employee representatives.

v. For each physical board meeting, a fee of SEK 20 K (10) is paid to members who live in Europe but outside the Nordic region, and USD 3,5 K (3) to each member who lives outside Europe.

5. Compensation & Benefits committee

The Compensation & Benefits committee's task is to recommend guidelines and principles for Sobi's remuneration programmes. This includes a review of and proposals for the remuneration of senior executives, the long-term incentive programmes, pension plans and other issues related to employee benefits. Sobi's Compensation & Benefits committee consists of three members, who are all independent of management:

- Håkan Björklund (chairman)
- Helena Saxon
- Matthew Gantz

Sobi's General Counsel and Head of HR serves as secretary of the committee but is not a member. The Compensation & Benefits committee met nine times during the year. At these meetings, the committee discussed and monitored annual salary revisions and bonus outcomes for the CEO and senior executives, and proposed guidelines and allotments for the long-term incentive programme. The committee reports regularly to the board about its work.

A remuneration report has been prepared and will be presented at the 2023 AGM for adoption by the shareholders. The board members' attendance and remuneration for committee meetings is presented in the table above. For information about salaries and remuneration of the CEO and senior executives, please see Note 10.

6. Scientific committee

The Scientific committee's task is to provide advice on scientific matters, to evaluate the company's R&D strategies and to monitor and report to the board on scientific trends and new fields of R&D. Sobi´s Scientific committee consist of two members, who are all independent of management

- Annette Clancy (chair)
- Bo Jesper Hansen

The committee held one meeting during the year.

Sobi's CEO and Head of Research & Development and Medical Affairs, Chief Medical Officer attended the meetings, but are not formal members. Head of Research & Development and Medical Affairs, Chief Medical Officer served as secretary of the committee.

The committee reports to the board about its work. The board members' attendance and remuneration for committee meetings is presented in the table above.

7. Chief Executive Officer and Executive committee

Sobi's Executive committee consists of the CEO and managers of the most important functions and regions. The Executive committee has a broad composition of members with extensive experience in R&D, the markets in which Sobi operates and the production and sale of medicines. In addition, members of the Executive committee hold the required competence in accounting, finance, law, communications and HR. In 2022, the Executive committee held one meeting every month. Due to the pandemic, several of these meetings were held virtually. For more detailed information about the Executive committee, see pages 116-118.

Each year, the board establishes the division of work between the board, the chair and the CEO. Operational management is based on the decision-making procedure adopted by the board, which is reflected in the organisational form and business model that govern Sobi and how the company works.

8. Auditor

Sobi's auditor is the auditing firm Ernst & Young AB (EY) with Authorised Public Accountant Jonatan Hansson as auditor in charge. EY was elected as Sobi's auditor until the end of the 2023 AGM and has been Sobi's auditor since the 2014 AGM. The auditor reviews the Q3 interim report and audits the Annual report and consolidated financial statements. The auditor also expresses an opinion on whether this corporate governance report has been prepared, and whether certain disclosures herein are consistent with, the annual accounts and consolidated financial statements. The auditor reports the results of their audit of the annual accounts and consolidated financial statements and their review of the corporate governance report in the auditor's report, with a separate opinion on the corporate governance report, which they present to the AGM. In addition, the auditor presents detailed findings from their reviews to the Audit committee three times a year, and to the full board once a year.

For information about remuneration of the company's auditors, please see Note 11.

Sobi's internal control over financial reporting

The board is responsible for ensuring effective internal control systems in accordance with the Swedish Companies Act (2005:551), the Swedish Annual Accounts Act (1995:1554) and the Swedish Corporate Governance Code. The board presents the most important elements of Sobi's internal control over financial reporting below.

Sobi´s internal control framework

Sobi´s description of internal control complies with the COSO Framework (Committee of Sponsoring Organizations of the Treadway Commission) which consists of five components: control environment, risk assessment, control activities, information and communication and monitoring activities.

The illustration below provides an overview of Sobi's framework for internal control over financial reporting and shows how the framework's components interact to ensure good internal control over financial reporting. The components are described in more detail below.

Control environment

The control environment constitutes the basis of Sobi's internal control. The control environment comprises culture on which the board and management base their work as well as processes and Sobi's internal regulations.

The control environment for financial reporting comprises processes with appointed key controls, clear roles and responsibilities, high competence and governing documents.

Sobi's governing documents are gathered on the company's intranet. Some of the governing documents with relevance for financial reporting are:

- Sobi's Code of Conduct
- Decision-making powers established by the board
- Authority policy
- Reporting instructions
- Accounting manual
- Treasury policy
- Risk management policy

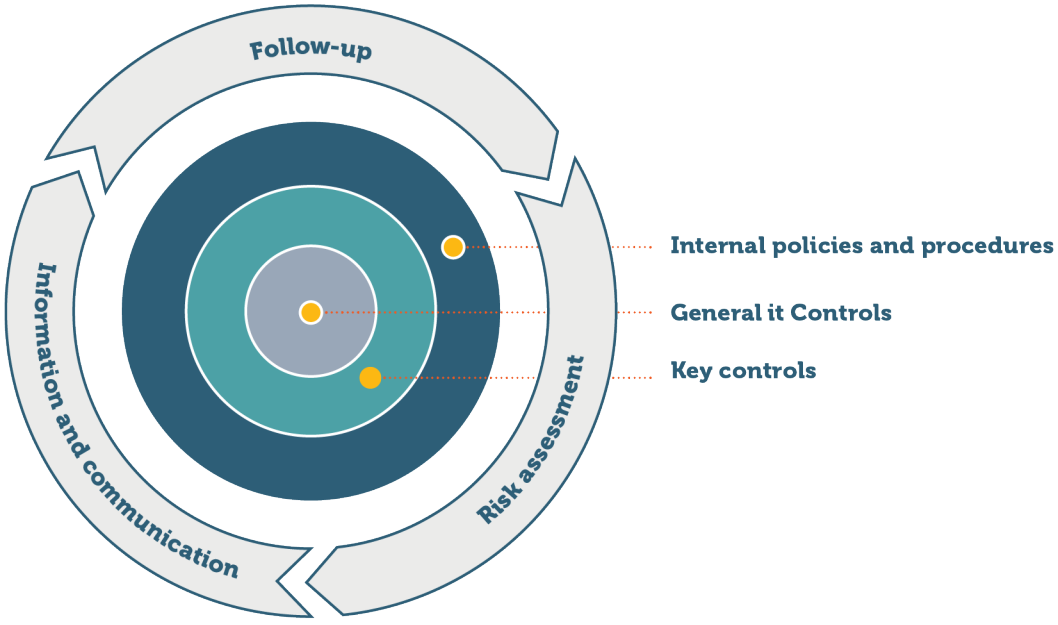
Risk assessment

The risk management process contributes with structures and systems to proactively identify and manage risks that could have a negative impact on the company's ability to achieve its targets. Sobi's risk management process is intra-organisational. In regard to financial reporting, risk assessment is performed at least annually.

Significant risks identified by Sobi are described on pages 40-42.

Control activities

The aim of control activities is to manage identified risks and contribute to strong internal control and organisational efficiency. Control activities applicable to financial reporting process include approval of decisions and transactions, account reconciliation and analytical monitoring. Sobi´s identified key controls concerning the financial reporting process are described and documented in Sobi´s control framework. Sobi´s control activities are either manual or automated in Sobi´s financial systems. Sobi also has general IT controls in place for managing its system environment. General IT controls include identity and access management and change management.



Information and communication

Sobi has internal information and communication channels to ensure that financial reporting disclosures are efficient and accurate. Sobi's intranet, which also includes the Finance Portal, is the main communication platform. The Group's financial organisation also holds continuous meetings with a focus on ensuring that everyone has enough information to ensure accurate financial reporting. The board and its Audit committee receive regular reports on the Group's financial position and performance.

Procedures for external information disclosure aim to provide the market with relevant, reliable and accurate information about Sobi's performance and financial position. The guidelines for financial reporting are set out in Sobi's Communication policy. Financial information is presented regularly in the form of:

- Interim reports
- Annual report
- Press releases about important news and events that could significantly affect the valuation of the company and the share price
- Presentations and teleconferences for financial analysts, investors and media representatives on the publication date of interim reports and in connection with the release of other important information
- Meetings with investors and financial analysts

Reports, presentations and press releases are published on sobi.com.

Follow-up

Forms of supervision of internal control are determined by the board and the Audit committee. Sobi's CFO is responsible for ensuring that internal control over financial reporting and have as support Head of Internal Control with the objective to strengthening, develop and monitor the internal control.

The board deals with all interim and annual reports prior to publication and monitors the review of internal control through the Audit committee.

Sobi's external auditor reports their observations and assessment of internal controls to the Audit committee.

Internal audit

Sobi does not have a separate internal audit function, but an internal control function that assess and monitor compliance with Sobi's internal control framework, together with the operational organisation.

The board and Audit committee regularly examine the issue of whether an internal audit function should be established and based on this year's internal control report do not consider that a separate Internal audit function is not necessary at present.

Activities that strengthened internal control in 2022

- Follow-up of the Group's internal control framework, using both self-assessment and internal control visits.
- Strengthening of controls in processes.
- Strengthening of collaboration with other control functions.

Activities in focus to further strengthen internal control in 2023

- Further development of the Group's framework for internal control over financial reporting.
- Implementation of system support for monitoring internal controls and risk.

Auditor's report on the corporate governance statement

To the general meeting of the shareholders of Swedish Orphan Biovitrum AB (publ), corporate identity number 556038-9321.

Engagement and responsibility

It is the board of directors who is responsible for the corporate governance statement for the year 2022 on pages 103-111 and 113-118 and that it has been prepared in accordance with the Annual Accounts Act.

The scope of the audit

Our examination has been conducted in accordance with FAR's standard RevR 16 The auditor's examination of the corporate governance statement. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

Opinions

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2-6 the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the annual accounts and the consolidated accounts and are in accordance with the Annual Accounts Act.

Stockholm, 31 March 2023
Ernst & Young AB

Jonatan Hansson
Authorised Public Accountant

Board

Håkan Björklund
Chairman and board member since 2016; member of the Nomination committee and chair of the Compensation & Benefits committee.
Born 1956; Swedish national.
Education: PhD from Karolinska Institutet, Stockholm, Sweden.
Other assignments: Chairman of Asker. Chairman of BioPhorum. Board member of Bonesupport. Partner at Tellacq Partners. Advisor to Rothschild Private Equity.
Prior experience: CEO of Nycomed. Extensive international background in the life-science industry, from both R&D and sales and marketing. Board member of several international life-science companies including Alere, Coloplast, Danisco and Lundbeck. Board member of Biovitrum 2001-2007.
Independent of Sobi and its executive management: Yes
Independent in relation to major shareholders of Sobi: Yes
Shares in Sobi: 15,800.

Bo Jesper Hansen
Deputy chairman and board member since 2022; member of the Scientific committee.
Born 1958; Danish national.
Education: MD and PhD from the University of Copenhagen, Denmark.
Other assignments: Chairman of Orphazyme A/S and board member of Reapplix A/S. Senior Advisor at EQT and Global Healthcare Advisor at Goldman Sachs as well as Venture Partner at Wellington Partners, Senior Business Advisor at HBM Ventures and advisor at Aescap Venture Fund.
Prior experience: CEO of Swedish Orphan International AB 1998-2010, co-founder of Swedish Orphan Biovitrum AB (publ) and Executive Chairman of the Board of Directors of Swedish Orphan Biovitrum AB (publ) 2010-2016. Board member of several listed companies and extensive experience from several executive positions within research and development in the international pharmaceutical industry.
Sustainability experience: Since 2019 engaged in the development of a sustainability strategy and implementation at Laborie Inc.
Independent of Sobi and its executive management: Yes
Independent in relation to major shareholders of Sobi: Yes
Shares in Sobi: 0.

Annette Clancy
Board member since 2014; chair of the Scientific committee.
Born 1954; British national.
Education: Bachelor of Science (Hons) in pharmacology from Bath University, UK.
Other assignments: Chair of the Board of Enyo SA. Operational Investor at Jeito Capital.
Prior experience: Senior Advisor, Biopharmaceutical Team of Frazier Healthcare. Chair of Genable Therapeutics and Lysogene SA. Board member of Silence Therapeutics plc. and Clavis Pharma. Head of Transaction and Alliance Management, Global Business Development at Glaxo SmithKline (GSK).
Sustainability experience: Participated in various sustainability projects, such as footprint reducing, during roles at venture capital and biotech companies.
Independent of Sobi and its executive management: Yes
Independent in relation to major shareholders of Sobi: Yes
Shares in Sobi: 3,414.

Matthew Gantz
Board member since 2012; member of the Compensation & Benefits committee.
Born 1965; American national.
Education: Bachelor of Arts from Princeton University, NJ, US and MBA from Harvard Business School, MA, US.
Other assignments: CEO of Castle Creek Biosciences Inc. Member of the board of the Marine Corps Scholarship Foundation.
Prior experience: CEO of OxThera AB. Executive Vice President of BTG Plc. Founder and CEO of Acureon Pharmaceuticals. President and CEO of Hydrabiosciences Inc. VP Europe for Chiron's Biopharmaceutical Division. GM for PathoGenesis Europe. Various US sales and marketing roles at Abbott Laboratories Diagnostic Division. Board member of Life Sciences of Pennsylvania Association.
Sustainability experience: Has participated in various sustainability projects connected to EHS management and operational eco-efficiency as part of previous operative roles within the pharmaceutical industry.
Independent of Sobi and its executive management: Yes
Independent in relation to major shareholders of Sobi: Yes
Shares in Sobi: 0.

Board, cont.

Helena Saxon
Board member since 2011; chair of the Audit committee and member of the Compensation & Benefits committee.
Born 1970; Swedish national.
Education: Master of Science from Stockholm School of Economics, Sweden.
Other assignments: CFO at Investor AB. Board member of SEB. Board member of Stockholm School of Economics.
Prior experience: CFO at Hallvarsson & Halvarsson. Vice President at Investor AB. Financial analyst at Goldman Sachs. Board member of Aleris and Mölnlycke Health Care.
Sustainability experience: Engaged in the development of Investor's sustainability strategy. Particularly strong in the Governance (G) given Investor's ownership model and the strategic priority to deliver on its ESG (environment, social, governance) targets.
Independent of Sobi and its executive management: Yes
Independent in relation to major shareholders of Sobi: No
Shares in Sobi: 20,000.

Staffan Schüberg
Board member since 2020; member of the Audit committee.
Born 1969; Swedish national.
Education: Bachelor of Arts (Hons) in business administration from the London Guildhall University, UK.
Other assignments: CEO and board member of the ESTEVE Group. Board member of Dizlin Pharmaceuticals AB, Hangzhou Jiuyuan Gene Engineering Co. Ltd and Corporacíon Químico Farmacéutical Esteve S.A.
Prior experience: More than 20 years of experience from board and executive management roles, including several senior positions within Lundbeck A/S, such as Regional Vice President for Southern and Western Europe, President and Chairman of the US operations and Global Chief Commercial Officer on Group level.
Sustainability experience: As CEO of the ESTEVE Group, Mr Schüberg led the implementation of a comprehensive ESG (environment, social and governance) strategy for the Group. He has also implemented ESG initiatives in other pharma companies.
Independent of Sobi and its executive management: Yes
Independent in relation to major shareholders of Sobi: Yes
Shares in Sobi: 4,500.

Filippa Stenberg
Board member since 2021; member of the Audit committee.
Born 1985; Swedish national.
Education: Master of Science in economics from Stockholm School of Economics, Sweden.
Other assignments: Managing Director at Investor AB.
Prior experience: Head of Strategy at Atlas Antibodies. Analyst at Swedbank LC&I.
Sustainability experience: Integrated sustainability in Atlas Antibodies as well as driven ESG as a part of Investor's strategic priority in portfolio companies.
Independent of Sobi and its executive management: Yes
Independent in relation to major shareholders of Sobi: No
Shares in Sobi: 500.

Board, cont.

Pia Axelson
Board member since 2019; employee representative of the council for negotiation and cooperation.
Born 1962; Swedish national.
Education: Medical laboratory engineer, University of Borås, Sweden.
Prior experience: Deputy for the employee representatives 2019, board member 2017 and deputy for the employee representatives 2009-2017.
Sobi position: Senior Laboratory engineer.
Independent of Sobi and its executive management: No
Independent in relation to major shareholders of Sobi: Yes
Shares in Sobi: 7,634.

Erika Husing
Board member since 2020; employee representative of the council for negotiation and cooperation.
Born 1973; Swedish national.
Education: Master of Science in chemistry, Linnaeus University, Sweden.
Sobi position: Head of Veeva Commercial, Information Systems.
Independent of Sobi and its executive management: No
Independent in relation to major shareholders of Sobi: Yes
Shares in Sobi: 75.

Deputies for the employee representatives:

- Linda Larsson
- Katy Mazibuko

Shares in Sobi reported as of 31 December 2022.

Executive committee

Guido Oelkers
Chief Executive Officer; employed since 2017.
Born 1965; German national.
Education: PhD in strategic management, University of South Australia, Adelaide, Australia. Master of Economics, South Bank University, London, UK. Complementary studies in economics, London School of Economics and Political Science, London, UK.
Other assignments: Chairman of Nanolive SA. Member of the Advisory Committee of Zentiva Group. Industrial advisor at EQT.
Prior experience: CEO of BSN Medical. President & CEO of Gambro. EVP Commercial Operations at Nycomed. CEO of Invida. Global Head of Healthcare at DKSH. Managerial roles at Aventis and preceding entities. Board member of Meda and Sartorius.
Shares in Sobi: 344,058.

Henrik Stenqvist
Chief Financial Officer; employed since 2018.
Born 1967; Swedish national.
Education: Master of Science in business administration and economics, University of Linköping, Sweden.
Other assignments: Board member of Midsona AB. Board member of Calliditas Therapeutics AB.
Prior experience: CFO of Recipharm. CFO of Meda. Regional Finance Director at AstraZeneca. Finance Director at Astra Export & Trading. Board member of MedCap.
Shares in Sobi: 43,082.

Duane H. Barnes
Head of North America; employed since 2021.
Born 1960; American national.
Education: Master of Business Administration, Master of Science, Indiana University, Kelley School of Business, IN, US. Bachelor of Arts, West Virginia University, WV, US. Eberly College of Arts and Sciences, WV, US.
Other assignments: Board member of BIO, Biotechnology Innovation Organization. Board member of HLC, Healthcare Leadership Council.
Prior experience: President and Head of US Operations at UCB. Vice President & General Manager, Value, Access, Reimbursement and Patient Experience at Amgen. Chief Operating Officer at Prime Therapeutics. Division President, Head of Pharmacy at Aetna Healthcare.
Shares in Sobi: 0.

Sofiane Fahmy
Head of Europe; employed since 2013.
Born 1972; French national.
Education: Degree in marketing, University of Paris XI, France. Degree in pharmacy, University of Poitiers, France.
Prior experience: General Manager Sobi France and North Africa. Managerial roles at Pfizer. Commercial roles at GSK. Brand Manager Hospital Products at Roche.
Shares in Sobi: 20,797.

Executive committee, cont.

Torbjörn Hallberg
General Counsel and Head of Legal Affairs, Head of Human Resources; employed since 2018.
Born 1969; Swedish national.
Education: Master of Law, University of Lund, Sweden.
Prior experience: Vice President, General Counsel, Emerging Markets at Takeda Pharmaceuticals. Corporate Counsel at Nycomed Pharma. Corporate Counsel at Ferring Pharmaceuticals. Senior Associate/ Lawyer at Advokatfirman Lindahl.
Shares in Sobi: 21,193.

Mahmood Ladha
Head of Strategic Transformation Operations; employed since 2019.
Born 1964; American national.
Education: Master of Business Administration and Bachelor of Science, University of South Carolina, SC, US.
Prior experience: Head of Business Development and Alliance Management, Sobi. President and Head of Dova Pharmaceuticals. Senior Advisor to the CEO, VP and Head of Transactions at AstraZeneca. Executive Director and Head of US Respiratory at AstraZeneca.
Shares in Sobi: 0.

