Annual and Sustainability Report 2021

sobi
rare strength

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This is Sobi's Annual and Sustainability Report 2021. The audited Annual Report includes pages 32–91. The Sustainability Report is on pages 23–27 and 104–127 and consists of the Company and the Group's legally required sustainability report according to the Annual Accounts Act. The report is also Sobi's Communication on Progress (COP) to the UN Global Compact.

Sobi is an international biopharmaceutical company specialising in rare diseases.

We bring something rare to rare diseases – a rare expertise and a strength in access that allows us to be a partner in care for those otherwise overlooked.

This is Sobi

Specialising in rare diseases, we develop and provide access to innovative medicines in the areas of haematology, immunology and specialty care.

15,529
Total revenue, SEK million

5,575
EBITA, SEK million

1,559
Number of employees[1]

- Two therapeutic areas – Haematology and Immunology – and medicines within Specialty Care
- Strong portfolio of on-market medicines and pre-market pipeline
- Our factor replacement treatments Elocta® and Alprolix® are the most prescribed extended half-life treatments for haemophilia A and B respectively in several markets
- We focus on where we can have the greatest impact: on in-licensing, clinical development, commercialisation and patient access
- We continue our expansion into new regions, bringing our medicines to more patients in previously underserved markets
- Global Head Office in Stockholm, Sweden, with own presence in over 30 countries, delivering treatments to patients in more than 70 countries
- The Sobi share (STO:SOBI) is listed in the Large Cap segment of Nasdaq Stockholm

1. Employee numbers are expressed as full-time equivalents (FTE).

Strong pre-market pipeline and strong portfolio of on-market medicines

Haematology
Dealing with diseases of the blood and blood marrow

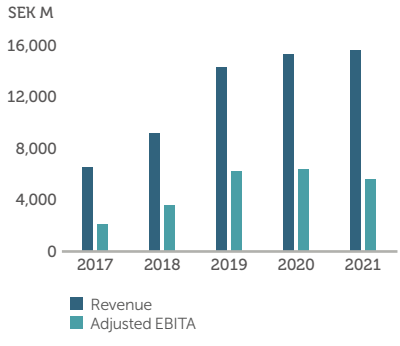
Immunology
Addressing problems affecting or stemming from the immune system

	Haematology	Immunology
Pre-market	Efanesoctocog alfa/BIVV001[1] – haemophilia A Pegcetacoplan[2] – multiple indications	Gamifant®/emapalumab – secondary HLH Nirsevimab[3] – RSV Pegcetacoplan – multiple indications SEL-212[4] – chronic refractory gout
On-market	Elocta® – haemophilia A Alprolix® – haemophilia B Aspaveli®/Empaveli – paroxysmal nocturnal haemoglobinuria Doptelet® – ITP, CLD	Gamifant – primary HLH Kineret® – multiple indications Synagis® – RSV Jyseleca® – multiple indications
Specialty Care (on-market)	Tegsedi® – hATTR amyloidosis polyneuropathy Waylivra® – familial chylomicronemia syndrome (FCS) Orfadin® – hereditary tyrosinaemia type 1 (HT-1) and alkaptonuria (AKU)	

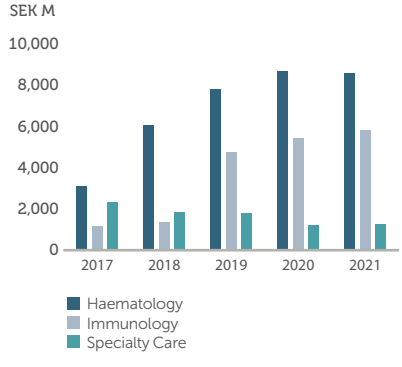
1. Developed and, if approved, will be commercialised in collaboration with Sanofi. 2. In collaboration with Apellis.
3. Financial interest only, in collaboration with AstraZeneca. 4. Strategic licensing agreement with Selecta.

Solid revenue growth in both therapeutic areas

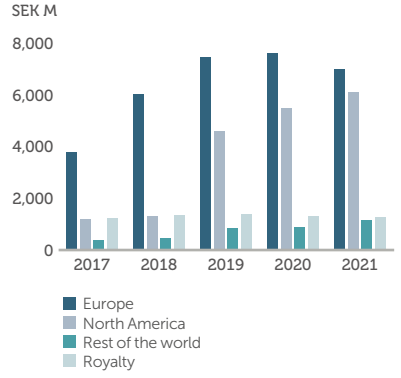
Revenue and adjusted EBITA



Revenue per business area



Revenue per geographic region



Year in brief

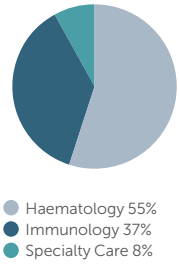
As much of the world began to emerge from the shadow of the COVID-19 pandemic, Sobi returned to solid growth during 2021. Geographical expansion took our medicines to new parts of the world, and new treatments were approved and launched.

7%
Revenue growth at CER

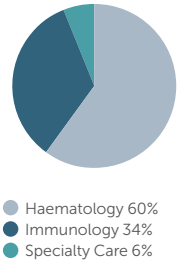
36%
EBITA margin

Significant progress in all strategy areas

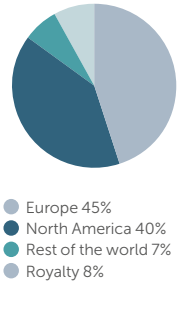
Revenue per business area



EBITA by business area



Revenue per geographic region



Key figures

SEK M	2017	2018	2019	2020	2021
Total revenue	6,511	9,139	14,248	15,261	15,529
Gross profit	4,657	6,723	10,913	12,036	12,045
Gross margin[1], %	72	74	77	79	78
Operating expenses	3,057	3,601	6,430	7,575	8,288
EBITA[1]	2,053	3,571	5,933	6,700	5,575
Adjusted EBITA[1,2]	2,053	3,571	6,145	6,301	5,575
EBIT	1,600	3,122	4,533	4,818	3,733
Profit for the year	1,149	2,148	3,304	3,245	2,679
Earnings per share, before dilution, SEK	4.27	8.97	11.29	11.01	9.08
Earnings per share, before dilution, SEK adjusted[1,2,3]	4.27	8.97	11.89	9.66	9.08
Cash flow from operations[4]	1,333	2,090	3,634	4,926	5,470
Equity per share[1,2,3] SEK	24.6	33.1	56.4	66.5	75.6
Equity/assets ratio[1], %	61	53	37	42	48
No. of employees (full-time equivalents)	800	902	1,335	1,509	1,559

1. Alternative Performance Measures (APMs). See Definitions p 130.
2. 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.
3. 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.
4. During 2021, Sobi has reclassified hedging arrangements for financing from cash flow from operating activities to cash flow from financing activities. Comparative figures for 2020 have been recalculated, see Note 2 for more information.

Business strategy

Continued patient growth in haemophilia A and B. Recovering activity levels and a successful awareness campaign encouraged patients to return to higher factor levels after a reduction during the COVID-19 pandemic.
Read more, p 12

Successful Doptelet launches in Germany, the UK & Ireland, and Iberia are providing people living with ITP and CLD with a new treatment alternative without dietary restrictions. Sales of Doptelet in Europe, North America and the International region have increased by 104 per cent at CER over the past year.
Read more, p 12

Kineret was approved in the EU for treatment of COVID-19 in adult patients with pneumonia who are at risk of developing severe respiratory failure.
Read more, p 15

Aspaveli/Empaveli (pegcetacoplan) has now been approved in the United States, the European Union and Saudi Arabia for the treatment of patients with paroxysmal nocturnal haemoglobinuria, and is under review in other markets. A targeted C3 therapy, pegcetacoplan is also being developed by Apellis and Sobi for several other indications.
Read more, p 13

Geographic expansion. Filings and approvals in Russia, filings in China and Japan, filing and approvals in Australia. Agreement with Pint Pharma providing access to Sobi medicines in up to seven countries in Latin America, including Brazil.
Read more, p 14, p 18–19

Sobi continued its support for the WFH (World Federation of Hemophilia) Humanitarian Aid Program, where we together with Sanofi are Founding Visionary Contributors. During 2021, the programme marked the milestone of 1 billion international units of replacement factor distributed.
Read more, p 24

LETTER FROM THE CEO

Building for growth

When we look back, we will see the current period as a time when we built the foundation for Sobi's future growth.

Our four strategy pillars – Lead in Haematology, Grow in Immunology and Specialty Care, Go global, and Capture the value of our pipeline – remain central to our business. We also see opportunities to bring in new medicines within Specialty Care that can add value to our portfolio and address unmet medical need.

We are increasing our emphasis on in-licensing and acquisitions, which have long been part of our success. This commitment to collaboration has allowed us to bring our ground-breaking extended half-life (EHL) factor replacement therapies for haemophilia to thousands of people around the world, protect vulnerable babies from RSV, and save and transform the lives of people with immunological, haematological, genetic and metabolic diseases.

I am proud that we are known as an honest and trustworthy partner, in bringing medicines to more patients, in collaboration with our suppliers and distributors, and in our dealings with healthcare professionals, patient organisations and other stakeholders.

As we build for growth, we will be selective regarding where we invest, committing to prioritised areas that enable long-term growth.

Solid financial performance

As many of Sobi's markets began to emerge cautiously from the COVID-19 pandemic, we saw clear signs of a recovery in sales. We delivered a strong year, with revenue once again showing sustainable growth. Revenue for the year reached SEK 15 529 million, with growth of 7 per cent at CER. Our launch medicines Doptelet and Gamifant grew by a combined 75 per cent for the year. EBITA for 2021 reached SEK 5 575 million, with an EBITA margin of 36 per cent.

Haematology

We were able during 2021 to make Doptelet (avatrombopag) available for people in the EU and the UK living with immune thrombocytopenia (ITP) and chronic liver disease (CLD), as well as expanding access in the United States and other global markets. In December, we received approval for Aspaveli/Empaveli in the EU – the only targeted C3 inhibitor on the market – as a new treatment option for people living with PNH who continue to experience anaemia after three months of treatment with a C5 therapy, and in Saudi Arabia for adults with PNH. For many people with PNH, anaemia and related fatigue can have a serious effect on their lives despite C5 therapy, and I am proud we can now offer a new treatment option.

Haemophilia

Elocta and Alprolix, our EHL factor replacement therapies, continue to liberate life for more people with haemophilia A and B respectively, and we saw patient growth in several markets over the year. We remain committed to factor replacement as an fundamental treatment option for people living with haemophilia, as shown in https://link.springer.com/article/10.1007/s40265-021-01615-w. We see further growth for both medicines, and are optimistic that efanesoctocog alfa has the potential to be a transformative treatment for people with haemophilia A.

Immunology

I am particularly proud of December's approval in the EU of Kineret (anakinra) as a treatment for adult patients with COVID-19-related pneumonia who are at risk of developing severe respiratory failure. COVID-19 is the medical challenge of this generation, and I am pleased that we have been able to make such a significant contribution to saving lives. We continue to work to make Kineret available for COVID-19 in other countries. Kineret is a central part of our Immunology portfolio and is a transformative medicine for many thousands of people living with autoimmune diseases.

Gamifant (emapalumab) continues to be a life-saving treatment for haemophagocytic lymphohistiocytosis (HLH) in the US and other countries. In China, Gamifant was approved in March 2022 for primary HLH. We see Gamifant as having utility in a broader HLH context and continue to pursue an extended label in the US.

Synagis continues to play a vital role in protecting vulnerable children from serious respiratory illness stemming from RSV, and Synagis sales increased slightly in 2021.

I am pleased that we were able to sign an agreement with Galapagos NV to commercialise Jyseleca® (filgotinib), an oral JAK1 preferential inhibitor, in Central and Eastern Europe, Greece, Portugal and the Baltics. Jyseleca is approved for the treatment of rheumatoid arthritis (RA) and ulcerative colitis in the EU and UK, and for RA in Japan. A phase 3 study is currently ongoing to investigate Jyseleca for Crohn's disease. I see Jyseleca as an exciting addition to our Immunology portfolio.

Geographical expansion

We continued to expand our geographical footprint in 2021 and are now present in Australia and represented in large parts of Latin America.

Through a new distribution agreement with Pint Pharma, we are now able to provide treatment to people living with rare diseases in Latin America: Argentina, Brazil, Chile, Colombia, Ecuador, Mexico and Peru.

We have also seen favourable early progress of our presence in Japan, China and Australia. In China, partnerships will be important for us to expand our reach, while an increased presence in Japan is paving the way for us to gain approvals. In Australia, we brought Orfadin and Kineret back under Sobi's stewardship, while approval of Aspaveli early this year as a treatment for PNH provides an important new treatment option for patients currently on C5 therapy.

Future-ready pipeline

I see our development pipeline as the engine driving our growth, by taking newly licensed or acquired projects through clinical development to the patient, by taking existing medicines into new indications and new markets, and by providing the expertise we need to assess acquisition and in-licensing targets.

Gaining approval for Aspaveli as a treatment for PNH in Europe was a major achievement, as was the extension of the Kineret label in the EU to COVID-19 in patients at risk of developing severe respiratory failure.

We are adapting our competences in this area to be an optimal resource for the demands of the future.

Sustainability

Sustainability is a natural part of our overall company mission and strategy, and we continue to work in the two prioritised areas where we can make a difference: commitment to patients and acting responsibly.

During 2021, we saw evidence of our improved performance in several external rankings. We continue to be committed to the UN Global Compact principles and the UN Sustainable Development Goals, and we are steadfast in our support for the WFH (World Federation of Hemophilia) Humanitarian Aid Program, together with Sanofi. Since the initial pledge, over 18,880 people with haemophilia have been treated with factor products donated through our collaboration.

We have also strengthened and formalised our sustainability governance internally and towards our supplier partners. This will help us accelerate our sustainability efforts even further and prepare for a coming formal commitment to science-based targets and the European Green Deal. I am fully committed to continuing to support our efforts and ensure continued progress.

Post-pandemic future

As we and the world begin to adapt to a post-pandemic future, we continue to support our teams all around the world to make this an even better place to work. Sobi is comprised of great people doing great things. I want to thank the entire Sobi team for their efforts during 2021. We as a company can be justifiably proud of what we do.

Guido Oelkers
Chief Executive Officer

Rare diseases

More than 6,000[1] identified rare diseases are estimated to affect 300 million people around the world.

High unmet medical need
Up to 70 per cent of identified rare diseases have a paediatric onset and many can have a devastating effect on life expectancy and quality of life. The severe nature of many rare diseases often leads to a great burden for patients and their families, and for healthcare systems.

Rare challenges
Those living with rare diseases face specific challenges, including that of obtaining a correct diagnosis. Many physicians may never have seen a specific rare condition before and symptoms may not be assessed correctly, which is why cases can go undiagnosed for years. This is often a time of uncertainty, frustration and worry, of being sent from one specialist to another in search of an answer.

Another challenge is the search for information and a community. Isolation, both physical and mental, is a major issue for people living with rare diseases and contributes both to stress and disease burden. The effects of the COVID-19 pandemic intensified the problems of isolation and difficulty in accessing treatment for many during 2020 and 2021[2].

Much focus has been placed on the high costs of treating rare diseases. However, leaving conditions untreated can lead to higher costs for patients, health systems, social services and governments. Without appropriate treatment and care, rare disease patients and carers are unable to achieve their full potential in society.

A lack of established clinical endpoints and expert knowledge about many conditions, as well as unclear comparator treatments, also make orphan drug development and approval challenging. This uncertainty means there is a high level of risk associated with the development of orphan drugs or medicines, and many projects fail, even in late-stage development.

Incentives for investment
The term "orphan drugs" describes medicines designed to treat diseases so rare that companies would be reluctant to develop them under normal market conditions.

To address the unique set of challenges, regulatory bodies such as the US Food & Drug Administration (FDA) and the European Medicines Agency (EMA) have developed incentives such as special programmes and regulations to encourage pharmaceutical companies to develop treatments for rare diseases.

Since the European Commission published its roadmap on the revision of the orphan and paediatric legislation in

Worldwide orphan drug market growth

High unmet need: More than 6,000 rare diseases globally – around 95 per cent have no approved treatment.

Great need outside EU and US: Of the 300 million people affected by rare diseases around the world, around 250 million are thought to be outside the US and EU[3, 4].

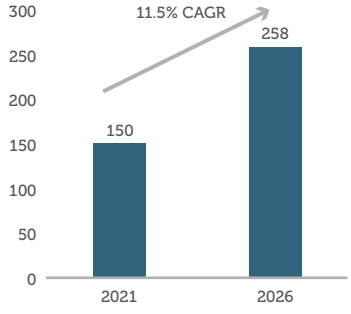
Attractive opportunity: Pricing reflects the investment needed and allows a return on capital to enable further investment in research and development of treatments.

Shorter time to market: Multiple ways to speed up R&D projects (including orphan drug designation, breakthrough therapy designation/PRIME designation, priority review by FDA and EMA, conditional approvals in case of unmet medical needs).

Limited competition: Few companies active in orphan indications – translating to sustainable market share advantage for early entrants.

Limited generic threat: Orphan drugs are less likely to face generic competition because of their often-biological nature and are less attractive targets for biosimilars because of the small patient population.

Global orphan drug market, USD Bn



Source: EvaluatePharma® Market Explorer February 2022 (including oncology)

1. https://www.nature.com/articles/s41431-019-0508-0. Excluding malignancies
2. Research and Management of Rare Diseases in the COVID-19 Pandemic Era: Challenges and Countermeasures (nih.gov)
3. https://rarediseases.info.nih.gov/diseases/pages/31/faqs-about-rare-diseases
4. https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/rare-diseases_en#:~:text=EU%20research%20on%20rare%20diseases,million%20people%20in%20the%20EU.

What is a rare disease?

In Europe, a rare disease is defined as one affecting fewer than one person per 2,000[1]. In the US, the Orphan Drug Act of 1983 defines a rare disease as a condition affecting fewer than 200,000 people in the country.

November 2020, Sobi together with European and national pharmaceutical trade associations have been engaging with different stakeholders from the European Commission, European Parliament, payers, patient advocacy groups and healthcare professionals to find common policy solutions for the issues outlined in the report.

Sobi has called on European policymakers to consider supporting an environment which fosters rare disease innovation in Europe, with the message that to address the remaining 95 per cent of rare diseases with no approved treatment, policymakers need to create a broad regulatory framework that attracts developers in these under-served areas[2].

Furthermore, Sobi believes that without appropriate incentives, or if current incentives are reduced, there is a risk of decreased investment in R&D into rare disease therapies, which could ultimately leave many patients without a treatment.

Growing market

In 2021, the size of the orphan drugs market was USD 150 billion (including oncology) and is projected to reach USD 258 billion by 2026, a 72 per cent increase over the next five years. This is double the growth forecast for the non-orphan market[3].

Many people living with a rare disease live in countries outside Sobi's existing markets. Expanding our geographical presence allows more people to access our medicines and takes Sobi into new markets with major growth potential.

Raising rare voices

Sobi has important, long-standing relationships with the rare disease community including top-level regional organisations such as EURORDIS (Rare Diseases Europe) and NORD (the US National Organization for Rare Diseases). Sobi's participation in the EURORDIS European Round Table of Companies, financial support for EURORDIS, the Black Pearl Awards, ECRD (European Conference on Rare Diseases) and further contributions towards NORD and EURORDIS events are helping to elevate the voice of the rare disease community.

1. https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/rare-diseases_en
2. OMP-Position-Paper_final.pdf (eucope.org)
3. EvaluatePharma® Market Explorer February 2022

Business model

Sobi's business model spans from clinical research to patient access and commercialisation.

An integrated, patient-centric model
Across the entire value chain, Sobi works in close dialogue with stakeholders such as patient organisations, healthcare systems, government authorities, regulatory bodies, payers and business partners in developing treatments that transform the lives of people living with rare diseases. Our strengths include evaluating and developing clinical projects, commercialisation and bringing treatments to patients as quickly as possible.

Partnership and cooperation
Partnership has long been a part of Sobi's success, in areas as varied as licensing of medicines and acquisition of projects to contract research and contract manufacturing. We see partnership as essential in our efforts to build and expand our clinical pipeline into new indications and areas within haematology and immunology, and in expanding into new geographical markets.

Patient access and commercialisation
Cross-functional teams bring together our many disciplines. By bringing in patient access specialists as early as possible into due diligence and development projects, approval applications and pricing negotiations, we are ensuring speedy access to life-changing and life-saving medicines for patients.

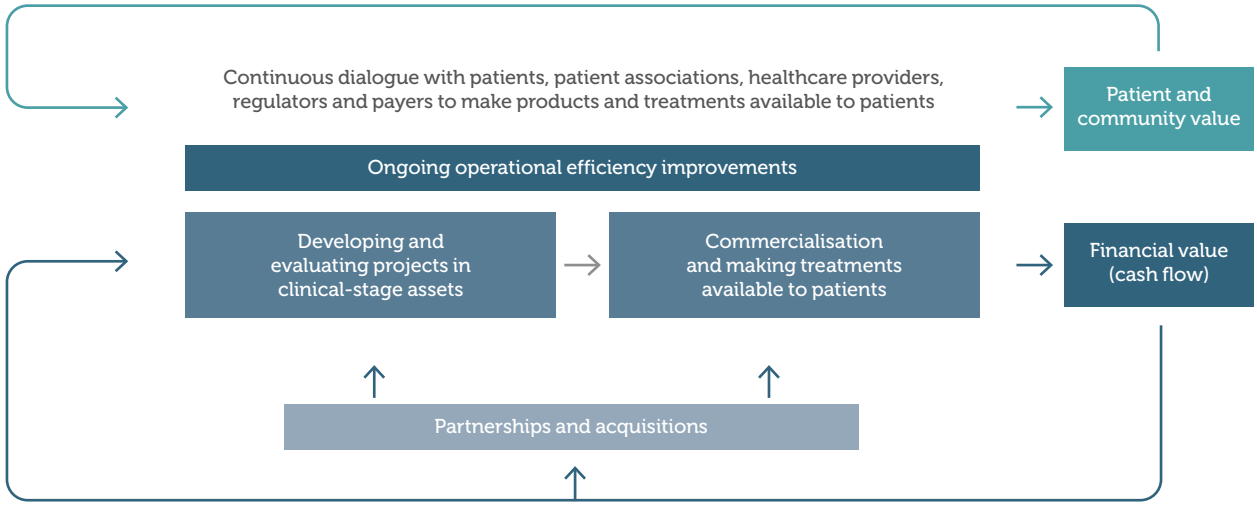
Our commercial, medical, patient access and R&D teams work with healthcare professionals, external researchers, patient organisations and other stakeholders to increase understanding of patients' and healthcare professionals' changing needs. This provides insight into needs that we continuously feed back into the system to improve our treatments and systems.

Ensuring that patients never risk going without their medicine is of the utmost importance. That is why we have built up robust processes and systems for delivery and distribution in all our markets.

Understanding the landscape, using patient insights and generating robust evidence enable development of appropriate access strategies and responsible pricing. This is vital in ensuring fast and sustainable access to treatment. It requires us to balance the roles of a sustainable company with being a sustainable part of a healthcare system. Through continuous dialogue with rare-disease stakeholders, we continue to provide treatments to patients efficiently and responsibly.

In all price-setting and subsequent negotiations, we consider the following basic principles: unmet medical need, the benefits the innovation brings to patients, benefits for the healthcare system, sustainability and affordability of access, and the cost required to continue innovation and meet future medical needs.

Sobi's business model



Strategy

Sobi's strategy remains firm.

Vision
Our vision is to be recognised as a global leader in providing innovative treatments that transform life for people living with rare diseases.

Mission
Our mission is to develop and deliver innovative therapies and services to improve the lives of people living with rare diseases.

Growth and strength
We will continue to be a leader in haematology. In haemophilia, we continue to expand access to our extended half-life factor replacement therapies Elocta and Alprolix, reaching more people with haemophilia A and B in more countries. We see efanesoctocog alfa, formerly known as BIVV001, as a future growth driver, with the potential to change the treatment paradigm for haemophilia A.

In haematology outside of haemophilia, we are expanding access to Doptelet, taking it to more countries in both indications, ITP and CLD. And with the approval of Aspaveli/Empaveli (pegcetacoplan) in the EU and Saudi Arabia for the treatment of PNH, we continue to expand our scope in haematology.

We will continue to grow in Immunology and Specialty Care. Work will continue to maximise the value of our existing medicines – for Kineret and Gamifant in new markets and new indications – and we will continue to look for licensing and acquisition opportunities. Further development of pegcetacoplan in indications within neurology and nephrology will continue. In Speciality Care, we are continuously looking for new in-licensing opportunities to complement our portfolio, in areas that match both our geographic footprint and our expertise, and where we can address unmet medical need.

Geographically, our expansion continues. We expanded further during 2021, reaching a distribution agreement that will initially expand access to Brazil, Colombia and Argentina. The contract with Pint Pharma also covers Chile, Ecuador, Mexico and Peru. This is our first official step into the region and marks another stage in our journey towards becoming a global company. Latin America follows our expansion into the Asia-Pacific in 2020, with offices established in China, Japan and Australia, and a presence in Russia. We are now examining other potential markets in Central and South America, as well as in South-East Asia.

We continue to capture the value of our development pipeline by concentrating on mid and late-stage opportunities that address unmet medical needs and have significant market potential. With around 10 programmes focused on five medicines, we expect to see more than 60 launches in key geographies over the coming years.

Sustainable access
Our sustainability strategy is closely linked to the business and based on two main priorities – our Commitment to Patients and our Responsible Behaviour.

By expanding our geographical reach, investing in the development of novel medicines and deepening our engagement in the areas of haematology and immunology, we can improve access to rare disease treatments for patients worldwide.

We see responsible behaviour as non-negotiable and expect the highest ethical standards from our employees and partners.

Success in our operations will positively impact the communities we serve.

Haematology

In Haematology, we continued to build on the success of our market-leading haemophilia medicines Elocta and Alprolix, expand access to Doptelet for ITP and CLD, and are bringing a new targeted C3 therapy, Aspaveli/Empaveli to the market for the treatment of paroxysmal nocturnal haemoglobinuria (PNH).

8,536
Sales in SEK M

55%
of total revenue

3%
Growth at CER

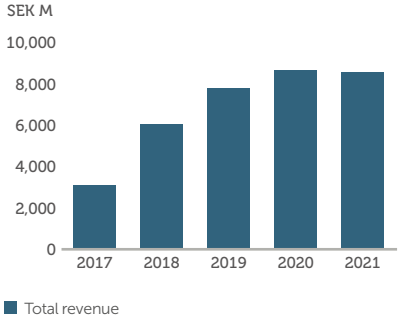
Elocta/Eloctate and Alprolix[1]
Elocta/Eloctate[2] and Alprolix, our extended half-life factor replacement medicines for haemophilia A and B, continued to show growth, notwithstanding competitive challenges in most of the markets, and a recovery from lower levels during the peak of the COVID-19 pandemic.

As pandemic restrictions ease and patients return to normal activities, they are also resuming their usual, optimised therapy and their contacts with healthcare providers. Clinical management of people with haemophilia is also returning to pre-pandemic levels. This includes elective surgical procedures for these patients, and the associated need for treatment optimisation.

As part of the Take Control campaign during 2021, Sobi worked with the haemophilia community, HCPs and patients to emphasise the importance of physical activity for sustaining joint health and helping prevent pain. The campaign included a series of educational and supportive activities in almost all markets, assisting people with haemophilia and their treaters to have valuable conversations around how to manage the return to normality. This contributed to a return to optimal factor consumption levels for patients, with individualised treatment empowering their active lives.

Doptelet
Doptelet (avatrombopag) was approved in the EU in January 2021 for the treatment of primary chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments. It had previously been approved for ITP in the United States, and in the US and EU for the treatment of thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo an invasive procedure.

Total revenue, Haematology



Revenue per product, Haematology

SEK M	2020	2021	Change at CER
Elocta	4,585	3,960	–11%
Alprolix	1,705	1,764	7%
Royalty[1]	1,301	1,251	3%
Doptelet	587	1,116	>100%
Aspaveli/Empaveli	–	1	n/a
Manufacturing[2]	481	445	–8%
Total	8,660	8,536	3%

1. Sanofi's sales of Eloctate and Alprolix.
2. Manufacturing of the drug substance for ReFacto AF®/Xyntha® for Pfizer.

1. Sobi and Sanofi collaborate on the development and commercialisation of Alprolix and Elocta/Eloctate
2. Marketed by Sobi as Eloctate in Russia

Doptelet was launched successfully in Germany, the first European market for both ITP and CLD, and has had good starts in CLD in Ireland, the Nordic countries, Netherlands and Belgium. All countries that have launched in ITP report good uptake and positive feedback from physicians. Targeting and segmentation adjustments are counteracting a slow start in the UK, Spain and Italy. Failure to reach agreement on reimbursement in France for either indication was a setback.

In CLD, a global omnichannel marketing project was launched in early 2022. As a non-orphan indication, CLD requires a different approach from most of Sobi's indications.

Aspaveli/Empaveli

With the approval of Aspaveli (pegcetacoplan) in the EU in December 2021, people living with PNH who are still anaemic after treatment with C5 inhibitors gained access to a new treatment. The medicine was previously approved in the US under the brand name Empaveli in May 2021, and is marketed in the United States by Sobi's collaboration partner Apellis. It was also approved in Saudi Arabia, under the name Empaveli, for adults with PNH in December.

PNH is a rare, chronic, life-threatening blood disorder caused by an acquired mutation, which leads to uncontrolled activation of the complement cascade within the immune system, and the destruction of red blood cells through intravascular haemolysis and extravascular haemolysis. People with PNH experience anaemia, blood clots and reduced bone marrow function in which the marrow cannot produce enough blood cells. It affects 0.5-1.5 people per million, and people with PNH are usually diagnosed during their 30s.[3]

Current treatments include medicines such as C5 inhibitors that suppress the immune system and help to slow the breakdown of red blood cells. In addition, blood transfusions may be needed. However, despite improvements during treatment with C5 inhibitors, up to 85 per cent of people living with PNH continue to experience anaemia, and have persistently low haemoglobin and fatigue[4]; as many as 36 per cent require one or more blood transfusions. The only cure currently available is a bone-marrow transfusion, but this is associated with high levels of morbidity and mortality.[5]

Aspaveli is the only targeted C3 therapy available. In the Pegasus phase 3 study, published in the New England Journal of Medicine in March 2021[6], pegcetacoplan demonstrated superiority to the C5 inhibitor eculizumab with a statistically significant improvement in haemoglobin levels and improvements in key clinical outcomes – such as reduced fatigue and less need for transfusions – in adults with PNH who had persistent anaemia at 16 weeks following treatment with eculizumab.

Aspaveli is expected to be launched first in Germany in early 2022, followed by the UK and other countries.

To support upcoming launches in the EU and Middle East, Sobi can draw on the experience of Apellis' presence in the US, including positive insights from treaters and patients.

Aspaveli is the only treatment in the EU to be granted orphan drug designation for PNH from the Committee for Orphan Medicinal Products (COMP), which found that it demonstrated "statistically significant and clinically meaningful increase in haemoglobin levels and reduced the need for transfusions as compared to the currently authorised products".

3. https://rarediseases.org/rare-diseases/paroxysmal-nocturnal-hemoglobinuria
4. Risitano AM, Peffault de Latour R. How we('ll) treat paroxysmal nocturnal haemoglobinuria: diving into the future. Br J Haematol. 2021 Aug 5. doi: 10.1111/bjh.17753
5. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2878778/
6. https://www.sobi.com/en/press-releases/nejm-publishes-phase-3-pegasus-study-results-comparing-pegcetacoplan-eculizumab-pnh

Efanesoctocog alfa
Together with Sanofi, we continue to see progress in the clinical study programme for efanesoctocog alfa (BIVV001), a potential future treatment for haemophilia A, with topline phase 3 results released in March 2022. Read more in R&D, page 20.

Growth
The confidence of the haemophilia community in the benefits of Elocta and Alprolix helped preserve the leading positions of these medicines. Growth was largely attributable to patients upgrading from other treatments, particularly from standard half-life factor, leading to a significant increase in volumes in most markets, including Spain, Italy, Germany and the Nordic countries, reaching double digits in some countries.

This positive volume development was however partially offset by price decreases in some markets, particularly Germany. Sobi's willingness to adjust prices illustrates our commitment to secure the broadest access to Elocta and Alprolix.

We are also seeing expanded access outside Europe. Patient support programmes were rolled out in the Middle East, and expansion into new markets is allowing more people with haemophilia to access our medicines. After the launch in Russia, new launches in other countries including Turkey, Algeria and Israel are scheduled for 2022.