Thomas Kudsk Larsen
Head of Communication and Investor Relations; employed since 2021.
Born 1974; Danish national.
Education: HD in Finance, Copenhagen Business School, Denmark.
Prior experience: Head of Investor Relations at AstraZeneca. Head of Investor Relations North America at Roche. Manager, Investor Relations, Stakeholder Relations at Novozymes. Financial analyst, controller, other finance positions, finance trainee at Novo Nordisk.
Shares in Sobi: 0.

Pablo de Mora
Head of Global Marketing & Access; employed since 2019.
Born 1968; Spanish national.
Education: Doctor in veterinary medicine, University of Barcelona, Spain. Master of Business Administration, HEC Business School, Paris, France. Master of economy of innovation, University of Madrid, Spain. Certified board member by ICA, Spain.
Prior experience: VP & GM Iberia at Sobi, COO at Altan, Head EMEA & Canada Mature Brands at MSD, GM Iberia at Hospira, Global Marketing VP at Novo Nordisk, Marketing Director EMEA & Canada at MSD, Marketing & Sales Director Europe at Rhone Mérieux.
Shares in Sobi: 0.

Norbert Oppitz
Head of International; employed since 2017.
Born 1967; Austrian national.
Education: Dipl. BW (FH)/Business Administrator, FH Rhenania Palatina, Mainz, Germany.
Prior experience: Member of the Executive Committee of BSN Medical in charge of Latin America. Member of the Executive Committee of Endo Pharmaceuticals, Emerging Markets. Head of Latin America at Takeda/Nycomed. Country management roles at Roche Pharmaceuticals and Aventis Pharma.
Shares in Sobi: 29,895.

Daniel Rankin
Head of Strategy and Corporate Development; employed since 2017.
Born 1980; Slovak and British national.
Education: PhD in biology, University of Helsinki, Finland. Master of Science in biology, Leiden University, The Netherlands. Bachelor of Science, University of York, UK.
Prior experience: Head of Corporate Development at Sobi. VP Chief of Staff to the CEO at Sobi. Management consultant at McKinsey & Company New York and Zurich. Group Leader at the University of Zurich.
Shares in Sobi: 11,220.

Executive committee, cont.

Armin Reininger
Senior Scientific and Medical Advisor; employed since 2017.
Born 1957; German national.
Education: MD, PhD, Ludwig Maximilian University of Munich, Germany. Certified specialist in Transfusion Medicine.
Prior and academic experience: Head of Medical Affairs EMEA Haematology at Baxalta/Shire. Head of Global Medical Affairs Haematology at Baxalta. Head of Medical Affairs EMEA Haemophilia at Baxter. Senior Physician at University Clinic of Munich, Germany. Harvard Medical School & Mass. General Hospital, Boston, MA, US. The Scripps Research Institute, La Jolla, CA, US. Professor of Anatomy at the Ludwig Maximilian University of Munich, Germany.
Shares in Sobi: 10,152.

Anders Ullman
Head of Research & Development and Medical Affairs, Chief Medical Officer; employed since 2022.
Born 1956; Swedish national.
Education: MD, PhD in clinical pharmacology, Gothenburg University, Sweden.
Other assignments: Board member of Verona Pharma plc.
Prior experience: Head of the COPD centre at the Sahlgrenska University Hospital 2015-2020. More than 20 years of experience from several executive positions within research and development in the international pharmaceutical industry, including Baxter Bioscience, Nycomed/Takeda, Biovitrum, Bayer Pharmaceuticals and AstraZeneca.
Shares in Sobi: 3,000.

Christine Wesström
Head of Technical Operations; employed since 2010.
Born 1975; Swedish national.
Education: Master of Science in chemical engineering, major in biotechnology, Mälardalens University, Västerås, Sweden.
Other assignments: Vice chairman of the Board in SwedenBIO.
Prior experience: Head of Global Manufacturing & Infrastructure, Head of External Manufacturing at Sobi. Project management roles within Manufacturing & CMC Development at Biovitrum.
Shares in Sobi: 8,304.

Shares in Sobi reported as of 31 December 2022.
In January 2023, Lena Bjurner was appointed Head of Human Resources.
In April 2023, Anton (Tony) Hoos was appointed Head of Research & Development and Medical Affairs, Chief Medical Officer and replaced Anders Ullman who retired.

Sustainability report

Sobi's main contribution to the global sustainable development agenda is closely aligned with the company's mission – to transform the lives of people living with rare diseases.

Business model and sustainable growth

Sobi's business model covers everything from clinical development to patient access and global commercialisation. Sobi's sustainability strategy is integrated into the business and is based on two priorities – maintaining the commitment to patients and always acting responsibly. By expanding geographical reach, investing in the development of novel medicines and deepening engagement in the areas of haematology, immunology and specialty care, Sobi enhances access to rare disease medicines for patients worldwide and positively impacts the people and communities it serves. Sobi is a signatory to the UN Global Compact and has integrated the Ten Principles of the Global Compact in all business operations. Sobi commits to operating in a way that contributes to achieving the UN SDGs and the Paris Agreement.

Sobi's strategy has four strategic business priorities:

- Lead in Haematology
- Grow Immunology and Specialty Care
- Go global
- Capture the value of the pipeline

... and two strategic sustainability priorities:

Maintain commitment to patients

- Access to treatment
- Patient centricity and engagement
- Patient and product safety
- Ethical marketing and sales
- Transparent and ethical R&D

Always act responsibly

- An inclusive and diverse workplace that grows people
- Safe, healthy and fair working conditions
- Reduction of environmental footprint
- Responsible sourcing
- Compliance and corruption prevention

Commitment to the UN Global Compact. Contribution to the 2030 Agenda, the UN Sustainable Development Goals and the Paris Agreement

Material sustainability topics

Sobi's material sustainability topics are areas where the business has or could contribute to a significant economic, environmental or social impact, and areas where the potential impact on Sobi is substantial.

Sobi's materiality process is based on the continuous mapping of external and internal stakeholder needs and priorities. This is done through surveys and targeted stakeholder dialogues, attending conferences, participating in ESG ratings and research, and conducting internal dialogues on future legislation. Sobi's key stakeholders are patients and their caregivers, Sobi's own employees and people in the Sobi supply chain. Other main stakeholders include shareholders, institutional investors, the financial market, healthcare providers and their procurement bodies, patient advocacy groups, NGOs, industry associations, as well as medicine practitioners and researchers.

In early 2022, a digital survey and series of interviews were made with key stakeholders to determine which topics mostly influenced their assessment of Sobi. This was a follow-up of a similar outreach made in 2019, and the results were very similar. Five of the top ten areas identified were connected to governance, and only two to environmental topics, which mirrored previous materiality assessments made by sustainability analysts.

To verify Sobi's material topics, an evaluation was made by internal functional leaders and experts to establish the size and probability of negative or positive impact by Sobi on its stakeholders connected to these topics. Finally, the Sobi senior management provided their assessment of how critical an adequate management of these topics are to Sobi as a business. Mapping both these dimensions provide the final list of Sobi's material topics, identified in the 'Governance of material topics' table in the next page.

Sustainability governance

The board

Sobi's board has overall responsibility for Sobi's sustainability performance and material topics. Plans and progress are reported to the board on a regular basis, together with outcomes of sustainability risk assessments and adverse events. The board approves the annual sustainability report.

Management

The CEO and the Executive committee approve Sobi's sustainability strategy, ensure compliance, decide on overall objectives, manage the implementation of the sustainability strategy and monitor overall progress. Leadership teams in each respective area are responsible for strategy implementation and follow-up. The Global Head of Sustainability is, on behalf of the Executive committee, responsible for driving implementation and communication of the strategy in close collaboration with the corporate functions and business units. Sobi's sustainability approach and performance is publicly reported on each year in the Annual and sustainability report.

Policies and responsibilities

The sustainability strategy is based on the Code of Conduct and other company policies governing sustainability-related topics. The Sobi Code of Conduct provides a framework for appropriate conduct and applies to all Sobi employees worldwide as well as temporary personnel.

Functions with critical roles and responsibilities for managing Sobi's material sustainability topics and delivering on the sustainability strategy are:

- The Sustainability function – evaluates materiality, creates guidelines, supports implementation of the strategy programme and reports on outcomes.
- The Compliance function – responsible for the implementation of anti-corruption and healthcare interaction policies, data privacy, third-party risk due diligence and the compliance hotline (whistleblowing hotline).
- The Technical Operations function – responsible for environmental compliance and the performance of in-house operations, and that of direct suppliers and partners, and driving development in accordance with the Responsible Sourcing Programme.
- Finance – including Indirect Procurement monitoring supplier performance, and Internal Control, which evaluates and improves processes for management, internal control and risk management.
- Sobi's affiliates – are required to deploy the principles of the Code of Conduct and other policies, execute the sustainability strategy and drive performance.
- The PACE (Patient Access and Community Engagement) organisation – supports patient needs at all stages of the patient journey and engages with key stakeholders.

Governance of material topics

Sobi sustainability governance summary

This table summarises Sobi's material topics, which were defined through the materiality process, and how these topics are managed and reported on. The material topics are linked to GRI reporting standards and are described in detail in each respective section of the Sustainability progress report.

	Maintain commitment to patients	Always act responsibly
Material topics	• Patient safety and product quality • Access to treatment • Research ethics • Responsible marketing and sales • Community engagement	• Compliance and anti-corruption • Attracting and retaining employees • Diversity and inclusion • Occupational health and safety • Fair working conditions • Training and education • Responsible procurement practices • Responsible tax • Resource management • Use of energy and GHG emissions
Applicable GRI topic standards	GRI 203: Indirect economic impact 2016; GRI 415: Public policy 2016; GRI 416: Customer health and safety 2016; GRI 417: Marketing and labelling 2016; GRI 418: Customer privacy 2016.	GRI 201: Economic performance 2016; GRI 204: Procurement practices 2016; GRI 205: Anti-corruption 2016; GRI 206: Anti-competitive behaviour 2016; GRI 207: Tax 2019; GRI 302: Energy 2016; GRI 305: Emissions 2019; GRI 303: Water and effluents 2016; GRI 306: Waste 2020; GRI 308: Supplier environmental assessment 2016; GRI 401: Employment 2016; GRI 402: Labour – management relations 2016; GRI 403: Occupational Health and Safety 2018; GRI 404: Training and education 2016; GRI 405: Diversity and equal opportunity 2016; GRI 406: Non-discrimination 2016; GRI 407: Freedom of association & collective bargaining 2016; GRI 414: Supplier social assessment 2016.
Relevance for Sobi	Sobi's mission is to transform the lives of people with rare and debilitating diseases. The most important commitment is to patients and the rare disease community as Sobi provides reliable and secure access to medicines and gives a voice to patients and promotes connectedness. A strong pipeline and expanded access through geographical expansion are key elements. Patient safety is a fundament.	Sustainability is built on responsible behaviour, which is expressed through strong business ethics and understanding and mitigating impacts throughout the value chain. To achieve this, it is critical to work together with partners to reduce the total environmental footprint, and by striving to make a positive contribution to individuals and societies throughout the value chain – both inside and outside the company.
Responsibility and actual and potential impact in the value chain	Described in the section Sustainability value chain.	
Delimitations of the report (boundaries)	Sobi reports the impacts and governance connected to its own operations and direct business partners, where the possibility to influence and monitor is real. Risks and opportunities are mapped throughout the value chain.	
How Sobi works to reduce negative impact and increase positive effect	See detailed descriptions in each section of the Sustainability progress report that corresponds to the material topics.	
What does Sobi want to achieve?	See the 'Ambitions' in each section of the Sustainability progress report.	
Policies	• Policy on healthcare interactions • Good pharmaceutical practice including: – Good manufacturing practice (GMP) – Good distribution practice (GDP) – Good clinical practice (GCP) and – Good pharmacovigilance practice (GVP)	• Code of Conduct • Partner Code of Conduct • Group risk management policy • Policy on fair competition • Sobi Group authority policy • Policy on anti-corruption due diligence on third parties • Global expense policy • Communication policy • Insider policy • Procurement policy • Environmental policy • Health and safety policy • Policy on processing of personal data • Policy on investigations • Tax policy
Specific processes, projects, programmes and initiatives	See detailed descriptions in each section of the Sustainability progress report, corresponding to the material topics.	
Tracking of effectiveness	See detailed descriptions in each section of the Sustainability progress report, corresponding to the material topics.	

The Sobi compliance function has overall responsibility for the company's policy framework and conducts annual reviews to ensure that policies are up to date and aligned. All sustainability-related polices have appointed owners who are responsible for updating, implementing and monitoring policy adherence. Regular internal reviews are performed, often as a collaboration between Compliance and Group Internal Control. The most important sustainability-related practices and policies are listed in the section Policies above.

Sustainability progress report

External recognition

Sobi plays an active role in environmental, social and governance (ESG) evaluations and aims for continuous improvement. In 2022, Sobi for the first time qualified as a component of the Dow Jones Sustainability Indices (DJSI) by joining DJSI Europe. Sobi also made progress in several other analyst indices, as the company's sustainability work was recognised by various organisations. For details, see below.

Sustainability rating institutes

Rating	2022	2021	2020	2019
MSCI	A	A	A	A
Sustainalytics (risk ranking in biotech)	20.4 medium risk (6 out of 439)	20.5 medium risk (3 out of 365)	26.4 medium risk (16 out of 367)	26.2 medium risk (24 out of 362)
Institutional Shareholder Services	B- High relative performance	C+ High relative performance	C High relative performance	C High relative performance
VigeoEiris		37	36	34

Sobi's sustainability rating.

Sustainability risk management

Sobi describes its climate risk management in detail in the section TCFD.

Sobi's overall risk management process is based on the Group risk management policy, and aims to identify and assess all relevant strategic, operational, financial, regulatory and sustainability risks. The outcome of the TCFD climate risk mapping is included in the company's overall risk mapping. The process and the results of the 2022 risk assessment are described in detail in the section Risk management. The risk management function reports the risk status to the Executive committee, and the board. Identifying the company's critical flows and implementing business continuity plans is part of the risk management process.

Sustainability reporting and communication

The aim of Sobi's sustainability reporting and communication is to provide investors and other stakeholders with accurate and relevant information about the company's sustainability performance, goals and strategy. Sobi is committed to transparency in its sustainability performance and progress.

To fulfil the EU Taxonomy Regulation, Sobi has carried out an analysis of the extent its economic activities meet the criteria set out in the Taxonomy Regulation. The analysis showed that Sobi's core business, which is developing, commercialising and manufacturing medicines, is an economic activity not yet included in the Taxonomy Regulation. Therefore, Sobi's share of eligible turnover as defined by the Taxonomy Regulation, is 0 per cent. The formal Taxonomy tables are included in the section Taxonomy.

Sobi's auditor has confirmed that a statutory sustainability report has been prepared.

Sustainability strategy

Sobi's sustainability strategy helps deliver on the company's vision of transforming the lives of people living with rare diseases and will be crucial to the execution of the business strategy. Progress in sustainability performance will also deliver value to Sobi's stakeholders and society in general. The Sobi sustainability strategy is based on a commitment to the realisation of the 2030 Agenda as expressed by the SDGs and the Paris Agreement and focuses on two areas – maintaining commitment to patients and always acting responsibly. It includes ten sustainability priorities, each linked to the SDGs and connected to targets perceived as business critical.

Maintain commitment to patients

For Sobi, meaningful engagement and cooperation with the rare disease community are essential. Sobi is in a position to improve health globally for a number of small and often overlooked patient populations and contributes actively to several of the SDGs through specific targets.

Commitment to patients and the SDGs

SDG	Sustainable Development targets	Actions and ambitions	Progress	Read more
SDG 3 Good health and well-being	3.2 End preventable deaths of new-borns and children under 5 years of age	Promote life expectancy by expanding access to paediatric treatments	Synagis remains the only approved medicine in the US for the prevention of serious lower respiratory tract infections caused by RSV in high-risk infants.	p 15
			Gamifant reached more patients in the US in the treatment of primary HLH, and the medicine was approved in China in 2022.	p 15, p 34
			The use of Kineret for Still's disease increased in Europe and international countries (adults and children from eight months and 10 kg).	p 15
	3.4 Reduce premature mortality from non-communicable diseases	Increase number of R&D programmes in rare diseases and areas of high unmet medical need	At year-end, Sobi's pipeline consisted of eight medicines or potential new medicines in around 15 projects.	p 19
			Ongoing studies with recent positive results in the US and Europe on efanesoctogog alfa, a potential new medicine for haemophilia A.	p 19
			An ongoing R&D programme centred around complement C3 inhibitor Aspaveli/Empaveli to broaden development outside the first approved indication of PNH into other diseases and patient groups, in collaboration with Apellis.	p 19
	3.8 Achieve universal health coverage	Continue 10-year commitment to the WFH Humanitarian Aid Program	Since the initial pledge, over 20,200 people with haemophilia have been treated with factor donated by Sobi and Sanofi.	p 23
		Contribute to cost-support programmes	Continued support of Kineret OnTrack and Orfadin4U support programmes in the US.	p 124
	3b Support R&D and make vaccines and medicines available for all	10-15% of revenue in R&D spend	R&D spend 12% of revenue in 2022.	p 35
		Expand the global market reach of medicines	Increased market availability of several Sobi medicines: Gamifant in China, Orfadin in Latin America, Empaveli and Kineret in Australia.	p 16, p 17
SDG 10 Reduced inequalities	10.3 Equal opportunity	Expand rare disease and orphan drug pipeline	Aspaveli/Empaveli is in clinical development for use in new indications.	p 19
SDG 16 Peace, justice and strong institutions	16.7 Inclusive, participatory and representative decision-making	Include patient and healthcare representatives in decision-making	Four international patient councils established to advise on early clinical development.	p 24, p 125
SDG 17 Partnerships for the goals	17.16 Global and multi-stakeholder partnership for sustainable development	Support rare disease organisations and participate in multi-stakeholder organisations	Sobi has important, long-standing relationships with the rare disease community and its peak bodies. It is a long-term sponsor of several patient organisations.	p 24, p 125
			Sobi is member of the PSCI since 2020.	p 133
	Science and technology innovation for recovery from COVID-19	Provide medicine to investigator sponsored studies and conduct own studies to support use in COVID-19	Kineret was granted Emergency Use Authorisation by the US FDA for treatment of COVID-19 in hospitalised adults with pneumonia requiring supplemental oxygen who are at risk of progressing to severe respiratory failure.	p 20, p 153

Expanded access to treatment

Sobi's growth and expansion strategy helps bring medicines to new markets and adds indications, which allow more patients to access medicine. Sobi also has a partnership strategy to serve currently underserved markets.

During 2022, Sobi increased the number of people it reached to approximately 75,000, measured in full-time equivalent patients. One of Sobi's objectives is to reach twice as many patients in 2025 as in 2020. During the year, four (five) of seven (six) of Sobi's main medicines were made available in a total of 12 (12) new markets. For a review of the current approval and reimbursement status in markets, see the section Market availability.

To increase access to medicine, Sobi works with communities to increase patient access through the established healthcare system. Sobi supports home nursing and medicine delivery programmes, telemedicine, patient navigation tools, culturally and linguistically adapted tools as well as adherence programmes.

In the US, Sobi has been running the patient support programmes Kineret On Track and Orfadin4U for several years. These programmes include services such as guidance on financial assistance and reimbursement, treatment guidance, mentor programmes, injection training and support, home delivery and waste management. Similar services are also available for patients and caregivers using other medicines in the US.

Pricing and reimbursement

Following regulatory approval, pricing and reimbursement are key factors in patient access that differ in each market.

Sobi strives to set a price that reflects the benefit that the innovation delivers to patients, healthcare systems, societies and payers – to create sustainable access to medicines for patients and continued long-term affordability to health systems to meet their patient and healthcare priorities. A means for this is generating evidence that helps quantify the clinical and patient value of a medicine. Sobi works continuously to develop data that reflects the resolution of unmet medical need on both an initial and an ongoing basis.

The EU Pharmaceutical Strategy adopted in 2020 is a policy document aimed at tackling important challenges for European patients and health sectors. It sets out a comprehensive set of actions to ensure access to affordable medicine and facilitate collaboration on unmet needs and evidence generation among key stakeholders. Sobi has participated in these collaborations for many years.

In some markets, patient access to medicine may be limited by the lack or complexity of reimbursement processes. Sobi has several initiatives in place, such as the above-mentioned US programme, to support patients and treaters and to bridge the gap.

Acting with a sense of urgency

Regulatory pathways for orphan drugs are implemented in several markets. Sobi's pipeline is positioned to use these pathways to shorten time to access for patients. A priority review will direct attention and resources to the evaluation of applications for therapies which, if approved, could provide significant improvements in the safety or efficacy of the medicine, or the diagnosis or prevention of serious conditions when compared with standard applications.

Sobi recognises that there may be circumstances when patients with serious or life-threatening diseases have exhausted all treatment options currently available to them and are unable or ineligible to participate in a clinical trial. Additionally, new medicines are often unavailable between the completion of a clinical study and regulatory approval or commercial availability. For such patients, upon an independent request from their treating physician and where legally permissible, Sobi considers making medicines available via managed access programmes[1]. Requests from treating physicians for managed access are assessed purely on the basis of medical need and managed by the R&D and Medical Affairs organisation.

Sobi has an established process for emergency orders within the EU and the US for life-saving medicines (Orfadin, Kineret and Gamifant), which are also available during non-office hours 365 days a year for immediate service if needed to save a patient's life.

1. Managed access describes areas regularly known as compassionate use, expanded access and other similar programmes.

WFH Humanitarian Aid Program donation

More than 75 per cent of people with haemophilia around the world have limited or no access to diagnosis and treatment, particularly in the developing world. The WFH Humanitarian Aid Program helps address the lack of access to care and treatment by providing support for people with inherited bleeding disorders in developing countries.

By providing a more predictable and sustainable flow of humanitarian aid donations, the Program allows for people living with haemophilia to receive consistent and reliable access to treatment and care. In addition, the Program provides educational training for treaters and patients, training that is critical in helping to develop in-country capacities to improve diagnosis and treatment monitoring. In 2020, Sobi and Sanofi announced the agreement to extend their support of the WFH Humanitarian Aid Program by an additional donation of up to 500 million IU of factor medicine for humanitarian aid, thereby fulfilling the 2014 pledge to donate up to an unprecedented 1 billion IU over a 10-year period.

Since the 2014 pledge, more than 661 (588) million IU of factor have been donated and 20,274 (18,881) people with haemophilia have been treated with factor donated by Sobi and Sanofi. Both companies are recognised by the WFH as Founding Visionary Contributors to the Program.

Training and workshops were organised for healthcare providers and other important stakeholders in donation countries by the WFH in both physical and digital format during 2022, supporting the envisaged future multi-channel approach of donation country interactions by the WFH.

Supply-chain continuity

Sobi's supply chain was not interrupted during 2022 despite geopolitical instability in Europe.

The key factors for the continuous supply of Sobi medicines are strong partner relationships throughout the production and warehouse network, good supply chain planning and close communication on demand management.

Expand access to treatment – ambitions

- Increase geographical and patient reach
- Continual medicine launches in the areas of rare diseases
- Support managed access[1]
- WFH Humanitarian Aid Program 500 million IU donations 2020-2025

1. Managed access describes areas regularly known as compassionate use, expanded access and other similar programmes.

Patient and community engagement

Sobi strives to apply patient centricity in all its ways of working and throughout the medicine's life cycle to develop solutions that are truly patient led.

Sobi supports connectedness so that patients, caregivers and patient organisations can connect with each other and the community, and access relevant information and resources to support timely diagnosis, optimal treatment and living well with their condition. Sobi applies a proactive outreach to patient organisations and supports the establishment or strengthening of patient organisations and networks in accordance with the policy on healthcare interactions.

Sobi is a long-term sponsor of patient organisations such as the European and North American rare disease organisations EURORDIS and NORD respectively, the WFH, the EHC, and also supports local patient organisations. An annual summary of support provided to patient organisations is published on sobi.com. Furthermore, important partnerships are in place with the PNH Global Alliance as well as with the not-for-profit organisations PFMD and EUPATI.

Integrating the patient perspective and insights into research design and set-up is critical to ensure that future medicines adhere to patient needs. Sobi has to date established four international patient councils to deliver insights into how clinical studies and study protocols should be designed. These enable Sobi to choose patient-reported outcomes more appropriately for the targeted patient populations, designing more patient-friendly forms and information materials for study participants, and adapting the design of the study to facilitate patient participation. Sobi co-develops patient support programmes, advocacy and evidence generation activities with patient advocacy groups in several disease areas.

To ascertain the integration of patient-centric practices, employees are trained in patient engagement. In 2022, 1,677 employees and consultants to Sobi from 34 countries completed training offered through a PFMD initiative.

Sobi also contributes to the wider community through collaborations with third parties: 25 per cent of corporate insurance premiums are put into investments with an additional social objective via QBE's Premiums4Good. These investments include social impact bonds, social bonds, green bonds and infrastructure – to support a range of projects and programmes that seek to create positive change.

Community engagement – ambitions

- Support patient organisations
- Integrate patient perspective in research design
- Create a patient centric culture

Knowledge contribution to enhance the practice of medicine

Sobi is committed to contributing to the increased understanding, diagnosis and treatment of rare diseases. Sobi engages by sponsoring and attending scientific meetings and arranging medical training designed to share medical advancements and by taking part in discussions to enhance the practice of medicine. Participation in medical events is governed by Sobi's policy on healthcare interactions. Sobi participated in several international scientific meetings and local events in 2022.

Sobi's annual support for the WFH Corporate Partner Program has enabled country development programmes, educational resources, training for healthcare professionals, capacity building and training for patients and patient organisations as well as support for the World Bleeding Disorder Registry.

Knowledge contribution – ambitions

- Active participation and sponsorship of medical conferences
- Continued support of community-led initiatives to increase knowledge sharing

Focus on patient safety

The safety profile and monitoring of Sobi's medicines is of the utmost importance.

By adhering to pharmaceutical standards, Sobi strives to provide safe medicines that meet the high-quality standards of the pharmaceutical industry. Safety surveillance, pharmacovigilance, continues across the medicine's life cycle, allowing potential safety risks to be identified at an early stage and mitigated to minimise or avoid harm. For all medicines under development or on the market, Sobi has systems in place for identifying and evaluating possible adverse effects. A robust pharmacovigilance system allows continuous monitoring of the benefit/risk profiles of all medicines and ensures alignment with the precautionary principle. To achieve this, Sobi has a safety team for each medicine, including a dedicated global safety physician.

As part of the commitment to patient safety, Sobi continues to develop staff, processes, systems and tools. Annual training is provided for employees, consultants and vendors to ensure that all safety information – such as any adverse events, product complaints or incorrect use – in relation to Sobi's medicines is reported.

Quality regulations

As part of the pharmaceutical industry, Sobi works in a heavily regulated environment. It is essential that Sobi meets all regulations and acts in compliance with GMP, GDP, GCP and GVP, including the dossier requirements of all countries in which the company's medicines are licensed, manufactured or sold.

Good Practice (GXP) guidelines are maintained to monitor and ensure medicine safety and quality compliance during the medicine's life cycle. The Quality Assurance department is responsible for release management which includes the evaluation of medicine testing and the manufacturing steps. In the EU, release is carried out by a qualified person. The qualified person for pharmacovigilance is responsible for safety (pharmacovigilance).

To ensure and evaluate compliance with current requirements, inspections of Sobi facilities by regulatory authorities are performed regularly. In addition to external inspections, Sobi continuously monitors the performance and internal processes and operations of suppliers.

Ensuring integrity

Sobi works to improve patient safety through updated medicine information, safe packaging and extensive safety monitoring of known or new side effects.

Product recalls are governed by standard operating procedures (SOP) and managed for all medicines for which Sobi is the marketing authorisation holder, and for Investigational Medicinal Products in Sobi-sponsored clinical trials in cases when a medicine may cause damage, injury or inconvenience to the consumer and may affect one or several batches or the whole product. An expert committee is responsible for assessing quality and compliance risks for medicines released into market and clinical studies, and a Recall Decision Body will take the decision on a recall together with the relevant regulatory authority or authorities.

Correct labelling is important to ensure proper use, and current and new safety information needs to be communicated consistently and promptly to authorities, prescribers, patients and within the organisation. SOPs are in place to ensure timely updates to medicine information and patient information leaflets in the medicine packaging. The labelling process consists of a series of processes and is a cross-functional responsibility involving the Benefit-Risk Council, Drug Safety, Regulatory Affairs, Medical Affairs, External Manufacturing/Packaging and Quality Assurance, and Supply Chain.

Counterfeit pharmaceuticals are an increasing concern worldwide. Governments all over the world are introducing regulations and systems to detect and prevent the distribution of counterfeit medicines. All Sobi medicines are serialised and given unique identification codes. Sobi's medicines have not yet been subject to falsification.

Patient safety – ambitions

- Patient safety training for all Sobi employees
- No critical or major incident of recall
- No incident of incorrect labelling

Responsible marketing and sales

Sobi is committed to employing high ethical standards of sales and marketing practice worldwide, in line with its Code of Conduct and supporting policy framework. Employees involved in promotional activities undergo regular training.

The policy on healthcare interactions provides guidance for promotional activities. The policy applies to all relevant Sobi employees, contractors, agents and third parties. General managers are accountable for ensuring compliance at local level and for instructing qualified representatives to design processes for local implementation and training, including approval processes incorporating the appropriate internal stakeholders. Promotional materials are always approved prior to external use and following each modification by a cross-functional team of qualified representatives, and review and approvals are documented and saved in a digital vault. Approvals relating to promotional and non-promotional material are retained for ten years after final use.

Ethical R&D focused on medical need

High-quality and ethical research is of the greatest importance to Sobi and contributes to the expansion of medicines for rare diseases in areas of unmet medical need.

Sobi's pipeline is focused on innovative and differentiated medicines. Sobi's medicines are developed and evaluated for multiple indications and an integrated lifecycle management approach is applied.

Sobi's development is based on scientific and medical need, and the design of the company's own studies and supported studies enables a scientifically sound evaluation of the medicine that Sobi develops and provides.

Ethics in clinical development

To avoid exposing participants to unnecessary risks, all studies are ethically and scientifically reviewed and approved, and conducted and reported in compliance with the International Conference on Harmonisation Guideline for good clinical practice and the latest revision of the Ethical Principles for Medical Research Involving Human Subjects (the Declaration of Helsinki).

Participants in clinical trials are given comprehensive, easy-to-understand information to confirm their voluntary willingness to participate and informed consent. Patients also have the right to withdraw from a study without compromising their current or future care.

Working in the rare disease area may pose extraordinary requirements regarding paediatric and vulnerable patients and people with genetic diseases. This can include special precautions in areas such as obtaining consent, considerations for data privacy in small patient populations and the research of genetic diseases. Through close collaboration with patient representatives, Sobi acts in the belief that this group should stand to benefit from the knowledge, practices or interventions resulting from the research.

Sobi conducts its own research openly and publishes clinical studies on the webpage clinicaltrials.gov. All clinical studies are registered and reported, and the complete results from clinical studies are shared even if they show an outcome that is not beneficial. Most clinical development is outsourced. Employees as well as sourced personnel undergo regular training in the medical aspects, processes and monitoring of disease.

Sobi recognises the important role that investigator-sponsored studies can play in expanding knowledge related to Sobi's medicines and their associated disease areas. In such a study, an investigator independently generates a development proposal to Sobi and a request for support. If these are approved, Sobi may provide support, which can include medicine, expert advice, funding and more. The investigator serves as the study sponsor and assumes full responsibility for ensuring regulatory compliance.

Bioethics

The use of human biological samples in research & development is a potentially sensitive area and internal SOPs ensure that all use complies with all relevant legislation, regulations and guidelines. Sobi does not conduct stem-cell research. Trials on cells of human origin could constitute a necessary step during development projects, to verify mechanisms of action and ascertain patient safety. Sobi does not perform in-house animal studies and only contracts from audited and validated suppliers. Where animal testing is necessary, it is carefully considered and justified, with the 3R (replacement, reduction and refinement) principles applied.

Ethical R&D focused on medical needs – ambitions

- Committed R&D budget for rare diseases
- Increased number of R&D programmes in rare diseases and areas of high medical need
- Shorten time to patient through the use of orphan drug regulations
- Support investigator-sponsored studies

Always act responsibly

As a company, Sobi works to always ensure responsible behaviour in its role as an employer, as a business and towards the communities in which Sobi operates. Sobi supports employees to act and make decisions that reflect its corporate principles. Sobi's ambitions are aligned with the SDGs and Sobi contributes through several targets.

Responsible behaviour and the SDGs

SDG	Sustainable Development targets	Action and ambitions	Progress	Read more
SDG 7 Affordable and clean energy	7.2 Increase share of - renewable energy	Shift to 100% renewable energy	Sobi entities worldwide track their use and sources of energy. Renewable energy with certificate of origin is sourced for offices and facilities in Sweden and Boston. Sobi encourages suppliers to switch to renewable energy. Among contract manufacturers tracked in EcoVadis, 88% report the use of renewable energy.	p 144 (E2) p 148 (G5)
		Transition to 100% hybrid/ electrical car fleet by 2030	46% (19) of car fleet hybrid/electrical. Parent Company car fleet reporting 86% reduced footprint since 2016.	p 144 (E1)
SGD 8 Decent work and economic growth	8.8 Protect labour rights and promote safe working environments	Ambition for zero workplace incidents	Lost time injuries per million working hours decreased, 3 of 4 accidents related to commute. 65% of Sobi employees have access to beyond statutory health insurances. Several local well-being initiatives in place.	p 146 - 147 (S6 & S7)
SDG 12 Responsible consumption and production	12.1 Implement the sustainable consumption and production framework	Implement the Sobi Responsible Sourcing Programme in supplier relationship management	The Partner Code of Conduct is a key part of supplier contracts. EcoVadis assessments are conducted on prospective and current partners. Important practices are monitored.	p 133, p 148 (G5)
	12.4 Achieve the environmentally sound management of chemicals and all wastes throughout their life cycles	Comply with REACH legislation Environmental assessments of medicines Increase data collection on waste to enable reduction of waste volumes	Sobi maintains REACH authorisation for the use of Triton X-100. Detailed analyses were carried out in 2021. Waste reporting covering 70% (57) of Sobi operations. Total amount of waste showing small decline, due to decreasing amounts of hazardous waste.	p 132 p 145 (E7)
SDG 13 Climate action	13.2 Integrate climate change measures	Apply TCFD risk analysis and adopt a climate strategy in response Complete scope 1, 2 and 3 reporting with targets	First formal TCFD report completed in 2022. The TCFD process is integrated into Sobi's overall risk management process. Targets for scope 1 and 2 set. A complete mapping of scope 3 emissions was completed in 2022.	p 40-42, p 137 - 141 p 133 p 132, p 143 (E1)
SDG 16 Peace, justice and strong institutions	16.4 Combat organised crime and illicit financial and arms flows	Zero incidents of medicine counterfeiting	100% serialisation of medicines to prevent counterfeiting.	p 127
	16.5 Anti-corruption and bribery	Zero incidents of bribery or corruption	An updated global investigations policy was launched in accordance with EU Whistleblowing Directive. 12 (14) cases reported via the hotline and investigated. 96% (96) completion rate in anti-bribery and anti-corruption training.	p 134 p 148 (G6)

Caring for employees

Sobi strives to always be a responsible and inclusive employer that creates a safe and equitable environment where all colleagues have opportunities to realise their potential.

Diversity, Equity and Inclusion

Every employee is offered equal opportunities regardless of their ethnicity, age, gender, religion, sexual orientation or physical abilities. Sobi's guidelines clearly prohibit discrimination and sexual harassment. During 2022, a company-wide DEI initiative was commenced with an external and internal mapping of best practice and the establishment of a governance structure. A workgroup with wide representation from different functions, geographies and cultural backgrounds leads the initiative, which is sponsored by the senior management team. Targets and activities will be set in 2023. In North America, a DEI Advisory Council is already in place as well as Employee Resource Groups for women; BIPOC and LGBTQ+.

In Sweden, an annual gender equality analysis is carried out to prevent discrimination and promote equal rights and opportunities. The results are evaluated in collaboration with trade unions and action is taken when required. Roles and responsibilities are mapped proactively to ensure that salaries and development opportunities are provided in an equitable manner.

Employee engagement

Sobi has committed to performing regular all-employee surveys, including pulse surveys to monitor employee satisfaction, inclusion and engagement.

A global engagement survey for all employees and full-time consultants in subsidiaries was conducted in 2022. Overall results were slightly down (69 compared to 73 in 2020), which was expected due to the societal effects of the pandemic and the extended company bid process in 2021. A continued high response rate of 86 per cent (87) and the positive effects of local actions on work-life balance and workload – which were identified as areas of concern in parts of the organisation in the 2020 survey – are reassuring signs. This demonstrates the importance of taking locally relevant measures.

Over the course of 2022, Sobi welcomed 329 (364) new individuals to Sobi and finished the year with more than 1,560 (1,580) highly skilled employees in around 30 countries.

Development, leadership, training and compensation

Skilled and high-performing teams are key to meeting Sobi's strategic objectives. Emphasis is placed on the development of methods to help managers, leaders and colleagues facilitate continuous growth. One example is the Sobi Management Toolbox, which helps managers to practise their leadership skills, identify their own strengths and development areas, and learn from their peers. During 2022, a global leadership competency model was established to identify the desired qualities of Sobi leaders. The model will be further implemented in 2023.

Business introduction sessions, where corporate leaders present their respective areas, are offered regularly and are open to the whole company.

All Sobi employees receive regular performance and career development reviews. A talent management process is used to support employee evaluation and development. Sobi applies a 70:20:10 learning and development model: training opportunities are offered as part of the role (70 per cent), through interactions with others (20 per cent) and formal educational events (10 per cent).

All Sobi employees have access to the Sobi Learning Management system, which lists available business, management and medicine training. Employees are assigned training based on their role, supported and documented by a training matrix system. The system meets regulatory requirements in the pharmaceutical field and serves as a comprehensive digital platform for ensuring individualised and specialised training as well as evidence of learning. Internal processes and control measures involve scientific, regulatory and compliance training which covers all employees (including part-time) and contractors. An online Learning Resource Guide is also available to all employees. In addition, Sobi offers locally managed training on topics such as product knowledge, IT-proficiency and leadership.

Competitive terms of employment are a prerequisite for recruiting and retaining highly qualified and skilled people. Sobi offers competitive salaries and benefits that are individually determined and adapted to the local labour market. All employees (except for North American and Asia-based employees due to tax reasons) are offered long-term incentive programmes as described in Note 10.

Health and safety

Sobi enforces a global Health and safety (H&S) policy. The management of occupational health and safety (OHS) is based on international ISO standards and is integrated into operational control as part of the company's daily work. The management follows the plan, do, check, act cycle, and H&S risks are continuously assessed to take action and prevent incidents. Sobi requires that OHS should be regularly addressed at meetings and any OHS aspects regarding activities are considered. Managers are responsible for addressing any concerns raised. The joint management-worker H&S committee operates from the head office and includes representatives from all operations. The committee meets quarterly and reports to the Executive committee. It is recommended that each Sobi entity appoints OHS employee representatives. Local practices also include extra health insurances, access to healthcare and support for well-being/fitness.

Investigating and identifying the cause(s) of each accident, dangerous situation or near-miss makes it possible to take action to prevent a similar occurrence in the future. All workers are required to report OHS-related incidents to management, and managers have a duty to ensure that legislative reporting requirements and internal reporting and follow-up processes are adhered to and that preventive measures are taken as necessary. Entities in Sweden are connected to a digital reporting system, and training is carried out to highlight the importance of reporting and follow-up.

Caring for Sobi employees – ambitions

- Offering all employees equal opportunities, with zero-tolerance for discrimination and sexual harassment
- Perform regular employee engagement surveys
- Offer all employees annual performance and career development discussions
- Build skilled and high performing teams through training and development tools to facilitate continuous personal growth
- No workplace accidents leading to lost workdays

Creating a safe working environment during COVID-19

COVID-19 has impacted employees around the world both privately and professionally. Actions taken to ensure a safe working environment have been applied since March 2020 according to the local and regional situations and regulations.