Commitment to factor replacement
At Sobi we remain fully committed to factor replacement as an irreplaceable, biologically meaningful and safe treatment option to secure elevation of protection. This conviction is supported by a recently published review[1] which reite-rated the role of factor VIII as the mainstay of haemophilia A treatment, with factor VIII prophylaxis as the standard of care for severe disease.

We see further growth potential for both Elocta and Alprolix, and remain committed to making them available to more people who can benefit from their advantages. For the same reason, we are dedicated to the development of efanesoctocog alfa as a potential transformative treatment for people with haemophilia A.

World Federation of Hemophilia Humanitarian Aid Program
Together with Sanofi, we continue our commitment to the WFH (World Federation of Hemophilia) Humanitarian Aid Program. Our commitment to the Program and to the benefits of replacement factor underline our determination to provide the broadest possible access to the advantages of factor replacement therapy.

Florio®

Sobi's subsidiary Florio develops next-generation digital solutions for patients and healthcare professionals that capture and visualise disease and treatment-related data in real time to enable better decision making and ultimately better care.
Florio HAEMO, a product for people with haemophilia, their caregivers and healthcare professionals, is available in 24 countries across Europe and the Middle East. In 2021 Florio launched florio ITP, a digital diary for patients with ITP in the US in partnership with PDSA (Platelet Disorder Support Association).
Florio continues to develop the app in co-creation with doctors and patients in line with Sobi's development portfolio.

1. https://link.springer.com/article/10.1007/s40265-021-01615-w

Immunology

2021 was a year of strong performance in Immunology, with our medicines reaching more patients than ever before.

5,780
Sales in SEK M

37%
of total revenue

15%
Growth at CER

All three on-market medicines – Kineret, Gamifant and Synagis – expanded to provide benefits to more patients and demonstrated strong growth, the result of solid underlying performance in existing markets and expansion to new territories.

The foundation for future growth has been strengthened with several ongoing clinical development programmes for Kineret, Gamifant and SEL-212 (read more in R&D), and with a new licensing agreement for commercialisation of JAK1 preferential inhibitor Jyseleca (filgotinib) in selected European markets.

Sobi's Immunology portfolio covers a spectrum of diseases in both children and adults, from respiratory tract infections to debilitating autoinflammatory diseases and hyperinflammation. The company remains committed to strengthening the portfolio by investing in the continued development of existing treatments and by adding strategic partnerships and acquisitions.

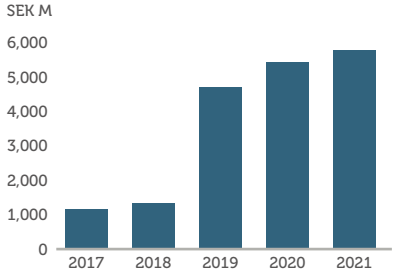
Kineret

Kineret (anakinra) is an interleukin-1 α/β receptor antagonist marketed in different countries for several autoinflammatory diseases, including CAPS (cryopyrin-associated periodic syndrome), RA (rheumatoid arthritis), FMF (familial Mediterranean fever), DIRA (deficiency of interleukin-1 receptor antagonist) and Still's disease, including systemic juvenile idiopathic arthritis (sJIA) and adult-onset Still's disease (AOSD)[1].

It was also approved in the EU in December 2021 for the treatment of COVID-19 related pneumonia in adult patients at risk of developing severe respiratory failure. An application for emergency use in COVID-19 in the US is planned for submission to the FDA in 2022.

The EU approval came after results from the landmark SAVE-MORE phase 3 study were published in the journal Nature Medicine[2]. The study showed that early treatment with Kineret had considerable efficacy and reduced the risk of disease progression and death by 64 per cent. Kineret's potential as a COVID-19 treatment was also acknowledged by the European Commission, which listed Kineret as one of the ten most promising pharmaceuticals for tackling COVID-19[3]. In the US, Sobi anticipates making a regulatory

Total revenue, Immunology



Revenue per product, Immunology

SEK M	2020	2021	Change at CER
Kineret	2,079	2,290	16%
Synagis	2,726	2,650	6%
Gamifant	609	840	48%
Total	**5,415**	**5,780**	**15%**

1. Note that the approved indications may vary by country.
2. Nature Medicine publishes phase 3 anakinra study results in patients with COVID-19 pneumonia | Sobi
3. https://ec.europa.eu/commission/presscorner/detail/en/ip_21_5366

submission for emergency use authorisation in COVID-19 with agency validation expected during the first half of 2022.

We see Kineret as an important, life-saving addition to the treatment armoury against COVID-19 and are proud to contribute to the global efforts to reduce the impact of the pandemic.

2021 was yet another year of double-digit sales growth for Kineret. Growth of 16 per cent was driven by strong underlying growth in all regions, with the largest share stemming from COVID-19-related sales in Russia, Romania and Turkey. Other contributing factors were several market approvals, as well as FDA approval in the DIRA indication in December 2020. For more on Russia, see the Directors' Report, p38.

The strong interest in Kineret from the scientific and medical community, seen in several ongoing investigator-sponsored studies, indicates potential utility in a broad spectrum of diseases. We expect Kineret to continue to make a significant contribution to the Immunology disease area.

Gamifant

Gamifant (emapalumab) is an interferon gamma (IFNγ) blocking monoclonal antibody used for treating primary haemophagocytic lymphohistiocytosis (HLH), a rare genetic disease characterised by life-threatening inflammatory symptoms.

Since Gamifant's launch in the US in 2018, our US team has continued to drive strong growth, helping to treat hundreds of patients. More institutions have begun to use Gamifant, and existing ones are expanding its use.

Global access to Gamifant also made progress in 2021 with approval in the United Arab Emirates for the treatment of primary HLH, which will significantly expand the number of patients who are able to access this medicine.

In 2021, global sales rose by 48 per cent at CER to SEK 840 million.

Beyond primary HLH, we believe Gamifant has expansive potential given its targeted mechanism of action and ability to help control hyperinflammation in patients with clinically relevant overexpression of IFNγ. We continue to pursue Gamifant's potential utility across HLH and other disease states. A form of secondary HLH, driven by rheumatologic diseases, is the next planned indication for Gamifant. Read more in R&D, page 20.

Synagis

Respiratory syncytial virus (RSV) is a common and highly contagious seasonal virus contracted by nearly all babies by the age of two. In most cases, RSV causes only a mild respiratory infection, but can be much more serious for some, especially babies considered high risk. RSV is the leading cause of hospital admission in infants aged less than one year in the United States.

Synagis (palivizumab) is the only approved medicine for the prevention of serious lower respiratory tract infections caused by RSV in high-risk infants, and significantly reduces the risk of RSV hospitalisation. Sobi has the US rights to Synagis.

RSV is a seasonal virus which has a major effect on sales, with the vast majority occurring during RSV season. With COVID-19 measures such as social distancing and reduced travel reducing the severity of the 2020-21 RSV season, Synagis sales were lower than usual in the first half of 2021. Extensive public awareness and educational activities, combined with an early start to the RSV season in Q3 2021, led to strong growth in Synagis sales in Q3 and Q4 compared with the same period of the previous year.

Jyseleca

In 2021, Sobi entered an agreement with Galapagos NV to commercialise Jyseleca in Central and Eastern Europe, Greece, Portugal and the Baltics. Jyseleca is a novel, oral once-a-day JAK1 preferential inhibitor approved by the European Commission for the treatment of rheumatoid arthritis and ulcerative colitis, and with a global phase 3 programme ongoing in Crohn's disease. We expect first sales from 2022, following local pricing and reimbursement approvals.

The introduction of Jyseleca into Sobi's portfolio strengthens the company's offering in Immunology while also allowing us to harness synergies from our existing contacts with customers and clinics.

Specialty Care

As well as Orfadin – a treatment for HT-1 and alkaptonuria – the Specialty Care portfolio now includes Tegsedi and Waylivra, allowing us to meet unmet medical need among people living with hATTR amyloidosis polyneuropathy and FCS.

1,213
sales in SEK M

8%
of total revenue

8%
Growth at CER

Orfadin (nitisinone), which has played a key role for many years in the health of people living with hereditary tyrosinaemia type 1 (HT-1), is now the first pharmacological treatment approved for treatment of alkaptonuria (AKU).

Sobi continues as the market leader to support those living with HT-1 and the healthcare professionals working to provide optimal management of this rare genetic disorder that can cause liver, renal and neurological complications. Orfadin is approved in the US, the EU, Latin America and Asia-Pacific markets for the treatment of HT-1, in combination with dietary restriction of tyrosine and phenylalanine.

Recently, generic competition has had an impact, with lower revenue mainly due to price decreases, but Orfadin has retained its role as the main treatment in the management of HT-1.

Following EU approval of Orfadin in 2020 as the first pharmacological treatment for adults with alkaptonuria (AKU), patients across Europe have been getting access to treatment for the first time.

AKU is a serious, multifaceted, debilitating and slowly progressive disease affecting approximately 1 in every 250,000 to 1 million people. Also known as black bone disease or black urine disease due to its characteristics, it is an extremely rare genetic condition that can cause significant damage to the bones, cartilage and tissue, and eventually lead to joint disease. The AKU Society in the UK has reported 777 identified patients in Europe[1] but because many with this disease are undiagnosed or misdiagnosed, the number in need is expected to be higher.

Launch, reimbursement and access activities are ongoing and some markets already have full access and have launched Orfadin for the new indication.

Sobi continues to work to ensure sustainable access to Orfadin for patients with HT-1 and AKU.

Tegsedi and Waylivra

In December 2020, Sobi signed a licensing deal with US-based Akcea, adding Tegsedi and Waylivra to our portfolio for Europe, the Middle East, some Central European countries and Russia. In April 2021, the Tegsedi agreement was extended to include the United States.

Tegsedi (inotersen) is approved in the EU, the US and other markets as a treatment for polyneuropathy in hereditary transthyretin-mediated (hATTR) amyloidosis in adults. hATTR-PN is a rare, progressive and debilitating genetic disease caused by a mutation or change in the gene coding for the transthyretin (TTR) protein, and is estimated to affect 40,000 people globally.

Underdiagnosed and sub-optimally treated, hATTR-PN is estimated to affect around 3,500 patients in Europe[2], with the highest prevalence in Portugal and Sweden, and large populations in Germany, Italy and France.

For people living with familial chylomicronaemia syndrome (FCS), Waylivra (volanesorsen) is approved in the EU and other markets for use in conjunction with an extremely low-fat diet. Waylivra significantly reduces triglycerides, decreases the risk of pancreatitis and the intensity of abdominal pain, and improves quality of life[3].

Prevalence is around 1–2 per million, with an estimated 3,000–5,000 patients worldwide. Waylivra is the only treatment globally indicated for FCS[4].

1. Zatkova A, Ranganath LR, and Kadasi L. Alkaptonuria: Current Perspectives. Appl Clin Genet. 2020; 13: 37–47. doi: 10.2147/TACG.S186773
2. Ref: Schmidt H et al, Muscle & Nerve, May 2018, 829-837
3. Waylivra (volenorsesn) SMPC
4. Gaudet et D, et al. Lipids Health Dis. 2020;19(120):1–13

Geographical expansion

Sobi continues to expand into new geographies. With significant unmet medical need in regions outside our current territories, we are committed to reaching more patients with our treatments.

As a rare disease company, we serve a relatively small proportion of the population and address areas of high unmet medical need. Expanding our geographical presence takes us into new markets with major growth potential while allowing more people living with rare diseases to access treatment.

One of our objectives is to reach twice as many patients with our treatments long term, with an established presence in selected new markets and partnerships in others. We are planning a large number of launches in markets outside the EU and North America within the same timeframe, and expect those geographies to make an important contribution to Sobi's long-term growth.

In 2021, a partnership was established in Latin America, following expansion into China, Japan, and Australia. For more on Russia, see the Directors' Report, p38.

Sobi operates within three regional clusters: Europe, North America and International. International includes all countries outside of North America and Western Europe.

In both China and Japan, developments in recent years have led to an increased focus on the needs of people living with rare diseases. These two countries represent the second and third-largest pharmaceutical markets in the world.

We continue to grow in Europe, the Middle East and North Africa, as well as in North America where operations have grown from 54 to 441 employees (FTE) in four years. The US, the single largest rare disease market in the world, is now home to Sobi's largest affiliate.

Increased attention to rare diseases

The rare disease market in China and Japan is developing rapidly, with increasing attention and awareness from governments, and with patient communities' support to increase access to orphan drugs. This means that there is both momentum for addressing the unmet medical need, and opportunities for growth from providing medicines to more patients.

To address the unmet medical needs of roughly 17 million patients in China with rare diseases, the Chinese National Medical Products Administration has been carrying out reforms, including allowing clinical study data from abroad to be submitted for the Chinese registry of rare disease drugs approved overseas, shortening the review and approval process, and extending clinical data exclusivity, ranging from six to twelve years.

In Japan, the Ministry of Health, Labour and Welfare has requested that Kineret be developed and submitted for approval in the country, a request Sobi aims to meet. In addition, Sobi started regulatory submission activity for Empaveli in Japan.

Both China and Japan generally require that medicines submitted for approval have been studied in local populations, contributing to greater scientific understanding of the challenges facing ethnic populations. In China, medicines with an urgent clinical need that have recently been approved overseas can be granted a waiver, but require post-market studies to confirm conditional approval.

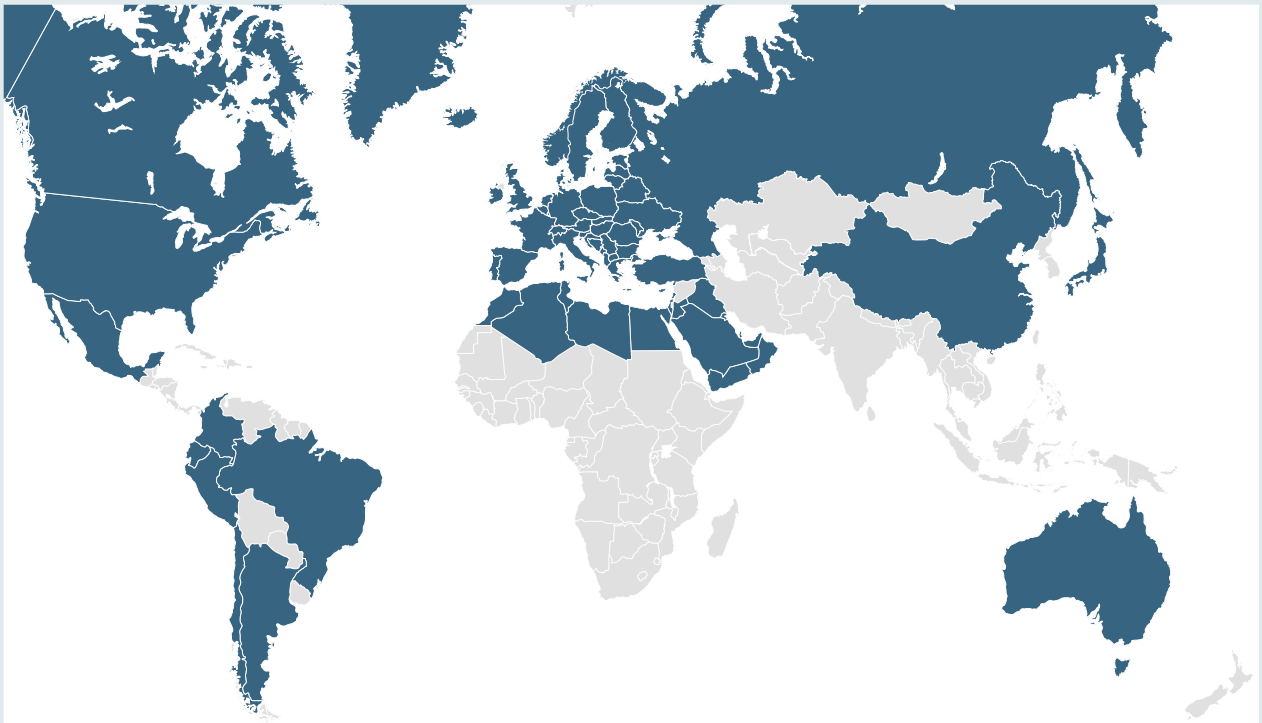
Extended presence in new markets

In Russia, Sobi has expanded its presence in recent years with the approval of Eloctate (Elocta) and the launch of Orfadin as a treatment for HT-1 and additional indications for Kineret.

In Australia, Kineret was re-integrated into the Sobi portfolio from a partner in 2020. Sobi sees further potential for growth in the Australian market. Empaveli was recently approved for PNH following submission last year and launch preparations are under way.

In 2021, Sobi took another strategic step with expansion into Latin America through a new commercial partner, Pint Pharma, to take our medicines to patients in seven countries in Latin America.

Expanded market presence outside Europe and North America



Sobi's markets 2021

	Haematology	Immunology	Specialty Care
USA	Doptelet	Synagis Gamifant Kineret	Orfadin Kepivance® Tegsedi
Europe	Elocta Alprolix Doptelet	Kineret	Orfadin Tegsedi, Waylivra Partner Products
Middle East	Elocta Alprolix Doptelet	Kineret Gamifant	Orfadin Tegsedi, Waylivra
Rest of the world	Doptelet[1]	Kineret	Orfadin

See p 123–124 for full details.

1. Out-licensed in China.

»One of our long term objectives is to reach twice as many patients, with an established presence in selected new markets, and partnerships to serve others.«

Future-ready pipeline

Sobi's broad and exciting pipeline is contributing to growth in several dimensions. With several programmes underway or planned, the pipeline is set to enable more than 60 launches over the coming years.

As we bring in new medicines through in-licensing or acquisitions, we increase the number of indications and consequently the number of patients who potentially can benefit from our medicines.

We are also growing geographically, with new medicines and indications taking us into new markets. And we continue to expand our collaborations with other companies, academics and stakeholder organisations.

Our Research & Development team is evolving to suit the changing needs of Sobi and the rare disease space. We must continue to innovate and deliver, and increase our efficiency and agility, emphasising a growth mindset that allows us to be competitive in the speed and quality of what we do.

Innovation characterises our operations: our portfolio is composed of first-in-class or best-in-class medicines, and we continue to innovate in both the design and execution of clinical studies.

This can also be seen in our innovative approach to patient selection, using biomarkers to identify patients who will benefit most from our medicines, in a step closer to precision medicine. For example, the anakinra programme in COVID-19 related pneumonia used the SuPAR biomarker to identify patients most at risk of developing severe complications.

We continue to make progress in increasing patient involvement in both design and execution of clinical studies, allowing us to gain a better understanding of the unmet need and the diseases themselves. Studies driven by Patient Access & Community Engagement and Global Medical & Scientific Affairs are looking for example at the unmet need in terms of anaemia and transfusion dependence among PNH patients treated with C5 inhibitors, among other areas.

We are working to bring in patients to our steering committees and involve them in reviewing protocols.

Haematology

Efanesoctocog alfa
We are convinced that efanesoctocog alfa has the potential to advance the treatment of people with haemophilia A. Top-line results were released in March 2022 for the phase 3 study of efanesoctocog alfa (fFVIIIFc-VWF-XTEN) in adults. The paediatric study is ongoing, with expected read-out in 2023. The progress in both studies during the COVID-19 pandemic has been a significant achievement.

Doptelet
Launched in the US and Europe, Doptelet (avatrombopag) will be submitted in Japan as a potential treatment for chronic liver disease (CLD) in 2022, with a study in ITP expected later in the year. Approval in Japan requires data from Japanese patients.

Immunology

The approval in the EU of Kineret (anakinra) as a treatment for COVID-19-related pneumonia in adult patients who are at risk of developing severe respiratory failure marked the culmination of intense efforts throughout much of 2021 by Sobi's R&D, Global Medical & Scientific Affairs, and colleagues in Greece and Italy, as well as close collaboration with Professor Giamarellos-Bourboulis and his team, and Virogates, the company behind SuPAR.

By utilising SuPAR, a robust biomarker, physicians are able to identify the right patient at the right time, intervening during a window of opportunity to stop the patient from progressing to more severe disease. The SAVE-MORE study showed that Kineret can keep patients out of intensive care, and get them home more quickly.

In the US, Sobi anticipates making a regulatory submission for emergency use authorisation with agency validation expected during the first half of 2022.

In 2021, Kineret was also approved in Russia for Still's disease (adult and juvenile) and will be submitted in China during 2022 for Still's, CAPS and FMF based on existing studies.

SEL-212
SEL-212 is a novel combination candidate treatment designed to sustain control of serum uric acid (SUA) levels in patients with chronic refractory gout, potentially reducing harmful tissue urate deposits which can lead to debilitating gout flares and joint deformity when left untreated.

The DISSOLVE phase 3 programme consists of two double-blind, placebo-controlled studies of SEL-212. Recruitment for the first study is complete and the second is progressing well. We expect data readout by the end of 2022, ahead of submission in 2023.

Overlap between Haematology and Immunology

Aspaveli/Empaveli
Approval in the EU, the UK, Australia and Saudi Arabia for complement C3 inhibitor Aspaveli/Empaveli (pegcetacoplan) as a treatment for PNH was a major advance in care for people living with this serious disease. A large majority of patients under treatment with C5 inhibitors continue to experience serious symptoms such as anaemia and related fatigue, and subsequently require regular transfusions.

The introduction of C5 inhibitors as a treatment for PNH 15 years ago was a revolution, allowing patients to survive their disease. We see Aspaveli/Empaveli as an important treatment option for those who fail to respond to C5 treatment.

We continue to work on taking Aspaveli/Empaveli to PNH patients in other countries. We have also filed in some countries in the Middle East, with approval and launch in Saudi Arabia, and a plan to file in Japan.

Aspaveli/Empaveli is also under investigation for other diseases. We activated sites for our phase 2 study in thrombotic microangiopathies (TMA) and phase 3 study in cold agglutinin disease (CAD) in January, and recruited our first patients to the CAD study. Based on advice regarding the patient population, we are seeking a broader label in CAD, focused on our territories and specifically Russia and Japan. The phase 2 dose study in TMA will pave the way for a phase 3 study planned to start in the second half of 2022.

Nirsevimab
Nirsevimab is a long-acting antibody currently in development for passive immunisation against respiratory syncytial virus (RSV). As part of Sobi's acquisition of US commercial rights to Synagis from AstraZeneca in November 2018, Sobi also acquired rights to participate in payments received by AstraZeneca from the US profit or loss for nirsevimab. Sobi does not have any active role in the development or commercialisation of nirsevimab. AstraZeneca and Sanofi are developing and planning to commercialise nirsevimab for use in all infants, in comparison to Synagis which is limited to infants at high risk. AstraZeneca announced positive results of its phase 2/3 (Medley) and phase 3 (Melody) study in 2021 and communicated plans to file in the US in the second half of 2022. The Melody trial will continue until Q2 2022 to collect additional safety data.

Our pipeline[1]

1. Shows studies that have started.
2. In collaboration with Apellis Pharmaceuticals.
3. In collaboration with Sanofi.
4. In collaboration with Selecta Biosciences.
5. Financial participation by Sobi.

»We are using the business priorities we have to drive the change we need.«

Our partner Apellis is developing Aspaveli/Empaveli in the indications C3 glomerulopathy (C3G), which is in phase 3, and amyotrophic lateral sclerosis (ALS), which is in phase 2.

Gamifant

We see an opportunity to expand the label for Gamifant (emapalumab) beyond its indication of primary HLH.

We recently started a multi-centre global phase 3 study, EMERALD, in macrophage activation syndrome (MAS) in paediatric and adult patients with underlying rheumatological diseases, to expand Gamifant utility across the spectrum of HLH disease. EMERALD currently has sites in the US, Canada, France, Spain and Poland, and we are looking at possible sites in other countries including Japan. The first patient was dosed in January 2022.

In prospective studies in acute graft failure, we are focusing on the relevant biomarker CXCL9, and have adopted a stage-gate approach.

Phase 4 studies

Sobi is undertaking or supporting several phase 4 studies in haematology, immunology and specialty care.

In haematology, these include studies of the effectiveness of Elocta and Alprolix in patients with haemophilia A and B, the effects of prophylaxis on joint outcomes in haemophilia A and B, and the impact of systematic joint examinations on physicians' treatment decisions in haemophilia A; and in ITP, a study to evaluate the use and effectiveness of Doptelet in adult patients.

In the area of immunology, studies include post-approval efficacy studies of Kineret in Chinese patients with Still's disease, colchicine-resistant familial Mediterranean fever (FMF) and cryopyrin-associated periodic syndrome (CAPS).

Post-approval commitments include a study on the safety and efficacy of emapalumab for the treatment of primary HLH in Chinese patients, and one describing the outcome of Orfadin treatment in HT-1 patients in China.

Sustainability

Our mission is to improve the lives of people with rare diseases. This is also our main contribution to sustainable development.

Sobi's sustainability strategy is focused on two main areas, each supporting our mission to improve lives for people living with rare diseases:

- Commitment to patients – by supporting the rare disease community, enabling connectedness, ensuring sustainable and secure access to care, and by giving a voice to patients. A strong pipeline and expanded access through geographical expansion are key elements of our commitment, which puts patient safety first by adhering to the highest pharmaceutical standards.
- Responsible behaviour – through strong business ethics and measures aimed at creating a healthy and well-functioning organisation designed to serve the community. We show our commitment by understanding and mapping our impact throughout the value chain, by setting ambitions and targets for ourselves, by working together with our partners to reduce our total environmental footprint, and by striving to make a positive contribution to individuals and societies.

Sobi is a signatory to the UN Global Compact, and we have integrated the ten principles of the Global Compact into our core business operations. Our sustainability strategy is based on our commitment to realisation of the 2030 Agenda as defined by the UN Sustainable Development Goals and the Paris Agreement.

Transform lives within rare diseases

Business strategy

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

Sustainability strategy

Commitment to patients

Our R&D is ethical and focused on medical need

We expand access to treatment

We are patient-centric and engage with our communities

We contribute to knowledge to enhance the practice of medicine

We focus on patient safety

Responsible behaviour

We help our people develop and keep them safe and healthy

We have zero tolerance for corruption

We source responsibly

We reduce our environmental footprint

Commitment to the 2030 Agenda, the UN Sustainable Development Goals and the Paris Agreement

Commitment to patients

Our business strategy reflects our ambition and commitment to reach more patients in more countries with novel and transformative treatments in areas of high unmet medical need.

R&D focused on medical need

In 2021, our R&D portfolio was expanded to include more new medicines and studies in multiple indications and countries, increasing the potential to make more treatments available to more patients.

To realise the potential of the portfolio, the R&D budget was increased to 13 per cent of revenue for 2021, compared with 10.4 per cent in 2020.

Five medicines are now under development, in more than ten programmes planned to allow for more than 60 launches in multiple countries in coming years; all medicines in the pipeline either have novel mechanisms of action or are first-in-class.

Orphan drug regulations can shorten time to patient. See chapter Rare diseases, pages 8–9.

The development strategy also includes exploring innovative approaches that help optimise treatment outcomes. In the digital health area, Sobi's subsidiary Florio provides a digital medical device florio HAEMO and the florio HAEMO kids app. In 2021, Florio launched several new features for adults and children. The digital diary app for ITP, which helps patients to organise, track and record their health and treatment information, was launched in collaboration with the Platelet Disorder Support Association (PDSA) in the United States.

Patient access

In 2021, we expanded the potential for access to treatments through a distribution agreement covering seven countries in Latin America, and by enlarging our operations in Russia, Japan, China and Australia. One of our objectives for 2025 is to reach twice as many patients with established presence or partnerships as in 2020.

The EU Pharmaceutical Strategy, adopted in 2020, is a policy document aiming to tackle important challenges for European patients and the health sector, and sets out a comprehensive set of actions to ensure access to affordable medicine and facilitate collaboration on unmet needs and evidence generation, among other things. Sobi has participated in these collaborations for many years. We also advocate for support for people living with rare diseases through collaboration within trade organisations to drive knowledge and expertise sharing.

Humanitarian aid

In 2020, together with Sanofi, we announced an extension of our support for the WFH (World Federation of Hemophilia) Humanitarian Aid Program, with an additional donation of up to 500 million international units (IU) of factor therapy for humanitarian use, fulfilling the 2014 pledge to donate up to an unprecedented 1 billion IU over a 10-year period. As Founding Visionary Contributors, Sobi and Sanofi continued the support for the Program throughout 2021.

Since the initial pledge, over 18,880 people with haemophilia have been treated with factor donated by Sobi and Sanofi.

By providing a more predictable and sustainable flow of treatment, the WFH Humanitarian Aid Program allows patients to receive consistent and reliable access to therapy 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.

Because donations do not provide sustainable or long-term access to treatment we strive to transform donations to access within the regulated healthcare system.

10
programmes in rare diseases

5
novel mechanisms of action

Sobi's and Sanofi's contribution to the WFH Humanitarian Aid Program

- Over 18,800 people reported treated in 41 countries
- Over 213,000 acute bleeds treated
- Over 3,200 surgeries, including limb-saving
- 588 million IU of factor donated

Community engagement
Sobi has long-standing relationships with the rare disease community including bodies such as patient organisations EURORDIS (Rare Diseases Europe) and NORD (the US National Organization for Rare Diseases), and provides support for their events, such as the 2021 Black Pearl Awards.

Other engagements include digital outreach such as Liberate Life, a Sobi-run digital resource centre and website that provides support and information for people with haemophilia, available in 21 local and regional versions. In 2021, Sobi continued to support social media and online communities as well as networking events and patient summits with a specific focus on COVID-19. Informational tools and materials for patient caregivers and healthcare personnel to facilitate knowledge sharing were part of this support.

Medical advancements
Sobi regularly participates in scientific meetings to share medical advancements to enhance the practice of medicine. We also arrange advisory boards to seek input in key clinical and scientific topics, continuing to develop our medicines.

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 (WBDR). Our sponsorship of the EHC enables capacity building across Europe, including youth leadership and activation of the youth community in Europe.

Focus on patient safety
Providing treatment for rare diseases adds another dimension to patient safety, because less information is available than for more widespread illnesses, and advanced analytical thinking is required.

Patient safety is part of a medicine's journey from development and into real-world use. Our global safety organisation focuses on detection, assessment, understanding and the prevention of adverse effects, and the correct management of safety information is a topic for regular employee training.

Responsible behaviour

Sobi aims always to act ethically and expects the highest standards of ethical behaviour from our employees. We offer a healthy workplace with continuous professional development opportunities.

Caring for our employees
Our workforce is key to our ability to deliver on the Sobi strategy. Over the course of 2021, we welcomed over 364 (400) individuals to Sobi,and finished the year with more than 1,580 (1,500) highly skilled employees in more than 30 countries around the world.

During the year, the COVID-19 pandemic continued to affect employees across the world. Sobi contributed to protecting the health of employees by promoting working from home and allowing only business-critical international travel while continuing precautions in the workplace, flexible working hours and office attendance planning.

Employee surveys
In 2021, further efforts were made to improve within areas identified in the 2020 Global Engagement Survey. Work-life balance continued to be a high priority, and follow-up surveys conducted during the year showed good results for improved employee wellbeing. To further improve wellbeing, employees have been encouraged to participate in developing the principles and set-up of the future, post-pandemic workplace.

Zero tolerance for corruption
Responsible behaviour is promoted by the company values and Code of Conduct. In 2020, a new, updated Code of Conduct was launched and made available to internal as well as external stakeholders, and the whistleblower hotline was extended to include external parties. In 2021, efforts were put into increasing internal awareness of the whistleblower reporting channel, and 14 cases were reported. During 2021, the Corporate Compliance Committee consisting of the CEO, CFO, General Counsel and Chief Compliance Officer assumed oversight of compliance investigations, ensuring both non-retaliation against whistleblowers and organisational fairness in the application of sanctions. To further underline Sobi's commitment to compliance, a global Ethics and Integrity Week was conducted including live global events with senior management and local awareness activities.

Expansion into new markets and the introduction of new employees into the company require continuous revision of policies, systems and training to ensure high standards are maintained, and that compliance is introduced to all new employees and included as a topic in induction programmes. 95 per cent of eligible Sobi employees completed the Code of Conduct training in 2021 and 96 per cent completed the Anti-Corruption and Anti-Bribery training. Both training modules are required for all personnel every second year.

80%
renewable energy in Sobi operations

95%
completed Code of Conduct training

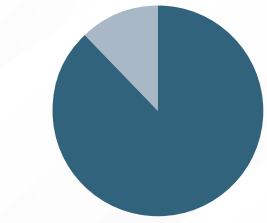
Responsible sourcing
As Sobi's supply chain is outsourced to a large extent, we depend on sustainable and dependable suppliers to produce, pack and distribute our products. As a consequence, a large part of our sustainability impact occurs outside Sobi's own operations.

Since 2020, Sobi has been 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.

We also use the EcoVadis sustainability reporting platform to monitor and drive

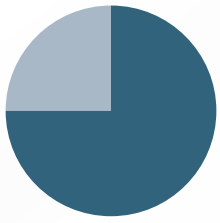
Proportion of suppliers with implemented practices
Calculated as share of suppliers reporting in EcoVadis who have implemented these principles. For more details, see page 115.

Energy consumption and GHGs



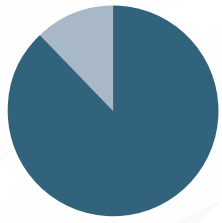
Share of suppliers with actions on energy consumption and GHGs, 88%

CSR-issues



Share of suppliers performing audits or assessments of suppliers on CSR-issuers, 75%

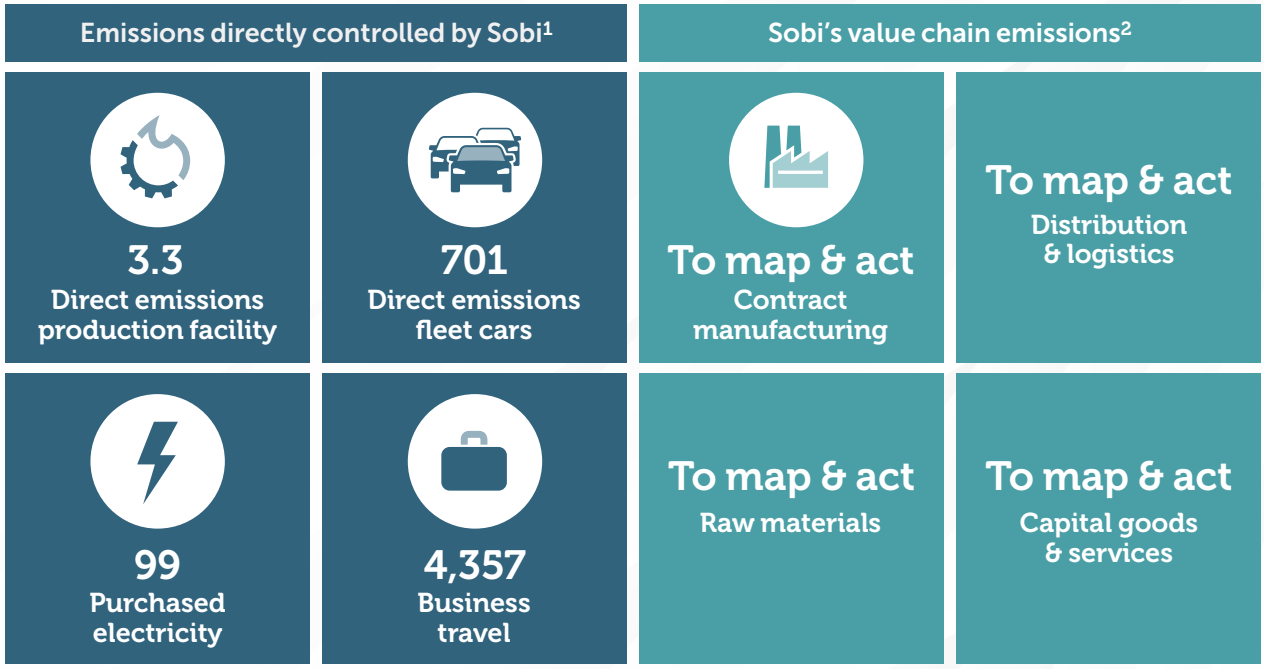
Whistleblowing



Share of suppliers with active whistleblowing procedures, 88%

Sobi's greenhouse gas emissions

Sobi's GHG emissions mapping (tonnes CO_2)



1. Full scope 1 and scope 2 emissions, and scope 3 business travel. Details in Sustainability notes p 118.

2. Remaining scope 3 emissions to be mapped by 2022. Details in Sustainability notes, p 118

performance and progress of our supplier partners across the four dimensions of Environment, Labour & Human Rights, Ethics and Sustainable Procurement.

Supplier status and progress is followed up in our regular business review meetings with each supplier, and improvement targets are set.

Reducing our environmental footprint

Sobi's Scope 1 and Scope 2 emissions from our own operations are limited. In 2021, we continued to expand our reporting practice by introducing a common reporting platform including all global operations and entities.

All electricity consumed at the Stockholm facility has been generated from a mix of certified renewable energy sources. The impacts of our global operations are described in detail on pages 118–120.

By avoiding, reducing and substituting we aim to achieve net zero emissions from our sites and ground fleet no later than 2030 and we are working to set targets for our operations and our Category 6 Scope 3 emissions (business travel).

We have begun mapping our Category 1, 4 and 9 Scope 3 emissions and are collecting data from a limited number of contract manufacturers and logistics partners. For 2022, Sobi plans to complete the mapping of our value chain emissions and set priorities with Scope 3 emission targets based on identified reduction opportunities.

In 2021, as a part of our Responsible Sourcing Programme, we started communicating our ambitions to suppliers, and integrating reporting and target reviews in business follow-ups.

The Responsible Sourcing Programme has been gradually implemented since it was introduced in 2019. It is based on three pillars:

1) Alignment of values and principles
We secure alignment between ourselves and our partners through the Partner Code of Conduct, a document Sobi suppliers must sign and adhere to as stated in our contracts.

2) Supplier risk assessment and qualification
We evaluate prospective and current partners and perform due diligence and screening for compliance with management, labour, human rights and environmental standards. We customise our approach, depending on the geographic and supplier category risk profile as well as the strategic importance of the supplier.

3) Performance management and monitoring
We strive to reduce complexity by using common platforms to drive supplier performance, where targets, activities and progress can be shared more effectively between suppliers and customers within the pharmaceutical industry.

The share

The Sobi share (STO:SOBI) is listed on Nasdaq Stockholm, under the company name of Swedish Orphan Biovitrum.

In 2021 the highest price paid was SEK 245.40 on 2 September, and the lowest was SEK 127.10 on 6 May. Sobi's market capitalisation at year-end 2021 was SEK 56.8 billion. Over 2021, the share price increased by 13.2 per cent.

Turnover and trading locations
The Sobi share is traded on several exchanges and trading platforms, including Nasdaq Stockholm, Bats CXE and Bats BXE. In 2021, trading on Nasdaq Stockholm accounted for 63 per cent of the total turnover.

Average daily total turnover in Sobi shares was 917,044 in official trading on Nasdaq Stockhol, and a total of 232 million shares were traded during 2021, corresponding to a value of approximately SEK 41.2 billion.

Share capital
At 31 December 2021, the total number of ordinary shares outstanding, excluding shares in treasury, was 295,155,297. All issued shares are ordinary shares and carry one vote per share.

At year-end, the share capital was SEK 168,520,825, distributed between 307,114,495 shares with a par value of approximately SEK 0.55.

Incentive programmes
Sobi has launched several share-based incentive programmes for senior executives and employees. Currently, there are six active share programmes, all vesting within three years. The programmes represent a total maximum of 2,868,185 shares, or 1.0 per cent of the total number of shares in the company. For more information, see Note 10.

Shareholders
At year-end, the number of shareholders was 24,685 (33,816). The largest shareholder, Investor AB, held 35.0 per cent (35.4) of the shares. Swedish legal entities, including institutions and funds, held 64.2 per cent (64.9) of the shares. Shares held by Swedish Orphan Biovitrum AB (publ) at year-end totalled 11,959,198 common shares.

During the year 255,819 shares were used for allotment under two performance-based long-term share programmes. See Note 10 for further information.

Dividend
The Board proposes that no dividend be paid for 2021. For more information about Sobi's dividend policy, please refer to the Corporate Governance Report.

Largest shareholders at 31 December 2021[1]

SHAREHOLDERS	Number of A shares	Share capital, %	Share votes, %
Investor AB	107,594,165	35.0	35.0
Morgan Stanley Smith Barney LLC, W9	24,193,950	7.9	7.9
Fjärde AP-fonden	20,532,666	6.7	6.7
BNY Mellon SA/NV (former BNY), W8IMY	19,956,508	6.5	6.5
Swedish Orphan Biovitrum AB (publ.)	11,959,198	3.9	3.9
Euroclear Bank S.A/N.V, W8-IMY	11,557,227	3.8	3.8
Bank of America, National Associati, ON	6,225,603	2.0	2.0
Handelsbanken fonder	6,019,115	2.0	2.0
State Street Bank and Trust Co, W9	5,616,632	1.8	1.8
Cbny-Norges Bank	5,226,793	1.7	1.7
Swedbank Robur Fonder	4,338,856	1.4	1.4
JP Morgan Chase Bank NA	3,963,896	1.3	1.3
SEB Equities Sweden	2,721,546	0.9	0.9
Folksam	2,655,974	0.9	0.9
Credit Suisse International	2,511,775	0.8	0.8
Total 15 largest shareholders	**235,073,904**	**76.6**	**76.6**
Other	72,040,591	23.4	23.4
Total	**307,114,495**	**100.0**	**100.0**

1. 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.
Source: Euroclear

Average value of daily trading volume for the Sobi share on Nasdaq Stockholm

VOLUME	2017	2018	2019	2020	2021
A shares	784,589	900,760	778,920	987,486	917,044

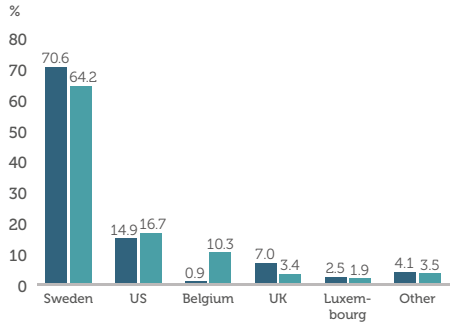
Source: Nasdaq

Shareholder categories

31 DECEMBER 2021	% of capital
Foreign shareholders	35.8
Swedish shareholders	64.2
whereof	
Institutions	60.9
Natural persons	3.2

Source: Euroclear.

Shareholders by country

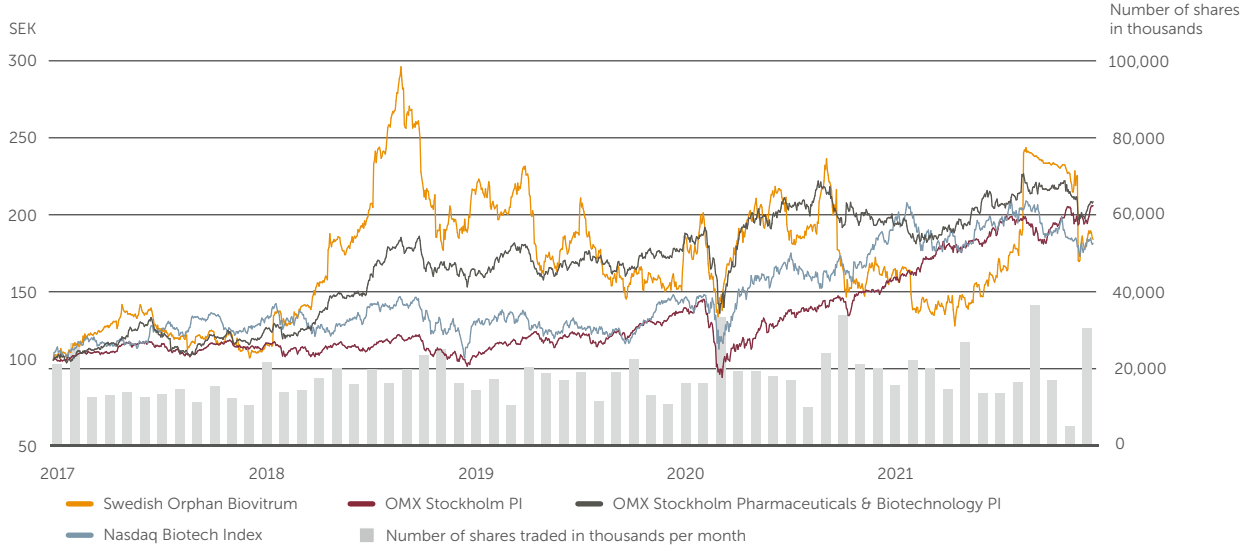


Source: Euroclear.

Key data per share

SEK	2017	2018	2019	2020	2021
Earnings/loss per share	4.27	8.97	11.29	11.01	9.08
Equity per share	24.6	33.1	56.4	66.5	75.6
Market price, Series A-share, 31 Dec., last paid price	112.3	193.0	154.5	166.1	185.1
P/E ratio	26.3	21.5	13.7	15.1	20.4
Number of shares at 31 Dec.	272,507,708	273,322,117	299,977,839	303,815,511	307,114,495

Sobi share price and trading volume 2017–2021



Five-year summary – Group development

	2017	2018	2019	2020	2021
Income statement, SEK M					
Operating revenue	6,511	9,139	14,248	15,261	15,529
Gross profit	4,657	6,723	10,913	12,036	12,045
EBITDA[1]	2,086	3,607	6,121	6,841	5,740
EBITA[1]	2,053	3,571	5,933	6,700	5,575
EBITA adjusted[1,2]	2,053	3,571	6,145	6,301	5,575
EBIT (operating profit)	1,600	3,122	4,533	4,818	3,733
Profit for the year	1,149	2,418	3,304	3,245	2,679
Capital, SEK M					
Total assets	10,903	17,183	45,658	48,283	48,661
Capital employed[1]	6,716	9,048	33,560	34,777	34,109
Equity	6,701	9,040	16,930	20,206	23,203
Cash and cash equivalents	1,478	2,999	737	404	1,045
Net debt (+)/net cash (–)[1]	–1,478	–2,999	15,404	13,748	9,500
Cash flow, SEK M					
Cash flow from operating activities before changes in working capital[3]	1,431	2,341	5,300	5,367	4,356
Cash flow from operating activities[3]	1,333	2,090	3,634	4,926	5,470
Cash flow from investing activities	–139	–575	–21,686	–3,964	–367
Cash flow from financing activities[3]	–500	–1	15,780	–1,282	–4,474
Change in cash and cash equivalents	694	1,514	–2,271	–320	629
Key figures, %					
Gross margin[1]	72	74	77	79	78
EBITA margin[1]	32	39	42	44	36
EBITA margin adjusted[1,2]	32	39	43	41	36
Return on capital employed[1]	23.8	34.5	13.5	13.9	10.9
Return on equity[1]	19.0	30.7	25.4	17.5	12.3
Equity ratio[1]	61	53	37	42	48
Debt/equity ratio[1]	63	90	170	139	110
Share ratio, SEK					
Earnings per share	4.27	8.97	11.29	11.01	9.08
Equity per share[1]	24.6	33.1	56.4	66.5	75.6
Cash flow per share[1]	2.6	5.6	–7.8	–1.1	2.1
Cash flow from operating activities per share[1]	5.0	7.8	12.4	16.7	18.5

1. Sobi presents certain financial measures in the annual report that are not defined according to 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 Definitions at the end of this report.
2. 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.
3. As of 2021, Sobi has 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. Comparative figures for 2020 have been recalculated. For more information see Note 2 Accounting policies.

Reporting

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Directors' Report

The Board of Directors and CEO of Swedish Orphan Biovitrum AB (publ.), organisation number 556038-9321, submit the following annual report and consolidated financial statements for the 2021 financial year.

Highlights 2021

Financial highlights

- Operating revenue amounted to SEK 15,529 M (15,261), an increase of 2 per cent, and 7 per cent at constant exchange rates (CER).
- Revenue in Haematology amounted to SEK 8,536 M (8,660), an increase of 3 per cent at CER.
- Revenue in Immunology amounted to SEK 5,780 M (5,415), an increase of 15 per cent at CER.
- The gross margin was 78 per cent (79).
- EBITA was SEK 5,575 M (6,700).
- Adjusted EBITA was SEK 5,575 M (6,301), a decrease of 12 per cent, corresponding to an adjusted EBITA margin of 36 per cent (41). In 2020, adjusted EBITA excluded a positive impact of SEK 399 M from reversal of the CVR liability. See page 34 under operating profit for more information.
- Profit for the year totalled SEK 2,679 M (3,245), representing earnings per share before dilution of SEK 9.08 (11.01). Adjusted earnings per share before dilution amounted to SEK 9.08 (9.66).
- Cash flow from operating activities was SEK 5,470 M (4,926), an increase of 11 per cent.

Business highlights

- Doptelet® (avatrombopag) was approved in the EU for the treatment of ITP.
- Kineret® (anakinra) was approved in Russia for the treatment of CAPS.
- Sobi signed a new distribution agreement with Galapagos for sales of Jyseleca® in Central- and Eastern Europe, Greece, Portugal and the Baltic countries.
- Sobi established operations in the Netherlands.
- Sobi signed a new agreement with Pint Pharma regarding the commercialisation of Sobi pharmaceuticals in seven Latin American countries, including Brazil.
- Advent and GIC announced a public cash offer to the shareholders of Sobi to tender their shares in Sobi to Agnafit Bidco. The offer was withdrawn as the level of acceptance was too low.
- Aspaveli® (pegcetacoplan) was granted orphan designation in the EU for the treatment of PNH.
- Kineret (anakinra) was approved in the EU for the treatment of COVID-19 pneumonia.

Sobi's operations

Sobi specialises in rare diseases, developing and providing access to innovative treatments in the areas of haematology, immunology and nisch indications.

In 2021, revenue was generated by:

- Haemotology, through sales of the medicines Elocta®, Alprolix®, Doptelet and Aspaveli/Empaveli®. Revenue is also derived from manufacturing 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, Synagis® and Gamifant®.
- Specialty Care, through sales of the medicines Orfadin®, Tegsedi®, Waylivra® and other medicines in the Speciality Care portfolio.

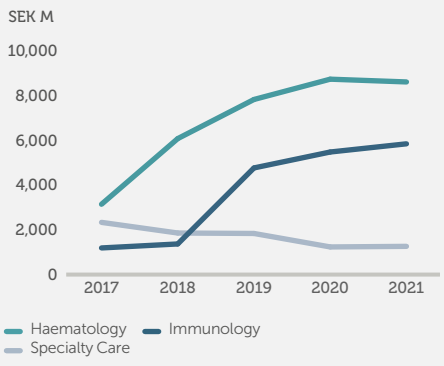
Key figures

SEK M	2021	2020
Operating revenue	15,529	15,261
Gross profit	12,045	12,036
Gross margin[1]	78%	79%
EBITA[1]	5,575	6,700
EBITA adjusted[1, 2]	5,575	6,301
EBITA margin[1]	36%	44%
Adjusted EBITA margin[1, 2]	36%	41%
Profit for the year	2,679	3,245
Earnings per share, before dilution, SEK	9.08	11.01
Earnings per share, before dilution, SEK adjusted[1, 2]	9.08	9.66

1. Alternative Performance Measures, see Definitions on p 130.
2. In 2020, adjusted EBITA excluded a positive effect of SEK 399 M from reversal of the CVR liability.

See p 30 for a five-year summary of revenue, expenses and earnings.

Five-year revenue trend



Operating revenue
Revenue amounted to SEK 15,529 M (15,261), an increase of 2 per cent, and 7 per cent at CER.

Revenue by business area
Haematology
Revenue for Haematology amounted to SEK 8,536 M (8,660), a decrease of 1 per cent, and an increase of 3 per cent at CER.

Sales of Elocta amounted to SEK 3,960 M (4,585), a decrease of 14 per cent and 11 per cent at CER. The negative effect of price adjustments, including a mandatory price reduction in Germany, was slightly offset by low single-digit patient growth and higher factor consumption.

Sales of Alprolix amounted to SEK 1,764 M (1,705), an increase of 3 per cent and 7 per cent at CER. The sales growth was mainly driven by underlying patient growth.

Royalty revenue amounted to SEK 1,251 M (1,301), derived from Sanofi's sales of Eloctate and Alprolix.

Sales of Doptelet amounted to SEK 1,116 M (587), an increase of 90 per cent and 104 per cent at CER. Growth was mainly driven by continued launch successes in the US, a launch in Europe and higher sales to the partner Fosun in China.

Manufacturing revenue for ReFacto AF/Xyntha amounted to SEK 445 M (481), a decrease of 8 per cent.

Immunology
Revenue for Immunology totalled SEK 5,780 M (5,415), an increase of 7 per cent and 15 per cent at CER.

Sales of Kineret amounted to SEK 2,290 M (2,079), an increase of 10 per cent and 16 per cent at CER. The strong trend for Kineret continued, driven by new applications and patient growth, where most of the sales growth was related to COVID-19.

Sales of Synagis amounted to SEK 2,650 M (2,726), a decrease of 3 per cent and an increase of 6 per cent at CER, driven by continued strong demand. 2020 was positively impacted by inventory build-up at distributors at the end of the year.

Sales of Gamifant amounted to SEK 840 M (609), an increase of 38 per cent and 48 per cent at CER, reflecting continued patient growth, higher volume per patient and longer treatment times.

Specialty Care
Revenue for Specialty Care amounted to SEK 1,213 M (1,186), an increase of 2 per cent and 8 per cent at CER. The increase was driven by Tegsedi and Waylivra, which were recently in-licensed. Generic competition with subsequent price erosion continued to impact sales of Orfadin.

Gross profit
Gross profit totalled SEK 12,045 M (12,036), representing a gross margin of 78 per cent (79). The lower margin was mainly due to a mandatory price reduction for Elocta in Germany, and an unfavourable product and country mix, driven by Kineret, Tegsedi and Waylivra.

Operating expenses
Operating expenses increased to SEK 8,312 M (7,218), an increase of 15 per cent.

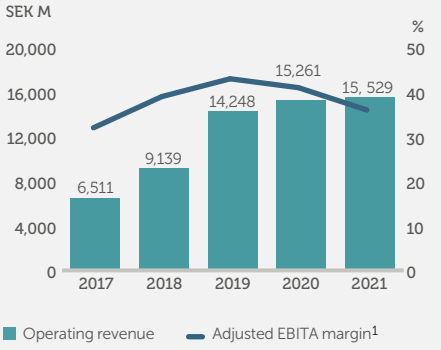
Sales and administrative expenses before amortisation/depreciation and impairment amounted to SEK 4,453 M (4,099),an increase of 9 per cent. Costs increased due to launch preparations for Aspaveli and activities related to Tegsedi and Waylivra.

Research and development costs before depreciations and write-downs amounted to SEK 1,994 M (1,594), an increase of 25 per cent. The increase reflects costs related to the development programmes for Aspaveli and SEL-212.

Other operating income and expenses amounted to SEK –24 M (357). In 2020, operating revenue mainly pertained to the reversal of SEK 399 M for the CVR liability, see also Operating profit.

Operating profit
Operating profit (EBIT) totalled SEK 3,733 M (4,818), a decrease of 22 per cent. Amortisation and impairment of intangible assets amounted to SEK 1,841 M (1,882). Operating

Operating revenue and adjusted EBITA margin[1]



Revenue by business area

SEK M	2021	2020
Haematology	8,536	8,660
Immunology	5,780	5,415
Specialty Care	1,213	1,186
Total revenue	**15,529**	**15,261**

1. Alternative Performance Measures, see Definitions on p 130.

profit before amortisation and impairment of intangible assets (EBITA) amounted to SEK 5,575 M (6,700), corresponding to a margin of 36 per cent (44). Adjusted EBITA was SEK 5,575 M (6,301), corresponding to a margin of 36 per cent (41). In 2020, adjusted EBITA excluded a positive effect of SEK 399 M from reversal of the CVR liability.

Following the completion of Sobi's acquisition of Dova Pharmaceuticals, Inc. (Dova) on 12 November 2019, Dova shareholders were provided one non-transferable Contingent Value Right (CVR) to an additional USD 1.50 per share to be paid upon approval of Doptelet for use in chemotherapy-induced thrombocytopenia (CIT) by the FDA. On 9 October 2020, Sobi announced topline results for a phase 3 CIT study of avatrombopag. The primary endpoints were not met and Sobi estimates that the conditions of the CVR will not be met. The corresponding liability on the balance sheet was subsequently reversed, which had a positive impact of SEK 399 M on other operating income.

Net financial items

Net financial expenses amounted to SEK −438 M (−601). The improvement for the year reflects lower indebtedness in 2021 and negative exchange-rate effects in 2020.

Tax

Recognised income tax amounted to SEK −616 M (−972), of which SEK −659 M (−1,125) pertained to current tax and SEK 43 M (153) to deferred tax. The effective tax rate was 18.7 per cent (23.1). See also Notes 15 and 20.

Profit

Profit for the year totalled SEK 2,679 M (3,245). Earnings per share before dilution amounted to SEK 9.08 (11.01).

Cash flow

Cash flow from operations before changes in working capital was SEK 4,356 M (5,367). Working capital had a positive impact of SEK 1,114 M (−441) on cash flow, reflecting lower receivables due to the timing of payments attributable to the early start of the RSV season. 2020 was also adversely impacted by inventory build-up. Cash flow from operating activities therefore amounted to SEK 5,470 M (4,926).

Cash flow from investing activities was SEK −367 M (−3,964). The amount for 2020 included investments of SEK −2,198 M in Aspaveli and SEK −977 M in SEL-212.

Cash flow from financing activities was SEK −4,474 M (−1,282). During the year, loan repayments were possible due to the strong cash flow from operating activities.

Financial position

At 31 December 2021, cash and cash equivalents and current investments amounted to SEK 1,045 M (404).

At 31 December 2021, undrawn committed credit facilities amounted to SEK 4,336 M (4,320) and drawn credit facilities totalled SEK 10,597 M (14,234). See Note 3 for more information about maturity structure. At 31 December 2021, net debt was SEK 9,500 M (13,748).

Revenue by business area

SEK M	2021	2020	Change
Elocta	3,960	4,585	−14%
Alprolix	1,764	1,705	3 %
Royalties	1,251	1,301	−4 %
Doptelet	1,116	587	90%
Aspaveli/ Empaveli	1	–	n/a
Manufacturing	445	481	−8%
Haematology	**8,536**	**8,660**	**−1%**
Kineret	2,290	2,079	10%
Synagis	2,650	2,726	−3%
Gamifant	840	609	38%
Immunology	**5,780**	**5,415**	**7%**
Orfadin	459	665	−31%
Tegsedi	427	–	n/a
Waylivra	121	–	n/a
Other Specialty Care	207	521	−60%
Specialty Care	**1,213**	**1,186**	**2%**
Total revenue	**15,529**	**15,261**	**2%**

Revenue by region

SEK M	2021	2020	Change
Europe	7,011	7,620	−8 %
North America	6,120	5,483	12%
Rest of the world	1,147	857	34%
Other[1]	1,251	1,301	−4%
Total	**15,529**	**15,261**	**2%**

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

Five-year summary

SEK M	2021	2020	2019	2018	2017
Operating revenue	15,529	15,261	14,248	9,139	6,511
Cost of goods sold	−3,484	−3,225	−3,335	−2,415	−1,854
Research and development costs	−1,994	−1,594	−1,495	−1,090	−908
Operating profit (EBIT)	3,733	4,818	4,533	3,122	1,600
Net financial items	−438	−601	−286	−40	−68
Profit for the year	2,679	3,245	3,304	2,418	1,149
Earnings per share, before dilution, SEK	9.08	11.01	11.29	8.97	4.27
Earnings per share after dilution, SEK	9.03	10.90	11.22	8.93	4.25
Number of shares, 000s	307,114	303,816	299,978	273,322	272,508
Equity/assets ratio[1]	48%	42%	37%	53%	61%

1. Alternative Performance Measures, see Definitions on p 130.

The Group also has other non-interest bearing financial liabilities that are recognised at discounted value and therefore generated interest expense. The liabilities are not included in net debt/net cash. For contractual obligations related to these liabilities, see Note 28.

Equity
At 31 December 2021, consolidated equity amounted to SEK 23,203 M (20,206).

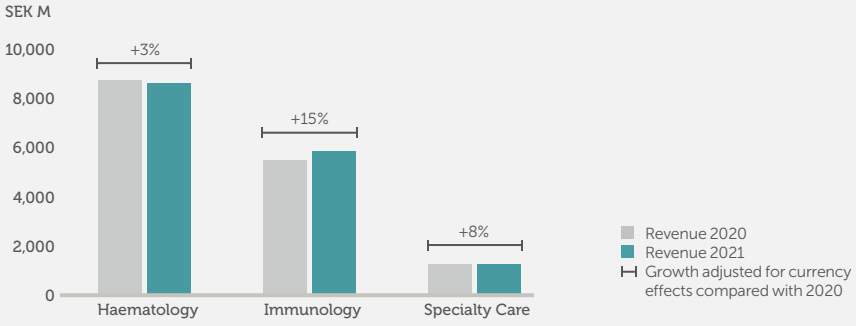
Parent Company
The Parent Company's business model is to develop, register, distribute and market drugs for rare diseases.

Operating revenue amounted to SEK 12,401 M (13,968) and operating profit totalled SEK 4,383 M (5,833). The decrease is due to the fact that sales of Synagis were transferred to the US subsidiary in 2020. Profit for the year totalled SEK 1,790 M (3,406), including excess depreciation of SEK –600 M (–107) and Group contributions of SEK –1,113 M (–1,583).

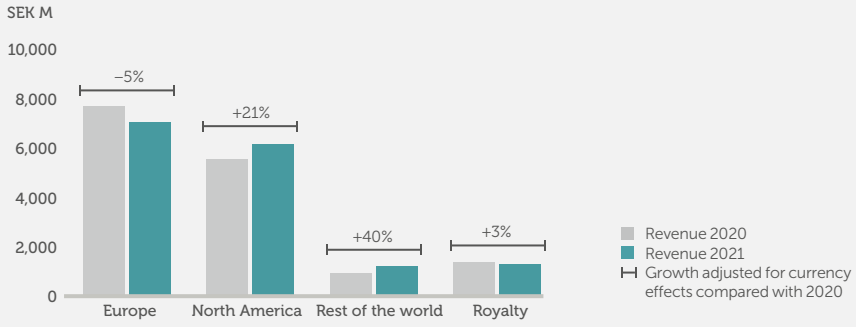
Cash flow from investing activities amounted to SEK –288 M (–3,760), largest investments for 2020 pertained to Apaveli SEK –2,198 M and to SEL–212 SEK –977 M.

At 31 December 2021, cash and cash equivalents amounted to SEK 878 M (240) and equity to SEK 19,069 M (17,200).

Revenue by business area



Revenue by region



Pipeline

Sobi's business model in support of becoming a global leader in rare diseases is based on 'search, develop and market' which necessitates in-licensing or acquisition of pipeline opportunities or already approved medicines. Sobi's pipeline includes projects from phase 2 through registration, with focus in the disease areas of haematology and immunology. In support of already marketed medicines, Sobi is conducting phase 4 trials to gather further evidence about their best use and potential expansion of patient benefits.

Pipeline events during the year
Haematology
Haemophilia
Efanesoctocog alfa (formerly BIVV001), a potential new treatment for haemophilia A, is in phase 3 clinical development with the collaborator Sanofi. The first data readout from the XTEND-1 phase 3 study in adults was released in March 2022, and results in adolescents are expected during the first half of 2022. Enrolment and dosing were initiated in the XTEND-Kids phase 3 paediatric study in patients younger than 12 years of age in early 2021 with the paediatric study data readout anticipated in 2023. If results are positive, efanesoctocog alfa could provide high sustained factor VIII activity and near-normal factor levels for the majority of the week. Von Willebrand factor is required as part of normal blood clotting; efanesoctocog alfa is the first von Willebrand-independent factor VIII treatment in clinical development and therefore has the potential to revolutionise replacement therapy for people with haemophilia A.

Aspaveli/Empaveli
In 2020, Sobi signed an agreement with Apellis Pharmaceuticals, Inc. Under the licensing agreement, Sobi obtained the rights to global development and ex-US commercialisation of pegcetacoplan – Aspaveli/Empaveli – for systemic use. Aspaveli/Empaveli is a targeted C3 therapy designed to regulate excessive activation of the complement cascade, part of the body's immune system, which can lead to the onset and progression of many serious diseases.

During 2021, the two companies achieved significant progress for the new medicine. While Apellis obtained US approval in May 2021 of Empaveli for use in adults with paroxysmal nocturnal haemoglobinuria (PNH), including those who are treatment naïve as well as patients switching from C5 inhibitors, clinical development for other rare disease indications advanced.