Reducing environmental footprint

Sobi's environmental and climate-related impacts comprise direct and indirect impacts, through sourced activities both upstream and downstream and through activities caused by the company's operations.

Sobi's carbon footprint is caused by energy consumption in pharmaceutical manufacturing, business travel, supply chain logistics and the distribution of medicines. Environmental impacts from production and laboratories are mainly due to the use of energy, water and chemicals, waste generated and the discharge of sewage.

The reduction of water and energy consumption, chemicals, waste and emissions is prioritised in Sobi's production and laboratory facilities. Specific and detailed environmental guidance for the facilities is given in specific SOPs and in the environmental compliance programme, which aims to improve the control of the environmental impact of production. Energy and water consumption at Sobi's production facility is continuously assessed with the aim of improving environmental performance. The production facility is scheduled for closure in a few years, and early steps of the manufacturing process have already been stopped.

Responsible handling of chemicals

All applicable chemical regulations are monitored closely and constitute an important aspect of Sobi's business. The use of Triton X-100 (a non-ionic surfactant, in the ReFacto AF/Xyntha production process) and for which Sobi was granted REACH authorisation, is decreasing due to the closing down of the Sobi production site. The use will stop completely during 2023.

Chemical regulations are extensive and continuously expanding. All the handling of chemicals in Sobi laboratory and manufacturing processes follows strict instructions. Sobi performs continuous risk assessments and internal audits. In 2022, Sobi's Swedish manufacturing site was inspected by the Swedish Work Environment Authority. The focus of the audit was the application of chemical requirements, and the results of the inspection were satisfactory. The Responsible Sourcing Programme is an important tool for influencing, managing and monitoring the sourcing and handling of chemicals in Sobi's supply.

Sobi's GHG emissions in tonnes CO_2

Scope 1	Direct emissions from Sobi's own operations	787
Scope 2	Indirect emissions from Sobi's own operations	563
Total emissions Scope 1 & 2:		1,351
Scope 3	Other indirect emissions that occur in Sobi's value chain	703,174

Pharmaceuticals in the environment

The environmental hazards of a specific medicine refer to its inherent properties, such as toxicity and ability to be broken down by nature. According to existing EU and US guidelines on the environmental risk assessment of medicines, biopharmaceuticals composed of proteins and peptides, for example, are not considered to have a significant negative environmental impact. A high proportion of Sobi's medicines are protein-based and are therefore not considered to have a significant impact on the environment. Environmental assessments of active pharmaceutical ingredients (API) have been conducted on Sobi's two small-molecule medicines, Orfadin and Doptelet, and they are considered to be of low risk to the environment.

Direct and indirect GHG emissions (scope 1 and 2)

Sobi's emissions occur from commercial operations in 30 country units as well as the biological production facility (reported as Manufacturing/Haematology) in Stockholm, Sweden, the legacy laboratory in Geneva, Switzerland, as well as the company's car fleet.

Sobi is committed to substantially reducing emissions from its sites and car fleet by 2025 and aims to achieve net-zero emissions and use 100 per cent renewable energy by 2030. Energy consumption in the Stockholm facilities, the biggest contributor, was reduced by 14 per cent through an energy housekeeping initiative.

Sobi's global and local car policies and car lease set-ups are being revised to promote electric and hybrid cars. Currently, 46 per cent of the leased car fleet is either hybrid or electric.

The details of the impact from global operations are described in detail in the section Sustainability notes.

Indirect GHG emissions (scope 3)

During 2022, Sobi has mapped and identified its relevant scope 3 categories, and emission data connected to these categories has been gathered and calculated. The table GHG emissions (CO_2e) - scope 3 in Sustainability notes E1 shows the list of the relevant categories, numbers and sources of emission data.

The mapping, made using a mix of spend-based and real emissions-based data, identified Categories 1 (Purchased goods), 4 (Upstream transport) and 6 (Business travel) as the largest contributors to Sobi's indirect emissions. Using spend-based data results in broad approximations, and the 2022 calculations are seen as a starting point for Sobi's efforts to address scope 3 emissions.

All the production of commercial medicines is outsourced to contract manufacturers. Sobi has obtained limited emission data from contract manufacturers. The use of supplier specific data will be gradually expanded to include all major contract manufacturers and transport and logistics partners.

Development of emissions-reduction targets

Target year	Topic	Ambitions
2022	Emissions – scope 3	Map emissions in supply chain (contract manufacturers, distribution) – set baseline and start to set reduction targets.
2025	Emissions – scope 1 and 2	Reduce operational GHG footprint by 50% from 2016 baseline.
2030	Emissions – scope 1 and 2	Reduce operational GHG footprint to net zero emissions.
2030	Emissions – scope 3	Set reduction target in 2023 based on 2022 mapping.
2030	Vehicle fleet	Achieve a 100% hybrid or electric vehicle fleet.

Waste

Sobi strives to continually increase data collection on waste and thereby enable continual reductions in waste volumes wherever possible. Measures are also taken to minimise the generation of waste.

In Sweden, Sobi has an established process for the reuse and recycling of its unwanted IT equipment via a certified technology life cycle management service partner. This process is being rolled out to Sobi's operations worldwide, including the training of local teams.

Responsible sourcing

As Sobi's manufacturing is to a large extent outsourced, a large part of its sustainability impact occurs outside the company's own operations. The Sobi Responsible Sourcing Programme is therefore an important process. The programme consists of three main pillars: the alignment of values and principles, risk assessment and qualification, and performance management and monitoring. All supplier categories are included in the scope of Responsible Sourcing.

Sobi's Partner Code of Conduct, outlines requirements for all partners on human rights, protection against child and forced labour, environmental protection, anti-corruption, research ethics, protection of information, and legal compliance.

Contracts include a requirement to comply with the Sobi Partner Code of Conduct. Sobi evaluates prospective and existing partners and performs due diligence and screening for responsible management and compliance with labour and human rights and environmental standards through the evaluation tool provided by the EcoVadis sustainability ratings platform.

Overall evaluation is customised depending on the geographic and supplier category risk profile as well as the strategic importance of the supplier.

Suppliers that do not achieve a total EcoVadis score of >40, which have a theme score <40 or lack processes or adequate performance in Sobi priority topics, are encouraged to improve through identified activities.

By the end of 2022, the average Sobi contract manufacturer scored 65, which means a performance level among the top 25 per cent of all companies scored in EcoVadis.

Sobi is part of the PSCI. PSCI brings together members of the global pharmaceutical and healthcare industry to define, establish and promote responsible supply chain practices. The platform offers an efficient way for both suppliers and customers to improve sustainability performance and increase knowledge.

Responsible sourcing is an integrated part of Sobi's supply chain and procurement strategies. Members of Sobi's procurement departments undergo regular training in responsible sourcing.

Responsible sourcing – ambitions

- Conduct ESG due diligence on all defined supplier risk categories
- Secure minimum performance and drive continuous improvement with special attention to Sobi priority topics

Dedication to ethics, compliance and fair competition

Sobi's Code of Conduct provides a framework for responsible and appropriate conduct. It is approved by the board and applies to everyone working at Sobi and its subsidiaries – including employees, temporary personnel and on-site consultants.

The Code of Conduct connects to essential corporate policies, Sobi values and sustainability priorities. Topics include human rights, health in the workplace, freedom of association, zero tolerance for child and forced labour, patient and community interactions, product safety and quality, ethical research, anti-corruption, fair competition, conflicts of interest, data privacy, intellectual property and environmental responsibility.

The Code of Conduct is available for both employees and external audiences.

Sobi promotes high ethical standards by supporting a corporate culture that embraces open discussion on ethics – both in its operations and among key stakeholders.

Compliance

Sobi's compliance programme is designed to be proactive and follows the elements and principles for effective compliance programmes established by regulators. All new employees are introduced to compliance as part of the induction programme. Other means of training and communication include general and topic-specific e-learning, videos and articles on Sobi's intranet, InsideSobi.

The Global Compliance Governance Charter ensures the management oversight of the compliance programme, including a governance structure with compliance committees, compliance accountability at different levels of the organisation and a network of country compliance subject-matter experts. The Chief Compliance Officer reports directly to the General Counsel, and regular updates on the compliance programme are provided to the Corporate compliance committee and board.

Sobi employees are encouraged to report potential misconduct or unethical behaviour openly to their line management, Human Resources, Compliance or the Legal Department, or by using the Sobi compliance hotline, which is a whistleblowing hotline run by a third party to allow for anonymity. The Sobi compliance hotline is also available for external audiences via a link on the company's website. All reports made through the whistleblowing hotline are reviewed by Compliance and are subject to investigation according to Sobi's Investigation policy and followed up with the appropriate remediation measures.

The Corporate compliance committee consisting of the CEO, the CFO, the General Counsel and the Chief Compliance Officer has oversight of compliance investigations, ensuring both non-retaliation against whistleblowers, and organisational fairness in regard to how sanctions are applied. During the year, a new global operating procedure governing compliance monitoring and self-inspections was implemented, and an updated global Investigations policy was launched in accordance with the EU Whistleblowing Directive.

In 2022, 12 (14) cases were reported via the hotline. To capture all cases, events reported outside the system can also be entered by proxy. More details in Note G6.

Anti-corruption

The pharmaceutical industry is exposed to several corruption risks. It is a highly regulated sector with global operations, multiple interactions with government officials and the widespread use of third parties throughout the pharmaceutical value chain. Sobi works actively to prevent any form of corruption.

Sobi's Anti-corruption policy, which is approved by the Executive committee, has a global scope and complements the Code of Conduct with Sobi's global minimum standards to prevent corruption in activities under Sobi's control. It is aligned with industry codes and legislation, such as the Foreign Corrupt Practices Act and the UK Bribery Act. Key principles outlined include not accepting any form of bribe, any offer or provision of facilitation payments, ensuring accurate book-keeping and records, and that no gifts are made to public officials or healthcare professionals. Risk assessments are carried out on a regular basis and risk-based due diligence procedures are carried out in respect to third parties.

All employees are required to undergo regular e-learning compliance training on the Code of Conduct, anti-corruption and data privacy, with records kept of the training. Training on the Code of Conduct, anti-corruption and anti-bribery are mandatory every second year. In 2022, 97 per cent (95) of eligible Sobi employees completed the Code of Conduct training and 96 per cent (96) completed the anti-corruption and anti-bribery training. Additional training for specific audiences is defined in annual compliance training plans and may include areas such as 'train the trainer' materials on relevant topics from appointed compliance subject-matter experts or face-to-face training on key compliance topics.

Managing corruption risks in the pharmaceutical industry

As a pharmaceutical company, the most apparent corruption risk lies within Sobi's interactions with healthcare stakeholders. All engagements are governed by the Code of Conduct, while a majority are also covered by the Anti-corruption policy and the more specific policy on healthcare interactions. Other policies relevant to preventing corruption are:
Anti-corruption due diligence on third parties, Group authority policy, Global expense policy, Procurement policy and Risk management policy.

Sobi's healthcare compliance programme includes system support to minimise the risk of corruption. This includes policies, mandatory training for customer-facing employees, as well as reporting and controls. The healthcare compliance programme is an important tool for ensuring that all interactions and value transfers remain legal and can withstand external scrutiny. It is also important that all healthcare interactions are intended for the benefit of patients or to enhance the practice of medicine, and that all interactions have the required prior approval and appropriate documentation. An annual compliance monitoring plan is adopted and executed that involves sample testing and the verification of key controls for different activity types and processes. The findings are categorised, logged and reported.

Monetary transactions and value transfers with healthcare providers and patient organisations follow local transparency initiatives such as under the European Federation of Pharmaceutical Industries and Associations Code, US Sunshine Act and national transparency laws, and are made public on an annual basis on sobi.com. Sobi publishes Transfers of Value to healthcare providers in 37 (36) markets across Europe (including Russia and Ukraine), Asia, Australia, the Middle East, and the US.

Third-party risk management

Compliance and sustainability requirements on third parties are reflected in the Partner Code of Conduct. In addition, using a risk-based approach, all relevant third parties undergo due diligence screening in alignment with the policy on anti-corruption due diligence on third parties. During 2022, the process was strengthened and digitalised. This also involved updating policies and SOPs related to third-party risk management and expanding the due diligence and screening to include sanctions and ultimate beneficial ownership. Additional controls were put in place to protect Sobi from engaging with third parties performing services that may violate the applicable international and local laws, regulations, industry codes, standards and principles in both the fields of anti-bribery and anti-corruption as well as human and labour rights and environmental protection.

Data privacy

Data privacy is part of Sobi's Code of Conduct and is a prioritised area throughout Sobi. It is important that customers, clinical study subjects, employees and others Sobi interacts with can trust the company processes personal data in a responsible and secure manner.

Sobi has implemented a data privacy programme to promote data privacy compliance, including appointing a Data Protection Officer (DPO), a global policy on processing of personal data and procedures for responding to data breaches and data subject access requests, and monitoring procedures. In addition, data privacy champions have been appointed throughout the Sobi organisation to promote compliance and support the business.

EU data privacy legislation requires Sobi to assess all suspected and confirmed personal data breaches. If a personal data breach is confirmed, Sobi must also determine whether reporting to supervisory authorities and/or data subjects is required. In order to comply with these requirements, Sobi has implemented a personal data breach process globally, which require all staff to report suspected and confirmed personal data breaches immediately to Sobi's DPO. The DPO assesses all cases and ensures that the appropriate actions are taken.

Corporate income tax

Sobi has a central Group tax function, which is responsible for the overall management of corporate income taxes, and reports to the CFO. The Group tax function maintains governing documents to secure tax compliance and continuously monitors the tax legislation affecting Sobi. Sobi pays taxes in a responsible way, meaning that taxes are paid where profits are earned in accordance with international tax rules. Sobi works to ensure compliance with all applicable tax legislation and regulations in each jurisdiction in which the Group has a taxable presence. A commercial approach, rather than a tax driven approach, is taken when operating the business and managing the legal structure. Sobi keeps a balanced tax risk profile and does not engage in tax-avoidance activities.

Compliance – ambitions

- All employees undergo regular e-learning training. Required for all employees: Code of Conduct, anti-corruption and anti-bribery, data privacy and safety training
- Zero tolerance for bribery
- No major violations of data privacy
- Transparent reporting of monetary transactions to healthcare-professionals and organisations

Report on climate risks and opportunities (TCFD report)

This report has been prepared using the framework defined by the TCFD[1]. Sobi adheres to the TCFD framework recommendations to disclose in four thematic areas: governance, strategy, risk management and metrics and targets.

Governance

Sobi's board has overall responsibility for Sobi's sustainability performance. Climate has been identified by Sobi as a material topic to manage. Plans and progress are reported to the board on a regular basis, together with the outcomes of sustainability risk assessments and adverse events.

The CEO and the Executive committee approve Sobi's climate strategy, ensure compliance, and decide on the overall objectives and implementation of measures related to energy and climate. Each area or function with impact on climate management is responsible for implementing relevant measures and following up on progress. Results are reported back to the Executive committee.

The Global Head of Sustainability is, on behalf of the Executive committee, responsible for driving the implementation and communication of the strategy in close collaboration with the corporate functions and business units, and to support with monitoring progress.

The functions managing Sobi's own manufacturing, its contract manufacturing relationships and logistics and distribution carry a special relevance. Within these functions, responsibilities and representatives (individuals or forums) have been identified to communicate Sobi's climate and energy ambitions and oversee that they are accepted and respected. Other functions, such as Indirect procurement, Access, Packaging and the regional and the country organisations are important stakeholders.

The Internal Control function oversees risk management, including climate risks. The risk management function aggregates and consolidates risks found in risk analyses throughout the organisation and presents a Group-wide risk map to the Executive committee and the board. Sobi's risk management process is described in the Sobi Group risk management policy and the Sobi Group risk management instructions.

Strategy

Introduction

Sobi is a specialised biopharmaceutical company providing access to innovative medicines in the areas of haematology, immunology and specialty care. Sobi operates in an international environment and has own presence in around 30 countries but delivers medicines to patients in many more.

The main business ambitions are leadership in haematology, growth in immunology and specialty care, growing globally and focusing on medicines in mid- and late-stage development. This frames Sobi's efforts to reduce its climate impact and improve its energy management.

Sobi's climate impacts are both direct, from pharmaceutical manufacturing and commercial operations, and indirect through sourced activities upstream and downstream such as the manufacturing of input materials and the contract manufacturing of medicines, logistics and the distribution of intermediates and medicines, and finally the use of Sobi medicines. Major impacting activities throughout the value chain have been identified as part of Sobi's ongoing sustainability management, and efforts are made to reduce climate impact where relevant and possible. Targets have been set to achieve net zero emissions from the company's own operations (scope 1 and 2) by 2030. Scope 3 emissions are being mapped.

More information on Sobi's strategies and activities related to climate and energy management can be found in the 'Reducing environmental footprint' and 'Responsible Sourcing' sections of the Sustainability report.

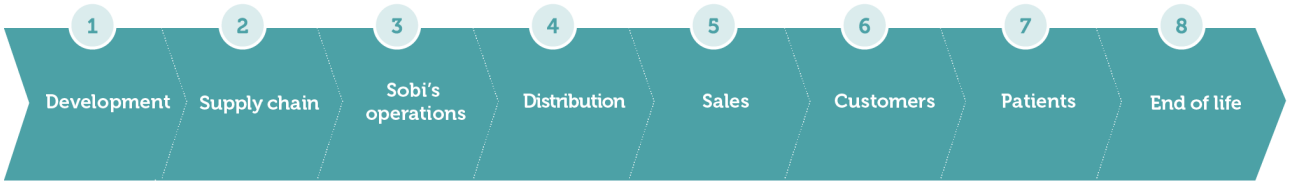
Sobi's business ambitions have also driven the analysis of climate-related risks and opportunities that Sobi may face. A more detailed description is found in the section Risk management.

1. Task Force on Climate-related Financial Disclosures (TCFD) (fsb-tcfd.org).

Identified risks and opportunities according to the TCFD framework

For a detailed description of the methodology and references, see the section Risk management.

The conclusions take into consideration both Sobi's value chain (see below and the description in section Sustainability value chain) – and the regional impacts more likely to occur in geographies of special importance to Sobi. The analysis has only been conducted for impacts related to CO_2. Currently there is no knowledge of any significant impact related to other greenhouse gases.



Sobi value chain

Main transition risks and opportunities

Under the two scenarios chosen, transitional risks and opportunities are mainly linked to the Net Zero 2050 scenario.

The table Sobi's main risks and opportunities shows the risks and opportunities that carry the highest impact and probability of occurrence for Sobi. The risks and opportunities are classified according to the Intergovernmental Panel on Climate Change (IPCC) impact table structure and listed in no particular order.

Net Zero 2050

In a net-zero world in 2050, global warming is limited to 1.5C through stringent climate policies and innovation, reaching net-zero CO_2 emissions and thereby limiting negative physical climate impact.

A rapid transition across all sectors of the economy and most geographies is forecasted to take place, bringing about the implementation of ambitious climate policies across jurisdictions. This will in turn have effects on energy sourcing and supply as well as energy pricing and an increased focus on energy efficiency measures. Changes in technology for mobility will result in effects on pricing and potentially transport capacity.[1]

1. https://www.ngfs.net/ngfs-scenarios-portal/explore/.

Sobi's main risks and opportunities connected to a rapid transition

		Short term (1-3 years)	Medium term (3-5 years)	Long term (5-15 years)
Policy or legal risk	**Financial impact of policy change**			
	Cost models affected due to cost increases connected to the implementation of new policies in the manufacturing of medicines or input materials.		x	
	Changes in requirements on packaging and input material leading to increased costs.	x		
	Electrification of transport in Europe – risks for cost increases or the availability of long-distance cold transport.		x	
Technology risk	**Risk that new technology displaces old systems and disrupts some parts of the existing economic system**			
	Strict power management or power distribution limitations could affect production at contract manufacturers.		x	
Market risk	**Shift in supply or demand when climate risks and opportunities are being considered**			
	Increasing customer requirements for good climate performance throughout value chain.	x		
Reputation risk	**Changing perception of a company connected to its contribution or lack thereof to transition**			
	The impact of climate performance on reputation will grow quickly.	x		
Resource efficiency and energy source opportunities	Cost reductions through focus on energy, water, materials, waste is an unexplored potential.	x		

It is believed that Sobi is reasonably well prepared to manage the risks identified. Sobi's Responsible Sourcing Programme already incorporates climate and energy management into the assessments of potential and onboarded suppliers, and existing work processes will be used to further increase the focus on climate and energy management in dialogue with contract manufacturers. This also improves Sobi's ability to deliver more climate data and information to customers.

Discussions are already ongoing with logistics and transport partners on increased climate requirements. It is believed that primarily the European transport market will see a shift from fossil fuels due to customer requests and Sobi should monitor these changes and make use of the potential opportunities.

Processes for third-party due diligence are in place and will be revisited to ascertain that climate and energy management is properly manifested. Business continuity processes and packaging strategies should also be analysed to make sure they include these perspectives.

Opportunities related to improved energy efficiency in facilities where Sobi operates today, or will operate in the short or mid-term, and possibilities to transition to renewable energy and decrease the energy footprint will be analysed as part of the ongoing activities to minimise Sobi's climate footprint.

Main physical risks

Under the two scenarios chosen, physical risks are mainly linked to the Current Policies scenario where no further measures beyond today's are implemented by society to curb climate change.

Current Policies

In the Current Policies scenario, the present global warming of about 1.2C compared to pre-industrial times would increase to 2C around 2050 and 3C within this century.

This is projected to lead to non-linear increases in severe and irreversible climate impacts, leading to regional and local exposure to different types of risks to eco-systems, human health and supply chains. This includes both irreversible impacts manifested as chronic risks and acute risks stemming from more volatile climate conditions.[1]

The table Sobi's main physical risks shows the chronic and acute physical risks that were identified to carry the highest impact and probability of occurrence for Sobi. The risks are classified according to the IPCC impact table structure and listed in no particular order.

1. https://www.ngfs.net/ngfs-scenarios-portal/explore/.

Sobi's main physical risks connected to keeping with current policies

		Short term (1-3 years)	Medium term (3-5 years)	Long term (5-15 years)
Acute	**Event driven, including weather-related**			
	Acute weather events such as heavy precipitation, floods or extreme winds could affect supply and distribution chains, and in the end patient health, especially during launch or in the event of low stock levels.	x		
	Extreme weather can affect possibilities for Sobi's suppliers to access input materials. It is more difficult to monitor and ascertain proper contingency planning in companies further up in the supply chain, thereby increasing risks.		x	
Chronic	**Permanent changes caused by climate change**			
	Increased energy costs and CO_2-emissions related to cooling due to higher temperatures and increased need for cooling.		x	
	Negative impact to the health of employees and supplier partner employees due to higher temperatures.			x

Sobi's business model creates a dependency on external partners within the supply eco-system. Sobi's biggest flows of medicines are within Europe and North America and between the two continents. Unchecked climate change will mean a considerable increase in the risk of extreme weather events in certain parts of Europe and on the North American continent.

Business continuity processes should be reinforced to include weather-related risks and a regular assessment of Sobi as well as suppliers' locations should take place to identify potential hazards and ensure suppliers also have business continuity plans that include climate change parameters. Climate change preparedness should be part of the regular dialogue with, and assessment of potential supplier partners. Critical materials should be listed, including materials used in manufacturing.

It is not assessed that any of Sobi's current manufacturing or distribution partners are in areas with high risk in the short-term.

There is a risk that extreme temperatures could affect single deliveries, but it is not considered a systemic risk. According to the same logic, extreme weather could have potential negative impact on the ability of patients to access medicines. Access to medicines is already a top priority for Sobi and processes exist to ensure timely deliveries.

Risk management

In 2022, Sobi conducted formal climate scenario planning sessions for the first time using the recommendations and impact tables identified by the TCFD[1], which divided potential impacts into transitional and physical risks and opportunities. A total of three risk and opportunity workshops were held that focused on the perspectives Finance and Legal, Technology and finally Product and Market, and included relevant senior representatives and internal experts from these functions. All workshops were conducted using the same methodology:

1. A review of the conclusions of the Intergovernmental Panel on Climate Change (IPCC) in its Sixth Assessment Report Working Group I (AR6 WGI)[2] and some of the more detailed conclusions on impacts, regional vulnerabilities, and potential adaptation effects from the Working Group II report (AR6 WGII)[3].
2. A discussion on the resulting effects on society and industry using two of the Representative Concentration Pathways (RCPs) described in AR6 WGI: Shared Socio-Economic Pathway SSP 1-1.9 and SSP 3-7.0.
3. An identification of risks and opportunities for Sobi using two of the climate scenarios identified by the Network of Central Banks and Supervisors for Greening the Financial System (NGFS)[4]. The chosen climate scenarios, illustrating two opposing evolutionary paths, are 'Current Policies' (similar to SSP 3-7.0) and 'Net Zero 2050' (resembling SSP 1-1.9).
4. A rough estimation of time horizons when risks or opportunities could appear. This was done using three different time horizons (short term – one to three years, medium term – three to five years, and long term – five to fifteen years). This exceeds the ten-year time horizon normally used for business planning and is also why a longer time horizon than 15 years was not deemed practical to use.
5. A judgment on the size of the impact and probability of the realisation resulting in a final ranking of main identified risks and opportunities.

1. FINAL-2017-TCFD-Report.pdf (bbhub.io).
2. IPCC_AR6_WGI_SPM_final.pdf.
3. https://www.ipcc.ch/report/ar6/wg2/.
4. https://www.ngfs.net/ngfs-scenarios-portal/explore/.

Sobi's overall risk management process is based on the Group risk management policy. The process aims to identify and assess all relevant strategic, operational, financial, and regulatory risks as well as sustainability risks. The risk assessment and the results of the 2022 risk management process are described in detail in the section Risk management. The risk management function reports the risk status to the Executive committee, and to the board. As part of the risk management process, the company's critical flows are identified, and business continuity plans are implemented. This process is managed by Sobi's Internal Control function.

The conclusions of the TCFD climate risk mapping have been included and integrated into the overall risk mapping conclusions. An annual workflow has been established where climate and overall sustainability risks will feed into the overall risk management process, see below.

Integrated processes for risk management and TCFD reporting

Metrics and targets

Sobi tracks its CO_2 footprint and reports scope 1 and 2 emissions annually in the Annual and sustainability report. Targets have been set to reach net-zero emissions from Sobi's own operations (scope 1 and 2) by 2030. The share of renewable energy is also tracked, and a target set to reach 100 per cent use of renewable energy in operations worldwide by 2030. The use of company cars is monitored and a target in place to switch to 100 per cent electric or hybrid technology by 2030.

The energy and CO_2 footprint of contract manufacturers and logistics partners is tracked, as well as these companies' climate ambitions. This is a part of the regular business reviews. A complete mapping of Sobi's scope 3 emissions was completed early 2023.

2022 was the first year that Sobi tracked and reported on the energy performance of the buildings in which it operates. This will continue in 2023.

More details on metrics and performance related to climate and energy can be found in the sections Reducing environmental footprint and Responsible Sourcing as well as in the section Sustainability notes.

Sobi participates in the S&P Corporate Sustainability Assessment (CSA) and reports to CDP (previously known as the Carbon Disclosure Project) to assess and benchmark its performance versus best practice.

KPIs for manufacturing and delivery performance are well established. These measurements can also be used to identify climate-related impact on company performance.

Sustainability notes

The Sustainability notes contains a summary of the progress and results obtained during 2022. During the year, Sobi updated its process for materiality assessments and completed a new assessment, identifying the most important sustainability topics on which to focus and report. A detailed description of stakeholder groups and outcomes of the assessment is to be found in section Material sustainability topics.

Economic performance

In 2022, revenue growth was 8 per cent with revenue of SEK 18,790 M. EBITA was SEK 5,930 M, resulting in an EBITA margin of 32 per cent for the full year. Cash flow from operating activities totalled SEK 4,665 M.

Direct economic value generated

SEK M	2022	2021	2020
Revenue	18,790	15,529	15,261
Operating expenses	10,201	8,288	7,575
Employee wages and benefits	3,081	2,481	2,250
Payments to providers of capital	229	302	249
Payments to governments[i]	673	1,124	918
Community investments[ii]	17	17	20

Calculation is based on the consolidated statement of comprehensive income.

i. Includes corporate income tax payments (i.e. no special payroll tax on pensions, VAT or social security contributions). Does not include other taxes such as pharmaceutical, environmental and individual employees' income tax.

ii. Community investments are based on costs for financial support to patient organisations. The largest recipients are the World Federation of Hemophilia and the European Haemophilia Consortium. Patient organisations receiving support are made public on sobi.com.

Indirect economic impact

Sobi reports on the humanitarian aid donation of haemophilia factor treatments as a significant indirect economic impact in the stakeholder community and in developing countries.

In 2020, Sobi and Sanofi announced the agreement to extend their support of the WFH Humanitarian Aid Program with an additional donation of up to 500 million IU of factor medicine for humanitarian use, thereby fulfilling the 2014 pledge to donate one billion IU over a 10-year period.

The impact created is a result of Sobi's and Sanofi's contribution to the Program and is reported in accordance with the WFH Humanitarian Aid Program Impact report.

Number	2022	2021	2020
Total MIUs[i] delivered	661	588	499
Total patients treated (cumulative)	20,274	18,881	17,329
Acute bleeds treated	32,866	31,528	21,900
Surgeries	648	412	470
Number of workshop attendees	400	1,468	691

i. Million international units.

In addition to the humanitarian aid donation to the WFH, Sobi contributes to the WFH Corporate Partner Program. Read more about the impacts of the Corporate Partner Program in section Maintain commitment to patients, and on sobi.com.

Environmental performance

The scope of Sobi's environmental impact reporting includes the Sobi-owned biological manufacturing facility, headquarters in Sweden and international offices, and business travel. Environmental data from subsidiaries was first included in 2020, and new data points have been added in since. In 2022, historical figures were recalculated to reflect the full company footprint

For the first year, Sobi is in 2022 reporting on value chain emissions of carbon dioxide equivalents (CO_2e-emissions).

E1. Greenhouse gas (GHG) emissions

GHG emissions (CO_2e) – scope 1 and 2

(tonnes)	2022	2021	2020	2019	2018	2016
GRAND TOTAL SCOPE 1 AND 2	**1,351**	**975**	**2,720**	**2,501**	**1,770**	**1,591**
Scope 1 (direct emissions)						
Heating	3.1	3.3	1.7	2.2	3	2.6
Oil	*1.0*	*3.3*	*1.7*	*2.2*	*3*	2.6
Gas	*2.1*	*0*	*0*	*0*	*0*	0
Company cars	784	701	676	558	464	432
Total scope 1	787	704	677	560	467	435
Scope 2 (indirect emissions) [i]						
Electricity (market based)	359	161	1,929	1,831	1,187	1,044
Electricity (location based)	415	233	1,337	1,079	728	617
Heating	195	110	113	110	116	113
Cooling	9	0	0	0	0	0
Total scope 2 (using market based numbers)	563	271	2,043	1,941	1,303	1,157

i. Scope 2 emissions calculated using both market- and location-based components.

GHG emissions (CO_2e) – scope 3

	Category	GHG emissions (tonnes CO2e) 2022	Calculation method	Source of emission factors
1	Purchased goods and services	640,615	Limited supplier specific data (scope 1 and 2). Spend based data	Quantis 2021, supplier data
2	Capital goods	7,710	Spend based data	Quantis 2021
3	Fuel and energy	159	Reported scope 1 and 2 data	DEFRA 2022
4	Upstream transportation and distribution	42,823	Spend based data	Quantis 2021
5	Waste	173	Reported waste data	DEFRA 2022 and other factors
6	Business travel	9,937	Reported data on physical travel and spend based data	Travel agency emission data, DEFRA, NTM (2018), RFI from IVL (2020), Quantis (2021), car manufacturer data (WLTP)
7	Employee commuting	1,732	Employee commuting survey conducted in 2022	NTM (2018), DEFRA (2022)
8	Upstream leased assets	not relevant		
9	Downstream transportation and distribution	not relevant		
10	Processing of sold products	not relevant		
11	Use of sold products	voluntary – not included in 2022		
12	End-of-life treatment	25	Primary packaging data (DEFRA 2022)	DEFRA 2022
13	Downstream leased assets	not relevant		
14	Franchises	not relevant		
15	Investments	not relevant		
	GRAND TOTAL SCOPE 3	**703,174**		

Relevant scope 3 categories and data sources

Emission factors used

For scope 1 and scope 2 emission calculations, a number of sources have been used, see below. Scope 3 emission factors are listed in the scope 3 table.

Aspect	Source
Location based emissions	AIB (2016-2021) Carbonfootprint.com
Market based emissions	AIB (2016-2021) Carbonfootprint.com
District heating	Energiföretagen (2020) IEA 2021
District cooling	Vattenfall Stockholm Energi, miljönyckeltal 2020
Fossil fuel (production facility Sweden)	DEFRA (2022)
Leased cars	Car manufacturer data, WLTP

Scope 1 and scope 2 emission data sources

Comments GHG emissions

Emissions include data from Sobi's global operations. Historically, emission data was only available for the Swedish Parent Company. Total scope 1 and 2 emissions for 2020 and back have therefore been restated to reflect Sobi's global footprint and updated to reflect both market-based and location-based calculation methods, as defined by the GHG Protocol Scope 2 Guidance. This extrapolation has been made using average employee consumption figures[1], which is believed to be a liberal estimation.

For 2021 and 2022, figures have been extrapolated to compensate for organisational units for which data was not available. In 2021, 92.6 per cent of Sobi facilities worldwide (measured as share of employees) reported all or some energy data, and in 2022 this number was 94.1 per cent. The majority of reporters for leased car data have not split between business and private travel. The share of electric and hybrid cars out of leased cars reported in scope 1 has increased to 46 per cent, however the total number of leased cars has also increased slightly in 2022.

A full scope 3 inventory was completed in 2022 where Sobi's relevant scope 3 categories were identified, and emission data connected to these categories gathered and calculated. The calculations were made using a mix of spend-based and real emissions-based data and identified Categories 1 (Purchased goods and services), 4 (Upstream transportation and distribution) and 6 (Business travel) as the largest contributors.

Spend numbers used represent the full year 2021. The 2022 calculations are seen as a starting point for Sobi in the effort to address scope 3 emissions and work towards setting Science Based Targets. The base for assumptions made and sources of emissions data is summarised in the scope 3 table in the previous page.

Category 1 contains a mix of spend-based and supplier specific emission data. 12 per cent of the spend in this category is represented by collected scope 1 and 2 emission data from Sobi's contract manufacturers.

Data in Category 6 connected to physical travel has been collected also in previous years. Emissions data stems from travel agency reporting. As the world is leaving the past years' COVID-19 restrictions behind, physical travel increased in 2022. This year, data on physical travel is accompanied by a full spend-based calculation of emissions connected to all travel-related activities.

Data in Category 7 stems from a Sobi employee commuting survey conducted in 2022.

E2. Energy use and mix

Energy consumption refers to all operations, including Sobi's in-house - manufacturing and all offices. Energy consumption by source of origin and the proportion that is renewable is included where data is available. Starting 2022, only energy sources with a certificate of origin are considered renewable.

In 2022, energy consumption was tracked completely or partially in 94 per cent of Sobi's sites (as measured by share of employees) and extrapolated to represent the full company. Renewable energy is sourced for offices and facilities in Sweden and the US, amounting to 83 per cent of consumed energy.

Three affiliates operate in office buildings with energy performance certifications, corresponding to 12% of Sobi's employees.

Energy consumption (Megawatt hours, MWh)

MWh	2022	2021	2020	2019	2018
Electricity	8,511	8,440	8,318	7,518	7,694
of which renewable	6,845	8,042	8,318	7,518	7,694
Heating	2,427	2,391	2,133	2,550	2,596
of which renewable	2,028	2,268	1,770	2,015	2,051
Fossil fuel (oil)[i]	4.0	9.6	5.6	7.2	10.0
Cooling	1,890	2,121	2,902	3,059	3,167
of which renewable	1,834	2,064	2,902	3,059	3,167
Total	**12,832**	**12,962**	**13,359**	**13,134**	**13,467**

i. Direct energy.

E2.1 Total amount of energy directly consumed

The direct energy produced and consumed on-site (scope 1 production facility) is generated by an emergency generator that is tested on a regular basis. The process to test the generator has been made more efficient, and the time spent and emissions were cut in half.

E2.2 Total amount of energy indirectly consumed

Energy-saving possibilities are regularly evaluated at the facilities in Stockholm, Sweden. During 2022, efficiency measures have been taken to reduce consumption, resulting in a 14 per cent reduction. Examples include improved time management and improved control of ventilation and laboratory equipment. Sobi targets to switch to 100% renewable energy and reach net zero emissions in operations by 2030.

E3. Energy intensity

Total direct energy use for in-house manufacturing per output scaling factor.

Total direct energy use (MWh/SEK M)

	2022	2021	2020	2019	2018
Energy (MWh)	4,989	5,958	6,597	5,867	6,313
Revenue manufacturing (SEK M)	413	445	481	376	436
MWh/SEK M	12.1	13.4	13.7	15.6	14.5

1. https://www.odyssee-mure.eu/publications/efficiency-by-sector/services/end-use-electricity-consumption-per-employee.htm.

E4. Water use

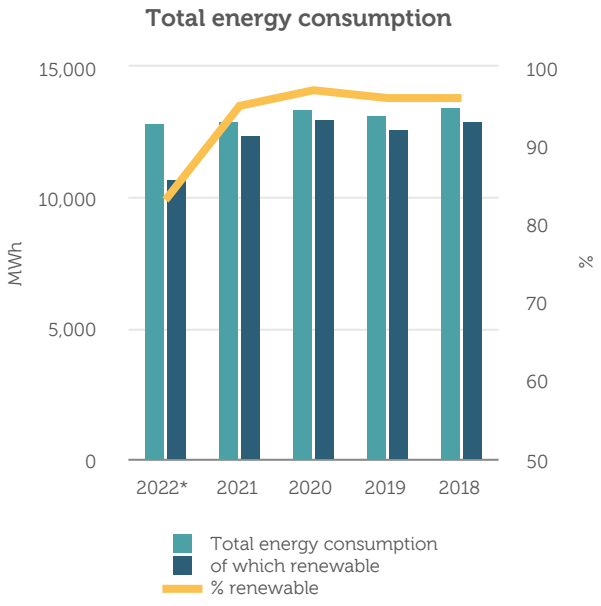
Water consumption data includes Sobi's head office and production facilities in Stockholm, Sweden as well as offices outside Sweden. In 2022, 53 (46) per cent of Sobi operations reported on water usage.

Water consumption

m^3	2022	2021	2020	2019	2018
Purchased water	26,469	53,728	56,725	31,776	57,374

In the production facility, water consumption is regularly followed up in relation to internal performance indicators. During previous years, water consumption readings at the corporate HQ have been incorrect resulting in readings considerably higher than real consumption. Starting 2022, the readings are correct.

Water in the production facilities is not reclaimed, but warm water is recycled from the production of steam to extract heating and cooling.



* Starting 2022, only sources with a certificate of origin included

Total energy consumption and share of renewable energy

E5. Environmental management

The Environmental policy states the principles and defines roles and responsibilities for managing environmental issues within all of Sobi operations, including affiliates and subsidiaries as well as Sobi's sphere of influence. It emphasises Sobi's commitment to complying with applicable laws and regulations, a proactive approach to protecting land, water, air, climate, natural resources and biodiversity, as well as a commitment to risk reduction and transparency.

To Sobi's best knowledge, there were no confirmed incidents resulting in administrative and judicial sanctions for failure to comply with environmental laws and/or regulations in 2022.

E6. Climate oversight and risk mitigation

Sobi describes its climate risk management in detail in the section TCFD and the outcome of the TCFD climate risk mapping is included in the company's overall risk mapping.

Sobi's direct GHG emissions are limited, and the company is not at risk of substantial exposure to climate change in the short term.

Supply chain partners with a high impact on Sobi's operations and which are impacted by climate-related risks are assessed and monitored as part of Sobi's Responsible Sourcing Programme.

Sobi is working to fulfil the EU Taxonomy Regulation with the aim of adapting the company's disclosures to evolving reporting practice. At present, Sobi's core business – developing, commercialising and manufacturing pharmaceutical products – are not yet included in the Taxonomy Regulation. The formal Taxonomy tables are included in the section Taxonomy.