The PEGASUS phase 3 study in treatment-experienced PNH patients was published in The New England Journal of Medicine in March 2021. The study demonstrated the superiority of Aspaveli/Empaveli in improving haemoglobin levels and showed improvements in other key clinical outcomes compared with eculizumab, a C5 inhibitor, in adults with PNH at 16 weeks who had persistent anaemia following treatment with eculizumab. Additional data has seen patient benefits sustained at 48 weeks.

The PRINCE phase 3 study in treatment-naïve PNH patients read out in May 2021. The study demonstrated statistical superiority on the co-primary endpoints of haemoglobin stabilisation and reduction in lactate dehydrogenase compared with standard of care, which did not include complement inhibitors, at week 26. The safety profile of Aspaveli/Empaveli was consistent with previous studies. The detailed PRINCE data were later presented at the 63rd American Society of Hematology annual meeting and exposition in Atlanta, Georgia, US.

In December 2021, Aspaveli, the trade name in the EU, was approved by the European Commission for the treatment of adult patients with PNH who are anaemic after treatment with a C5 inhibitor for at least 3 months. With the approval, Aspaveli became the first new medicine in the EU since 2007 for the treatment of PNH with a novel mechanism of action, providing expanded choice to treating physicians and patients.

Outside the approved indication in PNH, Sobi and Apellis are developing Aspaveli/Empaveli in collaboration for potential use in several new indications. A Sobi-sponsored phase 2 study in transplant-associated thrombotic microangiopathy after allogenic haematopoietic stem cell transplantation recently achieved the first patient dosed. A phase 3 study in cold agglutinin disease is awaiting the first patient to be dosed. Apellis is advancing the medicine in immune complex-mediated membranoproliferative glomerulonephritis and C3 glomerulopathy where a phase 3 study is awaiting the first patient to be dosed. In addition, Apellis has the ongoing MERIDIAN phase 2 study, potentially registrational, in amyotrophic lateral sclerosis with anticipated completion of enrolment in the first half of 2022.

Doptelet

Doptelet (avatrombopag), an approved medicine for the treatment of thrombocytopenia, has completed the formal phase 3 development for its use in patients with immune thrombocytopenia (ITP) as well as in patients with chronic liver disease who are scheduled to undergo a procedure.

In January 2021, Doptelet was approved by the European Commission for the treatment of primary chronic ITP in adult patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). In March 2021, the AVA-PED-301 phase 3 study for the treatment of thrombocytopenia in paediatric patients achieved the first patient dosed. Other studies are ongoing for Doptelet, including a phase 4 study assessing switching to Doptelet from eltrombopag or romiplostim, two older medicines used for the treatment of thrombocytopenia.

Immunology

Kineret

Kineret (anakinra), an approved medicine for the treatment of several immune-mediated diseases, including cryopyrin-associated periodic syndromes, familial Mediterranean fever and Still's disease, is assessed for potential new uses by clinical investigators.

In May 2021, Kineret demonstrated considerable benefit in the treatment of COVID-19 related pneumonia. In the SAVE-MORE phase 3 study, Kineret reduced the risk of mortality for patients with COVID-19 pneumonia, reduced intensive-care unit admission and increased the likelihood of full recovery. Conducted in Greece and Italy by Professor Evangelos J. Giamarellos-Bourboulis and other investigators with the Hellenic Institute for the Study of Sepsis as the regulatory sponsor, SAVE-MORE was the first, large, randomised and controlled study to specifically evaluate a patient population at risk of progressing to a critical state of COVID-19 infection. In September 2021, the study was published in Nature Medicine.

In December 2021, Kineret was approved by the European Commission for the treatment of COVID-19 in adult patients with pneumonia requiring supplemental oxygen (low- or high-flow oxygen) who are at risk of progressing to severe respiratory failure determined by plasma concentration of soluble urokinase plasminogen activator receptor (suPAR) ≥ 6ng/ml. suPAR is a biomarker which can be measured in the blood of patients. The EU approval followed a positive opinion by the Committee for Medicinal Products for Human Use of the European Medicines Agency which was issued just one day ahead. In the US, Sobi anticipates making a regulatory submission for emergency use authorisation with agency validation expected during the first half of 2022.

Gamifant

Gamifant (emapalumab), an approved medicine in the US for the treatment of primary haemophagocytic lymphohistiocytosis (HLH), a rare, severe systemic inflammatory syndrome which can be fatal, obtained further global approvals in 2021.

SEL-212

In 2020, Sobi signed a licensing agreement with Selecta Biosciences, Inc. Under the licensing agreement, Sobi is responsible for development as well as regulatory and commercial activities in all markets outside China, while Selecta will conduct the ongoing phase 3 development on behalf of Sobi for SEL-212. SEL-212 is a potential new medicine for the treatment of chronic refractory gout and combines a uricase enzyme (pegadricase) with Selecta's tolerogenic ImmTOR immune tolerance platform which is designed to reduce immunogenicity and achieve monthly dosing of the medicine.

In December 2021, Sobi and Selecta announced the completion of enrolment in the DISSOLVE I clinical study. The other study in the phase 3 DISSOLVE clinical study programme, DISSOLVE II, is anticipated to achieve the same milestone in the first half of 2022. Phase 3 data readout is anticipated during the second half of 2022.

Nirsevimab
Nirsevimab, a potential new immunisation for the prevention of RSV infections in infants, is nearing the completion of phase 3 clinical development by the collaborators AstraZeneca PLC and Sanofi. Phase 2b study data published in July 2020 showed a significant reduction in medically attended lower respiratory tract infections and hospitalisations caused by respiratory syncytial virus in healthy preterm infants. During 2021, results from the MELODY phase 3 efficacy study and the MEDLEY phase 2/3 safety study were presented at medical meetings. In MELODY, nirsevimab met its primary endpoint of a statistically significant reduction in the incidence of medically attended lower respiratory tract infections caused by RSV compared to placebo in healthy late preterm and term infants (35 weeks or more) during their first RSV season. In MEDLEY, nirsevimab had a similar safety and tolerability profile to Synagis in infants with coronary heart disease, chronic lung disease and those born pre-term.

AstraZeneca and Sanofi intend to make a regulatory submission for nirsevimab in the US in the second half of 2022 based on the earlier phase 2b study and the MELODY and MEDLEY studies. Sobi has the right to AstraZeneca's full share of US losses and profits for nirsevimab.

Other developments
Sobi's subsidiary Florio develops next-generation digital solutions for patients and healthcare professionals that capture and visualise disease and treatment-related data in real time to enable better decision making and ultimately better care. florio HAEMO, a solution for people with haemophilia, their caregivers and their healthcare professionals is available in 24 countries across Europe and the Middle East. In 2021 Florio launched florio ITP, a digital diary for patients with ITP in the US in partnership with the Platelet Disorder Support Association. Florio continues to develop the app in co-creation with doctors and patients in line with Sobi's development portfolio.

Other information

Changes in Management
In 2021, Duane H. Barnes was appointed Head of North America, Thomas Kudsk Larsen Head of Communication and Investor Relations. In 2021, Paula Treutiger stepped down from the Executive Committee.

In 2022, Anders Ullman replaced Ravi Rao, who stepped down and left Sobi, as new Head of Research & Development and Chief Medical Officer. Furthermore, Anne Marie De Jonge Schuermans has left Sobi and Christine Wesstrom has been appointed Head of Technical Operations and member of the Executive Committee.

At 31 December 2021, the Executive Committee consisted of:

CEO: Guido Oelkers

CFO: Henrik Stenqvist

General Counsel and Head of Legal Affairs, Head of Human Resources: Torbjörn Hallberg

Head of North America: Duane H. Barnes

Head of Europe: Sofiane Fahmy

Head of Technical Operations: Anne Marie De Jonge Schuermans

Head of Business Development: Mahmood Ladha

Head of Communication & Investor Relations: Thomas Kudsk Larsen

Head of International: Norbert Oppitz

Head of Global Portfolio and Product Strategy: Daniel Rankin

Head of Medical & Scientific Affairs: Armin Reininger

Head of Research & Development, Chief Medical Officer: Ravi Rao

For more information about the Executive Committee, refer to pages 102–103.

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 23–27 and 104–127. The Sustainability Report has been prepared using the Global Reporting Initiative's (GRI) standards for sustainability reporting.

Corporate Governance Report
Under the Swedish Annual Accounts Act, Sobi is required to prepare a Corporate Governance Report. In accordance with the Swedish Annual Accounts Act, Chapter 6, Section 8, 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 93–99.

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 2021, 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
At 31 December 2021, Sobi's share capital amounted to SEK 168,520,825, distributed between 307,114,495 shares, with a par value of about SEK 0.55. At 31 December 2021, the total number of shares outstanding, excluding treasury shares, was 295,155,297, each carrying one vote. At 31 December 2021, Investor AB was Sobi's largest single shareholder with a total of 107,594,165 shares, representing 35 per cent of the votes and 35 per cent of the capital.

Share conversions
The Annual General Meeting (AGM) on 4 May 2021 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.

At 31 December 2021, Sobi held 11,959,198 treasury shares (of which 3,298,984 ordinary shares were acquired during the year), with a par value of about SEK 0.55, totalling SEK 6,6 M. The shares represent about 3.9 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 2021, 255,819 shares were allotted to employees, in accordance with the terms of the programmes. The par value of these shares was about SEK 0.55, totalling SEK 0.1 M, and representing about 0.1 per cent of the total share capital. See Note 10 for more information about Sobi's outstanding share-based programmes at the end of 2021.

All C shares issued in 2021 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, refer to the section on shares on pages 28–29.

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 2021 will be presented to the 2022 AGM for adoption and be available on the website (www.sobi.com) three weeks prior to the meeting. For a complete version of the current guidelines, refer to Note 10.

Proposed appropriation of profit

The following funds are at the disposal of the Annual General Meeting:

KSEK	
Share premium reserve	9,152,505
Retained earnings	7,157,315
Profit for the year	1,790,394
Total	**18,100,214**

The Board proposes that no dividends be paid for the 2021 financial year.

The Board proposes that the share premium reserve, retained earnings and profit for the year, KSEK 18,100,214, be carried forward.

Events after the reporting period

Gamifant
The National Medical Products Administration of China (NMPA) has approved Gamifant (emapalumab) for use in China for treatment of primary haemophagocytic lymphohistiocytosis (HLH).

In January 2022, Gamifant initiated dosing in a new phase 3 study, EMERALD. EMERALD evaluates the treatment of macrophage activation syndrome in paediatric and adult patients with underlying rheumatological diseases, specifically Still's disease and systemic lupus erythematosus. If the results are positive at the conclusion of the study, the first regulatory submission for a new indication is planned for the US with other countries to follow.

ReFacto
The contract with Pfizer for the manufacture of drug substance for ReFacto AF®/Xyntha® (ReFacto) has been amended due to clarity of final order volumes and will now expire in the first quarter of 2024, earlier than the previous expiry date at the end of 2025. Manufacturing of drug substance for ReFacto will be transferred to Pfizer's production unit in Ireland, ensuring continued patient access.

The process of downsizing its Stockholm manufacturing facility will start in the second half of 2022, with the last volumes being delivered to Pfizer in the beginning of 2024. An estimated 80 positions are expected to be affected by the closure over the next 24 months. Sales of ReFacto amounted to SEK 445 M in 2021.

The conflict in Ukraine
It is unclear how and to what extent Sobi's operations will be affected by the conflict in Ukraine. Sobi has operations in Russia with 35 employees. Sales in Russia accounted for less than 1 per cent of Sobi's total revenue for 2021. At the time of signing this annual report, Sobi has outstanding accounts receivable related to Russia amounting to approximately EUR 22 M, which are currently being evaluated. Sobi is following events closely to assess the potential and actual risks stemming from the situation.

Financial outlook for 2022

In 2022, Sobi will continue to expand its presence in haematology and immunology and expand into new geographic markets. As a result of this growth strategy, Sobi expects solid revenue growth, where revenue is anticipated to grow by a mid to high single-digit percentage at CER.

Sobi will continue to invest in the pipeline and launches of new medicines to unlock the long-term value of the business. With these investments in the future, Sobi maintains a favourable margin, where the EBITA margin is anticipated to be at a low 30s percentage of revenue.

Risk management

The aim of Sobi's risk management process is to support the company's operations and create profitable business opportunities combined with good risk control. The risk management process contributes with structure to proactively identify and manage risks that could have a negative impact on the company's ability to achieve its set targets. Effective risk assessment aligns Sobi's business opportunities and value creation with shareholders' and other stakeholders' expectation for sustainable and 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 set 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 to present 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.

In this section, we describe the principal risks that may have a significant effect on our financial situation, results of operations, and/or reputation. We outline why effective management of these risks is important and relevant to the business, and how they are managed. These risks are not listed in any particular order of priority.

The COVID-19 coronavirus pandemic has had, and will likely continue to have, an impact on our business, financial situation and results of operations. We expect the COVID-19 pandemic to increase certain risks, such as those related to demand for medicines and treatment, risks related to supply chain management, risks related to government priorities and healthcare systems, and more.

Sobi carefully monitors external events that can affect Sobi operations. The conflict in Ukraine and consequences are judged to impact Sobi's access to markets in Russia and Ukraine, and Sobi's ability to reach patients, among other effects. Refer also to events after the reporting period.

The identification and assessment of environmental and climate risk has been included in our existing risk management processes during 2021, and conclusions from this are being used to update targets, processes and follow-up mechanisms. This work will be further accelerated in 2022.

Business conditions

Risk area	Description	Management response
Key medicines	Our business is dependent on a few key medicines, and any events that adversely affect our leading medicines could adversely affect our business, results of operation and financial situation.	A strongly profitable portfolio that enables the extension of existing medicines into new indications and the further expansion of the portfolio. Unique expertise in orphan drugs. Well organised operations to meet market expectations and needs.
Competitive pressure	Certain of our business areas operate in a highly competitive segments, which may adversely affect our sales, margins and operations.	
Healthcare systems	Future healthcare cost-containment reform measures by government health authorities or government-sponsored healthcare systems could adversely affect our business.	Close monitoring of changes in healthcare systems on all relevant markets.
Acquisition strategy	Our strategy of selectively pursuing acquisitions may present unforeseen integration obstacles and costs.	Continuously ongoing work to identify suitable acquisitions and collaborations. High focus on integration of acquired entities and products.

Product pipeline and intellectual property

Risk area	Description	Management response
Development pipeline	The development of a new drug is a complex, capital-intensive and overall risky process involving significant resources. A drug may fail or be delayed at any stage of the process due to a number of reasons which could reduce growth, revenue or profit.	Strengthen the pipeline through the acquisition of companies, medicines and licences, and through collaboration. Sobi focuses on late-stage development projects that address unmet medical need and which are judged to have significant market potential.
Drug approval	Prior to launch, a drug must meet the strict requirements on quality, safety and efficacy that are expected by regulators. Failure can lead to a delayed or cancelled launch and can materially affect our business or financial results.	Quality management systems in place. Monitoring of changes in the regulatory environment, including revised process, timelines and guidance. Close management of clinical trials to make sure that the evidence is aligned with regulators' demands.
IP protection	Our business depends on intellectual property and the ability to protect such intellectual property against infringements from third parties. We may be unable to successfully protect our intellectual property rights, trade secrets and unpatented property know-how, which could affect our business or financial results.	Active management of IP rights and IP litigation in all markets.

Commercialisation

Risk area	Description	Management response
Market authorisation	Our medicines are commercialised through marketing authorisation rights and the loss of, or inability to maintain, obtain or acquire, such rights may affect our business and financial results.	Strong focus to keep and gain market authorisation, especially for newly acquired medicines.
Pricing	Marketing authorisation does not guarantee that the products 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 prices. A decline may lead to a reduction in revenue, profit and cash flow.	Value-based pricing model demonstrating value of medicines/health economics.
Market access	Our ability to market our medicines successfully depends, in part, upon the acceptance of and access to the products not only by patients, but also by independent third parties, including public health insurers, doctors and pharmacists depending on the jurisdiction in which we operate. Failure to access patients and third parties may lead to lower demand on Sobi's medicines and affect our financial results.	Close collaboration with stakeholders throughout the entire development process, to anticipate market needs and demands. The EU Pharmaceutical Strategy, a collaboration on unmet needs and evidence generation. We also advocate for support for people living with rare diseases through collaboration within trade organisations to drive knowledge and expertise sharing.

Business execution

Risk area	Description	Management response
Supply chain	We rely on third parties to manufacture and distribute our medicines, which increases the risk that we will not have sufficient quantities of our medicines available at an acceptable cost or quality, on time or at all. As a result, our current and anticipated future dependence upon others for the manufacture and distribution of our medicines may affect our business, our results and financial situation.	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 when possible dual sourcing and multiple suppliers. Responsible sourcing programme.
IT and cybersecurity	A breakdown of our information technology systems or cybersecurity incidents could result in a significant disruption of our business. This could include disruptions to our distributors, suppliers and other business partners. If a security breach were to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our reputation could be harmed. Any of this may have a material effect on our business and financial situation.	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	We 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 highly skilled employees required for our activities may have a material effect on our business and financial situation.	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 refers to fluctuations in exchange rates, interest rates, refinancing, liquidity and credit obligations. Negative impacts could affect our business and financial situation.	Our financial risk management is presented in Note 3.
Impairment of assets	Impairment of intangible assets may adversely affect our financial situation and results of operations. The future development of the macroeconomic environment, unsuccessful acquisitions or other factors could lead to possibly significant impairments to be recognised in the future, which could have a material adverse effect on our business and financial situation.	Significant accounting judgements, and the estimates and assumptions entailing a considerable risk of material adjustment to carrying amounts, are presented in Note 4.
Tax	We are subject to complex tax laws, and our operations include cross-border transactions. Changes in tax laws or challenges to our tax position could adversely affect our business, our results and financial situation.	Strong tax-compliance processes with close collaboration between the Group Tax function and subsidiaries. Combined internal and external counsel management.

Legal, regulatory and compliance

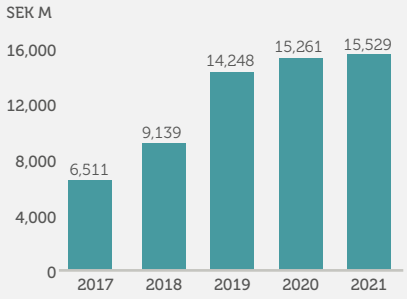
Risk area	Description	Management response
Patient safety	Patient safety is very important to us and we monitor and following up the safety profiles of all our products. Failure to do this could adversely impact our reputation, our business, our financial results and lead to liability claims.	All clinical studies are conducted and reported in accordance with applicable laws and Good Clinical Practice (GCP). Compliance with the European Medicines Agency's (EMA) policy on the publication of data for medicinal products for human use. Robust processes and systems in place to manage patient safety and efficacy trends. These include include a worldwide service for adverse reactions reporting. Regular training for employees in patient safety. All collaborations with contract research organisations (CROs) correspond to the same standard.
Litigation and other claims	From time to time, we are involved in various litigation matters, including product liability claims, warranty obligation claims, alleged violations of trade confidentiality and others. Any of these events could result in considerable costs, including damages, legal fees and temporary or permanent bans on the marketing of certain medicines, and this may have a material effect on our business and financial situations.	Combined internal and external counsel management.
Compliance with laws and regulations, including business ethics, environmental, climate, health and safety, information security and privacy	Any failure to comply with applicable laws, rules and regulations, including anti-bribery and anti-corruption legislation, trade sanctions, information security and privacy legislation, environmental legislation, and health and safety laws, may result in civil and/or criminal legal proceedings and/or regulatory sanctions, fines or penalties, and affect our reputation, our business and financial results. Since our business model relies on third parties for a large portion of the manufacturing and supply of our medicines this also includes all our 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 available to internal and external parties. Third-party risk management and Responsible Sourcing Programme.

Consolidated statement of comprehensive income

SEK M	Note	2021	2020
	1–4		
Operating revenue	5	15,529	15,261
Cost of goods sold		–3,484	–3,225
Gross profit		**12,045**	**12,036**
Selling and administrative expenses		–6,294	–5,981
Research and development costs		–1,994	–1,594
Other operating income	7	32	401
Other operating expenses	8	–56	–44
Operating profit	6, 9, 10, 11, 12, 16, 17, 29	**3,733**	**4,818**
Financial income	13	16	1
Financial expenses	14	–454	–602
Net financial items		**–438**	**–601**
Profit before tax		**3,295**	**4,217**
Income tax	15	–616	–972
Profit for the year[1]		**2,679**	**3,245**
Other comprehensive income[2]	25		
Items that cannot be reclassified into profit or loss			
Remeasurement of defined-benefit pension plans and similar plans (net of tax)		17	–3
Remeasurement of equity instruments (net of tax)		11	9
Other comprehensive income that cannot be reclassified into profit or loss (net of tax)		**28**	**6**
Items that may be reclassified to profit or loss			
Translation differences		464	–434
Net investment hedges (net of tax)		–242	246
Cash flow hedges (net of tax)		–63	130
Other comrehensive income that may be reclassified to profit or loss (net of tax)		**159**	**–58**
Other comprehensive income		**187**	**–52**
Comprehensive income[1, 2]		**2,866**	**3,193**
Earnings per share, SEK	25		
Earnings per share		9.08	11.01
Earnings per share, adjusted[3]		9.08	9.66
Earnings per share after dilution		9.03	10.90
Earnings per share after dilution, adjusted[3]		9.03	9.56

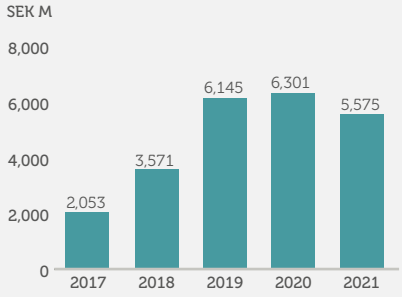
1. Everything attributable to Parent Company shareholders.
2. Under the revised IAS 1, all non-owner changes in equity are to be presented in the consolidated statement of comprehensive income. Translation differences are entirely related to the consolidated net assets of subsidiaries in foreign currency.
3. Alternative Performance Measures, see Definitions on p 130.

Operating revenue



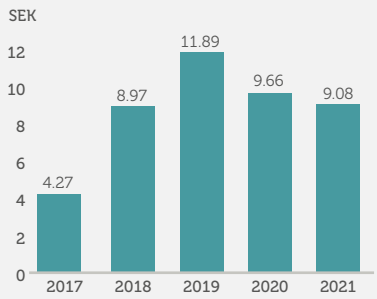
Operating revenue
In 2021, revenue amounted to SEK 15,529 M (15,261), an increase of 2 per cent.

Adjusted EBITA[3]



Adjusted EBITA amounted to SEK 5,575 M, a decrease of 12 per cent year-on-year.

Adjusted earnings/share[3]

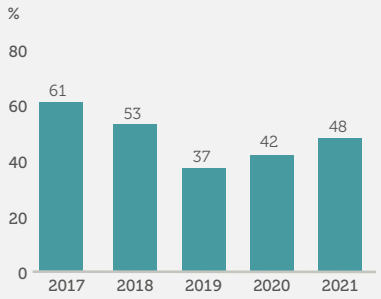


Consolidated balance sheet

SEK M	Note	31 Dec 2021	31 Dec 2020
ASSETS	1–4		
Non-current assets			
Intangible assets	16	38,424	38,791
Tangible assets	17	493	534
Financial assets	19	199	179
Deferred tax assets	20	767	611
Total non-current assets		**39,883**	**40,115**
Current assets			
Inventories	21	3,424	3,053
Accounts receivable	22	3,439	3,756
Other receivables	22	345	465
Prepaid expenses and accrued income	23	525	490
Cash and cash equivalents	24	1,045	404
Total current assets	26	**8,778**	**8,168**
TOTAL ASSETS		**48,661**	**48,283**
EQUITY AND LIABILITIES			
Equity			
Share capital		169	167
Other contributed capital		9,945	9,816
Other reserves	25	–66	–253
Retained earnings		10,476	7,232
Profit for the year		2,679	3,245
Equity attributable to Parent Company shareholders		**23,203**	**20,206**
Liabilities			
Non-current liabilities			
Borrowings	27	8,777	10,137
Deferred tax liabilities	20	3,605	3,464
Lease liabilities	9	247	308
Provisions	29, 30	234	252
Other liabilities, non-interest-bearing	28	3,834	3,473
Total non-current liabilities	26	**16,697**	**17,634**
Current liabilities			
Borrowings	27	1,768	4,015
Accounts payable		558	569
Tax liabilities		40	518
Lease liabilities	9	114	111
Other liabilities, non-interest-bearing	28	1,314	1,302
Accrued expenses and deferred income	31	4,967	3,928
Total current liabilities	26	**8,761**	**10,443**
TOTAL EQUITY AND LIABILITIES		**48,661**	**48,283**

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

Equity/assets ratio[1]



Net debt (+)/net cash (–)

SEK M	2017	2018	2019	2020	2021
Borrowings	–	–	16,141	14,152	10,545
Cash and cash equivalents	1,478	2,999	737	404	1,045
Net debt (+)/net cash (–)	**–1,478**	**–2,999**	**15,404**	**13,748**	**9,500**

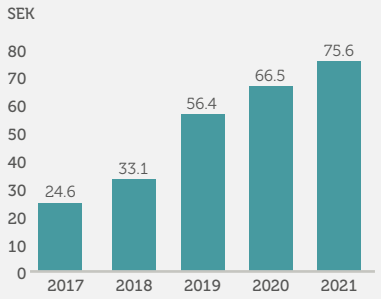
1. Alternative Performance Measures, see Definitions on p 130.

Consolidated statement of changes in equity

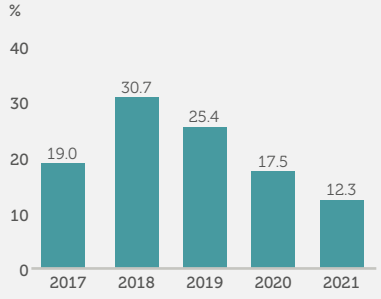
SEK M	Share capital	Other contributed capital	Other reserves[1]	Retained earnings	Total equity
Opening equity, 1 Jan 2020	**165**	**9,697**	**–202**	**7,270**	**16,930**
Adjusted opening balance for post-employment benefits from prior years[2]	–	–	–	–45	–45
Tax on adjusted opening balance for post-employment benefits from prior years[2]	–	–	–	7	7
Comprehensive income					
Profit for the year	–	–	–	3,245	3,245
Other comprehensive income					
Remeasurement of defined-benefit pension plans and similar plans (net of tax)	–	–	–3	–	–3
Remeasurement of equity instruments (net of tax)	–	–	9	–	9
Other comprehensive income that cannot be reclassified into profit or loss (net of tax)	**–**	**–**	**6**	**–**	**6**
Translation differences	–	–	–434	–	–434
Net investment hedges (net after tax)	–	–	246	–	246
Cash flow hedges (net of tax)	–	–	130	–	130
Other comrehensive income that may be reclassified to profit or loss (net of tax)	**–**	**–**	**–58**	**–**	**–58**
Other comprehensive income	**–**	**–**	**–52**	**–**	**–52**
Total comprehensive income	**–**	**–**	**–52**	**3,245**	**3,193**
Shareholder transactions					
Issue of shares	2	–2	–	–	–
Share-based compensation to employees	–	114	–	–	114
Tax deductions for share programmes[3]	–	7	–	–	7
Total shareholder transactions	**2**	**119**	**–**	**–**	**121**
Closing equity, 31 Dec 2020	**167**	**9,816**	**–253**	**10,476**	**20,206**
Opening equity,1 Jan 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 comrehensive 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 deductions for share programmes[3]	–	–3	–	–	–3
Total shareholder transactions	**2**	**129**	**–**	**–**	**131**
Closing equity, 31 Dec 2021	**169**	**9,945**	**–66**	**13,155**	**23,203**

1. For a specification of other reserves, see Note 25.
2. Refers to post-employment benefits, mainly in Switzerland, not previously included at Dec 2019.
3. The additional deductions relate to the difference between the market value of allotted shares and recognised IFRS 2 expense.

Equity/share[4]



Return on equity[4]



Return on equity was 12.3 per cent.

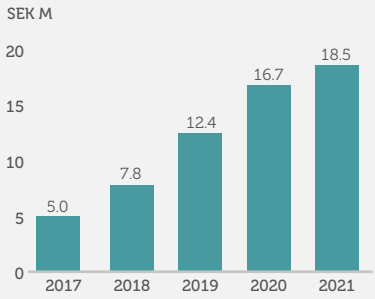
4. Alternative Performance Measures, see Definitions on p 130.

Consolidated cash flow statement

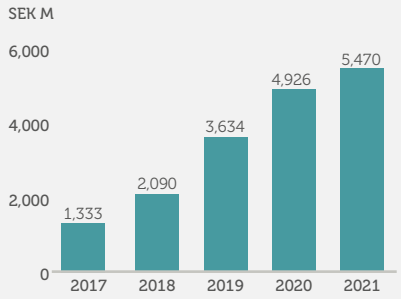
SEK M	Note	2021	2020
Cash flow from operating activities			
Profit before tax[1]		3,295	4,217
Non-cash items			
Depreciation/amortisation and impairment		2,006	2,023
Other non-cash items		529	390
Cash items			
Interest received		0	1
Interest paid		–324	–333
Payment to pension funds		–26	–13
Income tax paid		–1,124	–918
Cash flow from operating activities before changes in working capital		**4,356**	**5,367**
Cash flow from changes in working capital			
Changes in inventories		–318	–1,325
Changes in operating receivables		452	–185
Changes in operating liabilities		980	1,069
Cash flow from operating activities		**5,470**	**4,926**
Investing activities			
Investments in intangible assets[2]	16	–323	–3,811
Investments in tangible assets	17	–47	–41
Investments in financial assets[3]	19	–	–120
Disposal of tangible assets	17	3	8
Cash flow from investing activities		**–367**	**–3,964**
Financing activities			
Borrowings	27	14,193	13,575
Repayment of borrowings		–18,191	–15,027
Hedging arrangements for financing		–351	288
Repayment of leasing		–125	–118
Cash flow from financing activities		**–4,474**	**–1,282**
Change in cash and cash equivalents		**629**	**–320**
Cash and cash equivalents at beginning of year		**404**	**737**
Exchange difference in cash and cash equivalents		**12**	**–13**
Cash and cash equivalents at end of year		**1,045**	**404**

1. As of 2021, Sobi has 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. Comparative figures for 2020 have been recalculated. For more information see Note 2 Accounting policies.
2. In 2020, the largest investments pertained to Aspaveli and SEL-212, see Note 16 for more information.
3. Relates to shares in Selecta Biosciences, Inc.