E7. Waste

Waste figures mainly emanate from Sobi's head office and production facilities in Stockholm, Sweden but for two years also include data from operations outside Sweden, now covering 70 (57) per cent of global Sobi operations. Several entities have limited possibilities to report per treatment method.

Amounts of non-hazardous waste per employee has decreased in recent years, a result of several measures, including digitalisation of deviation management and changes to available archive spaces, but adding more entities has meant increases in total amounts. One example is adding data from the Sobi US entities, which means an increase in for instance non-hazardous waste to landfill.

Used IT equipment is sent for repurposing through a collection system that in 2021 was expanded from Sweden to cover all Sobi countries, except Asia, the Middle East and Russia. This volume is increasing.

Landfill of hazardous waste is increasing due to the decommissioning of laboratory and production material and equipment in Stockholm.

Office and production site waste

Tonnes	2022	2021	2020	2019	2018
Total amount of waste	**52.8**	**55.4**	**35**	**39**	**42**
Production	42.0	36	–	–	–
Office	10.9	19.4	–	–	–
Non-hazardous waste					
Recycling	7.9	7.9	5	6	–
Reuse	0	0.3	0	0.6	–
Combustion with energy recovery	20.1	20.3	16	17.5	–
Other treatment	0	0	0	0.6	–
Landfill[i]	4.2	1.9	1	0.2	0.1
Total non-hazardous	**32.3**	**30.4**	**22**	**24.3**	**24**
Hazardous waste					
Recycling	6.8	13.8	6	5	–
Reuse[ii]	1.3	0.5	1	–	–
Combustion with energy recovery	9.2	8.4	0	0	–
Other treatment	3.0	1.9	7	8.6	–
Landfill[iii]	0.2	0.3	0	0	–
Total hazardous	**20.5**	**25**	**13**	**14**	**18**

i. A limited amount of Sobi's waste cannot be recycled and is therefore sent to landfill. The waste is mostly construction related. The 2022 increase stems from the addition of entities in the US.

ii. IT equipment sent for repurposing, a system expanded to cover all Sobi markets, except Asia, Middle East and Russia.

iii. Obsolete chemicals from production that were sent for final, authorised, treatment and where remaining residue (ash/calcified end product) is subsequently landfilled.

Social performance

In 2022, Sobi had commercial operations in Europe, North America, North Africa, the Middle East, Eastern Asia and Australia. Biological manufacturing is based in Sweden with one laboratory facility in Switzerland.

To Sobi's best knowledge, there were no confirmed incidents resulting in administrative or judicial sanctions for failure to comply with laws and/or regulations in the social and economic area in 2022.

S1. CEO remuneration

Please see Note 10 for information about CEO remuneration. See also the Remuneration report available on the sobi.com website in connection with documentation for the 2023 AGM.

S2. Gender pay ratio

In Sweden, a gender equality analysis is carried out annually, designed to prevent discrimination and promote equal rights and opportunities. Results are evaluated in collaboration with trade unions and actions taken if necessary. Roles and responsibilities are mapped proactively to ensure fair and equitable salaries as well as development opportunities.

S3. Employee turnover

In 2022, Sobi declined slightly in number of employees and had a turnover rate of 18 (15) per cent due to voluntary terminations. The movement is believed to be caused partially by the job market shifts caused by the pandemic and the fact that Sobi grew in new geographies. During the year, 39 employees were affected by a planned lay off due to the upcoming closure of the Sobi manufacturing site. Numbers below are headcount, fixed term employees excluded.

Year	New hires	Voluntary termination	Total number employees (year end)
2022	329	260	1,567

S4. Gender diversity

Sobi has strong representation of women in management roles within STEM-related (Science, Technology, Engineering, and Mathematics) areas. Positions such as SVP Technical Operations, Head of Global Quality and Head of Internal Manufacturing are all held by women.

	2022		2021		2020	
% per gender	Female	Men	Female	Men	Female	Men
Board	50	50	50	50	38	62
Executive committee	8	92	8	92	18	82
Senior management[i]	40	60	40	60	42	58
All employees	59	41	59	41	59	41

i. Senior management – management positions reporting to Executive committee. Data includes permanent and fixed term employees.

New hires diversity

The share of female new hires decreased slightly in 2022 and the 30-49 age group increased its share slightly. The age profile of new hires reflects the industry and the company's need for highly qualified and experienced staff.

Split of new hires – gender and age[i]	<30	30-49	50–	Total 2022
Female	12	129	47	188
Male	7	93	41	141
Total new hires per age group	**19**	**222**	**88**	**329**

i. Includes both permanent and fixed term employees.

S5. Temporary worker ratio

Typically, Sobi does not have part-time positions. Employees may be granted voluntary part-time equivalent employment for personal needs such as childcare.

Employees, contract type

Employees[i]		Total 2022	Total 2021
Permanent contract	An employee employed by Sobi without a predetermined end date.	1,520	1,536
Fixed-term contract	An employee employed by Sobi with a predetermined end date.	36	22
FTE consultants	Consultants acting as line staff and temporarily replacing a Sobi employee.	106	120

i. Employee numbers are expressed as full-time equivalents (FTE).

S6. Injury rate

The total number of accidents includes those that did not lead to absence from work but that may have required medical care. Accidents during the commute to and from the workplace is since 2021 part of the total. In 2022, three of four accidents happened during commuting, due to winter conditions.

Incidents	2022	2021	2020	2019	2018
No. of accidents	17	17	10	26	28
Lost workday injury (LWI)	4	4	0	0	1
Lost time incident rate LTFIR (LTIR)	1.29	1.33	0	0	(0.39)

- LWI – Accidents that led to a lost workday (in addition to the day of the accident).
- LTFIR – Lost time injuries / 1,000,000 * total number of hours worked.
- LTIR – Lost time incident rate per million hours worked.

S7. Global health & safety

A number of Sobi affiliates operate joint worker-management H&S committees to monitor and develop the local H&S practices.

Joint H&S committees	2022	2021	2020	2019	2018
% of employees[i] represented by H&S committees	43	53	–	–	–

i. Calculated using headcount per unit.

Health insurances follow statutory requirements, and 65 per cent of employees also have access to additional health insurances. Company insurances for accidents cover all employees, also for activities done off-site. 73 per cent of Sobi employees have access to health, wellness or fitness activities.

S8. Training and education

All Sobi employees receive regular performance and career development reviews. Training documentation and performance management processes are digitalised.

A number of training modules are identified as compulsory for all or parts of the Sobi workforce, and participation tracked centrally. In, 2022, completion rates among eligible Sobi employees were between 94 and 99 per cent, maintaining the high completion rates of 2021.

Main trainings completion rate

Training title	Completion rate
Sobi all – introduction	94%
Sobi all – anti-corruption and anti-bribery training	96%
Sobi all – data privacy and information security training	99%
Sobi all – environment, health and safety training	98%
Sobi all – GXP introduction	96%
Sobi all – patient safety core	97%
Sobi all – patient safety refresher	96%
Sobi all – Sobi Code of Conduct training	97%
Sobi local EHS training for production and lab	96%

In addition to the above, Sobi started collecting data on locally managed training in 2021. In 2022, over 16,000 hours of product knowledge training and over 10,000 hours of training connected to leadership and personal development was registered.

All employees (100 per cent) completed their performance management process (PMP) in 2022. All managers and employees are encouraged to set up individual development plans. In 2022, the first year this measure was centrally tracked the share of employees that have a confirmed development plan was 14 per cent.

S9. Patient safety

To ensure and evaluate statutory compliance with quality and patient safety regulations, facilities are regularly inspected. In 2022, Sobi hosted three GXP inspections. In addition to external inspections, Sobi continuously monitors the performance of its suppliers and internal processes and operations.

Sobi had no incidents of product recall in 2022.

S10. Marketing and labelling

In 2022, no incident of non-compliance with regulations and/or voluntary codes concerning product and service information and labelling was reported.

S11. Forced and child labour

Sobi has zero tolerance for forced and child labour and is a signatory to the UN Global Compact. The company's statement on forced and child labour is included in the Code of Conduct and Partner Code of Conduct, the latter applying specifically to the supply chain. The Partner Code of Conduct is part of the contractual agreements with suppliers. Both documents are available on sobi.com.

S12. Human rights

Sobi is a UN Global Compact signatory and the company's statement on human rights is included in the Code of Conduct and Partner Code of Conduct, the latter applying specifically to the supply chain. The Partner Code of Conduct is part of the contractual agreements with suppliers. Both documents are available on sobi.com

Governance performance

Sobi sets high ethical standards in operations globally. The aim is to maintain a culture of compliance with corporate principles. This objective extends to Sobi's supply chain. Sobi has a well-developed governance system for compliance. For more details, see sections Sustainability governance and Compliance.

G1. Board diversity

The Nomination committee applies rule 4.1 of the Swedish Corporate Governance Code in regard to composition of the board.

Board diversity

	2022	2021	2020
Male	4	4	5
Female	3	4	3
Nationalities	4	3	4
30-50 years	1	1	0
Over 50 years	6	7	8
Committee chairs (three committees)			
Male	2 (3)	2 (3)	2 (3)
Female	1 (3)	1 (3)	1 (3)

G2. Board independence

See the corporate governance report.

The company meets the Swedish Corporate Governance Code's requirements that a majority of board members must be independent of the company and its executive management, and that at least two board members must also be independent of the company's major shareholders.

G3. Incentivised pay

Executives are formally incentivised for objectives that are determined for the promotion of the company's business strategy and long-term development, including its sustainability, in accordance with the remuneration guidelines set out in Note 10. Remuneration involves base salary, bonus and share programmes. Note 10 outlines the principles of total remuneration – market-competitive, enabling international hiring and supporting diversity within the Executive committee.

G4. Collective bargaining agreements

All of Sobi's employees are free to form, join or refrain from joining organisations that represent their interests as employees. All employees are also allowed to negotiate collectively. 36 (39) per cent of Sobi's employees (Sweden, Austria, France, Italy, Spain, Portugal) are covered by collective bargaining agreements.

Employees covered by collective bargaining

Percentage of employees in country or region	2022
Sweden	100
Europe[i]	31
North America[ii]	0
Rest of the world	0
Total	**36**

i. Excluding Sweden.

ii. US and Canada.

G5. Supplier Code of Conduct

Sobi has a Partner Code of Conduct in place for vendors, suppliers and partners. The Code is available on sobi.com.

Since 2020, Sobi has been a formal associate member of the PSCI and participates in several PSCI working groups to promote responsible supply chain practices as well as human rights, environmental sustainability and responsible business practices in the global pharmaceutical supply chain.

Sobi engages EcoVadis to rate supplier sustainability performance in supplier categories identified to carry sustainability risks. Among contract manufacturing suppliers, 90 per cent calculated in spend are scored, with a mean score of 65, which is among the top 25 per cent scored in EcoVadis. 21 per cent calculated in spend of indirect suppliers in risk categories are so far scored in EcoVadis, with a mean score of 54. Three suppliers among these scored <40 using the EcoVadis CSR Rating Methodology.

Sobi also encourages implementation of key practices among its suppliers and tracks the implementation rate through the EcoVadis platform and as part of business review meetings.

Proportion of contract manufacturers reporting implemented practices (in per cent)	2022
Actions on energy consumption and GHGs	94
Use of renewable energy	88
Audit or assessment of suppliers on CSR issues	75
Policy on anti-corruption	100
Active whistleblowing procedure	88

At end of 2022, a majority of the Sobi contract manufacturers, measured in spend, either had approved SBTi's or commitment to set such targets.

For more details about the Sobi Responsible Sourcing Programme, see page 133.

G6. Ethics and anti-corruption

Sobi's ethical standards statement is included in the Code of Conduct and Partner Code of Conduct, the latter applying specifically to the supply chain. Sobi's Anti-corruption policy applies to all employees.

In 2022, 12 cases were reported via the Sobi compliance hotline and reviewed by the Corporate compliance committee. All cases are investigated, and the appropriate corrective and disciplinary actions are taken where needed.

97 per cent of the eligible workforce completed the Code of Conduct e-learning. 96 per cent completed the assigned anti-corruption training.

More information about Sobi's work on ethics and compliance can be found on pages 133 - 134. R&D-related ethics principles are found in page 127-128.

G7. Data Protection

Sobi's data protection programme is described on page 135. To allow for continuous improvements as well as compliance with data protection legislation, it is of great importance to establish and maintain a robust data breach reporting process.

Sobi's data protection office received 4 (10) internal reports of suspected personal data breaches during 2022, showing that there is a continued readiness to report potential issues. All incidents were investigated, and corrective actions taken. Two cases (one in 2021) were reported to the supervisory authority, as required by applicable data protection laws.

Taxonomy

The EU Taxonomy Regulation is a key component of the European Commission's action plan to redirect capital flows towards a more sustainable economy. In the following section, Sobi presents the Group's share of revenue, capital expenditure (CapEx) and operating expenditure (OpEx) for 2022, which are associated with Taxonomy-eligible and Taxonomy-aligned economic activities related to the first two environmental objectives (Climate change mitigation and Climate change adaptation) laid down in Article 8 of Regulation (EU)2020/852 and the Climate Delegated Act (EU)2021/2139.

Sobi activity

Sobi is a provider of biopharmaceutical medicines and only generates revenue from sales and manufacture of pharmaceutical products. Following a review involving the relevant divisions and functions, Sobi has concluded that the Group's main economic activity is not covered by the Delegated Act and was therefore not Taxonomy-eligible in 2022. Activities within Sobi's medicine value chain that are not revenue-generating, but that result in assets or processes that are essential for the revenue-generating activity, are not considered economic activities on their own, and are not therefore covered by the Taxonomy.

Sobi foresees that the activity will be covered by upcoming Delegated Acts on the remaining four environmental objectives, and that medicines will be a prioritised area when establishing KPIs for Sustainable use and protection of water and marine resource as well as Pollution prevention and control. Therefore, Sobi expects that at least some of its economic activity will be Taxonomy-eligible (under Manufacture of chemicals and chemical products or Manufacture of basic pharmaceutical products and pharmaceutical preparations) in the future.

Reporting principles

The EU Taxonomy KPIs are defined as follows.

Revenue

Revenue is defined as Taxonomy-eligible economic activity (numerator) divided by total revenue (denominator). The denominator is Sobi's total revenue in accordance with IFRS 15 as presented in the Consolidated statement of comprehensive income and Note 5.

CapEx

CapEx is defined as Taxonomy-eligible CapEx (numerator) divided by total CapEx (denominator). Total CapEx cover investments in tangible- and intangible assets including right-of-use assets before depreciation, amortisation and any re-measurements, including those resulting from impairments and excluding changes in fair value. CapEx also covers investments from above arising from business combinations. Goodwill is excluded. Total CapEx can be reconciled to the consolidated financial statements, please see Note 16 and 17. Sobi has not presently established a capital expenditure plan.

OpEx

OpEx is defined as Taxonomy-eligible OpEx (numerator) divided by total OpEx (denominator). Total OpEx consists of research & development expenses and short-term lease expenses and can be reconciled to the consolidated statement of comprehensive income and Note 9. The volume of non-capitalised leases was determined in accordance with IFRS 16.

For further information about Sobi's reporting principles, see Note 2 and 4.

Revenue that is Taxonomy-eligible and Taxonomy-aligned

Since Sobi's main economic activity as a pharmaceutical company is not covered by the Climate Delegated Act, the proportion of Taxonomy-eligible economic activities in total revenue is 0 per cent. For details, see table Revenue below.

Revenue[i]				Substantial contribution criteria						DNSH criteria (Does Not Significantly Harm)						Minimum safeguards	Taxonomy-aligned proportion of turnover, year 2022	Taxonomy-aligned proportion of turnover, year 2021	Category (enabling activity)	Category (transitional activity)
Economic activities	Code(s)	Absolute turnover	Proportion of turnover	Climate change mitigation	Climate change adaptation	Water and marine resources	Circular economy	Pollution	Biodiversity and ecosystems	Climate change mitigation	Climate change adaptation	Water and marine resources	Circular economy	Pollution	Biodiversity and ecosystems					
		SEK M	%	%	%	%	%	%	%	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	%	%	E	T
A. TAXONOMY-ELIGIBLE ACTIVITIES																				
A.1 Environmentally sustainable activities (Taxonomy-aligned)		0	0														0			
A.2 Taxonomy-Eligible but not environmentally sustainable activities (not Taxonomy-aligned activities)		0	0																	
Total (A.1 + A.2)		0	0														0			
B. TAXONOMY-NON-ELIGIBLE ACTIVITIES																				
Revenue of Taxonomy-non-eligible activities (B)		18,790	100																	
Total (A+B)		18,790	100																	

i. Proportion of turnover from products or services associated with Taxonomy-aligned economic activities – disclosure covering year 2022.

CapEx and OpEx that is Taxonomy-eligible and Taxonomy-aligned
Since Sobi's proportion of economic activities associated with total revenue covered by the Taxonomy is 0 per cent, the proportion of related CapEx and OpEx is also 0 per cent. In its product value chain, however, Sobi is active in several sectors and the CapEx and OpEx to be disclosed also include those related to the purchase of output from Taxonomy-eligible economic activities and individual measures enabling the target activities to become low-carbon, or to lead to greenhouse gas reductions.

Sobi's analysis has included CapEx and OpEx relating to the purchase of output from Taxonomy-eligible economic activities and measures to improve energy efficiency listed in the Climate Delegated Act. See below for an overview of the translation between Sobi activities and the economic activities defined in the Delegated Act. The analysis has identified one activity, the leasing of company vehicles, for which CapEx is Taxonomy-eligible (NACE Code 6.5, Transport by motorbikes, passenger cars and light commercial vehicles).

Sobi signed an agreement with Pfizer to produce Kineret where Sobi will compensate Pfizer for parts of its investment in a production facility up to completion. Please see Note 9 for further information. As Sobi does not own the production facility, the CapEx for this economic activity is not identified as Taxonomy-eligible (NACE Code 7.1, Construction of new buildings). Additionally, Sobi invests in technology transfers whereby Sobi, for example, invests in the reconstruction and adaptation of a production facility ahead of production of the company's medicines at a third party on behalf, or partly on behalf of Sobi. Equally, CapEx for this economic activity is not Taxonomy-eligible (NACE Code 7.2, Renovation of existing buildings) as Sobi does not own the production facilities.

As Sobi does not own the buildings in which it operates, and as costs for data centre leases are not material, no eligible activities pertaining to renovation, maintenance or leasing have been identified. Therefore, the proportion of OpEx associated with Taxonomy-eligible economic activities is 0 per cent.

Taxonomy eligible purchased output/individual measures	Corresponding economic activity (Annex I to Climate Delegated Act)	In Sobi defined as	Comment
Vehicle fleet (leasing) including maintenance and repair	6.5 Transport by motorbikes, passenger cars and light commercial vehicles	CapEx	New leases added in 2022 are included in the reporting of taxonomy eligible economic activity.

Based on the above, Sobi reports total KPIs for CapEx and OpEx in the tables below.

CapEx

The economic activity *Transport* has a major potential to contribute to environmental objective 1, Climate change mitigation, through decarbonisation of the vehicle fleet. Company cars are a significant part of Sobi's climate footprint which is being reduced by choosing electric or low emission (hybrid) vehicles. Sobi reports company cars that were added to the car fleet in 2022 and are zero or low emission (< 50g CO_2e/km) as Taxonomy aligned, meeting the technical screening criteria in activity 6.5 of the Climate Delegated Act (EU)2021/2139. Sobi assesses that this activity complies with the applicable DNSH criteria since climate risk evaluation is now a mandatory part of sustainability reporting (criteria 2), vehicles fall under Directive 2000/53/EC on end-of-life vehicles (criteria 4) as well as rules on emission class Euro6 (criteria 5). For activities defined as Taxonomy-aligned, Sobi has found no violations of the Minimum Safeguards. Sobi suppliers shall accept and adhere to the Sobi Partner Code of Conduct and sustainability performance is monitored within the Responsible Sourcing Programme. Sobi's policies and processes are based on the OECD Guidelines for Multinational Enterprises and the UN Guiding Principles on Business and Human Rights.

CapEx[i]				Substantial contribution criteria						DNSH criteria (Does Not Significantly Harm)										
Economic activities	**Code(s)**	**Absolute CapEx**	**Proportion of CapEx**	**Climate change mitigation**	**Climate change adaptation**	**Water and marine resources**	**Circular economy**	**Pollution**	**Biodiversity and ecosystems**	**Climate change mitigation**	**Climate change adaptation**	**Water and marine resources**	**Circular economy**	**Pollution**	**Biodiversity and ecosystems**	**Minimum safeguards**	**Taxonomy- aligned proportion of CapEx, year 2022**	**Taxonomy-aligned proportion of CapEx, year 2021**	**Category (enabling activity)**	**Category (transitional activity)**
		SEK M	**%**	**%**	**%**	**%**	**%**	**%**	**%**	**Y/N**	**Y/N**	**Y/N**	**Y/N**	**Y/N**	**Y/N**	**Y/N**	**%**	**%**	**E**	**T**
A. TAXONOMY-ELIGIBLE ACTIVITIES																				
A.1 Environmentally sustainable activities (Taxonomy-aligned)																				
6.5 Transport by motorbikes, passenger cars and light commercial vehicles	6.5	16	1	100	0					Y	Y	Y	Y	Y	Y	Y	1			
CapEx of environmentally sustainable activities (Taxonomy-aligned) (A.1)		16	1														1			
A.2 Taxonomy-Eligible but not environmentally sustainable activities (not Taxonomy-aligned activities)																				
6.5 Transport by motorbikes, passenger cars and light commercial vehicles	6.5	17	1																	
CapEx of Taxonomy-eligible but not environmentally sustainable activities (not Taxonomy-aligned activities) (A.2)		17	1																	
Total (A.1 + A.2)		33	2														1			
B. TAXONOMY-NON-ELIGIBLE ACTIVITIES																				
CapEx of Taxonomy-Non-eligible activities (B)		1,810	98																	
Total (A+B)		1,843	100																	

i. Proportion of CapEx from products or services associated with Taxonomy-aligned economic activities – disclosure covering year 2022.

OpEx

OpEx[i]				Substantial contribution criteria						DNSH criteria (Does Not Significantly Harm)						Minimum safeguards	Taxonomy-aligned proportion of OpEx, year 2022	Taxonomy-aligned proportion of OpEx, year 2021	Category (enabling activity)	Category (transitional activity)
Economic activities	**Code(s)**	**Absolute OpEx**	**Proportion of OpEx**	**Climate change mitigation**	**Climate change adaptation**	**Water and marine resources**	**Circular economy**	**Pollution**	**Biodiversity and ecosystems**	**Climate change mitigation**	**Climate change adaptation**	**Water and marine resources**	**Circular economy**	**Pollution**	**Biodiversity and ecosystems**					
		SEK M	**%**	**%**	**%**	**%**	**%**	**%**	**%**	**Y/N**	**Y/N**	**Y/N**	**Y/N**	**Y/N**	**Y/N**	**Y/N**	**%**	**%**	**E**	**T**
A. TAXONOMY-ELIGIBLE ACTIVITIES																				
A.1 Environmentally sustainable activities (Taxonomy-aligned)		0	0														0			
A.2 Taxonomy-Eligible but not environmentally sustainable activities (not Taxonomy-aligned activities)		0	0																	
Total (A.1 + A.2)		0	0														0			
B. TAXONOMY-NON-ELIGIBLE ACTIVITIES																				
OpEx of Taxonomy-Non-eligible activities (B)		2,375	100																	
Total (A+B)		2,375	100																	

i. Proportion of OpEx from products or services associated with Taxonomy-aligned economic activities – disclosure covering year 2022.

Market availability of key Sobi medicines

Regulatory approvals and indications for Sobi's medicines vary by geographical region. In addition to regulatory approval, local agreements on pricing and reimbursement are also required for the medicine to be fully available through regular healthcare pathways.

The table below shows the countries for which Sobi has been granted marketing authorisation, including the indication, and whether market access is achieved through approved pricing and/or reimbursement (x in table below) or managed access programmes (MAP in table below) or Named Patient Use (NPU in table below). In the EU, the marketing authorisation approval and indication is valid for all EU member and EFTA states.

Sobi is commercialising the following main and/or proprietary medicines: Alprolix, Aspaveli/Empaveli, Doptelet, Elocta/Eloctate, Gamifant, Kineret and Orfadin, listed in the table below. In addition, and not reflected in the table below, Zynlonta was approved in the EU for the treatment of relapsed or refractory diffuse large B-cell lymphoma in December 2022. In November 2022, Kineret was granted an Emergency Use Authorization by the FDA for the treatment of COVID-19 in the US, following an EMA marketing authorization for COVID-19 in the EU in December 2021. Furthermore, Synagis for RSV is not included in the table as Sobi sells this medicine in the US exclusively.

See section Definitions for more information on the listed indications.

	Access to Sobi's medicines						
Region	**Elocta**[i]	**Alprolix**[i]	**Doptelet**	**Aspaveli/ Empaveli**	**Kineret**	**Gamifant**	**Orfadin**
EU and EFTA states	**Haemophilia A**	**Haemophilia B**	**CLD/ITP**	**PNH**	**RA, CAPS, Still's, FMF**	**N/A**	**HT-1 and AKU**
Austria	x	x	x	x	x		x
Belgium	x	x	x		x		x
Bulgaria	x	x			x		x
Croatia	x	x	x		x		x
Cyprus	x				x		x
Czech Republic	x	x	x		x		x
Denmark	x	x	x	x	x		x
Estonia	x				x		x
Finland	x	x	x		x		x
France	x	x			x		x
Germany	x	x	x	x	x		x
Greece	x	x			x		x
Hungary	x	x	x (ITP only)	x	x		x
Iceland					x		x
Ireland	x	x	x		x		x
Italy	x	x	x	x	x		x
Latvia					x		
Liechtenstein	x	x			x		x
Lithuania					x		x
Luxembourg	x	x	x		x		x
Malta					x		
Netherlands	x	x	x		x		x
Norway	x	x	x		x		x
Poland	x	x			x		x
Portugal	x	x			x		x
Romania	x	x			x		x
Slovakia	x	x	x		x		x
Slovenia	x	x	x		x		x
Spain	x	x	x		x		x
Sweden	x	x	x (ITP only)		x		x

i. Sobi has final development and commercialisation rights in Europe, most Middle Eastern markets, North Africa and Russia.

Market availability of Sobi medicines, cont.

	Access to Sobi's medicines						
Region	**Elocta**[i]	**Alprolix**[i]	**Doptelet**	**Aspaveli/Empaveli**	**Kineret**	**Gamifant**	**Orfadin**
Europe – other	**Haemophilia A**	**Haemophilia B**	**CLD/ITP**	**PNH**	**RA, CAPS, Stills, FMF**	**pHLH**	**HT-1**
Russia	x		Approved, not marketed		x + COVID-19	MAP	
Switzerland	x	x	x		(x)		x
Turkey	x				x		NPU
United Kingdom	x	x	x	x	x		x + AKU
Ukraine							x
North America	**Not Sobi territory**	**Not Sobi territory**	**CLD/ITP**		**RA, NOMID**	**pHLH**	**HT-1**
Canada					x		x
Mexico							x + AKU
United States			x	Not Sobi territory	x + DIRA	x	x
Asia	**Haemophilia A**	**Haemophilia B**			**RA, CAPS, Stills, FMF**	**pHLH**	**HT-1**
Bahrain					NPU		x
China	Not Sobi territory	Not Sobi territory	Outlicensed			x	
Kuwait	x	x	x		NPU		NPU
Iraq		x					
Israel	x				x		x
Japan	Not Sobi territory	Not Sobi territory					x
Jordan					NPU		x
Oman	x	x			NPU		NPU
Palestine							x
Qatar	x	x			NPU		x
Saudi Arabia	x	x	x	x	x + COVID-19	MAP	x
United Arab Emirates	x	x	x		NPU	x	x (MAP)
North Africa	**Haemophilia A**	**Haemophilia B**	**CLD/ITP**		**RA, CAPS, Stills, FMF**	**pHLH**	**HT-1**
Algeria	x				NPU		x
Tunisia					NPU		x
South America	**Not Sobi territory**	**Not Sobi territory**	**CLD/ITP**		**RA, CAPS**	**pHLH**	**HT-1**
Argentina					NPU		x + AKU
Chile					NPU		x
Australia (Oceania)	Not Sobi territory	Not Sobi territory		x	x + sJIA		x

i. Sobi has final development and commercialisation rights in Europe, most Middle Eastern markets, North Africa and Russia.

About the Sustainability report

The Sobi Sustainability report 2022 is included in the Annual and sustainability report 2022 and has been prepared in accordance with GRI Standards 2021. It also fulfils the requirements on sustainability reporting outlined in the Swedish Annual Accounts Act. The Sustainability report has been approved by Sobi's board of directors. The report is not assured by an independent party.

Scope of the report

Sobi reports its sustainability performance on an annual basis, in the Annual and sustainability report. The report covers data collected for the calendar year 2022 and was published on 3 April 2023. Unless otherwise stated, the report has the same scope as the financial report and Includes all Sobi operations. Please see Note 10 for list of employee locations and Note 18 for list of Group companies. No mergers or acquisitions have taken place during 2022 with an impact on the sustainability reporting.

Consolidations

The GRI disclosures have been selected based on the materiality analysis, further described in section Material sustainability topics. All page references refer to pages in Sobi's Annual and sustainability report 2022 or sobi.com. The sections mainly used are:

- Sobi's business model, strategy and description of activities on pages 9-11.
- A description of the Sobi approach to sustainability is found on pages 22-27 and 119-141.
- A report on the 2022 performance is found in the Sustainability notes section, on pages 142-152.

Restatements

The Stockholm production facility is scheduled for closure after the contract manufacturing for Pfizer is stopped in the first quarter of 2024, and early stages of the manufacturing process have already been phased out.

In some cases, CO_2-emissions reported earlier years have been recalculated to be more comparable. This is highlighted in the report.

Omissions

Omissions of information on material topics, and the reasons for the omissions, are noted in the GRI Content Index.

For questions regarding the Annual and sustainability report, please contact info@sobi.com.

GRI content index

Statement of use		Swedish Orphan Biovitrum AB has reported in accordance with the GRI standards for the period 1 January 2022 to 31 December 2022.		
GRI 1 used		GRI 1: Foundation 2021		
GRI STANDARD/ OTHER SOURCE	DISCLOSURE	LOCATION	OMISSION	
		SECTION & PAGE(S)	REQUIREMENT(S) OMITTED	REASON & EXPLANATION
General disclosures				
GRI 2: General Disclosures 2021	2-1 Organizational details	p11, 28-9, 32, 52, 84, 103-105		
	2-2 Entities included in the organization's sustainability reporting	About the Sustainability report p155		
	2-3 Reporting period, frequency and contact point	About the Sustainability report, p155		
	2-4 Restatements of information	About the Sustainability report, p155		
	2-5 External assurance	Auditor's report on the statutory sustainability statement, p160		
	2-6 Activities, value chain and other business relationships	p1-3, 7, 10, 13-18, 27, 32, 33-37, 133-134		
	2-7 Employees	Note 10 p69, S3-S5 p146	No regional split in type of employment.	Sobi is a small and relatively homogenous organisation.
	2-8 Workers who are not employees	S5 p146		
	2-9 Governance structure and composition	Corporate governance report p103,.3. Board, p105		
	2-10 Nomination and selection of the highest governance body	Corp governance pp103-111, Sustainability governance, p120, G2 p147		
	2-11 Chair of the highest governance body	Board p113		
	2-12 Role of the highest governance body in overseeing the management of impacts	Sustainability governance, p120		
	2-13 Delegation of responsibility for managing impacts	Sustainability governance, p120		
	2-14 Role of the highest governance body in sustainability reporting	Sustainability governance, p120		
	2-15 Conflicts of interest	Compliance, p134		
	2-16 Communication of critical concerns	Sustainability governance, p120 + Compliance p134		
	2-17 Collective knowledge of the highest governance body	Board p113		
	2-18 Evaluation of the performance of the highest governance body	Evaluation of the board's work, p107		
	2-19 Remuneration policies	Note 10 p70-71, S1 p146, Remuneration report on sobi.com		
	2-20 Process to determine remuneration	Compensation & Benefits committee p108, Minutes from AGM on sobi.com		
	2-21 Annual total compensation ratio	Minutes from AGM on sobi.com	x	Data incomplete due to lack of systems.
	2-22 Statement on sustainable development strategy	From the CEO, p5		
	2-23 Policy commitments	Sustainability governance pp120-121		
	2-24 Embedding policy commitments	Sustainability governance p121, topics pp 123-136, Compliance p134		
	2-25 Processes to remediate negative impacts	Risk management pp40-42, Sustainability governance p121, Compliance p134		
	2-26 Mechanisms for seeking advice and raising concerns	Compliance p134		
	2-27 Compliance with laws and regulations	E5 p145, Social performance p146		
	2-28 Membership associations	Trade association memberships on sobi.com		
	2-29 Approach to stakeholder engagement	Sustainability value chain p27, Material sustainability topics p120,		
	2-30 Collective bargaining agreements	S7 p147, G4 p148		
Material topics				
GRI 3: Material Topics 2021	3-1 Process to determine material topics	Material sustainability topics p120		
	3-2 List of material topics	Material topics table, p121		

Economic performance				
GRI 201: Economic Performance 2016	201-1 Direct economic value generated and distributed	Economic performance, p142		
	201-2 Financial implications and other risks and opportunities due to climate change	Report on climate risks and opportunities (TCFD) pp 137-141		
	201-3 Defined benefit plan obligations and other retirement plans	Note 2 pp58-9; Note 10 p70-1; Note 29, pp92-3		
	201-4 Financial assistance received from government		x	Information unavailable/incomplete.
Indirect economic impacts				
GRI 3: Material Topics 2021	3-3 Management of material topics	Material topics table p121, SDG table p123, Patient and community engagement, pp 125-6		
GRI 203: Indirect Economic Impacts 2016	203-1 Infrastructure investments and services supported		x	No involvement in support of development of significant infrastructure investments and services.
	203-2 Significant indirect economic impacts	Indirect economic impact, p118		
Procurement practices				
GRI 3: Material Topics 2021	3-3 Management of material topics	Material topics table p121, Responsible sourcing p133		
GRI 204: Procurement Practices 2016	204-1 Proportion of spending on local suppliers		x	Not relevant due to Sobi's business model.
Anti-corruption				
GRI 3: Material Topics 2021	3-3 Management of material topics	Material topics table p121, Compliance p134-5		
GRI 205: Anti-corruption 2016	205-1 Operations assessed for risks related to corruption	Risk management p42, Compliance p134-5		
	205-2 Communication and training about anti-corruption policies and procedures	Compliance p134-5		
	205-3 Confirmed incidents of corruption and actions taken	Compliance p134-5, G6 p148		
Anti-competitive behaviuor				
GRI 3: Material Topics 2021	3-3 Management of material topics	Policy on fair competition p105, Dedication to ethics p133		
GRI 206: Anti-competitive Behaviour 2016	206-1 Legal actions for anti-competitive behaviour, anti-trust, and monopoly practices	Risk management p42, Compliance p134-5, G6 148		
Tax				
GRI 207: Tax 2019	207-1 Approach to tax	Corporate income tax p136, note 2 p54		
	207-2 Tax governance, control and risk management	Corporate income tax p136, Risk management p42		
	207-3 Stakeholder engagement and management of concerns related to tax	Corporate income tax p136		
	207-4 Country-by-country reporting		x	Confidentiality constraints.
Energy				
GRI 3: Material Topics 2021	3-3 Management of material topics	Material topics table p121, Reducing environmental footprint p131		
GRI 302: Energy 2016	302-1 Energy consumption within the organization	E2 p144		
	302-2 Energy consumption outside of the organization	E1 & E2 p143-144, G5 p148		
	302-3 Energy intensity	E3 p144		
	302-4 Reduction of energy consumption	E1 & E2 p143-144		
	302-5 Reductions in energy requirements of products and services		x	No energy required for Sobi medicines.
Water and effluents				
GRI 3: Material Topics 2021	3-3 Management of material topics	Material topics table p121, Reducing environmental footprint p131		
GRI 303: Water and Effluents 2018	303-1 Interactions with water as a shared resource	E4, p145		
	303-2 Management of water discharge-related impacts		x	No material emissions to water or other impact from water discharge.
	303-3 Water withdrawal		x	No material water withdrawal.
	303-4 Water discharge	E4 p145		
	303-5 Water consumption	E4 p145		

Emissions				
GRI 3: Material Topics 2021	3-3 Management of material topics	Material topics table p121, E1 p143-4		
GRI 305: Emissions 2016	305-1 Direct (s cope 1) GHG emissions	E1 pp143-144		
	305-2 Energy indirect (scope 2) GHG emissions	E1 pp143-144		
	305-3 Other indirect (scope 3) GHG emissions	E1 pp143-144		
	305-4 GHG emissions intensity	E1 pp143-144		
	305-5 Reduction of GHG emissions	E1 pp143-144		
	305-6 Emissions of ozone-depleting substances (ODS)		x	No known emissions of ODS.
	305-7 Nitrogen oxides (NOx), sulphur oxides (SOx) and other significant air emissions		x	No known material emissions..
Waste				
GRI 3: Material Topics 2021	3-3 Management of material topics	Material topics table p121, Waste p133		
GRI 306: Waste 2020	306-1 Waste generation and significant waste-related impacts	Waste p133, E7 p145		
	306-2 Management of significant waste-related impacts	Waste p133, E7 p145		
	306-3 Waste generated	E7 p145		
	306-4 Waste diverted from disposal	E7 p145		
	306-5 Waste directed to disposal	E7 p145		
Supplier environmental assessment				
GRI 3: Material Topics 2021	3-3 Management of material topics	Material topics table p121, Responsible sourcing p133		
GRI 308: Supplier Environmental Assessment 2016	308-1 New suppliers that were screened using environmental criteria	Responsible sourcing p133, G5 p148		
	308-2 Negative environmental impacts in the supply chain and actions taken	Responsible sourcing p133, G5 p148		
Employment				
GRI 3: Material Topics 2021	3-3 Management of material topics	Material topics table p121, Caring for employees p130		
GRI 401: Employment 2016	401-1 New employee hires and employee turnover	S3 & S4 p146		
	401-2 Benefits provided to full-time employees that are not provided to temporary or part-time employees		x	Not applicable to Sobi's employment model.
	401-3 Parental leave		x	Information unavailable/incomplete.
Labour/management relations				
GRI 3: Material Topics 2021	3-3 Management of material topics	Material topics table p121, Caring for employees p130		
GRI 402: Labour/ Management Relations 2016	402-1 Minimum notice periods regarding operational changes	G4 p148	x	36% of Sobi employees are covered by collective agreements. but data from all countries not available.
Occupational health and safety				
GRI 3: Material Topics 2021	3-3 Management of material topics	Materiality topics table p121, Health and Safety p131		
GRI 403: Occupational Health and Safety 2018	403-1 Occupational health and safety management system	Health and Safety p131, S7 p 147		
	403-2 Hazard identification, risk assessment, and incident investigation	Health and Safety p131		
	403-3 Occupational health services	Health and Safety p131, S7 p 147		
	403-4 Worker participation, consultation, and communication on occupational health and safety	Health and Safety p131, S7 p 147		
	403-5 Worker training on occupational health and safety	Health and Safety p131, S8 p147		
	403-6 Promotion of worker health	Health and Safety p131, S7 p 147		
	403-7 Prevention and mitigation of occupational health and safety impacts directly linked by business relationships	Responsible sourcing p133, G5 p148		
	403-8 Workers covered by an occupational health and safety management system	Health and Safety p131, S7 p 147		
	403-9 Work-related injuries	S6 p 146-147		
	403-10 Work-related ill health		x	Information unavailable/incomplete.
Training and education				
GRI 3: Material Topics 2021	3-3 Management of material topics	Material topics table p121, Caring for employees p130		