Cash flow from operating activities/share[4]



Cash flow from operating activities[4]



4. Alternative Performance Measures, see Definitions on p 130.

Parent Company income statement

SEK M	Note	2021	2020
	1–4		
Operating revenue	5	12,401	13,968
Cost of goods sold		–2,933	–3,134
Gross profit		**9,468**	**10,834**
Selling and administrative expenses		–4,179	–4,174
Research and development costs		–1,256	–923
Other operating income	7	353	96
Other operating expenses	8	–3	–
Operating profit	6, 9, 10, 11, 12, 16, 17	**4,383**	**5,833**
Financial income	13	336	663
Financial expenses	14	–728	–469
Net financial items		**–392**	**194**
Profit after financial items		**3,991**	**6,027**
Group contributions, net		–1,113	–1,583
Excess depreciation		–600	–107
Appropriations		**–1,713**	**–1,690**
Profit before tax		**2,278**	**4,337**
Income tax	15	–488	–931
Profit		**1,790**	**3,406**

Parent Company statement of comprehensive income

SEK M	2021	2020
Profit	1,790	3,406
Items that cannot be reclassified into profit or loss		
Remeasurement of equity instruments (net of tax)	11	9
Items that may be reclassified to profit or loss		
Cash flow hedges (net of tax)	–63	130
Other comprehensive income	**–52**	**139**
Comprehensive income	**1,738**	**3,545**

Parent Company balance sheet

SEK M	Note	31 Dec 2021	31 Dec 2020
ASSETS	1–4		
Non-current assets			
Intangible assets	16	10,107	10,205
Tangible assets	17	89	64
Financial assets			
Participations in Group companies	18	7,676	7,676
Receivables from Group companies		14,298	15,312
Other financial assets	19	190	176
Deferred tax assets	20	27	24
Total non-current assets		**32,387**	**33,457**
Current assets			
Inventories	21	2,536	2,527
Current receivables			
Accounts receivable	22	1,126	731
Other receivables	22	292	405
Receivables from Group companies		4,308	3,947
Prepaid expenses and accrued income	23	455	430
Cash and cash equivalents	24	878	240
Total current assets		**9,595**	**8,280**
TOTAL ASSETS		**41,982**	**41,737**

SEK M	Note	31 Dec 2021	31 Dec 2020
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital		169	167
Statutory reserve		800	800
Total restricted equity		**969**	**967**
Unrestricted equity			
Share premium reserve		9,153	9,024
Retained earnings		7,157	3,803
Profit for the year		1,790	3,406
Total unrestricted equity		**18,100**	**16,233**
Total equity		**19,069**	**17,200**
Untaxed reserves			
Excess depreciation		3,691	3,091
Total untaxed reserves		**3,691**	**3,091**
Liabilities			
Non-current liabilities			
Borrowings	27	8,777	10,137
Liabilities to Group companies		–	157
Provisions	30	79	82
Other liabilities, non-interest-bearing	28	2,818	2,475
Total non-current liabilities		**11,674**	**12,851**
Current liabilities			
Borrowings	27	1,768	4,015
Accounts payable		359	398
Liabilities to Group companies		3,229	1,674
Tax liabilities		–	467
Other liabilities, non-interest-bearing	28	896	727
Accrued expenses and deferred income	31	1,296	1,314
Total current liabilities		**7,548**	**8,595**
TOTAL EQUITY AND LIABILITIES		**41,982**	**41,737**

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

Parent Company statement of changes in equity

	Restricted equity		Unrestricted equity		
SEK M	Share capital	Statutory reserve	Share premium reserve	Retained earnings and profit/loss for the year[1]	Total equity
Opening equity, 1 Jan 2020	**165**	**800**	**8,905**	**3,665**	**13,534**
Profit	–	–	–	3,406	3,406
Other comprehensive income	–	–	–	139	139
Comprehensive income	**–**	**–**	**–**	**3,545**	**3,545**
Shareholder transactions					
Issue of shares	2	–	–2	–	–
Share-based compensation to employees	–	–	114	–	114
Share-based compensation to employees, tax effect[2]	–	–	7	–	7
Total shareholder transactions	**2**	**–**	**119**	**–**	**121**
Closing equity, 31 Dec 2020	**167**	**800**	**9,024**	**7,209**	**17,200**
Opening equity, 1 Jan 2021	**167**	**800**	**9,024**	**7,209**	**17,200**
Profit	–	–	–	1,790	1,790
Other comprehensive income	–	–	–	–52	–52
Comprehensive income	**–**	**–**	**–**	**1,738**	**1,738**
Shareholder transactions					
Issue of shares	2	–	–2	–	–
Share-based compensation to employees	–	–	134	–	134
Share-based compensation to employees, tax effect[2]	–	–	–3	–	–3
Total shareholder transactions	**2**	**–**	**129**	**–**	**131**
Closing equity, 31 Dec 2021	**169**	**800**	**9,153**	**8,948**	**19,069**

1. See specification of other comprehensive income.
2. The additional deductions relate to the difference between the market value of allotted shares and recognised IFRS 2 expense.

At year-end, Sobi's share capital amounted to KSEK 168,521 distributed between 307,114,495 ordinary shares with a par value of about SEK 0.55 and one voting right. At the balance sheet date, the company held 11,959,198 ordinary shares in treasury, corresponding to 3.9 per cent of the total number of shares in the company.

Other comprehensive income	Cash flow hedges	Equity instruments	Total
Opening balance, 1 Jan 2020	**–62**	**–**	**–62**
Gain/loss on remeasurement of hedging instruments recognised in equity	133	–	133
Tax on gain/loss on remeasurement of hedging instruments recognised in equity	–29	–	–29
Transferred to profit or loss	34	–	34
Tax on transferred to profit or loss	–7	–	–7
Gain/loss on remeasurement of equity instruments recognised in equity	–	11	11
Tax effect on equity instruments	–	–2	–2
Closing balance, 31 Dec 2020	**68**	**9**	**77**
Opening balance, 1 Jan 2021	**68**	**9**	**77**
Gain/loss on remeasurement of hedging instruments recognised in equity	–81	–	–81
Tax on gain/loss on 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 on remeasurement of equity instruments recognised in equity	–	14	14
Tax effect on equity instruments	–	–3	–3
Closing balance 31 Dec 2021	**6**	**20**	**25**

Parent Company cash flow statement

SEK M	Note	2021	2020
Cash flow from operating activities			
Profit/loss after financial items[1]		3,991	6,027
Non-cash items			
Depreciation/amortisation and impairment		385	347
Other non-cash items		392	61
Cash items			
Interest received		273	387
Interest paid		−406	−343
Income tax paid		−960	−747
Cash flow from operating activities before changes in working capital		**3,675**	**5,732**
Cash flow from changes in working capital			
Changes in inventories		−9	−994
Changes in operating receivables		942	1,456
Changes in operating liabilities		2,250	−1,461
Cash flow from operating activities		**6,858**	**4,733**
Investing activities			
Investments in intangible assets[2]	16	−261	−3,633
Investments in tangible assets	17	−30	−15
Investments in financial assets[3]	19	–	−120
Disposal of intangible assets	16	3	8
Cash flow from investing activities		**−288**	**−3,760**
Financing activities	27		
Borrowings		14,193	13,575
Repayment of borrowings		−18,191	−15,027
Group contribution		−1,584	–
Hedging arrangements for financing		−351	288
Cash flow from financing activities		**−5,933**	**−1,164**
Change in cash and cash equivalents		**638**	**−191**
Cash and cash equivalents at beginning of year		**240**	**431**
Cash and cash equivalents at end of year		**878**	**240**

1. As of 2021, Sobi has 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. Comparative figures for 2020 have been recalculated. For more information see Note 2 Accounting policies.
2. In 2020, the largest investments pertained to Aspaveli and SEL−212, see Note 16 for more information.
3. Relates to shares in Selecta Biosciences, Inc.

Notes

1 General information

Swedish Orphan Biovitrum AB (publ), Corporate Registration Number 556038-9321, the Parent Company and its subsidiaries, collectively the Group, is a publicly listed international pharmaceutical company dedicated to rare diseases.

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

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

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, the Swedish Financial Reporting Board's recommendation RFR 1, Supplementary Accounting Rules for Groups, International Financial Reporting Standards (IFRS) and International Financial Reporting Interpretations Committee (IFRIC) interpretations 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 incomes (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, in the 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 2021

The IFRIC published an agenda decision in April 2021 about how to account for the costs of configuring or customising software in cloud computing arrangements. Due to the IFRIC's decision, some previously recognised intangible assets have been reclassified on the balance sheet or expensed retroactively during the period. In addition, the decision means that future costs for configuring or customising software in cloud computing arrangements cannot be capitalised to the same extent in the Group's future financial statements.

No other new or revised standards and interpretations applied since 1 January 2021 have had any effect on the consolidated financial statements.

New or revised accounting policies that will come into effect after 2021

No 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

Cash flow

As of 1 January 2021, Sobi changed the presentation of cash flow, and reclassified hedging arrangements hedging arrangement for financing from cash flow from operating activities to cash flow from financing activities to better reflect the financial meaning of the hedging arrangement. The change of the presentation form means that certain items in the cash flow from operating activities are now reported on separate lines and that the starting point for the cash flow has been changed to profit before tax. The change of the presentation form has no effect on the cash flow from operating activities, but comparative figures have been added. For reclassification of hedging arrangement for financing comparative figures for 2020 has been recalculated whereby the cash flow from operating activities has changed from SEK 5,214 M to SEK 4,926 M. Cash flow from financing activities has been changed for the corresponding period from SEK –1,570 M to SEK –1,282 M.

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, which normally means that Parent Company owns more than 50 per cent of the votes for all shares and participations. 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 and non-contingent considerations are recognised as financial liabilities and measured at fair value at the acquisition date. These are remeasured to fair value at each reporting date where the interest component is recognised on the income statement as a financial expense 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, or 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 business areas: Haematology, Immunology and Speciality 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. The internal reporting to the CEO uses three segments that represents Sobi's three business areas. The accounting policies applied by the segments are consistent with the Group's. 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.

Note 2, cont.

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 an financial income or expense.

Exchange differences for non-monetary financial assets valued at fair value, such as shares that are classified as financial assets valued at fair value via 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 on 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.

OPERATING REVENUE
Operating revenue mainly comprises sales of proprietary products, products for which Sobi holds the distribution and/or licensing agreements, revenue from manufacturing and royalty revenue. Revenue comprises invoiced gross revenue according to agreement for goods sold excluding VAT, discounts, pharmaceutical taxes and returns. 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 product sales is recognised when Sobi has satisfied its performance obligations, which means that the customer has taken control over the product. In practice, this arises when the goods have been delivered from the company's consignment stock to the customer. The performance obligations associated with the contracts between Sobi and its customers consist mainly of distinct goods that are transferred to the customer against payment. The products are not customised and can be used by the customers in the condition they are delivered. The products 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, which are recognised as accounts receivable.

The price of the goods is identified in contract. The considerations are variable to some extent before 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 transport warranties, i.e. if the product is damaged 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 is 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 (ReFacto) 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.

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 product. 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. In 2021, milestone payments received amounted to SEK – M (87).

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

Government grants
Government grants are recognised when the company fulfils the criteria attached to the grant and there is reasonable assurance that the grants will be received. Grants received are recognised as deferred income in the balance sheet and are recognised in profit or loss as a reduced cost in the period in which expenses are recognised for the costs for which the grants compensate. In 2021 and 2020, Sobi did not receive any government grants.

Other operating income/expenses
Other operating income/expenses are income and expenses arising from activities outside the company'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, 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.

Note 2, cont.

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, or 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, that 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 fair value of the consideration paid and future contingent consideration plus transaction costs. Fair value is determined by totalling the payment obligations in connection with the acquisition. The future contingent 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 section on financial instruments – 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 and 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 and 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 as soon as they are incurred. Costs directly associated with identifiable software products developed specifically for Sobi that are controlled by the company 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.

Manufacturing relocation costs

Costs at relocation of manufacturing of Sobi's products are capitalised, if they meet the requirements of IAS 38, and classified as intangible assets. Costs that are capitalised are costs directly attributable to the construction of new production lines. Amortisation commences when the asset is available for use.

Amortisation of capitalised costs

Amortisation of capitalised costs is charged to selling and administrative expenses. For more information, 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 the company 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 test on goodwill, product and market rights and development projects are 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 the 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

Note 2, cont.

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, see Note 9.

Sobi has a provision for restoration of a leased property in Stockholm when the lease expires.

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 in the balance sheet, including transaction costs, at the transaction date.

Financial instruments recognised as assets in the balance sheet include equity instruments, endowment policies, accounts receivable, derivatives, and cash and cash equivalents. Financial liabilities mainly include borrowings, contingent 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:

1. The objective of the business model is to hold the financial asset to collect the contractual cash flows.
2. 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 a model for expected future losses, which have been calculated using historical losses and forward-looking estimates. Any impairments of accounts receivable based on expected credit losses, as well as any impairment on individually assessed receivables, 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 (see above). 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 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.

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 twelve months after the balance sheet date.

Liabilities related to contingent considerations are initially measured at the fair value of future obligations. 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 as described below. 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 in the balance sheet. This category includes derivatives and contingent considerations in connection with 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.

Note 2, cont.

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 income/expenses. See below for the recognition of derivatives that meet the criteria for hedge accounting.

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 CASH EQUIVALENTS
The cash and cash equivalents of the Parent Company and the Group include the Group's balances in consolidated accounts and other bank accounts, and investments with a maturity of less than three months from the acquisition date.

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
Provisions are recognised on the balance sheet when Sobi has a legal or constructive obligation as a result of an event that has occurred and where it is probable that an outflow of resources will be required to settle the obligation. It must also be possible to make a reliable estimate of the amount. Provisions are recognised in the amount corresponding to the best estimate of the payment required to settle 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. Provisions are recognised on the balance sheet under other current and non-current liabilities.

Restructuring provisions, which substantially change the way in which Sobi works, are 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. Provisions for restructuring often include termination benefits, which can be either voluntary or involuntary. Termination benefits are recognised as described above, except in those cases in which a service obligation is tied to the benefit, in which case costs are distributed over the period in which the services are carried out.

Restructuring provisions entail estimates of the time and cost of planned future activities. The most significant estimates relate to those costs required for severance pay or other obligations in connection with termination of employment, as well as costs for the termination of agreements and other costs for withdrawal. Such estimates are based on the actual situation in negotiations with the affected parties and/or their representatives. Salaries relating to periods following the termination of duty to work are expensed when the decision is made and communicated.

Sobi recognises endowment policies gross on the balance sheet as a financial asset and a provision. For more information, see under the heading Direct pensions.

CONTINGENT LIABILITIES
Contingent liabilities are recognised when there is a possible commitment 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
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. 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. 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 for pensions. 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.

Note 2, cont.

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, that include all employees in the US and Canada. Since awards under these programmes are contingent upon continued employment at the company, 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.

Termination benefits
A provision for costs in connection with termination of personnel is recognised only if the company 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 the company 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.

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 from, 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:

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. 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.

Change in external reporting
Cash flow
As of 2021, Sobi has 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 to better reflect the financial meaning of the hedging arrangement.

The change of the presentation form means that certain items in the cash flow from operating activities are now reported on separate lines and that the starting point for the cash flow has been changed to profit after financial items. The change of the presentation form has no effect on the cash flow from operating activities, but comparative figures have been added. For reclassification of hedging arrangement for financing comparative figures for 2020 has been recalculated whereby the cash flow from operating activities has changed from SEK 5,021 M to SEK 4,733 M. Cash flow from financing activities has been changed for the corresponding period from SEK –1,452 M to SEK –1,164 M.

3 Financial risk management

Financial risks and risk management
Through its operations, Sobi is exposed to various kinds of risks that may impact the company'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 monitoring and payments, continuously monitoring financial risk and supporting the business operations in finance-related issues.

The Treasury Policy, which is adopted by the Board, establishes the division of responsibilities and control of financial 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, which may affect the company's profitability, cash flow and financial position. This risk is limited in the subsidiaries as their commercial flows are mainly denominated in their local currencies. This risk is significant for the Parent Company, since the company has considerable flows of

foreign currencies, primarily EUR and USD. If the SEK had weakened 5 per cent against other currencies in 2021, sales would have increased SEK 742 M (696) and EBITA would have risen SEK 332 M (402), for more details see the tables below.

Impact at 5 per cent weakening of SEK:

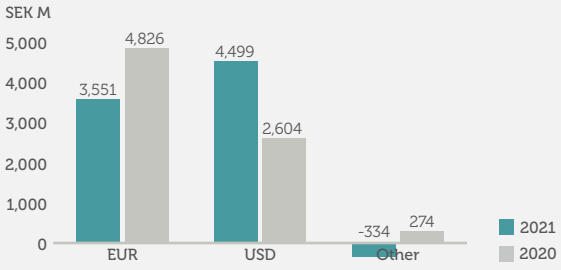
2021	Sales	EBITA
USD	377	171
EUR	297	167
Other currencies	68	–5
Total	**742**	**332**

2020	Sales	EBITA
USD	330	178
EUR	306	220
Other currencies	60	4
Total	**696**	**402**

Financial instruments, such as currency futures, 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 Synagis, Elocta and Alprolix products.

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

Transaction exposure, annual volume



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 by using 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 weakened 5 per cent against other currencies in 2021, the group equity and the net financial assets and liabilities would have been impacted as shown in the tables below.

Impact at 5 percent weakening of SEK:

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

2020	Equity	Financial assets and liabilities
CHF	–211	–13
EUR	135	148
USD	51	365
Other currencies	–13	–11
Total	**–38**	**489**

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 there is sufficient cash and undrawn credit facilities 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. At 31 December 2021, the company's undrawn committed credit facilities totalled SEK 4,336 M (4,320). At 31 December 2021, SEK 10,597 M (14,234) of the facilities had been drawn. See the distribution in the table below.

Credit facilities, maturity structure

GROUP	2022	2023	2024	Total
Credit facilities, undrawn	1,954	264	2,117	4,336
Credit facilities, drawn	1,768	5,104	3,725	10,597
Credit facilities, total	**3,722**	**5,368**	**5,842**	**14,932**

The following table shows the contractual, non-discounted cash flows 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

AT 31 DECEMBER 2021, GROUP	Less than 1 year	Between 1–2 years	Between 2–5 years	More than 5 years
Derivatives[1]	10	–	–	–
Borrowings	1,953	5,260	3,792	–
Accounts payable	558	–	–	–
Leases	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**

AT 31 DECEMBER 2020, GROUP	Less than 1 year	Between 1–2 years	Between 2–5 years	More than 5 years
Derivatives[1]	269	–	–	–
Borrowings	4,231	3,748	6,817	–
Accounts payable	569	–	–	–
Leases	111	114	209	42
Contingent considerations	491	–	2,836	11,259
Non-contingent considerations	205	102	962	–
Total	**5,876**	**3,964**	**10,824**	**11,301**

1. 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 at 31 December 2021. For information in the balance sheet, see Note 26.

Interest rate risk

Interest rate risk is the risk that Sobi would be adversely impacted 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 its earnings volatility. 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.

Note 3, cont.

Interest-rate sensitivity is measured by assuming a constant interest-rate change of 1 percentage point. At 31 December 2021, such a change would have had an annual impact of SEK 100 M (132) on net financial items. At 31 December 2021, Sobi's interest-bearing liabilities amounted to SEK 10,545 M (14,152). 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. At the balance sheet date, these amounted to SEK 3,439 M (3,756), of which SEK 607 M (622) was overdue. 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 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. At 31 December 2021, these amounted to SEK 71 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 its Treasury Policy, Sobi has established principles that limit the amount of exposure to financial credit risk per counterparty. To further limit financial credit risk, financial transactions are primarily conducted with counterparts with a high credit rating. Any surplus liquidity is 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, 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 works with its capital structure and indebtedness 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 indebtedness as a measure of the company's capital structure, which is calculated using net debt/adjusted EBITDA. The aim is to keep indebtedness at a level that is appropriate for the company's operations, and that enables relevant acquisitions and investments.

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

GROUP	2021	2020
Net debt	9,500	13,748
Adjusted EBITDA[1]	5,740	6,442
Indebtedness	1.66	2.13

1. In 2020, adjusted EBITDA excluded a positive impact of SEK 399 M pertaining to reversal of the liability for the Contingent Value Right (CVR). See also Directors' report under operating profit for more information.

Hedge accounting

As described above, 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 2021 and their effects on profit or loss during the year. In 2021, Sobi's total ineffectiveness was SEK 0 M (0).

Cash flow hedges 2021

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

Cash flow hedges 2020

Currency	Nominal value in SEK M	Hedging instrument	Hedged item	Hedged risk	Maturity interval
EUR	335	Borrowings	Highest probable inflows of EUR	Foreign-exchange risk (Avista)	2021–2023
USD	19	Non-contingent consideration	Highest probable inflows of USD	Foreign-exchange risk (Avista)	2021

Net investment hedges 2021

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

Net investment hedges 2020

Currency	Nominal value in SEK M	Hedging instrument	Hedged item	Hedged risk
USD	345	Contingent consideration	Net assets in USD	Foreign-exchange risk (Avista)

In 2021 and 2020, 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, 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. At 31 December 2021, sales-related accruals amounted to SEK 3,053 M (2,158). 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 2021, Sobi had not completed any business acquisitions considered as an asset acquisition.

Intangible assets

Upon the acquisition of intangible assets that include terms for contingent 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. 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 emapalumab.

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. At 31 December 2021, Sobi's goodwill amounted to SEK 6,288 M (5,873). 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 effect on the carrying amount of the asset. At 31 December 2021, Sobi's product and marketing rights amounted to SEK 31,559 M (32,307).

Sales forecast assumptions have a major impact on future value and are based on assumptions of underlying growth, future product development and expanded applications for the drug. For product development projects, assumptions about positive outcomes in clinical trials 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 products. Right of use is consumed over the asset's useful life, which corresponds to the related product's estimated useful life in the market.

Research and development costs

Sobi conducts research and 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 contingent 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 2021, 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.

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. 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 recovered through future taxable profits in the various tax jurisdictions.

At the end of 2021, Sobi recognised deferred tax assets of SEK 767 M (611) and deferred tax liabilities of SEK 3,605 M (3,464), as well as unused tax loss carry-forwards of SEK 2,716 M (2,708). Changes in estimates of future taxable profits, as well as changes in tax rates, could therefore have either a positive or negative effect on earnings when determining the value of deferred tax. 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. At the end of 2021, recognised liability amounted to SEK 2,818 M (2,846) and total obligations amounted to SEK 17,295 M (14,587). 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 product. 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, see Note 2. Also refer to Note 28 for more information about financial liabilities linked to contingent considerations.

5 Segment information and segment revenue

SEGMENT INFORMATION

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

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

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 the Specialty Care portfolio.

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 adjusted EBITA for each segment comprise their contribution to the Group's revenue, EBITA and adjusted EBITA. 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 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**
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**

GROUP 2020	Haematology	Immunology	Specialty Care	Group – other	Total
Revenue and EBITA per segment					
Revenue	8,660	5,415	1,186	–	15,261
EBITA[2]	4,775	1,902	564	–541	6,700
EBITA adjusted[2]	4,376	1,902	564	–541	6,301
Depreciation	–652	–1,009	–179	–42	–1,882
Financial expenses	–	–	–	–602	–602
Financial income	–	–	–	1	1
Profit/loss after financial items	**4,123**	**893**	**385**	**–1,184**	**4,217**
Assets					
Goodwill	4,761	1,112	–	–	5,873
Other intangible assets	13,573	18,447	701	198	32,918
Total intangible assets	**18,334**	**19,559**	**701**	**198**	**38,791**

1. EBITA 2020 excluding non-recurring items; other operating income related to reversal of the CVR liability of SEK 399 M.
2. The CVR liability in 2020 has been reclassified from Group - other to Haematology.

GROUP	2021	2020
Haematology		
Elocta	3,960	4,585
Alprolix	1,764	1,705
Royalties	1,251	1,301
Doptelet	1,116	587
Aspaveli/Empaveli	1	–
Manufacturing	445	481
Total	**8,536**	**8,660**
Immunology		
Kineret	2,290	2,079
Synagis	2,650	2,726
Gamifant	840	609
Total	**5,780**	**5,415**
Specialty Care		
Orfadin	459	665
Tegsedi	427	–
Waylivra	121	–
Other Specialty Care	207	521
Total	**1,213**	**1,186**
Total revenue	**15,529**	**15,261**

GROUP	2021	2020
Revenue – Gross-To-Net		
Product sales, gross	19,195	18,401
Contractual discounts	–1,778	–1,243
Statutory discounts	–3,418	–3,849
Tender-based discounts	–74	–77
Product returns	–43	–44
Cash discounts	–64	–47
Total discounts	**–5,378**	**–5,260**
Product sales, net	**13,817**	**13,141**
Manufacturing	445	481
Royalties	1,251	1,301
Milestone payment	–	87
Service fees	16	251
Operating revenue	**15,529**	**15,261**

Note 5, cont.

PARENT COMPANY	2021	2020
Revenue – Gross-To-Net		
Product sales, gross	11,595	13,690
Contractual discounts	–769	–543
Statutory discounts	–136	–1,211
Cash discounts	–1	–
Total discounts	**–906**	**–1,754**
Product sales, net	**10,689**	**11,936**
Manufacturing	445	481
Royalties	1,251	1,301
Service fees	16	251
Operating revenue	**12,401**	**13,968**

	Group		Parent Company	
	2021	2020	2021	2020
Total contract assets[1]				
Accounts receivable	3,439	3,756	1,126	731
Accrued royalties[2]	321	302	321	302
Total	**3,760**	**4,058**	**1,448**	**1,033**

1. For maturity structure and the year's change, see Note 22.
2. Included in prepaid expenses and accrued income on the balance sheet.

5

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 Jan 2020	**424**	**546**	**22**	**38**	**2**	**1,032**
Reserves for current year	854	2,169	44	103	6	3,176
Adjusted reserves for prior years	–31	–34	0	–5	–2	–72
Payments	–650	–1,026	–2	–105	–1	–1,784
Translation differences	–36	–147	–7	–4	0	–194
Closing balance, 31 Dec 2020	**561**	**1,509**	**56**	**28**	**5**	**2,158**
Opening balance, 1 Jan 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 Dec 2021	**658**	**2,270**	**88**	**34**	**4**	**3,053**

Revenue and assets by segment and geographic area

	Haematology		Immunology		Specialty Care		Group – Other	Total	
GROUP 2021	Revenue	Non-current assets	Revenue	Non-current assets	Revenue	Non-current assets	Non-current assets	Revenue	Non-current assets
Europe	5,743	8,996	627	7,011	641	544	121	7,011[1]	16,671
North America	1,079	9,879	4,600	11,873	441	–	–	6,120[2]	21,753
Rest of the world	463	–	553	–	131	–	–	1,147	–
Other[3]	1,251	–	–	–	–	–	–	1,251	–
Total	**8,536**	**18,875**	**5,780**	**18,884**	**1,213**	**544**	**121**	**15,529**[4,5]	**38,424**

	Haematology		Immunology		Specialty Care		Group – Other	Total	
GROUP 2020	Revenue	Non-current assets	Revenue	Non-current assets	Revenue	Non-current assets	Non-current assets	Revenue	Non-current assets
Europe	6,377	8,984	618	6,985	625	701	198	7,620[1]	16,868
North America[6]	586	9,350	4,509	12,574	388	–	–	5,483[2]	21,924
Rest of the world	396	–	288	–	173	–	–	857	–
Other[3]	1,301	–	0	–	–	–	–	1,301	–
Total	**8,660**	**18,334**	**5,415**	**19,559**	**1,186**	**701**	**198**	**15,261**[4,5]	**38,791**

1. Sales revenue from external customers in France amounted to SEK 1,805 M (1,960), in Germany to SEK 1,233 M (1,445), and in Sweden to SEK 678 M (720).
2. Sales revenue from external customers in the US amounted to SEK 6,054 M (5,435).
3. Other pertains to royalties derived from our haemophilia products that are not attributable to a specific region according to the distribution above. All royalties pertain to Sanofi's sales of Eloctate and Alprolix.
4. Total sales revenue from external customers in other countries amounted to SEK 4,508 M (4,400).
5. In 2021, Sobi's largest customer accounted for approximately 17 per cent (12) of sales. The customer was reported under the Immunology and Specialty Care segments. See also Note 22 for more information about Sobi's customers.
6. Pegcetacoplan has during the year been reclassified from the business area Immunology to Haematology.

Note 5, cont.

PARENT COMPANY	2021	2020
Revenue by geographic area[1]		
Europe[2]	5,837	7,174
North America[3]	4,313	4,799
Rest of the world	1,000	694
Other[4]	1,251	1,301
Total	**12,401**	**13,968**

1. The geographic distribution is based on where the customer is located.
2. Revenue in Sweden amounted to SEK 678 M (720).
3. Revenue from external customers in the US amounted to SEK – M (1,247). The change is attributable to the fact that sales of Syngais were transferred to the US subsidiary in 2020.
4. Other pertains to royalties derived from our haemophilia products that are not attributable to a specific region according to the distribution above. All royalties pertain to Sanofi's sales of Eloctate and Alprolix.

6 Depreciation/amortisation and impairment of assets[1]

GROUP	2021	2020
Depreciation/amortisation according to plan by type of asset		
Licences and patents	–8	–38
Product and marketing rights	–1,758	–1,779
Capitalised costs	–75	–65
Plant and machinery	–15	–17
Equipment, tools, fixtures and fittings	–25	–18
Right-of-use assets	–114	–102
Other non-current assets	–4	–4
Total	**–2,000**	**–2,023**
Impairment by type of asset		
Plant and machinery	–7	–
Total	**–7**	**–**
Total depreciation/amortisation and impairment by type of asset	**–2,006**	**–2,023**
Depreciation/amortisation according to plan by type of function		
Cost of goods sold	–34	–36
Selling and administrative expenses	–1,953	–1,974
Development costs	–13	–13
Total	**–2,000**	**–2,023**
Impairment by type of function		
Development costs	–7	–
Total	**–7**	**–**
Total depreciation/amortisation and impairment by type of function	**–2,006**	**–2,023**

PARENT COMPANY	2021	2020
Depreciation/amortisation according to plan by type of asset		
Licences and patents	–1	–1
Product and marketing rights	–282	–262
Capitalised costs	–75	–65
Plant and machinery	–12	–13
Equipment, tools, fixtures and fittings	–14	–6
Other non-current assets	–1	–1
Total	**–385**	**–347**
Depreciation/amortisation according to plan by type of function		
Cost of goods sold	–10	–12
Selling and administrative expenses	–375	–336
Development costs	0	0
Total	**–385**	**–347**

1. See Notes 16 and 17 for further information.

7 Other operating income

GROUP	2021	2020
Contingent consideration recognised[1]	–	399
Expenses re-invoiced to partners	3	–
Exchange-rate gains[2]	2	–
Other	27	2
Total	**32**	**401**

PARENT COMPANY	2021	2020
Expenses re-invoiced to Group companies	350	95
Expenses re-invoiced to partners	3	–
Exchange-rate gains[2]	–	1
Total	**353**	**96**

1. Contingent consideration recognised related to CVR liability, see p 34 for more information.
2. Exchange-rate effects are recognised net as other operating income or other operating expense. In 2021, exchange rate effects generated a gain of SEK 2 M (–42) for the Group. For the Parent Company, exchange rate effects generated a loss of SEK –2 M (1). See Note 8.

8 Other operating expenses

GROUP	2021	2020
Exchange-rate losses[1]	–	–42
Scrapping/disposal of non-current assets[2]	–56	–2
Total	**–56**	**–44**

PARENT COMPANY	2021	2020
Exchange-rate losses[1]	–2	–
Scrapping/disposal of non-current assets	–1	–
Total	–3	–

1. Exchange-rate effects are offset against other operating income or other operating expense. In 2021, exchange rate effects generated a gain of SEK 2 M (–42) for the Group. For the Parent Company, exchange rate effects generated a loss of SEK –2 M (1). See Note 7.
2. Disposals in 2021 mainly pertain to disposal of the opt-in right to the early-stage development projects, NI-1701 and NI-1801, for more information 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 2 and 10 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 during 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 10-year period. In total, Sobi expects to pay approximately EUR 90 million (around SEK 960 M) over the life of the contract. The contract is treated by the Group as a leasing contract. At the end of the year, Sobi had paid SEK 7 M to Pfizer, which is listed as a prepaid cost in the balance sheet 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
At 1 January 2020	**364**	**31**	**395**
Addition	96	25	121
Depreciation and impairment	–83	–18	–102
Divestments and disposals	0	–2	–2
Translation differences	–3	0	–4
At 31 December 2020	**373**	**36**	**409**
Addition	33	25	58
Depreciation and impairment	–92	–22	–114
Divestments and disposals	–1	–4	–5
Translation differences	9	1	10
At 31 December 2021	**322**	**37**	**359**

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

GROUP LEASE LIABILITIES	2021	2020
At 1 January	**419**	**419**
Addition	57	121
Divestments and disposals	–3	–2
Accumulated interest	6	7
Payments	–125	–118
Translation differences	7	–8
At 31 December	**361**	**419**
Non-current	247	308
Current	114	111

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

The following amounts were recognised in profit or loss:

GROUP	2021	2020
Depreciation and impairment of right-of-use assets	–114	–102
Interest expense on lease liabilities	–6	–7
Costs attributable to short-term leases	–7	–9
Costs attributable to low-value leases	–1	–1
Costs attributable to variable lease payments not included in the measurement of the lease liability	–1	–1
Total amount recognised in profit or loss	**–129**	**–120**
Amounts recognised in the cash flow statement		
Repayment of lease liability	–125	–118
Short-term leases	–7	–9
Low-value leases	–1	–1
Variable lease payments not included in the measurement of the lease liability	–1	–1
Total cash flow	**–134**	**–129**

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 RENT AND MINIMUM LEASE PAYMENTS

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

	Parent Company	
	2021	2020
Within 1 year	60	61
Between 1–5 years	173	218
Later than 5 years	–	27
Total	**233**	**306**
Rental payments for the year	62	60

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

	Parent Company	
	2021	2020
Within 1 year	2	0
Between 1–5 years	2	–
Later than 5 years	–	–
Total	**4**	**0**
Lease payments for the year	3	0

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

No. of employees[1]

GROUP	2021	of whom women, %	of whom men, %	2020	of whom women, %	of whom men, %
US	441	58	42	444	57	43
Sweden	399	62	38	438	64	36
Switzerland	143	59	41	148	64	36
Germany	86	63	37	80	56	44
UK	80	46	54	62	52	48
Italy	69	51	49	56	46	54
France	65	60	40	61	61	39
Spain/Portugal	54	61	39	44	66	34
United Arab Emirates	37	27	73	34	41	59
Central and Eastern Europe	35	49	51	30	49	51
Russia	35	69	31	22	77	23
Belgium/ Netherlands	25	53	47	21	41	59
China	19	79	21	12	100	0
Canada	15	40	60	11	45	55
Japan	13	38	62	6	50	50
Denmark	12	75	25	14	71	29
Austria	10	60	40	10	62	38
Greece	9	56	44	7	71	29
Finland/Baltics	7	71	29	7	57	43
Norway	4	75	25	4	75	25
Australia	2	50	50	–	–	–
Total	**1,559**	**58**	**42**	**1,509**	**59**	**41**

1. At 31 December 2021, the number of full-time employees was 1,559 people, while the number of employees at the same date was 1,615.