GRI 404: Training and Education 2016	404-1 Average hours of training per year per employee	S8 p147		
	404-2 Programs for upgrading employee skills and transition assistance programs	S8 p147		
	404-3 Percentage of employees receiving regular performance and career development reviews	S8 p147		
Diversity and equal opportunity				
GRI 3: Material Topics 2021	3-3 Management of material topics	Material topics table p121, Caring for employees p130		
GRI 405: Diversity and Equal Opportunity 2016	405-1 Diversity of governance bodies and employees	S4 p146		
	405-2 Ratio of basic salary and remuneration of women to men		x	Information unavailable/incomplete.
Non-discrimination				
GRI 3: Material Topics 2021	3-3 Management of material topics	Material topics table p121, Caring for employees p130		
GRI 406: Non-discrimination 2016	406-1 Incidents of discrimination and corrective actions taken	Compliance p134, G6 p148		
Freedom of association and collective bargaining				
GRI 3: Material Topics 2021	3-3 Management of material topics	Material topics table p121		
GRI 407: Freedom of Association and Collective Bargaining 2016	407-1 Operations and suppliers in which the right to freedom of association and collective bargaining may be at risk	Responsible Sourcing p133, G4 p148, G5 p148		
Local communities				
GRI 3: Material Topics 2021	3-3 Management of material topics	Material topics table p121		
GRI 413: Local Communities 2016	413-1 Operations with local community engagement, impact assessments, and development programs	Patient and community engagement p125	x	Only patient communities relevant and therefore included.
	413-2 Operations with significant actual and potential negative impacts on local communities		x	Not applicable.
Supplier social assessment				
GRI 3: Material Topics 2021	3-3 Management of material topics	Material topics table p121, Responsible sourcing p133		
GRI 414: Supplier Social Assessment 2016	414-1 New suppliers that were screened using social criteria	Responsible sourcing p133		
	414-2 Negative social impacts in the supply chain and actions taken	Responsible sourcing p133, G5 p148		
Public policy				
GRI 3: Material Topics 2021	3-3 Management of material topics	Material topics table p121		
GRI 415: Public Policy 2016	415-1 Political contributions		x	Political contributions not allowed. https://www.sobi.com/en/code-conduct.
Customer health and safety				
GRI 3: Material Topics 2021	3-3 Management of material topics	Material topics table p121		
GRI 416: Customer Health and Safety 2016	416-1 Assessment of the health and safety impacts of product and service categories	Focus on patient safety, 126-7		
	416-2 Incidents of non-compliance concerning the health and safety impacts of products and services	S9 p147		
Marketing and labelling				
GRI 3: Material Topics 2021	3-3 Management of material topics	Material topics table p121		
GRI 417: Marketing and labelling 2016	417-1 Requirements for product and service information and labelling	Focus on patient safety, 126-7		
	417-2 Incidents of non-compliance concerning product and service information and labelling	S10, p147		
	417-3 Incidents of non-compliance concerning marketing communications	S10, p147		
Customer privacy				
GRI 3: Material Topics 2021	3-3 Management of material topics	Material topics table p121		
GRI 418: Customer Privacy 2016	418-1 Substantiated complaints concerning breaches of customer privacy and losses of customer data	G7, p148		

Auditor's report on the statutory sustainability statement

To the general meeting of the shareholders of Swedish Orphan Biovitrum AB (publ), corporate identity number 556038-9321

Engagement and responsibility

It is the board of directors who is responsible for the statutory sustainability statement for the year 2022 on pages 22-27 and 119-159 and that it has been prepared in accordance with the Annual Accounts Act.

The scope of the audit

Our examination has been conducted in accordance with FAR's auditing standard RevR 12 The auditor's opinion regarding the statutory sustainability statement. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

Opinions

A statutory sustainability statement has been prepared.

Stockholm, 31 March 2023
Ernst & Young AB

Jonatan Hansson
Authorised Public Accountant

Annual general meeting 2023

Annual general meeting 2023

Swedish Orphan Biovitrum AB (publ) will hold its annual general meeting on Tuesday 9 May 2023.

Shareholders who wish to participate in the meeting must be listed as a shareholder in the presentation of the share register prepared by Euroclear Sweden AB (the Swedish Central Securities Depository) concerning the circumstances on 28 April 2023 and must give notice of participation in accordance with what is stated in the notice convening the annual general meeting.

Shareholders whose shares are registered in the name of a nominee through the trust department of a bank or similar institution must, to be entitled to participate in the meeting, register their shares in their own name, so that the shareholder is listed in the presentation of the share register as per 28 April 2023. Such registration may be temporary (so-called voting rights registration) and request for such voting rights registration shall be made to the nominee, in accordance with the nominee's routines, at such time in advance as decided by the nominee. Voting rights registrations that have been made by the nominee no later than 3 May 2023 will be considered in the presentation of the share register.

Additional instructions will be stated in the notice convening the annual general meeting, which will be issued not later than four weeks prior to the annual general meeting.

Financial calendar 2023

Q1 2023 report	27 April
Annual general meeting	9 May
Q2 2023 report	18 July
Q3 2023 report	26 October

The Annual and sustainability report can be downloaded in PDF format from sobi.com, as well as previous annual and quarterly reports and press releases.

Alternative performance measures – financial measures not defined according to IFRS

Sobi uses certain financial measures, Alternative performance measures, in this report that are not defined according to IFRS. Sobi considers these measures to provide valuable supplementary information for stakeholders and company management, as they enable an assessment and benchmarking of the company's reporting. Since not all companies calculate financial measures in the same way, these are not always comparable to measures used by other companies. These financial measures should not, therefore, be regarded as substitutes for measures defined according to IFRS. As of 2022, Sobi has updated its definition of items affecting comparability, formerly called non-recurring items, to provide better guidance for stakeholders and company management on what type of initiatives and costs that can be considered part of restructuring. See below metrics not defined according to IFRS and definitions used, referred to and presented in this report. Numbers are presented in SEK M unless otherwise stated.

Change at CER

Definition: change at CER on total revenue excludes the effect of exchange rates by recalculating total revenue for the relevant period using the exchange rates that were used for the comparable period.

Reason to use: the measure is important in order to understand the underlying performance of the operations and increases the comparability between periods

Full year 2022	Total revenue	FX impact	Total revenue, adjusted for FX impact	Total revenue, comparable period	Change at CER
Haematology					
Elocta	4,402	-245	4,157	3,960	5 %
Alprolix	1,885	-110	1,775	1,764	1 %
Royalty	1,427	-232	1,195	1,251	-4 %
Doptelet	2,526	-395	2,130	1,116	91 %
Aspaveli/Empaveli	178	-15	163	1	>200%
Manufacturing	413	—	413	445	-7 %
Total	**10,831**	**-997**	**9,834**	**8,536**	**15 %**
Immunology					
Kineret	2,284	-254	2,031	2,290	-11 %
Synagis	3,501	-544	2,957	2,650	12 %
Gamifant	895	-142	752	840	-10 %
Total	**6,679**	**-939**	**5,740**	**5,780**	**-1 %**
Specialty Care	**1,280**	**-124**	**1,156**	**1,213**	**-5 %**
Total	**18,790**	**-2,060**	**16,730**	**15,529**	**8 %**

Full year 2021	Total revenue	FX impact	Total revenue, adjusted for FX impact	Total revenue, comparable period	Change at CER
Haematology					
Elocta	3,960	133	4,093	4,585	-11 %
Alprolix	1,764	53	1,817	1,705	7 %
Royalty	1,251	93	1,344	1,301	3 %
Doptelet	1,116	82	1,198	587	104 %
Aspaveli/Empaveli	1	—	1	—	n/a
Manufacturing	445	—	445	481	-8 %
Total	**8,536**	**361**	**8,898**	**8,660**	**3 %**
Immunology					
Kineret	2,290	116	2,406	2,079	16 %
Synagis	2,650	249	2,899	2,726	6 %
Gamifant	840	61	901	609	48 %
Total	**5,780**	**427**	**6,207**	**5,415**	**15 %**
Specialty Care	**1,213**	**66**	**1,279**	**1,186**	**8 %**
Total	**15,529**	**854**	**16,384**	**15,261**	**7 %**

Gross margin

Definition: gross profit as a percentage of total revenue.

Reason to use: gross margin is an important measure which provides a better understanding of the business development. Gross margin is impacted by several factors such as business, product and region mix and price development.

Items affecting comparability

Definition: items that are of significant value, have no clear connection to recurring, ordinary operations and are of such a type that they cannot be expected to occur often. This may, for example, refer to capital gains/losses from divestments, restructuring, impairments and other unusual one-time income and expenses. Restructuring refers to structural efficiency programmes that impact the scope of the business or other changes to business operations. Costs for carrying out restructuring are identified on a project basis and may be incurred over more than one year.

Reason to use: provides a better understanding of the company's underlying operating activities.

SEK M	2022	2021
Total revenue	18,790	15,529
Total cost of goods sold	-4,776	-3,484
Gross profit	**14,014**	**12,045**
Gross margin	**75 %**	**78 %**
Items affecting comparability		
-Restructuring costs:		
-Discontinuation of contract manufacturing	*-363*	—
Items affecting comparability[i]	**-363**	**—**
Gross profit adjusted	**14,377**	**12,045**
Gross margin adjusted	**77 %**	**78 %**
EBIT[2]	**3,813**	**3,733**
Items affecting comparability		
-Restructuring costs:		
-Discontinuation of contract manufacturing	*-363*	—
-Consolidation of sites	*-72*	—
-Efficiency programmes	*-134*	—
-Other:		
-Provision for expected credit losses in Russia	*-106*	—
Items affecting comparability	**-675**	**—**
EBIT adjusted	**4,488**	**3,733**

EBITA and EBITA margin

Definition: earnings before interest, tax, amortisation and impairment of intangible assets. EBITA margin; EBITA as a percentage of total revenue.

Definition: earnings before interest, tax, amortisation and impairment of intangible assets. EBITA margin; EBITA as a percentage of total revenue.

SEK M	2022	2021
EBIT[ii]	3,813	3,733
Plus amortisation and impairment of intangible assets	2,117	1,841
EBITA[ii]	**5,930**	**5,575**
EBITA margin	**32 %**	**36 %**

SEK M	2022	2021
Items affecting comparability		
-Restructuring costs:		
-Discontinuation of contract manufacturing	*-363*	—
-Consolidation of sites	*-72*	—
-Efficiency programmes	*-134*	—
-Other:		
-Provision for expected credit losses in Russia	*-106*	—
Items affecting comparability	**-675**	**—**
EBITA adjusted	**6,605**	**5,575**
EBITA margin adjusted	**35 %**	**36 %**

EBITDA

Definition: earnings before interest, taxes, depreciation, amortisation and impairment of intangible and tangible assets.

Reason to use: it is a relevant measure to present profitability aligned with industry standard.

SEK M	2022	2021
EBITA	5,930	5,575
Plus depreciation and impairment of tangible assets	301	165
EBITDA	**6,231**	**5,740**
Items affecting comparability		
-Restructuring costs:		
-Discontinuation of contract manufacturing	*-227*	—
-Consolidation of sites	*-60*	—
-Efficiency programmes	*-134*	—
-Other:		
-Provision for expected credit losses in Russia	*-106*	—
Items affecting comparability	**-527**	**—**
EBITDA adjusted	**6,758**	**5,740**

Earnings per share, adjusted

Definition: profit for the period adjusted divided by the average number of ordinary shares.

Reason to use: earnings per share adjusted is a good measure of the company's profitability and is used to determine the value of the company's outstanding shares

SEK M	2022	2021
Profit for the period	2,638	2,679
Items affecting comparability	-675	—
Tax on items affecting comparability		
-Restructuring costs:		
-Discontinuation of contract manufacturing	*75*	—
-Consolidation of sites	*6*	—
-Efficiency programmes	*28*	—
-Other:		
-Provision for expected credit losses in Russia	*22*	—
Tax on items affecting comparability	*130*	—
Items affecting comparability (net of tax)	-545	—
Profit for the period adjusted	**3,183**	**2,679**
Average number of ordinary shares (excluding shares in treasury)	295,604,246	295,051,119
Average number of ordinary shares after dilution (excluding shares in treasury)	298,448,376	296,799,459
EPS before dilution, SEK adjusted	**10.77**	**9.08**
EPS after dilution, SEK adjusted	**10.66**	**9.03**

Net debt

Definition: borrowings less Cash and cash equivalents.

Reason to use: net debt is relevant to present as it is useful to illustrate the indebtedness, financial flexibility and capital structure.

SEK M	2022	2021
Borrowings	8,768	10,545
Cash and cash equivalents	1,361	1,045
Net debt	**7,406**	**9,500**

Equity ratio

Definition: shareholders' equity as a proportion of total assets.

Reason to use: a measure for showing financial risk, expressing the percentage of total assets that is financed by the owners.

Equity per share

Definition: equity divided by the number of ordinary shares.

Reason to use: a measure of the amount of equity that exists per outstanding share and is used for measuring the share against the share price.

SEK M	2022	2021
Shareholders' equity	26,525	23,203
Total assets	52,496	48,661
Equity ratio	**51 %**	**48 %**
Number of ordinary shares	309,804,782	307,114,495
Number of ordinary shares after dilution	312,648,912	308,862,835
Equity per share, SEK	**85.6**	**75.6**
Equity per share after dilution, SEK	**84.8**	**75.1**

Capital employed
Total assets less non-interest-bearing liabilities.

Cash flow from operating activities per share
Cash flow from operating activities divided by the weighted average number of shares outstanding.

Cash flow per share
Changes in cash and cash equivalents divided by the weighted average number of shares outstanding.

Debt-to equity ratio
The proportion of shareholders' equity and debt used to finance the company's assets.

EPS adjusted, SEK
Profit for the period adjusted divided by the weighted average number of ordinary shares.

EPS after dilution adjusted, SEK
Profit for the period adjusted divided by the weighted average number of ordinary shares after dilution.

Equity per share
Equity divided by the weighted average number of ordinary shares.

Return on capital employed
Earnings before interest and taxes (EBIT) divided by capital employed.

Return on equity
Net income divided by shareholders' equity.

Return on total capital
Profit/loss after financial items plus financial income as a percentage of average total assets.

Definitions

Alprolix (eftrenonacog alfa)	A recombinant, extended half-life (EHL) clotting factor IX medicine for the treatment of haemophilia B.
Amyotrophic lateral sclerosis, ALS	A neurodegenerative disorder characterised by the progressive degeneration and eventual death of nerve cells (neurons) in the brain, brainstem and spinal cord.
Aspaveli/Empaveli (pegcetacoplan)	A medicine targeting complement component 3 (C3) designed to regulate excessive complement activation, which can lead to the onset and progression of many serious rare diseases.
Chronic liver disease, CLD	A liver disease becomes chronic when it has been present for more than 6-12 months without signs of resolution. Chronic liver disease can be inherited (genetic) or caused by a variety of factors such as viruses, auto-immunity, obesity and alcohol use.
Cold agglutinin disease, CAD	A rare autoimmune disorder characterised by the premature destruction of red blood cells (haemolysis). More specifically, CAD is a subtype of autoimmune haemolytic anaemia. The disease is termed "cold" because the disease is active and cause haemolysis at cold temperatures, usually 3 to 4^{0}C.
Diffuse large B-cell lymphoma, DLBCL	A form of non-Hodgkin lymphoma and the most common blood cancer. Lymphomas occur when cells of the immune system, known as B lymphocytes, grow and multiply uncontrollably. DLBCL occurs mostly in adults and is a fast-growing (aggressive) lymphoma.
Doptelet (avatrombopag)	A second-generation, small-molecule, thrombopoietin-receptor agonist used in the treatment of thrombocytopenia by increasing platelet count.
Efanesoctocog alfa	A new factor VIII medicine designed to extend protection from bleeds with once-weekly prophylactic dosing for the treatment of haemophilia A. It adds a region of von Willebrand factor and XTEN® polypeptides to extend its time in circulation and is the first new factor VIII medicine to break through the von Willebrand factor ceiling.
Elocta (efmoroctocog alfa)	A recombinant, EHL clotting factor VIII medicine for the treatment of haemophilia A. It is also known as Eloctate in some countries.
Full-time equivalents	A unit that indicates the workload of an employee in a way that makes it comparable.
Gamifant (emapalumab)	A monoclonal antibody medicine that binds to and neutralises interferon gamma for the treatment of ultra-rare syndromes of hyperinflammation.
Gout	A disorder of purine metabolism, occurring especially in men, characterised by a raised but variable blood uric acid level and severe recurrent acute arthritis of sudden onset resulting from deposition of crystals of sodium urate in connective tissues and articular cartilage.
Haemophilia	A genetic bleeding disorder caused by insufficient levels of blood proteins, including factor VIII (haemophilia A) and factor IX (haemophilia B). Clotting factors are essential for proper clotting, the process by which blood clumps together to plug the site of a wound to stop bleeding. Haemophilia A occurs in about one in 5,000 male births annually, and haemophilia B occurs in about one in 25,000 male births annually.
Immune-complex membranoproliferative glomerulonephritis, IC-MPGN and C3 glomerulopathy, C3G	Are complement-mediated renal diseases. Although IC-MPGN is considered a distinct disease from C3G, the underlying cause and progression of the two diseases are remarkably similar and include overactivation of the complement cascade, with excessive accumulation of C3 breakdown products in the kidney causing inflammation and damage to the organ.
Kineret (anakinra)	A recombinant protein medicine that blocks interleukin-1α and β by binding to interleukin-1 type 1 receptors. Interleukin-1 is a key mediator of inflammation and a significant contributor to autoinflammatory diseases, including several rare diseases.

Launch medicines	Include Doptelet (outside China), Aspaveli/Empaveli and Gamifant.
Nirsevimab	A single dose long-acting antibody, developed and commercialised in partnership by AstraZeneca and Sanofi. It is designed to protect infants entering or during their first RSV season and for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.
Orfadin (nitisinone)	A medicine used to treat hereditary tyrosinaemia type 1. It blocks the breakdown of tyrosine, thereby reducing the amount of toxic tyrosine by-products in the body. Patients must maintain a special diet in combination with Orfadin treatment as tyrosine is not adequately broken down. Orfadin can also be used for alkaptonuria.
Paroxysmal nocturnal haemoglobinuria, PNH	A rare disorder in which red blood cells break apart prematurely. It is an acquired haematopoietic stem cell disorder. Some haematopoietic stem cells in individuals with PNH are defective and consequently produce defective blood cells. These defective red blood cells of PNH are extremely susceptible to premature destruction by a particular part of a person's own immune system called the complement system.
Primary haemophagocytic lymphohistiocytosis, pHLH	A rare, life-threatening condition caused by an overactive, abnormal response of the immune system. In heamophagocytic lymphohistiocytosis, the immune system responds to a stimulus or 'trigger', often an infection, but the response is ineffective and abnormal. Some affected individuals may have a genetic predisposition to developing haemophagocytic lymphohistiocytosis. This is known as the primary or familial form.
Respiratory syncytial virus, RSV	A common virus and the most common cause of lower respiratory tract infections in young children. The RSV season usually occurs from early autumn until late spring and peaks during the winter.
SEL-212	A novel combination therapy and potential new medicine designed to sustain control of serum uric acid levels in people with chronic refractory gout. SEL-212 consists of pegadricase, co-administered with ImmTOR, designed to mitigate the formation of anti-drug antibodies.
Synagis (palivizumab)	An RSV F protein inhibitor monoclonal antibody immunisation indicated for the prevention of serious lower respiratory tract infection caused by RSV in infants and young children at high risk of RSV disease.
Tegsedi (inotersen)	A medicine for the treatment of polyneuropathy of hereditary transthyretin amyloidosis in adults.
Waylivra (volanesorsen)	A medicine for the treatment of genetically confirmed familial chylomicronaemia syndrome.
Zynlonta (loncastuximab tesirine)	A CD19-directed antibody-drug conjugate medicine. Once bound to a CD19-expressing cell, Zynlonta is internalised by the cell, where enzymes release a pyrrolobenzodiazepine payload which ultimately results in cell cycle arrest and tumour cell death in DLBCL.

Forward-looking statements

This report includes forward-looking statements. Actual results may differ from those stated. Internal factors such as the successful management of R&D programmes and intellectual property rights may affect future results. There are also external conditions such as the economic climate, political changes and competing R&D programmes that may affect Sobi's results.

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