Gender composition of the Board and management

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

GROUP	2021	2020
Board		
Men	4	4
Women	4	3
Total	**8**	**7**
CEO and other senior executives		
Men	11	8
Women	1	2
Total	**12**	**10**

GENDER COMPOSITION EMPLOYEES

58% ♀ ♂ 42%

Salaries, other remuneration and social security costs

GROUP AND PARENT COMPANY	2021 Salaries and remunera-tion	2021 Social security costs	2020 Salaries and remunera-tion	2020 Social security costs
Parent Company	500	247	477	250
(of which pension expense)		*(75)*	–	*(72)*
Subsidiaries	1,981	300	1,773	276
(of which pension expense)		*(101)*	–	*(96)*
Group, total	**2,481**	**548**	**2,250**	**526**
(of which pension expense)		*(176)*	–	*(168)*

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

	2021 Board and CEO	2021 Other employees	2020 Board and CEO	2020 Other employees
Parent Company				
Salaries and other remuneration	27	473	24	453
(of which bonus)	*(10)*	*(56)*	*(8)*	*(61)*
Subsidiaries				
Salaries and other remuneration	–	1,981	–	1,773
(of which bonus)	–	*(544)*	–	*(435)*
Group, total	**27**	**2,455**	**24**	**2,226**
(of which bonus)	*(10)*	*(600)*	*(8)*	*(496)*

Guidelines and remuneration 2021

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

The members of the Executive Committee of Swedish Orphan Biovitrum AB (publ) ('**the company**' or '**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 General Meeting, may only consist of consultancy fees.

Note 10, cont.

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	Total
Chair of the Board						
Håkan Björklund	1,663					1,663
Other Board members						
Annette Clancy	587					587
Matthew Gantz	570					570
Lennart Johansson[2]	217					217
Helena Saxon	720					720
Filippa Stenberg[2]	413					413
Staffan Schüberg	620					620
Elisabeth Svanberg	570					570
Anders Ullman[2, 3]	420					420
Executive Committee, 2021						
Guido Oelkers, Chief Executive Officer	10,120	10,403[4]	2,880		18,734[7]	42,137
Other senior executives (10–11 people)[4, 5, 6]	48,639[5]	24,240[4]	6,530	3,775	40,397[7]	123,581
Total	**64,539**	**34,643**	**9,410**	**3,755**	**59,131**	**171,498**

1. Other senior executives refers to Sobi's Executive Committee, which consisted of eleven people in addition to the CEO at 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 company's costs (excluding social security contributions). For more information about Board fees, see the Corporate Governance Report.
2. At the AGM on 4 May, Lennart Johansson stepped down from his position as ordinary Board member, while Filippa Stenberg and Anders Ullman were appointed new ordinary Board members.
3. During the year, the Board member invoiced consulting fees of KSEK 600, in addition to Board fees, for business strategic work initiatives that do not pertain to Board work.
4. In addition to standard variable pay, a non-recurring payment of KSEK 1,618 was made to the CEO, and KSEK 1,321 to other executives for extraordinary efforts.
5. Basic salary, variable remuneration, pension and other benefits include severance pay in accordance with an agreement of KSEK 4,104 to former senior executives.
6. 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.
7. The year's cost for Sobi is not to be equated with employee benefits.

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

2020	Base salary/fees	Bonus	Pension expense	Other benefits	Share programmes	Total
Chair of the Board						
Håkan Björklund	1,610					1,610
Other Board members						
David Allsop[2]	193					193
Annette Clancy	610					610
Matthew Gantz	578					578
Lennart Johansson	650					650
Helena Saxon	650					650
Hans GCP Schikan[2]	227					227
Staffan Schüberg[2]	403					403
Elisabeth Svanberg	560					560
Executive Committee, 2020						
Guido Oelkers, Chief Executive Officer	9,625	8,126	2,840		12,463[5]	33,054
Other senior executives (9–10 people)[3, 4]	43,433	18,598	6,687	3,167	19,267[5]	91,152
Total	**58,539**	**26,724**	**9,527**	**3,167**	**31,730**	**129,687**

1. Other senior executives refers to Sobi's Executive Committee, which consisted of nine people in addition to the CEO at 31 December 2020. 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 company's costs (excluding social security contributions). For more information about Board fees, see the Corporate Governance Report.
2. At the AGM on 13 May 2020, David Allsop and Hans GCP Schickan stepped down from their positions as ordinary Board members, and Stefan Schüberg was appointed new ordinary Board member.
3. Base salary, variable pay, pension and other benefits include severance pay of KSEK 8,731 to former senior executives, according to agreement.
4. Henrik Stenqvist was appointed Deputy CEO in 2018. Since he did not serve as Deputy CEO during the 2020 financial year, his remuneration is presented with other senior executives.
5. The year's cost for Sobi is 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. The Company 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 the Company's business strategy, long-term development, including its sustainability, value creation and

1. Earnings before interest, tax and amortisation.

Note 10, cont.

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 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 (3) 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.

10

Long-term incentives
Long-term share-related incentive plans have been implemented in the Company. 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 the Company's long-term value creation.

Pension and benefits
The Company's preferred type of pension plan is defined contribution[1]. 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.

The pension premiums or allowance for pension shall amount to not 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 in total exceed 40 per cent of the annual gross base salary.

Termination of employment
The notice period may not exceed twelve (12) months. Fixed base salary during 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 (2) years.

Consultancy fees to Board members
The members of the Board elected by the general meeting may receive consultancy fees for services provided to the Company. Such services must contribute to the Company'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 for each member of the Board not exceed the annual remuneration for the 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 the Company 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 general meeting. 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 the Company. The members of the Compensation & Benefits Committee are independent of the Company and the Executive Committee. The CEO and other members of the Executive Committee do not participate in the Board of Directors' 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 the Company's long-term interests, including its sustainability, or to ensure the Company'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 the company to recruit and retain highly qualified personnel. Remuneration of AGM-elected Board members is paid in accordance with a resolution adopted by the 2021 AGM. No pensions are paid to Board members. The CEO's remuneration is reviewed and proposed by the Chair 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 in close cooperation with the Compensation & Benefits Committee and approved by the Board. 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 refers 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 2021 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. In 2021, Sobi paid out a premium of KSEK 2,880. 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.

1. 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.

Note 10, cont.

Incentive programmes
At the balance sheet date, Sobi had three active share programmes. To participate in the share programmes, employees must be permanently employed. All programmes run for three years. The Company also has four active cash-based programmes for employees in the US and Canada and one programme for the employees in China and Japan. The programmes in US and Canada for 2018 and 2019 run for four years, while the 2020 and 2021 programmes run for three years. The programme in China and Japan for 2021 runs for three years.

Long-term incentive programmes
The 2018–2021 AGMs adopted the Board's proposal to introduce long-term incentive programmes. The aim has been to create long-term commitment to Sobi, to offer participants the opportunity to share Sobi's long-term success and value creation, and to enable the company to attract and retain senior executives and senior managers. The company's long-term incentive programmes are described below.

The structure of the 2018–2021 share programmes is based on the same principles, and they all have a three-year vesting period.

The Management Programmes which includes the CEO, senior executives and managers require no personal investment in Sobi shares, but performance shares are allotted only if the programme's 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 budget for annual revenues.

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 that applies to 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.

The 2019, 2020 and 2021 AGMs also adopted programmes comprising both shares and share options for senior executives, comprising 50 per cent performance shares and 50 per cent share options. The performance targets for the share option programme are a strike price of up to 105 per cent and that actual average sales must meet or exceed the budgets for the financial years during the vesting period. The relevant employees and how performance targets are formulated differ between the programmes.

2018 share programmes (paid in 2021)
During the rollout of the 2018A share programme, a number of employees were insiders and not therefore eligible to participate in the programme. In light of this, the Board approved the rollout of the 2018B LTI programme for these employees, and for new employees since the rollout of 2018A.

For the 2018A and 2018B Management Programme that was redeemed on 11 May 2021 respectively 1 November, the Board determined that 40 per cent and 47.13 per cent respectively of the performance obligations and other vesting conditions had been met. To achieve a maximum 60 per cent allotment of the performance shares, the performance target was a 15–50 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 not achieved, Management Programme 2018A, but achieved with 11.88 per cent for 2018B. 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 2018, 2019 and 2020. Therefore, 215,703 and 8,446 shares with respective market values of SEK 32.1 M and SEK 1.9 M were allotted under the programme.

The 2018A and 2018B All Employee Programmes were redeemed on 11 May and 1 November 2021. Participants in the programmes were allotted two matching shares for every investment share. To qualify for the allotment of matching shares, programme participants must have retained the investment shares they have acquired. 29,448 shares and 2,222 respectively with a market value of SEK 4.4 M and SEK 0.5 M respectively were allotted under the programme.

2018 Cash-based Programme (expired 2021)
A long-term cash-based programme for all employees in the US and Canada was presented at the 2018 AGM. The programme 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. The other performance target (50 per cent) was that sales in North America must be at least 95 per cent per year in relation to the budget over a four-year period. Any payouts of a quarter of the programme are made annually over a four-year period. The programme expired in 2021 and the outcome for the final year was 99.55 per cent.

2019–2021 share programmes
At the 2019, 2020 and 2021 AGMs, long-term share programmes were approved for the CEO, senior executives and managers, and one programme was approved for other employees.

Management Programmes
Participants in the Management Programme are allotted performance shares provided that certain performance targets are achieved. The maximum possible allotment of shares in the Management Programme is 695,974 (2019), 721,905 (2020) and 1,320,760 (2021).

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 2019–2020 Management Programmes, 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 Management Programme, 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 straight-line 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. The performance target for 2019, 2020 and 2021 were achieved.

All-Employee Programmes
Participation in the programmes for other employees requires a personal investment in Sobi shares. The maximum possible allotment of shares in All-Employee Programmes is 30,128 (2019), 45,196 (2020) and 54,222 (2021).

Participants in All-Employee Programmes are allotted two matching shares for every investment share. To qualify for the allotment of matching shares, programme participants must have retained the investment shares they have acquired 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 programme. In view of the legal obstacles to participation in the programmes, the Board decided to establish long-term three-year cash-based incentive programmes for each year instead.

2019–2021 share-option programmes
The AGMs in 2019, 2020 and 2021 resolved that, in addition to the right to long-term share programmes, share option programmes would be launched, in accordance with the Board's proposal, for the CEO and a maximum of 15 members of Sobi's Executive Committee, and 15 pre-selected key individuals in the Sobi Group. The programmes comprise 27 people (2019), 24 people (2020) and 28 people (2021). The total number of share options granted is 1,454,718 (2019), 1,363,514 (2020) and 2,062,909 (2021). The vesting period is three years, followed by a two-year exercise period. A requirement for share option grants is that the Sobi Group's average sales meet or exceed the Sobi Group's target for average sales in the budget determined by the Board during the vesting period. The exercise price was SEK 180.65 (2019), SEK 213.86 (2020) and SEK 153.01 (2021), representing 105 per cent of the volume-weighted average price for the Sobi share when the programmes were launched (SEK 172.05 (2019), SEK 203.68 (2020), and SEK 145.72 (2021)). The maximum value of a share that can be obtained by exercising share options is capped at five times the exercise price for the 2019 programme and three times the exercise price for the 2020 and 2021 programmes. Should the share value exceed this level, the conditions must be recalculated.

2019–2021 Cash-based Programmes, North America
Long-term cash-based programmes for all employees in the US and Canada were presented at the AGMs in 2019, 2020 and 2021. The programmes consist of two components: a time-based component (50 per cent), and a performance-based component (50 per cent) based on two performance

Note 10, cont.

targets. The first performance target (50 per cent) is a share price increase of 10 per cent per year over a four-year period for the 2019 program, and over a three-year period for the 2020 and 2021 programmes. 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 a four-year period for the 2019 programme, and over a three-year period for the 2020 and 2021 programmes. Any payouts of a quarter or third, respectively, of the programme are made annually over a four-year or three-year period, respectively. The outcome for 2021 was 99.55 per cent.

2021 Cash-based Programme, Asia
A long-term cash-based programme for all employees in China and Japan was presented at the 2021 AGM. The programme consists 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 (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.

Development of share programmes in 2021

2021 PROGRAMMES	No. of shares					Theoretical value, SEK M		Market value, SEK M	
	Opening	New programme	Forfeited	Allotted	Closing	Opening	Closing	Opening	Closing
2018 Management	677,876		–453,727	–224,149	0	82	0	113	0
2018 Employee	38,084		–6,414	–31,670	0	7	0	6	0
2019 Management	742,951		–46,977		695,974	82	77	123	129
2019 Employee	38,998		–8,870		30,128	7	5	6	6
2020 Management	794,110		–72,205		721,905	106	96	132	134
2020 Employee	51,446		–6,250		45,196	10	9	9	8
2021 Management	0	1,351,930	–31,170		1,320,760	0	133	0	244
2021 Employee	0	55,864	–1,642		54,222	0	11	0	10
Total	2,343,465	1,407,794	–627,255	–255,819	2,868,185	294	330	389	531

Development of share programmes in 2020

2020 PROGRAMMES	No. of shares					Theoretical value, SEK M		Market value, SEK M	
	Opening	New programme	Forfeited	Allotted	Closing	Opening	Closing	Opening	Closing
2017 Management	740,059		–177,634	–562,425	0	65	0	114	0
2017 Employee	41,668		–4,355	–37,313	0	6	0	6	0
2018 Management	747,290		–69,414		677,876	91	82	115	113
2018 Employee	42,328		–4,244		38,084	8	7	7	6
2019 Management	807,824		–64,873		742,951	89	82	125	123
2019 Employee	41,726		–2,728		38,998	7	7	6	6
2020 Management	0	794,110	0		794,110	0	106	0	132
2020 Employee	0	51,446	0		51,446	0	10	0	9
Total	2,420,895	845,556	–323,248	–599,738	2,343,465	265	294	374	389

Expensing of the 2019–2021 Share Programmes is calculated using the following parameters and the Monte Carlo simulation model:

	Start date	End date	Number of matching shares	Number of performance shares	Service in months	Fair value of matching share	Fair value of performance share[1]	Fair value of performance share[2]	Expected personnel turnover, %	Max. allotment of shares	Forfeited shares 2021
2019 Share Programme: All Employee	28 May 2019	28 May 2022	30,128	n/a	36	179.26	n/a	n/a	7	30,128	8,870
2019 Share Programme: Management	28 May 2019	28 May 2022	n/a	695,974	36	n/a	67.75	173.5	7	695,974	46,977
2020 Share Programme: All Employee	28 May 2020	28 May 2023	45,196	n/a	36	200.49	n/a	n/a	7	45,196	6,250
2020 Share Programme: Management	28 May 2020	28 May 2023	n/a	721,905	36	n/a	85.77	203.68	7	721,905	72,205
2021 Share Programme: All Employee	1 June 2021	1 June 2024	54,222	n/a	36	175.25	n/a	n/a	7	54,222	1,642
2021 Share Programme: Management	1 June 2021	1 June 2024	n/a	1,320,760	36	n/a	72.24	143.85	7	1,320,760	31,170

1. Fair value of performance shares linked to share price performance, see above, under 2019, 2020 and 2021 share programmes.
2. Fair value of performance shares linked to revenue, see above under 2019, 2020 and 2021 share programmes.
3. The cost for the year for the Share Programmes amounted to SEK 134 M (114).

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	2021	2020
EY		
Auditing assignments[1]	–8	–8
Audit activities in addition to the auditing assignment	–2	0
Other services	0	0
Total	**–10**	**–9**
Other auditors		
Auditing assignments[1]	0	–
Total other auditors	**0**	**–**
Total	**–11**	**–9**

PARENT COMPANY	2021	2020
EY		
Auditing assignments[1]	–3	–3
Audit activities in addition to the auditing assignment	–1	0
Other services	–	0
Total	**–5**	**–4**

1. Auditing 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	2021	2020
Raw materials and consumables	–3,028	–2,778
Other external costs	–3,509	–3,044
Employee benefit costs	–3,227	–2,965
Depreciation/amortisation and impairment	–2,006	–2,013
Other operating expenses	–56	–44
Total	**–11,827**	**–10,844**

PARENT COMPANY	2021	2020
Raw materials and consumables	–2,538	–2,759
Other external costs	–4,678	–4,380
Employee benefit costs	–767	–755
Depreciation/amortisation and impairment	–385	–337
Other operating expenses	–3	–
Total	**–8,370**	**–8,230**

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

13 Financial income

GROUP	2021	2020
Interest income	0	1
Exchange-rate gains[1]	16	–
Total	**16**	**1**

PARENT COMPANY	2021	2020
Interest income, Group companies	336	486
Interest income, other	0	0
Exchange-rate gains[1]	–	177
Total	**336**	**663**

1. Exchange-rate effects are offset and in 2021, were recognised as a gain in the Group and a loss in the Parent Company. In 2020, the corresponding item was recognised as a loss in the Group and a gain in the Parent Company. See also Note 14.

14 Financial expenses

GROUP	2021	2020
Interest expense, borrowings	–284	–330
Interest expense, other[1]	–135	–124
Exchange-rate losses[2]	–	–115
Management costs	–35	–32
Other	0	–1
Total	**–454**	**–602**

PARENT COMPANY	2021	2020
Interest expense, Group companies	–18	–38
Interest expense, borrowings	–284	–330
Interest expense, other[1]	–88	–69
Exchange-rate losses[2]	–302	–
Management costs	–35	–31
Other	–1	–1
Total	**–728**	**–469**

1. Includes interest expense linked to liabilities for contingent consideration, see Note 26 and 28.
2. Exchange-rate effects are offset and in 2021, were recognised as a gain in the Group and a loss in the Parent Company. In 2020, the corresponding item was recognised as a loss in the Group and a gain in the Parent Company. See also Note 13.

15 Income tax

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

GROUP	2021	2020
Current tax		
Current tax on profit for the year[1]	–655	–1,133
Prior year adjustments[1]	–4	8
Total current tax recognised	**–659**	**–1,125**
Deferred tax		
Excess depreciation	–396	–479
Inventories	95	295
Acquired product rights	178	166
Other intangible assets	11	–4
Tax loss carry-forwards	107	100
Net investment hedges	–63	64
Pharmaceutical tax	14	14
Interest limitations	60	–
Other	38	–3
Total deferred tax recognised	**43**	**153**
Total tax recognised	**–616**	**–972**

PARENT COMPANY	2021	2020
Current tax		
Current tax on profit for the year[1]	–486	–944
Prior year adjustments[1]	–5	7
Total current tax recognised	**–491**	**–938**
Deferred tax		
Other	3	7
Total deferred tax recognised for the Parent Company	**3**	**7**
Total tax recognised	**–488**	**–931**

Reconciliation of effective tax

GROUP	2021	2020
Profit before tax	**3,295**	**4,217**
Tax at applicable tax rate for the Parent Company[2]	–679	–902
Tax effect, non-deductible/non-taxable items		
Remeasurement of Contingent Value Right (CVR)	–	82
Capitalised tax loss carry-forwards	162	–
Non-capitalised tax loss carry-forwards	–11	–101
Changed tax rate in Sweden[2]	–	–17
Difference foreign tax rates	–43	8
Non-deductible expenses	–38	–51
Adjustment of tax prior years	–4	8
Other	–4	0
Total effective tax recognised	**–616**	**–972**

PARENT COMPANY	2021	2020
Profit before tax	**2,278**	**4,337**
Tax at applicable tax rate for the Parent Company[2]	–469	–928
Tax effect, non-deductible/non-taxable items		
Changed tax rate in Sweden[2]	–	0
Controlled Foreign Company taxation	0	–
Non-deductible expenses	–19	–9
Adjustment of tax prior years	0	7
Other	–	–
Total effective tax recognised	**–488**	**–931**

1. In addition to tax recognised in earnings, current tax of SEK –17 M (35) was recognised in other comprehensive income, attributable to exchange rate effects on the Parent Company's liabilities/derivatives in other comprehensive income. Additionally, current tax of SEK 6 M (9) was recognised directly in equity, attributable to the Parent Company's long-term incentive programme. Deferred tax of SEK 0 M (5) was also recognised directly in equity, see Note 20 for other deferred tax items.
2. The current tax rate for the Swedish Parent Company is 20.6 per cent (21.4). Deferred tax was valued using the applicable tax rate for the period that reversal/resolution is expected to occur.

Non-capitalised tax loss carry-forwards

GROUP	2021	2020
Tax loss carry-forwards for which no deferred tax asset was recognised	2,716	2,708
Potential tax benefit	509	523

Of non-capitalised tax loss carry-forwards, SEK 1,463 M will expire within the next seven 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[4]	Ongoing capitalised costs[4]	Total
1 January–31 December 2020						
Opening cost	6,678	572	34,003	258	336	41,846
Investments[1]	–	–	4,890	9	113	5,012
Business acquisitions[2]	–313	–	–	–	–	–313
Disposals	–	–	–3	0	–	–3
Reclassifications	–	–	–	164	–165	–1
Translation differences	–491	–1	–1,023	–1	–	–1,517
Closing cost	**5,873**	**570**	**37,867**	**429**	**284**	**45,023**
Opening accumulated amortisation and impairment	–	–467	–3,864	–102	–	–4,434
Amortisation	–	–38	–1,779	–65	–	–1,882
Disposals	–	–	3	–	–	3
Translation differences	–	1	80	–	–	81
Closing accumulated amortisation and impairment	–	**–505**	**–5,560**	**–167**	–	**–6,232**
Closing carrying amount	**5,873**	**66**	**32,307**	**262**	**284**	**38,791**
1 January–31 December 2021						
Opening cost	5,873	570	37,867	429	284	45,023
Investments	–	–	184	21	76	281
Disposals[3]	–	–	–	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
Depreciation	–	–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. In the preceding year, investments were mainly related to Aspaveli (SEK 3,060 M) and SEL–212 (SEK 1,776 M).
2. The preceding year's decrease of SEK –313 M in goodwill pertained to adjustment of the acquisition analysis for Dova. The value of a deferred tax asset pertaining to the liability to Eisai was adjusted by SEK 320 M, which is assessed as deductible. Goodwill and other liabilities and provisions were therefore adjusted by SEK –313 M and SEK –7 M, respectively.
3. Disposals for the year, 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.
4. Capitalised costs comprise IT projects and expenses for transferring the manufacture of an active substance. Items under capitalised costs are amortised according to plan.

Specification of major intangible assets

GROUP	2021[1]	Amortisation rate, years	Remaining amortisation period, years
Synagis	11,873	20	17
Doptelet	6,080	15	13
Gamifant	3,818	20	17
Aspaveli	3,196	20	20
BIVV001/BIVV002[2]	1,925	–	–
SEL-212[2]	1,776	–	–
Alprolix	1,217	20	13
Elocta	1,223	20	14
Orfadin	488	15	3
Other – launched	452	3–15	4
Other – not yet launched[2]	88	–	–
Total	**32,135**		

1. Closing carrying amount, excluding goodwill.
2. Amortisation has not yet started.

Note 16, cont.

PARENT COMPANY	Licenses and patents	Product and marketing rights	Capitalised costs[2]	Ongoing capitalised costs[2]	Total
1 January–31 December 2020					
Opening cost	40	6,593	240	282	7,155
Investments[1]	–	4,849	–	113	4,961
Reclassifications	–	–	164	–165	–1
Closing cost	**40**	**11,442**	**404**	**230**	**12,116**
Opening accumulated amortisation and impairment	–37	–1,447	–98	–	–1,583
Amortisation	–1	–262	–65	–	–328
Closing accumulated amortisation and impairment	**–38**	**–1,709**	**–163**	**–**	**–1,911**
Closing carrying amount	**2**	**9,732**	**240**	**230**	**10,205**
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. In the preceding year, investments were mainly related to Aspaveli (SEK 3,060 M) and SEL–212 (SEK 1,734 M).
2. Capitalised costs comprise IT projects and expenses for transferring the manufacture of an active substance. Items under capitalised costs are amortised according to plan.

16

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 Speciality Care – to which goodwill is allocated. At 31 December 2021, Sobi's goodwill amounted to SEK 6,288 M (5,873). 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 product development and coming product 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, %	2021	2020
Growth rate beyond the initial five-year period	2	2
Discount rate before tax	10.0	10.0
Discount rate after tax	8.0	8.0

Assumptions regarding Sobi's weighted average cost of capital (WACC):

- Risk-free interest rate: ten-year treasury bills or comparable financial investment with the lowest possible risk.
- Market risk premium: 6.8% (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 product, the life of the products 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 trials 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 drug 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 product'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.

Note 16, cont.

Impairment
There were no impairment losses in 2021 or 2020.

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) is 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 products BIVV001 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.

Under the agreement, Sanofi takes full responsibility for the development, manufacturing and costs associated with the BIVV002 programme until Sobi exercises its opt-in right. Sobi exercised its opt-in right to BIVV001 in 2019.

Sobi's opt-in right for development and commercialisation of the programmes 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 rights, Sobi will be obligated to reimburse Sanofi for 50 per cent of the development and production costs incurred by each programme. Sobi will reimburse Sanofi for 100 per cent of the development costs that only benefit Sobi's territory.

BIVV001/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 280–290 M less USD 50 M which has already been paid. At 31 December 2021, the value of BIV001, which is recognised as an intangible asset, was SEK 1,868 M (1,868). For liabilities related to BIVV001, see Note 28, liability to Sanoti.

BIVV002
In February 2017, Sobi decided to include the preclinical development programme for the potentially long-acting haemophilia B treatment, BIVV002, in the agreement with Sanofi. Under the agreement between Sobi and Sanofi, Sobi will therefore have an exclusive opt-in right to the programme, and the possibility of obtaining the commercial rights in Sobi's territory according to the principles described above.

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 commercial product 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. USD 130 M (approximately SEK 1.2 billion) was outstanding at year-end. This obligation is recognised as a financial liability on Sobi's balance sheet. See Note 28, liability to Eisai.
- Sobi will pay royalties to Astella Inc. based on net sales of Doptelet.

Synagis and MEDI8897
On 23 January 2019, Sobi completed the acquisition of the rights to Synagis (palivizumab) in the US from AstraZeneca, as well as the rights to 50 per cent of future earnings from the drug candidate MEDI8897 (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 (approximately SEK 525 M) in 2019, 2020 and 2021.

Provided that some terms related to sales of Synagis are met, an additional consideration of up to USD 470 M (approximately SEK 4.3 billion) may be payable as of 2026. Sobi may also pay USD 175 M (approximately SEK 1.6 billion) for the submission of a Biologics License Application (BLA) for MEDI8897 to the FDA. The agreement also includes potential net payments corresponding to about USD 110 M (approx. SEK 1 billion) on the achievement of other profit and development-related milestones for MEDI8897. In this case, these will be paid as of 2023. At the end of 2021, Sobi had not reported any asset or liability linked to these potential future milestone payments as Sobi has 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 105 M (approximately SEK 977 M) to Selecta, including a payment of USD 75 M for the licence fee, USD 25 M for shares in Selecta Biosciences, Inc., and a milestone payment of USD 5 M related to randomisation of the first patient in the phase 3 clinical programme with SEL 212. Provided that certain regulatory and commercial milestones are met, Selecta will be entitled to receive additional potential milestone payments of up to USD 625 M (approximately SEK 5.7 billion). The consideration of SEK 1,896 M for the acquired intangible and financial 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, see Note 28, liability to Selecta. Selecta will also be entitled to incremental double-digit royalties on future sales.

Aspaveli
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 treatments.

Sobi made a payment of USD 250 M (approximately SEK 2,180 M) to Apellis. Provided that certain regulatory and commercial milestones are met, Apellis will be entitled to receive additional potential milestone payments of up to USD 915 M (approximately SEK 8.3 billion). The consideration of SEK 3,196 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, 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 55 M (approximately SEK 500 billion) was outstanding at year-end. 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	Construction in progress	Total
1 January–31 December 2020						
Opening cost	483	178	515	16	8	1,200
Investments	3	17	121	5	15	162
Divestments and disposals	–47	–1	–8	0	–	–55
Reclassification	5	12	–	0	–14	2
Translation differences	0	–4	–9	–1	–	–14
Closing cost	**444**	**203**	**620**	**20**	**9**	**1,295**
Opening accumulated depreciation and impairment	–418	–135	–120	–8	–	–682
Depreciation	–17	–18	–102	–4	–	–141
Divestments and disposals	49	0	5	0	–	55
Reclassification	–	–1	–	0	–	–1
Translation differences	1	1	6	0	–	9
Closing accumulated depreciation and impairment	**–386**	**–154**	**–210**	**–11**	**–**	**–761**
Closing carrying amount	**58**	**49**	**409**	**9**	**9**	**534**

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
Reclassification	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
Reclassification	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**

For further information about leases, see Note 9.

Note 17, cont.

PARENT COMPANY	Plant and machinery	Equipment, tools, fixtures and fittings	Other non-current assets	Construction in progress	Total
1 January–31 December 2020					
Opening cost	451	121	5	8	585
Investments	–	–	–	15	15
Divestments and disposals	–46	–1	–	–	–47
Reclassification	5	10	–	–14	1
Closing cost	**409**	**131**	**5**	**9**	**554**
Opening accumulated depreciation and impairment	–404	–113	–3	–	–520
Depreciation	–13	–6	–1	–	–19
Divestments and disposals	49	1	–	–	49
Closing accumulated depreciation and impairment	**–369**	**–118**	**–4**	–	**–491**
Closing carrying amount	**40**	**13**	**2**	**9**	**64**
1 January–31 December 2021					
Opening cost	409	131	5	9	554
Investments	0	0	0	54	54
Divestments and disposals	–20	0	0	0	–20
Reclassification	5	36	0	–40	0
Closing cost	**394**	**166**	**5**	**23**	**588**
Opening accumulated depreciation and impairment	–369	–118	–4	0	–491
Depreciation	–12	–14	–1	0	–26
Divestments and disposals	17	0	0	0	17
Closing accumulated depreciation and impairment	**–364**	**–131**	**–4**	0	**–500**
Closing carrying amount	**30**	**35**	**1**	**23**	**89**

18 Participations in Group companies

PARENT COMPANY	2021	2020
Cost		
Opening balance	8,853	8,853
Closing balance[1]	**8,853**	**8,853**
Accumulated impairment		
Opening balance	–1,177	–1,177
Closing balance	**–1,177**	**–1,177**
Closing carrying amount	**7,676**	**7,676**

1. In the sub-group, Swedish Orphan Biovitrum International AB has formed two new subsidiaries, Swedish Orphan Biovitrum (The Netherlands) B.V in the Netherlands and SOBI Pharma (Shanghai) Company Limited, in China.

Note 18, cont.

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

SUBSIDIARY/CORP. REG. NO./REGISTERED OFFICE	No. of participations	Participations, %[1]	Carrying amount[2]
Swedish Orphan Biovitrum International AB, 556329–5624, Stockholm, Sweden	100	100	3,248,584
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[3]	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	1,000	100	4,201,336
Sobi, Inc EIN 68–0682244, Delaware, USA			
Dova Pharmaceuticals Inc., 5997129, Delaware, US			
AKaRx, Inc., 20-1990243, Delaware, US			
Dova Pharmaceuticals Ireland Limited, 610709, Dublin, Ireland			
Total			7,675,935

1. The participation refers to the ownership of capital, which also corresponds to the proportion of the votes.
2. Carrying amount stated in KSEK.
3. The remaining portion owned by Swedish Orphan Biovitrum International AB.

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19 Financial assets

GROUP	2021	2020
Equity instruments[1]	145	131
Endowment policy	45	44
Deposits	4	2
Other financial receivables	5	1
Total	199	179

GROUP	2021	2020
Change in financial assets		
Opening balance	179	50
Equity instruments[1]	14	131
Endowment policy	1	–3
Deposit	2	1
Other financial receivables	4	–1
Closing balance	199	179

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

PARENT COMPANY	2021	2020
Equity instruments	145	131
Endowment policy	45	44
Total	190	176

PARENT COMPANY	2021	2020
Change in financial assets		
Opening balance	176	47
Equity instruments[1]	14	131
Endowment policy	1	–3
Other	–	–
Closing balance	190	176

1. See comment for the Group.

20 Deferred tax assets and deferred tax liabilities

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
Other	107	–18	90
Total	**1,229**	**–4,067**	**–2,838**
Offsetting	**–462**	**462**	0
Tax assets/liabilities, net	**767**	**–3,605**	**–2,838**

GROUP 2020	Deferred tax assets	Deferred tax liabilities	Net
Excess depreciation	–	–1,817	–1,817
Inventories	562	–	562
Acquired product and marketing rights	–	–1,859	–1,859
Other intangible assets	50	–	50
Tax loss carry-forwards	130	–	130
Pharmaceutical tax	30	–	30
Other	71	–19	52
Total	**843**	**–3,696**	**–2,853**
Offsetting	–232	232	0
Tax assets/liabilities, net	**611**	**–3,464**	**–2,853**

The Parent Company's total deferred tax assets amounted to SEK 27 M (24), and mainly comprised a deferred tax asset of SEK 11 M (12) related to pension provisions, a deferred tax asset of SEK 10 M (6) related to long-term incentive programmes, a provision of SEK 7 M (9) for expected credit losses on external and internal receivables, a deferred tax asset of SEK 5 M (–) related to adjusted excess depreciation, and a deferred tax liability of SEK –5 M (–2) related to the market value of a financial asset. Deferred tax has been estimated using the enacted future tax rate in Sweden, see Notes 2 and 15.

Change in deferred tax

GROUP 2021	Amount at beginning of year	Recognised in profit or loss	Recognised in other comprehensive income	Recognised directly in equity	Increase through business combinations	Amount at end of year
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[1]	130	107	20	–	–	256
Pharmaceutical tax	30	14	1	–	–	44
Net investment hedges	–	–63	63	–	–	–
Interest limitations	–	60	3	–	–	63
Other	52	38	–3	3	–	90
Total	**–2,853**	**44**	**–32**	**3**	–	**–2,838**

1. The increase of deferred tax asset related to loss carry-forwards for the year refers to foreign tax losses accrued during the year that are expected to be utilised, and the settlement of last year's deferred tax on loss carry-forwards that were either utilised or have expired. See also Note 4.

GROUP 2020	Amount at beginning of year	Recognised in profit or loss	Recognised in other comprehensive income	Recognised directly in equity	Increase through business combinations	Amount at end of year
Excess depreciation	–1,338	–479	–	–	–	–1,817
Inventories	318	295	–51	–	–	562
Acquired product and marketing rights[1]	–2,524	166	178	–	320	–1,859
Other intangible assets	53	–4	0	–	–	50
Tax loss carry-forwards[2]	47	100	–18	–	–	130
Pharmaceutical tax	17	14	–1	–	–	30
Net investment hedges	–	64	–64	–	–	–
Other	54	–3	4	–3	–	52
Total	**–3,372**	**153**	**92**	**–3**	**320**	**–2,853**

1. The decrease of SEK 320 M in deferred tax liability for acquired product and marketing rights refers to a previous unrecognised deferred tax related to liability in the acquisition analysis related to Dova.
2. The increase of Deferred tax on loss carry-forwards for the year relates to foreign tax losses accrued during the year that are expected to be utilised, and the settlement of last year's deferred tax on loss carry-forwards that were either utilised or have expired. See also Note 4.

21 Inventories

GROUP	2021	2020
Raw materials and consumables	147	21
Work in progress	1,973	1,929
Finished goods and goods for resale	1,304	1,103
Total	**3,424**	**3,053**

The cost of inventories is included in cost of goods sold as expenses, and amounted to SEK 3,130 M (2,778). Recognised inventories include a provision of SEK 442 M (453) for obsolete inventory. During the year, an impairment loss of M 49 SEK (95) was recognized for inventories.

PARENT COMPANY	2021	2020
Raw materials and consumables	62	21
Work in progress	1,735	1,929
Finished goods and goods for resale	739	577
Total	**2,536**	**2,527**

The cost of inventories is included in cost of goods sold as expenses, and amounted to SEK 2,538 M (2,759). Recognised inventories include a provision of SEK 429 M (440) for obsolete inventory. During the year, an impairment loss of M 23 SEK (80) was recognized for inventories.

22 Accounts receivable and other receivables

GROUP	2021	2020
Accounts receivable	3,509	3,827
Less: Provision for credit losses	–71	–71
Accounts receivable, net	**3,439**	**3,756**
Tax assets	26	25
Other receivables	319	440
Total other receivables	**345**	**465**
Total accounts receivable and other receivables	**3,783**	**4,221**

PARENT COMPANY	2021	2020
Accounts receivable	1,135	747
Less: Provision for credit losses	–8	–16
Accounts receivable, net	**1,126**	**731**
Tax assets	22	10
Other receivables	270	396
Total other receivables	**292**	**405**
Total accounts receivable and other receivables	**1,419**	**1,136**

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. 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.

At 31 December 2021, the Group's overdue receivables amounted to SEK 607 M (662), of which SEK 71 M (71) is included in the provision for credit losses. Actual credit losses of SEK 6.1 M (0.7) were charged to profit for the year, of which SEK 5.9 M (0.6) was attributable to the Parent Company.

Changes in the provision for credit losses are as follows:

Expected credit losses

GROUP	2021	2020
At beginning of year	–71	–69
Provision for credit losses	–11	–14
Reversed provisions	12	12
At end of year	**–71**	**–71**

PARENT COMPANY	2021	2020
At beginning of year	–16	–8
Provision for credit losses	–	–9
Reversed provisions	8	1
At end of year	**–8**	**–16**

Maturity structure

GROUP	2021	2020
Not past due	2,832	3,094
Past due 1–30 days	374	505
Past due 31–90 days	145	93
Past due 91–120 days	12	8
Past due > 121 days	75	56
Total	**3,439**	**3,756**

PARENT COMPANY	2021	2020
Not past due	835	565
Past due 1–30 days	187	135
Past due 31–90 days	71	20
Past due 91–120 days	6	1
Past due > 121 days	28	11
Total	**1,126**	**731**

Note 22, cont.

Recognised amounts per currency for accounts and other receivables

GROUP	2021	2020
CHF	81	67
EUR	1,115	919
GBP	126	109
SEK	669	747
USD	1,637	2,316
Other currencies	155	63
Total	**3,783**	**4,221**

PARENT COMPANY	2021	2020
CHF	76	62
EUR	499	277
SEK	668	740
USD	43	2
Other currencies	132	56
Total	**1,419**	**1,136**

23 Prepaid expenses and accrued income

GROUP	2021	2020
Accrued royalty revenue[1]	321	302
Other prepaid expenses	204	186
Total	**525**	**490**

PARENT COMPANY	2021	2020
Accrued royalty revenue[1]	321	302
Other prepaid expenses	133	127
Total	**455**	**430**

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

24 Cash and cash equivalents

	2021		2020	
GROUP	Fair value	Carrying amount	Fair value	Carrying amount
Cash and cash equivalents	1,045	1,045	404	404
Total	**1,045**	**1,045**	**404**	**404**

	2021		2020	
PARENT COMPANY	Fair value	Carrying amount	Fair value	Carrying amount
Cash and cash equivalents	878	878	240	240
Total	**878**	**878**	**240**	**240**

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

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25 Shareholders' equity

Other reserves	Translation differences	Cash flow hedges	Net investment hedges	Equity investments	Defined-benefit pension plans and similar plans	Total
Other reserves 1 Jan 2020	–110	–104	42	–	–30	–202
Translation differences	–434	–	–	–	–	–434
Hedging instruments:						
Gain/loss on remeasurement of hedging instruments recognised in equity	–	133	309	–	–	442
Tax on gain/loss on remeasurement of hedging instruments recognised in equity	–	–29	–64	–	–	–93
Transferred to profit or loss	–	34	–	–	–	34
Tax on transferred to profit or loss	–	–7	–	–	–	–7
Gain/loss on remeasurement of equity instruments recognised in equity	–	–	–	11	–	11
Tax effect on equity instruments	–	–	–	–2	–	–2
Gain/loss on remeasurement of defined-benefit pension plans and similar plans	–	–	–	–	–3	–3
Tax on gain/loss on remeasurement of defined-benefit pension plans and similar plans	–	–	–	–	0	0
Other reserves 31 Dec 2020	**–544**	**26**	**288**	**9**	**–32**	**–253**
Other reserves 1 Jan 2021	**–544**	**26**	**288**	**9**	**–32**	**–253**
Translation differences	464	–	–	–	–	464
Hedging instruments:						
Gain/loss on remeasurement of hedging instruments recognised in equity	–	–81	–305	–	–	–386
Tax on gain/loss on 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	–	–	–	0
Gain/loss on remeasurement of equity instruments recognised in equity	–	–	–	14	–	14
Tax effect on equity instruments	–	–	–	–3	–	–3
Gain/loss on remeasurement of defined-benefit pension plans and similar plans	–	–	–	–	20	20
Tax on gain/loss on remeasurement of defined-benefit pension plans and similar plans	–	–	–	–	–3	–3
Other reserves 31 Dec 2021	**–80**	**–36**	**46**	**20**	**–15**	**–66**

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At year-end, Sobi's share capital was SEK 169 M, distributed between 307,114,495 shares with a par value of about SEK 0.55. All shares issued at the balance sheet date were ordinary shares. Ordinary shares carry one vote per share. The company held 11,959,198 shares in treasury at the balance sheet date. The own shares item corresponds to 3.9 per cent of the total number of shares in the company.

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.

	2021	2020
Earnings attributable to Parent Company shareholders (in MSEK)	2,679	3,245
Earnings per share (SEK per share)	9.08	11.01
Earnings per share, adjusted (SEK per share)[1, 2]	9.08	9.66
Diluted earnings per share (SEK per share)	9.03	10.90
Diluted earnings per share, adjusted (SEK per share)[1, 2]	9.03	9.56
Number of ordinary shares	307,114,495	303,815,511
Number of ordinary shares (treasury)	11,959,198	8,918,672
Number of ordinary shares (excluding treasury shares)	295,155,297	294,896,839
Number of ordinary shares after dilution	308,862,835	306,797,549
Average number of ordinary shares (excluding treasury shares)	295,051,119	294,658,136
Average number of ordinary shares after dilution (excluding treasury shares)	296,799,459	297,640,174

1. Alternative Performance Measures, see Definitions on p 130.
2. EBITA 2020 excluding non-recurring items; other operating income related to reversal of the CVR liability of SEK 399 M.

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 2021				
Assets on the balance sheet				
Accounts receivable	3,439	–	–	3,439
Endowment policy	–	45	–	45
Derivatives[1]	–	11	–	11
Equity instruments[2]	–	–	145	145
Cash and cash equivalents	1,045	–	–	1,045
Total	**4,484**	**56**	**145**	**4,685**
31 December 2020				
Assets on the balance sheet				
Accounts receivable	3,756	–	–	3,756
Endowment policy	–	44	–	44
Derivatives[1]	–	117	–	117
Equity instruments[2]	–	–	131	131
Cash and cash equivalents	404	–	–	404
Total	**4,160**	**162**	**131**	**4,453**

1. Of the 2021 derivatives, SEK 11 M (117) is measured at fair value through profit or loss, and SEK 0 M (0) is included in cash-flow hedges. The derivatives are classified as other liabilities on the balance sheet.
2. Equity instruments relates to the shares in Selecta Biosciences, Inc. The shares are measured at fair value through other comprehensive income.

	Liabilities measured at amortised cost	Liabilities measured at fair value through profit or loss	Total
31 December 2021			
Liabilities on the balance sheet			
Borrowings	10,545	–	10,545
Lease liabilities	361	–	361
Derivatives[1]	–	10	10
Accounts payable	558	–	558
Contingent considerations[2]	2,818	–	2,818
Non-contingent considerations[2]	1,707	–	1,707
Other liabilities	0	–	0
Total	**15,989**	**10**	**15,999**
31 December 2020			
Liabilities on the balance sheet			
Borrowings	14,152	–	14,152
Lease liabilities	419	–	419
Derivatives[1]	–	269	269
Accounts payable	569	–	569
Contingent considerations[2]	2,845	–	2,845
Non-contingent considerations[2]	1,191	–	1,191
Other liabilities	94	–	94
Total	**19,270**	**269**	**19,540**

1. Of the 2021 derivatives, SEK 10 M (269) is measured at fair value through profit or loss, and SEK 0 M (0) is included in cash-flow hedges. The derivatives are classified as other liabilities on the balance sheet.
2. Liabilities are reported per counterparty in Note 28.

See Note 2 for more information about what is included in the various categories.

Note 26, cont.

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.

AT 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 policies[1]	–	–	45	45
Equity instruments	145	–	–	145
Total	**145**	**1**	**45**	**191**

AT 31 DECEMBER 2020	Level 1	Level 2	Level 3	Total
Financial assets measured at fair value through profit or loss				
Derivatives held for trading	–	–151	–	–151
Endowment policies[1]	–	–	44	44
Equity instruments	131	–	–	131
Total	**131**	**–151**	**44**	**24**

1. Endowment policies are reported gross with the corresponding liability, which is reported as a provision, see Note 30.

All derivatives are measured at fair value based on market data in accordance with IFRS. At 31 December 2021, the net value of derivatives recognised on the balance sheet was SEK 1 M (–151).

27 Borrowings

At the balance sheet date, Sobi had credit facilities totalling EUR 1,140 M and SEK 3,000 M. One credit facility of EUR 190 M under the loan agreement of EUR 390 M from 2019 was extended by one year from the original maturity date. The new maturity date is November 2023. During the year, two credit facilities of EUR 200 M each matured. In addition to these, Sobi has two overdrafts of SEK 250 M and USD 5 M. Sobi has customary covenants in its facility agreements and has been fully compliant with those in 2021. For further information about maturity structure, see Note 3.

GROUP AND PARENT COMPANY	2021	2020
Non-current liabilities to banks and credit institutions	8,777	10,137
Current liabilities to banks and credit institutions	1,768	4,015
Total	**10,545**	**14,152**

Specification per currency, translated to SEK M

GROUP AND PARENT COMPANY	2021	2020
Currency		
EUR	3,426	7,377
SEK	4,004	2,918
USD	3,116	3,857
Total	**10,545**	**14,152**

28 Other liabilities, non-interest-bearing, current and non-current

GROUP	2021	2020
Non-current		
Liability to Sanofi	1,337	1,163
Liability to Eisai	1,015	993
Liability to Selecta	873	773
Liability to Apellis	608	539
Other	1	5
Total	**3,834**	**3,473**
Current		
Liability to Eisai	113	41
Liability to Selecta	90	81
Liability to Apellis	452	265
Liability to AstraZeneca	–	157
Derivatives	10	269
VAT	264	322
Other	384	167
Total	**1,314**	**1,302**

Note 28, cont.

PARENT COMPANY	2021	2020
Non-current		
Liability to Sanofi	1,337	1,163
Liability to Selecta	873	773
Liability to Apellis	608	539
Other	0	0
Total	**2,818**	**2,475**
Current		
Liability to Selecta	90	81
Liability to Apellis	452	265
Derivatives	10	269
Other	344	112
Total	**896**	**727**

Sanofi
In 2019, Sobi entered into a contract with Sanofi for BIVV001 where Sobi, conditional upon marketing authorisation from the European Medicines Agency (EMA), will make a one-time payment corresponding to 50 per cent of the total development costs, estimated to be USD 280–290 M less USD 50 M that has already been paid. At 31 December 2021, the obligation was recognised as a non-interest bearing non-current liability of SEK 1,337 M (1,163) on the balance sheet.

Eisai
Under a contract with Eisai, Sobi will pay up to USD 135 M based on annual net sales of Doptelet, calculated per calendar year. In 2021, Sobi paid USD 5 M. At 31 December 2021, the obligation was recognised as a non-interest bearing non-current liability of SEK 1,015 M (993) and a non-interest bearing current liability of SEK 113 M (41) on the balance sheet.

Selecta
In 2020, Sobi terminated the strategic licensing agreement for the SEL-212 product candidate with Selecta Biosciences, Inc. Provided that certain regulatory and commercial milestones are met, Selecta will be entitled to receive potential milestone payments of up to USD 625 M. At 31 December 2021, the obligations were recognised as a non-interest bearing non-current liability of SEK 873 M (773) and a non-interest bearing current liability of SEK 90 M (81) 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 treatments. Provided that certain regulatory and commercial milestones are met, Apellis will be entitled to receive potential milestone payments of up to USD 915 M. At 31 December 2021, the obligations were recognised as a non-interest bearing non-current liability of SEK 608 M (539) and a non-interest bearing current liability of SEK 452 M (265) on the balance sheet.

AstraZeneca
Acquisition of the rights to Synagis included an obligation for Sobi to pay USD 60 M in addition to an up-front consideration to AstraZeneca, which has been paid in full at the balance sheet date.

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.

Sweden
Defined-contribution plan via Alecta and pension benefits
For white-collar employees in Sweden, the ITP 2 plan's defined-benefit pension obligations for retirement and family 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 2021 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 2022, expected contributions for ITP 2 plans insured through Alecta amounted to SEK 18 M (20). 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 155 per cent. If Alecta's collective funding ratio falls below 125 per cent or exceeds 155 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 2021, Alecta's surplus in the form of the collective funding ratio was 172 per cent (148). 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. The company secures the direct pension by taking out an endowment policy that is pledged to the senior executive.

Defined-benefit pension plan
The defined-benefit pension obligations are calculated annually or when required, based on actuarial principles. Sobi has defined-benefit pension plans in Switzerland, Norway, France, Italy and for a few former employees in Sweden.

The present value of the obligations includes special payroll tax, in accordance with IAS 19, for these pension plans. Pension expenses are recognised under the items of selling costs, administrative expenses and research and development costs, depending on the function in which the insured is/was employed.

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 the company. 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. At 31 December 2021, the plans covered 149 (157) employees, of whom all were active.

Other
At 31 December 2021, the liability recognised for other defined-benefit pension plans was SEK 16 M (21). Other pension obligations are attributable to France, Italy, Norway and Sweden.

Note 29, cont.

SEK M	2021	2020
Present value of funded obligations	431	349
Fair value of plan assets	–299	–220
Deficit in funded plans	132	129
Present value of unfunded obligations	11	15
Net	**143**	**144**

SEK M	2021	2020
Net assets[1]	5	0
Net obligation	148	144
Net	**143**	**144**

1. Plans with a net surplus, ie where plan assets exceed the defined benefit obligations, are reported as an asset and included in financial fixed assets

Changes in defined-benefit pension obligations during the year are as follows:

1 JANUARY–31 DECEMBER 2021	Present value of obligations	Fair value of plan assets	Total
At beginning of year	**364**	**–220**	**144**
Amount in profit or loss			
Costs for service in current year	35	–	35
Interest expense	1	–	1
Interest income	–	–1	–1
Amount in cash flow			
Contributions from employees	11	–11	0
Contribution into plans from employer	–1	–25	–26
Payment from the plans	19	–19	0
Amount in other comprehensive income			
Remeasurement			
Return on plan assets, excl. amounts included in interest expense	–	–2	–2
Changed demographic assumptions	–32	–	–32
Changed financial assumptions	–9	–	–9
Experience-based assumptions	28	–6	22
Translation difference	26	–15	11
At end of year	**442**	**–299**	**143**

1 JANUARY–31 DECEMBER 2020	Present value of obligations	Fair value of plan assets	Total
At beginning of year	**227**	**–145**	**83**
Additional pension plans[1]	125	–80	45
Reclassification	2	–	2
Amount in profit or loss			
Costs for service in current year	30	–	30
Interest expense	1	–	1
Interest income	–	–1	–1
Amount in cash flow			
Contributions from employees	5	–5	0
Contribution into plans from employer	–1	–13	–13
Payment from the plans	–17	18	1
Pension payments directly from the company	–1	–	–1
Amount in other comprehensive income			
Remeasurement			
Return on plan assets, excl. amounts included in interest expense	–	–4	–4
Changed demographic assumptions	–3	0	–3
Changed financial assumptions	11	–	11
Experience-based assumptions	–2	1	–1
Translation difference	–12	7	–6
At end of year	**364**	**–220**	**144**

1. Refers to pension plans in Switzerland and France, and part of the plan in Italy, which were not previously recognised in accordance with IAS 19 in the Group.

Net obligation per country

	2021	2020
Sweden[1]	–5	0
Italy	4	3
Norway	10	6
France	7	12
Switzerland	127	123
Total	**143**	**144**

1. In Sweden, the total net obligation is an asset and is included in other financial assets.

Actuarial assumptions at the balance sheet date

AVERAGE FOR PENSION PLANS	2021	2020
Discount rate, %	0.6	0.3
Expected annual salary increase, %	2.2	1.9
Pension increases	0.1	0.9
Remaining life expectancy after retirement age, male, years	20.9	18.1
Remaining life expectancy after retirement age, female, years	24.9	22.2

Demographic assumptions
During the year, mortality assumptions were updated for the Swedish and the Swiss pension plan and is based on the DUS14 respectivley BVG2020 mortality table. The Italian and the Norwegian pension plan is based on the RG48 respectively K2013 BE mortality table. The retirement age is set at 65 years except in Switzerland, where the retirement age for women starts at 64 years.

Note 29, cont.

Distribution by plan assets

	2021	Quoted, %	2020	Quoted, %
Equity funds	113	100	75	100
Interest-bearing securities	105	100	67	100
Properties	57	–	40	–
Other funds	8	–	27	–
Other	16	–	11	–
Total	299	73	220	65

Sensitivity analysis

	2021	2020
Pension obligation under current assumptions	442	364
Discount rate –0.5%	477	396
Discount rate +0.5%	409	339
Salary decrease –0.5%	432	357
Salary increase +0.5%	450	371
Life expectancy after retirement –1 year	432	359
Life expectancy after retirement +1 year	450	366

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) has been applied as when calculating the pension liability recognised on the balance sheet.

Other information

For the 2022 financial year, contributions to plans for post-employment benefits are expected to be SEK 25 M (22). The weighted average duration of the obligation is an estimated 17.1 years (19.2).

Risks

Through its defined-benefit pension plans, the Group is exposed to a number of risks. The most significant risks are described in the table below:

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 (fixed-rate bonds), or weakly correlated with (shares) inflation, 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 Provisions

	Group		Parent Company	
	2021	2020	2021	2020
Provision at beginning of year	252	179	82	84
Endowment policy[1]	1	–2	1	–2
Milestone obligations[2]	–23	12	–	–
Restoration reserve[3]	–	0	–	0
Changes in pension obligations	4	61	–3	–
Other	1	1	–	–
Provisions at 31 December	234	252	79	82

	Group		Parent Company	
	2021	2020	2021	2020
Endowment policy[1]	45	44	45	44
Provision, milestone obligations[2]	–	23	–	–
Restoration reserve[3]	34	34	34	34
Pension obligations	148	144	–	3
Other	7	6	–	–
Provisions at 31 December	234	252	79	82

1. For corresponding assets, see Note 19.
2. A provision related to the licensing agreement with Astella for Doptelet was reversed during the year.
3. Sobi will restore the rented Paradiset 14 property to an acceptable condition with consideration for the operations conducted by the company, in accordance with the Rental Agreement (IAS 16).

	Group		Parent Company	
	2021	2020	2021	2020
Non-current portion	234	249	79	82
Current portion	–	3	–	–
Total provisions	234	252	79	82

31 Accrued expenses and deferred income

GROUP	2021	2020
Sales-related	3,053	2,158
Employee-related	659	572
Royalties	223	207
R&D	163	194
Co-Promotion	246	191
Inventory-related	172	164
Other	450	442
Total	4,967	3,928

PARENT COMPANY	2021	2020
Sales-related	275	226
Employee-related	245	257
Royalties	197	189
R&D	144	179
Co-Promotion	245	191
Inventory-related	49	116
Other	139	156
Total	1,296	1,314

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32 Pledged assets and contingent liabilities

GROUP	2021	2020
Pledged assets		
Endowment policy	45	44
Other pledged assets	3	2
Total	48	46

PARENT COMPANY	2021	2020
Pledged assets		
Endowment policy	45	44
Total	45	44

PARENT COMPANY	2021	2020
Contingent liabilities		
Guarantee commitment	88	26
Total	88	26

Guarantees for subsidiaries relate to general guarantees up to a specified amount and relate to all types of credit, such as rental guarantees, credit cards, etc., that the relevant subsidiary holds with various banks.

TAX AND LEGAL DISPUTES

Legal disputes

Sobi is involved in several ongoing disputes, a not-uncommon situation for pharmaceutical companies. None of these is currently considered material.

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.

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 Annual General Meeting:

KSEK	
Share premium reserve	9,152,505
Retained earnings	7,157,315
Profit for the year	1,790,394
Total	18,100,214

The Board of Directors proposes that no dividends be paid for the 2021 financial year.

The Board of Directors proposes that the share premium reserve, retained earnings and profit for the year, totalling KSEK 18,100,214, be carried forward.

35 Events after the reporting period

Gamifant

The National Medical Products Administration of China (NMPA) has approved Gamifant (emapalumab) for use in China for treatment of primary haemophagocytic lymphohistiocytosis (HLH).

In January 2022, Gamifant initiated dosing in a new phase 3 study, EMERALD. EMERALD evaluates the treatment of macrophage activation syndrome in paediatric and adult patients with underlying rheumatological diseases, specifically Still's disease and systemic lupus erythematosus. If the results are positive at the conclusion of the study, the first regulatory submission for a new indication is planned for the US with other countries to follow.

ReFacto

The contract with Pfizer for the manufacture of drug substance for ReFacto AF®/Xyntha® (ReFacto) has been amended due to clarity of final order volumes and will now expire in the first quarter of 2024, earlier than the previous expiry date at the end of 2025. Manufacturing of drug substance for ReFacto will be transferred to Pfizer's production unit in Ireland, ensuring continued patient access.

The process of downsizing its Stockholm manufacturing facility will start in the second half of 2022, with the last volumes being delivered to Pfizer in the beginning of 2024. An estimated 80 positions are expected to be affected by the closure over the next 24 months. Sales of ReFacto amounted to SEK 445 M in 2021.

The conflict in Ukraine

It is unclear how and to what extent Sobi's operations will be affected by the conflict in Ukraine. Sobi has operations in Russia with 35 employees. Sales in Russia accounted for less than 1 per cent of Sobi's total revenue for 2021. At the time of signing this annual report, Sobi has outstanding accounts receivable related to Russia amounting to approximately EUR 22 M, which are currently being evaluated. Sobi is following events closely to assess the potential and actual risks stemming from the situation.

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The Board and CEO confirm that the consolidated financial statements have been prepared in accordance with international financial reporting standards (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 Director's 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 Annual General Meeting on 10 May 2022 for adoption.

Stockholm, 29 March 2022

Håkan Björklund
Chair

Annette Clancy
Board member

Matthew Gantz
Board member

Helena Saxon
Board member

Staffan Schüberg
Board member

Filippa Stenberg
Board member

Elisabeth Svanberg
Board member

Pia Axelson
Employee representative

Erika Husing
Employee representative

Guido Oelkers
Chief Executive Officer

Our auditor's report was submitted on 31 March 2022
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 2021. The annual accounts and consolidated accounts of the company are included on pages 32–87 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 2021 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 2021 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (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 income statement and balance sheet for the parent company and the group.

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 Auditor's Responsibilities section. 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.

Valuation of product and market rights and goodwill

Description	How our audit addressed this key audit matter
Per 31 December 2021 the majority of (79% or 37,847 MSEK) 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 weighted average cost of capital ("WACC") used to discount future cash flows. The Company's process for assessing impairment requirements also includes the use of management's and the board of director's 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: • sobtained an understanding of the Company's process 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. We have also assessed the disclosures in the annual report.

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 at 31 December 2021 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 is 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 and the Company's calculation of liabilities for the revenue adjustment 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.

Contingent considerations

Description	How our audit addressed this key audit matter
During 2021 and in previous years, the Company and the Group (hereinafter 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. As of December 31, 2021, the reported liabilities for contingent consideration amounted to SEK 2,818 million and SEK 2,818 million in the Group and the Parent Company respectively. As described in Note 2, contingent considerations are initially recognized at fair value of the future commitments. Subsequent valuation of contingent considerations for business combinations are made at fair value and is recognized in the statement of comprehensive income. Subsequent valuation of contingent considerations for asset acquisitions are measured at amortized cost and recognized against the value of the asset with the exception of currency movements and interest expense. 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, 26, 28 and 33. 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 not insignificant 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: • sobtained 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 1–31, 92, 100–103 and 129–134. The remuneration report for the financial year 2021 also constitutes other information. 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 Director's 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 skepticism 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

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 2021 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 Auditor's Responsibilities section. 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 fulfill 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 skepticism 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 CEO 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 2021.

Our examination and our opinion relate only to the statutory requirements.

In our opinion, the ESEF report #4e0e19749673409690bcc01de8aef15c4c1879ff20ff551c287f885a85ceb9fc 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 Auditors' responsibility section. 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 CEO
The Board of Directors and the CEO 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 CEO 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 CEO, 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 CEO.

The procedures mainly include a technical validation of the Esef report, i.e. if the file containing the Esef report meets the technical specification set out in the Commission's Delegated Regulation (EU) 2019/815 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 Esef report has been marked with iXBRL which enables a fair and complete machine-readable version of the consolidated statement of financial performance, financial position, changes in equity and cash flow.

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 13 May 2021 and have been the company's auditor since 8 May 2014.

Stockholm, March 31, 2022
Ernst & Young AB

Jonatan Hansson
Authorized Public Accountant

Letter from the chairman

Sobi continues to build for growth, with a solid strategy setting out the path ahead.

2021 was an eventful year for Sobi. Looking back, I want first to highlight the way the company continued to generate long-term value and deliver on its strategy for growth, extending access to treatment to more people with rare diseases.

Secondly, a public cash offer by Advent and GIC for all shares in Sobi was eventually withdrawn after narrowly failing to reach an acceptance level of 90 per cent. The Board had recommended shareholders accept the offer, which we saw as a fair and competitive offer, a premium valuation that recognised the long-term value that Sobi represents.

The offer indicated that we are not alone in seeing the potential that Sobi has. The Board and I continue to have full confidence in the CEO, the Executive Committee, and the vision and strategy we have set out for Sobi.

By expanding into new geographical markets and bringing new medicines to patients during 2021, Sobi made clear progress towards its vision of becoming a global leader in rare diseases. The strategy is clear, and it is vital that all staff continue to focus and deliver on the objectives, which will improve and expand access to innovative treatments that transform life for people with rare diseases.

Recognising the need to change to ensure Sobi stays ahead of the game, the Board is providing support to the management in the ongoing transformation that is building a platform for continued growth. We do this by providing a clear governance structure, as well as expertise in crucial corporate decisions.

Governance continues to be vital, and the Code of Conduct remains a foundation stone for Sobi's governance structure. Introduced in Q4 2020, the updated Code of Conduct is a compulsory part of the education package for every Sobi employee. Compliance is the minimum standard accepted by Sobi.

The same high standard is expected of Sobi's suppliers and partners. As part of the Responsible Sourcing Programme introduced in 2020 and expanded throughout 2021, Sobi has committed to work only with partners who embrace standards consistent with Sobi's own when it comes to ethics, human rights and protection of the environment.

Sobi is intent on continuing to contribute to the fulfilment of the United Nations Sustainable Development Goals and the Paris Climate Agreement, and continues to report on expanded key performance indicators in line with its commitments under the UN Global Compact and the Global Reporting Initiative to improve transparency.

COVID-19 continued to cast a shadow over 2021. The commitment of all staff to ensuring continuity of operations, to ensuring that patients continued to receive their medicines, was and continues to be commendable. The EU approval of Kineret as a treatment for COVID-related pneumonia represented a major step forward in Sobi's efforts to address this medical challenge of a generation.

Lastly, I want to pay tribute to the commitment and expertise of Sobi management and staff as they continue to transform the lives of people with rare diseases.

Håkan Björklund
Chairman of the Board

Corporate Governance Report

Swedish Orphan Biovitrum AB (publ) ("Sobi") is a Swedish public limited liability company with its registered office in Stockholm, Sweden. Sobi is listed on Nasdaq Stockholm. This report for the 2021 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 or 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, with the deviation in 2021 from item 2.5, first sentence, that the name of the members of the Nomination Committee was published on the company's website later than six months prior to the 2022 AGM. The reason for the deviation was that it was deemed appropriate to wait for the outcome and possible changes in ownership arising from the all-cash public offer from Advent and GIC to Sobi's shareholders, which was ongoing during the period, before appointing the Nomination Committee. Sobi 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 2021. 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 the company's affairs. The Annual General Meeting (AGM) must be held within six months of the end of the financial year, and Extraordinary General Meetings (EGM) may be held if the Board of Directors 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.

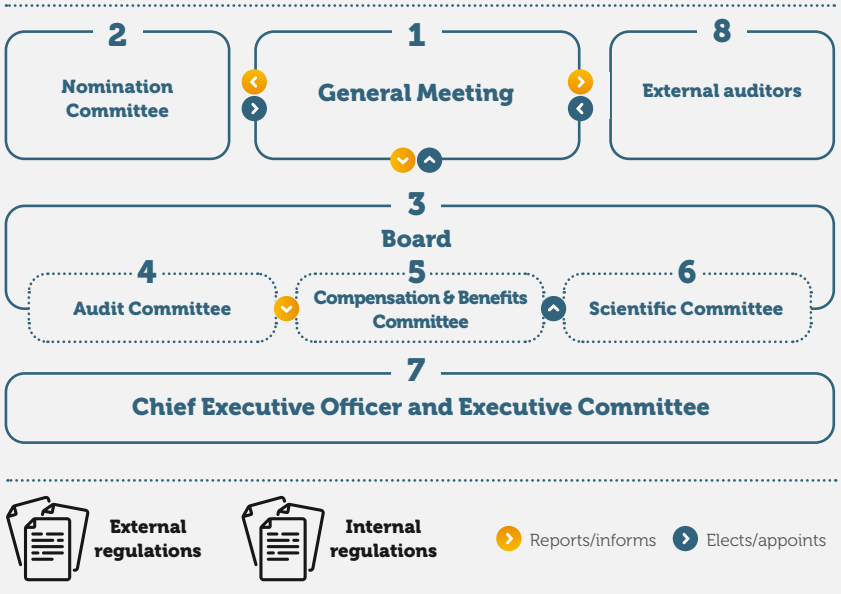
The company does not apply any special arrangements with regard to the function of the general meeting, either on the basis of provisions in the Articles of Association or, to the extent they are known to the company, shareholder agreements.

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 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.

2021 AGM

The Annual General Meeting was held on 4 May 2021 in Stockholm. Due to the coronavirus and in order to reduce the risk of spreading infection, the Meeting was held exclusively through postal voting pursuant to the temporary regulations in force in 2021. The Meeting was attended by 328 shareholders (292), in person or by proxy. They represented 64.3 per cent (66.7) of the total number of votes. Lawyer Eva Hägg was elected to chair the meeting.

The complete minutes and information from the 2021 AGM are available at www.sobi.com.



Resolutions 2021 AGM
The following resolutions were inter alia adopted by the 2021 AGM:
- Re-election of six Board members
- Election of two new Board members
- Re-election of the Chair
- Re-election of Ernst & Young AB as auditor
- Remuneration of the Board and auditors
- Approval of the Board's remuneration report for 2020
- Discharge from liability for the Board and CEO for the 2020 financial year
- Introduction of long-term incentive programmes
- Amendment of the Articles of Association

2022 Annual General Meeting
The Annual General Meeting will be held on Tuesday, 10 May 2022. For more information about the AGM, refer to page 129.

Shareholders, share capital, the share and voting rights
At year-end, Sobi had a total of 24,685 (33,816) shareholders. Investor AB was the largest shareholder, with 35.0 per cent (35.4) of the share capital and 35.0 per cent (35.4) of the votes. The 15 largest shareholders accounted jointly for 73.4 per cent (70.8) of the share capital and 73.4 per cent (70.8) 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 of Directors

In order to secure commitments under long-term incentive programmes, the AGM on 4 May 2021 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 215,908 of Sobi's own shares in order to cover some expenses, mainly social security contributions, that may arise due to the 2018 Incentive Programme. The AGM also resolved to authorise the Board of Directors to make decisions regarding the issue of shares and/or convertibles and/or warrants.

At 31 December 2021, Sobi held 11,959,198 shares in treasury. In 2021, all previously issued C shares were converted into ordinary shares. 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, refer to the section on shares on page 28.

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, and
- the dividen's impact on liquidity in terms of cash flow.

The Board proposes that no dividend be paid for 2021. In the short term, the company intends to use accrued profits to finance the continued licensing and acquisition of medicines for the pipeline as well as the global expansion of its business.

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 2022 AGM were published on the company's website on 3 December 2021.

In the period up to the 2022 AGM, the Nomination Committee had the following composition: Petra Hedengran (Investor AB), Chair of the Nomination Committee, Lennart Francke (Swedbank Robur Fonder AB), Thomas Ehlin (Fourth Swedish National Pension Fund) and Håkan Björklund, Chair of the Board of Sobi. Prior to the 2022 AGM, the Nomination Committee held three minuted meetings. As a basis for its work, the Nomination Committee has taken note of the Chair's account of the Board's work. The Nomination Committee has prepared proposals for the AGM regarding the election of Board members, the remuneration of Board and Committee members, the appointment of auditor, auditor fees and Chair of the AGM.

3. Board/Chair of the Board

Sobi is a biopharmaceutical company with a focus on marketing, developing and manufacturing pharmaceutical products to treat rare diseases. The product portfolio contains both marketed products and products 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, acquisi-

Nomination Committee prior to the 2022 AGM

Name/Representing	Votes 31 Dec 2021, %	Votes 31 Dec 2020, %
Petra Hedengran (Chair of the Nomination Committee) Investor AB	35.0	35.4
Lennart Francke Swedbank Robur Fonder AB	1.4	4.9
Thomas Ehlin Fourth Swedish National Pension Fund (AP4)	6.7	4.5
Håkan Björklund Chair of Swedish Orphan Biovitrum AB (publ)	0.0	0.0
Total	43.1	44.8

tions, divestments and major investments. The Board produces Annual and Interim Reports and proposes dividends to the AGM. 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 reasoned opinion to the 2021 AGM, the Nomination Committee has taken into account the importance of a well-functioning Board in terms of diversity, including sex, nationality, professional experience and experience of sustainability work, and believes that achieving and maintaining a gender balance is important. The current composition of the Board is the result of the Nomination Committee's work prior to the 2021 AGM.

The 2021 AGM adopted the Nomination Committee's proposal that the Board, as of the 2021 AGM and until 31 December 2021, has consisted of eight elected members (six re-elected and two newly elected by the 2021 AGM) as well as two employee representatives appointed by the trade union organisations (plus two deputies for the employee representatives). When Anders Ullman took office as Head of Research & Development at the turn of the year, he stepped down from the Board, after which the Board consisted of seven elected members. Four of the elected Board members are women.

For more information about the Board, see pages 100–101.

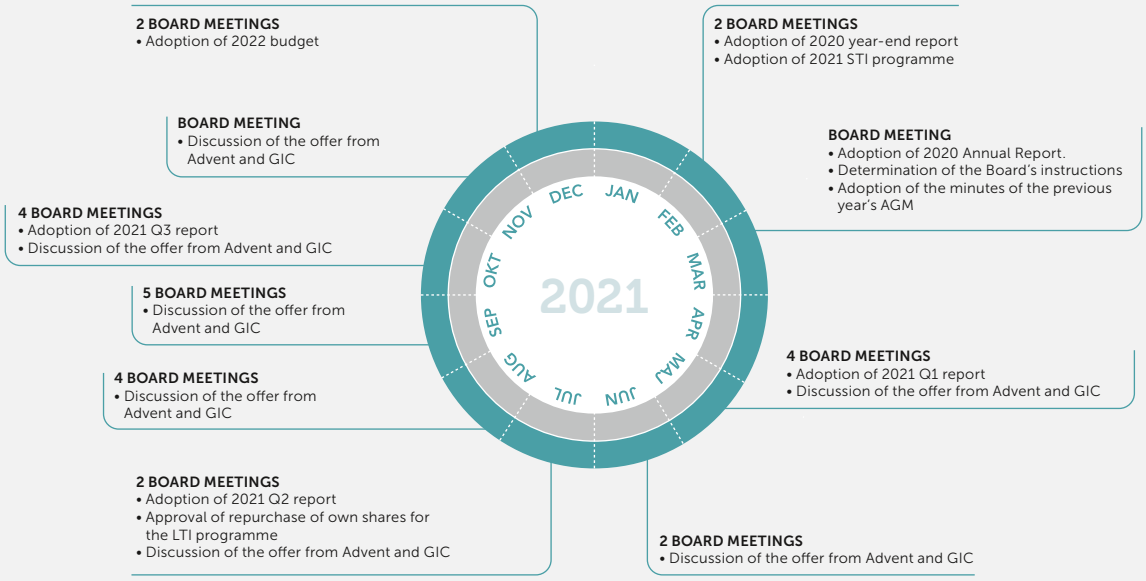
Independence

The company 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 96 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.

Important events in Board work in 2021



In order to carry out effective board work, the Board has established three committees – the Audit Committee, Compensation & Benefits Committee and Scientific Committee. The committees observe the rules of procedure established by the Board. The committees prepare relevant proposals and recommendations within their own areas of expertise, and submit them to the Board.

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 2022, the Board has scheduled a total of nine ordinary meetings.

Board work in 2021
In 2021, the Board held a total of 27 meetings, of which eight were scheduled in addition to the statutory meeting, and 18 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 mainly motivated by the all-cash public offer by Advent and GIC to Sobi's shareholders, and by discussions related to business development projects. The matters addressed are shown in the illustration on page 95. The Board members' attendance at Board meetings is presented in the table below.

Board fees
At the AGM on 4 May 2021, the Board resolved that for the period until the next AGM, a fee of KSEK 515 would be paid to each of the elected Board members except for the Chair, who would be paid a fee of KSEK 1,575. Fees for the Audit Committee's work would be KSEK 175 for the Chair and KSEK 105 for each of the other members. Fees for the Compensation & Benefits Committee's work would be KSEK 115 for the Chair and KSEK 65 for each of the other members. Fees for the Scientific Committee's work would be KSEK 115 for the Chair and KSEK 65 for each of the other members. In 2021, Board fees of KSEK 5,770 were paid, including remuneration for committee work.

It was further resolved that for each physical Board meeting, a fee of KSEK 10 would be paid to Board members residing in Europe but outside the Nordic region, and KUSD 3 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 2021, the evaluation took the form of individual discussions between the Chair and individual Board members. The Chair 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. Up until the AGM in May 2021, the Audit Commmitte consisted of: Lennart Johansson (Chair), Helena Saxon and Staffan Schüberg. After the AGM in May 2021, the Audit Committee consisted of three members, all whom 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[1]			
	Independence	Fees	Audit Committee	Compensation & Benefits Committee	Scientific Committee	Other[5]	Total	Board	Audit Committee	Compensation & Benefits Committee	Scientific Committee
Håkan Björklund	x	1,550	–	113	–	–	1,663	27/27	–	8/8	–
Annette Clancy	x	507	–	–	80	–	587	24/27	–	–	3/3
Matthew Gantz	x	507	–	63	–	–	570	25/27	–	6/8	–
Lennart Johansson[2]	x	163	53	–	–	–	217	4/4	3/3	–	–
Helena Saxon	[3]	507	150	63	–	–	720	18/18	6/6	8/8	–
Staffan Schüberg	x	507	103	–	–	10	620	27/27	6/6	–	–
Filippa Stenberg[2]	[3]	343	70	–	–	–	413	14/14	3/3	–	–
Elisabeth Svanberg	x	507	–	63	–	–	570	27/27	–	–	3/3
Anders Ullman[2, 6]	x	343	–	77	–	–	420	20/21	–	–	2/3
Pia Axelson	[4]	–	–	–	–	–	–	27/27	–	–	–
Erika Husing	[4]	–	–	–	–	–	–	27/27	–	–	–
Linda Larsson	[4]	–	–	–	–	–	–	16/20	–	–	–
Katy Mazibuko	[4]	–	–	–	–	–	–	20/20	–	–	–

1. The figures in the table show the totals for attendance/meetings. In 2021, the Board held a total of 27 meetings, of which eight were scheduled in addition to the statutory meeting and 18 were extra meetings. The Audit Committee held six meetings, the Compensation & Benefits Committee held eight meetings, and the Scientific Committee held three meetings.
2. At the AGM on 4 May, Lennart Johansson stepped down from his position as ordinary Board member, while Filippa Stenberg and Anders Ullman were appointed new ordinary Board members.
3. Board member does not qualify as independent in relation to major shareholders.
4. Employee representatives.
5. For each physical Board meeting, a fee of KSEK 10 is paid to members who live in Europe but outside the Nordic region, and KUSD 3 to each member who lives outside Europe.
6. In addition to Board fee the Board member has invoiced consulting fees of K 600 SEK for business strategic work initiatives that do not pertain to Board work.

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 (Chair)
- 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 eight 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 2022 AGM for adoption by the shareholders. The Board members' attendance and remuneration for committee meetings is presented in the table on page 96. For information about salaries and remuneration of the CEO and senior executives, 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. Up until the AGM in May 2021, the Scientific Committee consisted of two members: Anette Clancy (Chair) and Elisabeth Svanberg. After the AGM in May 2021, the Scientific Committee consisted of three members:

- Anders Ullman (Chair)
- Annette Clancy
- Elisabeth Svanberg

When Anders Ullman took office as Head of Research & Development, the Board decided to declare the Scientific Committee temporarily dormant.

Sobi's CEO and Chief Medical Officer/Head of Research & Development attended the meetings, but are not formal members. Chief Medical Officer/Head of Research & Development served as secretary of the Committee. During the year, the Committee held three meetings. The following issues were discussed at these meetings:

- Development of the company's R&D portfolio
- The R&D organisation
- Review of individual projects
- Review and follow-up of the organisation's targets
- Budget
- Business development opportunities

The Committee reports regularly to the Board about its work. The Board members' attendance and remuneration for committee meetings is presented in the table on page 96.

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 drugs. In addition, members of the Executive Committee hold the required competence in accounting, finance, law, communications and HR. In 2021, 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 102–103.

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 2022 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, see Note 11.

Risk management and 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 and risk management systems in connection with the financial reporting process.

Sobi's internal control framework

Sobi's 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 & 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 mainly comprises the culture on which the Board and management base their work and communication to the operations through Sobi's internal regulations. The control environment for financial reporting comprises an organisational structure with clear powers, areas of responsibility, decision-making paths and governing documents that support the financial processes. 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
- Signing authorisation instructions
- Reporting instructions
- Accounting manual
- Treasury Policy
- Risk Management Policy

Risk assessment

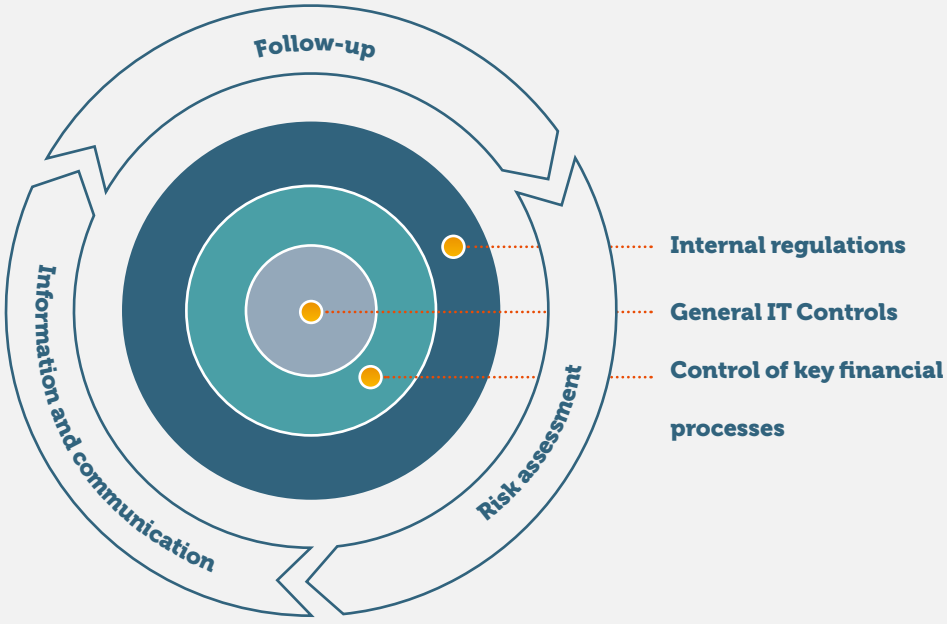
Effective risk assessment aligns Sobi's business opportunities and profits with shareholders' and other stakeholders' demands for stable, long-term value growth and control. The aim of Sobi's risk management process is to support the company's operations and create profitable business opportunities combined with good control over risk. 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 set targets. Sobi's risk management process is intra-organisational. In regard to financial reporting, the operational units perform risk assessments together with the responsible Group controllers to identify, assess and ensure control over risks in accounting and reporting processes.

Significant risks identified by Sobi are described on pages 39–41.

Control activities

The aim of control activities is to manage identified risks and contribute to good internal control and efficiency. Control activities applicable to financial reporting include approval of decisions and transactions, account reconciliation and analytical monitoring. Sobi's control activities are either manual or integrated with the ERP systems used, such as IFS, Cognos, Business Intelligence and so forth. Sobi also has General IT Controls in place for managing its system environment. General IT Controls include Identity and Access Management and Change Management.

Sobi's internal control framework



Information and communication

Sobi has internal information and communication channels to ensure that financial reporting disclosures are efficient and accurate. Sobi's intranet is the main communication platform. The Group's financial organisation also holds annual 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 the Group's website www.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 controls are conducted in accordance with the Board's decisions. Sobi has had one employee with responsibility for strengthening the Group's internal control since 2017. The function reports to the CFO and prepares an internal control plan every year, which is approved and monitored by the CFO.
The Board deals with all interim reports and annual report prior to publication, and monitors the review of internal control through the Audit Committee.
The company'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 has decided that those responsible for internal control together with the existing organisation, primarily in the Treasury function, assess and monitor compliance with Sobi's internal control framework every year. 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 makes the assessment that a separate internal audit function is not necessary at present.

Activities in 2021 that strengthened internal control

- Clarification of the Group's internal control framework
- Implementation of risk and control matrices for the Group's core financial processes
- Implementation of an internal evaluation process for the Group's internal control framework
- Adjustments to the Group's risk management process

Activities in focus for 2022 to further strengthen internal control

- Further development of the Group's framework for internal control over financial reporting.
- Implementation of process for internal control review.
- Implementation of systems support for managing risk, control and monitoring.

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 2021 on pages 93–103 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 Report was prepared. Disclosures in accordance with Chapter 6, Section 6, second paragraph, points 2–6 of the Annual Accounts Act and Chapter 7, Section 31, second paragraph of the same law are consistent with the annual accounts and the consolidated accounts, and are in accordance with the Annual Accounts Act.

Stockholm, March 31, 2022
Ernst & Young AB

Jonatan Hansson
Authorised Public Accountant

The Board

Håkan Björklund

Born 1956

Chair. Board member since 2016. Member of the Compensation and Benefits Committee (Chair).

PhD from Karolinska Institutet

Other assignments: Chairman of OneMed. Chairman of BioPhorum. Board member of Bonesupport. Partner at Tellacq Partners. Advisor to Rothschild Private Equity.

Previous positions: 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 the company and its executive management: Yes

Independent in relation to major shareholders of the Company: Yes

Shares: 15,800

Annette Clancy

Born 1954

Board member since 2014.

BSc Hons Pharmacology from Bath University

Other assignments: Non-executive Chair of the Board of Enyo SA. Board member of Obseva SA. Investor at Jeito Capital.

Previous positions: Senior Advisor, Biopharmaceutical Team of Frazier Healthcare. Chair of the Board of Directors of Genable Therapeutics and Lysogene SA. Non-Executive Board Director at Silence Therapeutics plc. and Clavis Pharma. Head of Transaction and Alliance Management at Glaxo-SmithKline (GSK).

Independent of the company and its executive management: Yes

Independent in relation to major shareholders of the Company: Yes

Shares: 3,414

Matthew Gantz

Born 1965

Board member since 2012. Member of the Compensation and Benefits Committee.

BA Princeton University and MBA from Harvard Business School

Other assignments: CEO of Castle Creek Biosciences Inc. Member of the board of the Marine Corps Scholarship Foundation.

Previous positions: 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.

Independent of the company and its executive management: Yes

Independent in relation to major shareholders of the Company: Yes

Shares: 0

Helena Saxon

Born 1970

Board member since 2011. Member of the Audit Committee (chair) and Compensation and Benefits Committee.

MSc from Stockholm School of Economics

Other assignments: CFO at Investor AB. Board member of SEB.

Previous positions: CFO at Hallvarsson & Halvarsson. Vice President at Investor AB. Financial analyst at Goldman Sachs. Board member of Aleris and Mölnlycke Health Care.

Independent of the company and its executive management: Yes

Independent in relation to major shareholders of the Company: No

Shares: 20,000

Staffan Schüberg

Born 1969

Board member since 2020. Member of the Audit Committee.

BA Hons Business Administration from the London Guildhall University.

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.

Previous positions: More than 20 years of experience from Board and executive management roles, including a number of senior positions within Lundbeck A/S, such as Regional Vice President for Southern and Western Europe, President and Chairman of the U.S. operations and Global Chief Commercial Officer on Group level.

Independent of the company and its executive management: Yes

Independent in relation to major shareholders of the Company: Yes

Shares: 4,500

Filippa Stenberg

Born 1985

Board member since 2021. Member of the Audit Committee.

MSc in Economics from Stockholm School of Economics.

Other assignments: Investment Manager at Investor AB.

Previous assignments: Analyst at Swedbank LC&I.

Independent of the company and its executive management: Yes

Independent in relation to major shareholders of the Company: No

Shares: 500

Elisabeth Svanberg

Born 1961

Board member since 2018.

MD and PhD from the University of Gothenburg, Sweden, Associate Professor of surgery.

Other assignments: Chief Development Officer at Ixaltis SA. Board member of Egetis Pharmaceuticals (formerly PledPharma AB), Galapagos NV, Amolyt Pharma and Pharnext.

Previous positions: Board member of Follicum AB and of the Swedish American Chamber of Commerce New York. Head of the Established Products Group at Janssen Pharmaceuticals. Development Leader and Head of Medical Affairs (Intercon) at Bristol Myers Squibb. Various senior R&D management roles at Serono International.

Independent of the company and its executive management: Yes

Independent in relation to major shareholders of the Company: Yes

Shares: 2,658

Pia Axelson

Born 1962

Employee representative

Board member since 2019. Deputy Board member 2019. Board member 2017. Deputy board member 2009 to 2017. Representative of the council for negotiation and cooperation.

Medical laboratory scientist

Laboratory engineer

Independent of the company and its executive management: No

Independent in relation to major shareholders of the Company: Yes

Shares: 7,381

Erika Husing

Born 1973

Employee representative

Board member since 2020

Representative of the council for negotiation and cooperation.

CRM Application Manager, Commercial Effectiveness

MSc Chemistry

Independent of the company and its executive management: No

Independent in relation to major shareholders of the Company: Yes

Shareholding in the company: 75

Deputies for the employee representatives:

- Katy Mazibuko
- Linda Larsson

All shareholdings reported as per 31 December 2021.

Executive committee

Guido Oelkers

Chief Executive Officer

Born 1965

Employed since 2017

PhD in Strategic Management, University of South Australia. Master of Economics, South Bank University, London. Complementary studies in Economics, London School of Economics and Political Science.

Other assignments: Chair of the Advisory Committee of Zentiva Group. Industrial Advisor EQT.

Previous positions: CEO of BSN Medical GmbH. 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 AG.

Shares: 298,675

Henrik Stenqvist

Chief Financial Officer

Born 1967

Employed since 2018

Degree in Finance and Business Administration, University of Linköping.

Other assignments: Board member of Midsona AB.

Previous positions: CFO at Recipharm. CFO at Meda. Regional Finance Director at AstraZeneca. Finance Director at Astra Export & Trading. Board member of MedCap AB.

Shares: 33,449

Torbjörn Hallberg

General Counsel and Head of Legal Affairs, Head of Human Resources

Born 1969

Employed since 2018

Master of Laws, University of Lund.

Previous positions: 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: 13,949

Duane H. Barnes

Head of North America

Born 1960

Employed since 2021

MBA and MSc, Indiana University, Kelley School of Business. BA, West Virginia University, Eberly College of Arts and Sciences.

Other assignments: Board member of BIO, Biotechnology Innovation Organization. Board member of HLC, Healthcare Leadership Council.

Previous positions: 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: 0

Sofiane Fahmy

Head of Europe

Born 1972

Employed since 2013

Degree in Marketing, University of Paris XI. Degree in Pharmacy University of Poitiers.

Previous positions: General Manager Sobi France and North Africa. Managerial roles at Pfizer. Commercial roles at GSK. Brand Manager Hospital Products at Roche.

Shares: 11,720

Christine Wesström

Head of Technical Operations

Born 1975

Employed since 2010

MSc in Chemical Engineering, major in Biotechnology, Mälardalens University.

Previous positions: Head of Global Manufacturing & Infrastructure, Head of External Manufacturing at Sobi. Project Management roles within Manufacturing & CMC Development at Biovitrum.

Shares: 5,406

Thomas Kudsk Larsen

Head of Communication and Investor Relations

Born 1974

Employed since 2021

HD in Finance, Copenhagen Business School.

Previous positions: 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: 0

Mahmood Ladha

Head of Business Development

Born 1964

Employed since 2019

MBA and BS, University of South Carolina.

Previous positions: President and Head of Dova Pharmaceuticals. Senior Advisor to CEO, VP and Head of Transactions at AstraZeneca. Executive Director and Head of US Respiratory at AstraZeneca.

Shares: 0

Norbert Oppitz

Head of International

Born 1967

Employed since 2017

Dipl. BW (FH)/Business Administrator, FH Rhenania Palatina/Mainz.

Previous positions: 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: 19,949

Daniel Rankin

Head of Global Portfolio and Product Strategy

Born 1980

Employed since 2017

PhD in Biology from University of Helsinki. MSc in Biology from Leiden University. BSc from University of York.

Previous positions: 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: 5,454

Armin Reininger

Head of Medical and Scientific Affairs

Born 1957

Employed since 2017

MD, PhD, Ludwig-Maximilians University Munich. Certified specialist in Transfusion Medicine. Professor of Anatomy at the Ludwig Maximilians University Munich.

Previous positions: Head of Medical Affairs EMEA Haemophilia at Baxter. Head of Global Medical Affairs Haematology at Baxalta. Head of Medical Affairs EMEA Haematology at Baxalta/Shire. Senior Physician at University Clinic Munich, Harvard Medical School & Mass. General Hospital, Boston, MA. The Scripps Research Institute, La Jolla, CA. Professor of Anatomy at the Ludwig Maximilians-University Munich.

Shares: 12,454

Anders Ullman

Head of Research & Development, Chief Medical Officer

Born 1956

Employed since 2022

MD, PhD in Clinical Pharmacology.

Other assignments: Board member of Verona Pharma plc.

Previous positions: Head of the COPD center 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 AstraZeneca, Bayer Pharmaceuticals, Biovitrum, Nycomed/Takeda and Baxter Bioscience.

Shares: 3,000

All shareholdings reported as per 31 December 2021.

Sustainability Report 2021

Sobi's key contributions to sustainable development and the overall sustainability objective are closely aligned with the company vision and strategy – to transform the lives of people living with rare diseases.

Business model and sustainable growth

Sobi's business model spans from clinical development to patient access and global commercialisation. The sustainability strategy is closely linked to the business and based on two priorities – commitment to patients and responsible behaviour. 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 we serve. 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 Sustainable Development Goals (SDGs) and the Paris Agreement.

Material sustainability topics

Sobi's material sustainability topics reflect areas where the business has a significant impact on the economic, environmental or social environment, and where the potential impact on Sobi is substantial.

Since 2019, Sobi has conducted comprehensive materiality assessments. This work includes web surveys and targeted interviews with internal and external stakeholders, attending conferences, participating in ESG ratings and research, and conducting internal dialogues on future legislation. Government procurement bodies and tender processes, as well as institutional investors and banks, are increasing their expectations for a solid sustainability performance. To meet these expectations, Sobi started implementing a periodic materiality process in 2021, where stakeholder dialogue is conducted continuously, and the results provide a basis for senior management decision-making.

Compared to the 2019 outreach to identify the most influential sustainability topics, only one topic among the top five has changed. All top five topics are scored between important and very important. Notably, five of the top ten areas identified in 2021 are connected to governance, and only two to environmental topics. In some of the most influential topics, stakeholders perceive that Sobi demonstrates a strong performance.

2021 most influential topics	Perceived strong performance (2021)	2019 most influential topics (reference)
Patient safety & product quality	●	Patient safety & product quality
Compliance & anti-corruption		Compliance & anti-corruption
Research ethics		Access to treatment
Fair working conditions	●	Responsible marketing & sales
Access to treatment	●	Research ethics
Occupational health & safety	●	Diversity & inclusion
Responsible marketing & sales		Occupational health & safety
Responsible procurement practices		Impact on communities
Resource management		Drug residues
Pharmaceuticals in the environment	●	Use of input materials & chemicals

Relative weighted ranking of the top sustainability topics influencing assessments of Sobi. Data collected in web survey December–January 2021–22 with 62 external and internal stakeholders. External stakeholder groups include shareholder representatives/analysts, suppliers, public procurers/healthcare providers, patient advocacy groups, NGOs and trade associations.

The results show a good correspondence between Sobi's identified priority areas, and the existing sustainability strategy. The feedback on perceived performance highlights a need for continued development of sustainability processes at Sobi, and increased communication around approach and results, to align with stakeholder expections. In 2022, these results will be used in internal dialogue, to identify the topics that are material to Sobi from both a financial and impact perspective. Conclusions from this will then be used to further develop strategy and priorities.

Sustainability governance

Management

Sobi's Board of Directors has overall responsibility for Sobi's sustainability performance, publicly reported each year in the Annual and Sustainability Report. The CEO and the Executive Committee approve Sobi's sustainability strategy, ensure compliance, and decide on overall objectives and implementation of the sustainability strategy. The leadership teams in each respective area are responsible for implementing and following up on the strategy. 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.

Policies and responsibilities

The sustainability strategy rests on the Code of Conduct and other policies governing sustainability-related topics. The Sobi Code of Conduct provides a framework for responsible and appropriate conduct, and applies to all Sobi employees worldwide as well as temporary personnel.

Important roles and responsibilities for managing Sobi's material sustainability topics and delivering on the sustainability strategy are:

- The Sustainability function, which evaluates materiality, creates guidelines, supports implementation of the strategy programme and reports on outcomes.
- The Corporate Compliance function, responsible for the implementation of anti-corruption and healthcare interaction policies, data privacy, third party risk due diligence and the compliance hotline (whistleblower hotline).
- The Internal Control function, which evaluates and improves processes for management, internal control and risk management.
- The Technical Operations function, which includes Procurement, is responsible for environmental compliance and performance of in-house operations, and for monitoring suppliers' and partners' adherence, and driving development in accordance with the Responsible Sourcing Programme.
- Sobi's affiliates, which 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, supporting patient needs at all stages of the patient journey and engaging with key stakeholders.

Sustainability-related policies

Commitment to patients

- 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)

Responsible behaviour

- Group Risk Management Policy
- Policy on Fair Competition
- Anti-corruption policy
- 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

The Sobi Group Compliance function has overall responsibility for Sobi's policy framework and conducts yearly 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 Group Compliance and Group Internal Control. While a complete list can be found at www.sobi.com, the most important sustainability-related practices and policies are listed on page 105.

External recognition
Sobi plays an active role in environmental, social and governance (ESG) evaluations aiming at continuous improvement in ratings. In 2021, Sobi had positive momentum in several indices, indicating a positive external response to the effort.

Sustainability Rating Institutes

Rating	2021	2020	2019
MSCI	A	A	A
Sustainalytics (risk ranking in Biotech)	20.5 medium risk (3 out of 365)	26.4 medium risk (16 out of 367)	26.2 medium risk (24 out of 362)
ISS	C+ High relative performance	C High relative performance	C High relative performance
VigeoEiris	37	36	34

Sobi's sustainability rating

Sobi's sustainability performance and progress is validated by the external sustainability ratings provider EcoVadis. In 2021, Sobi increased its EcoVadis score from 47 to 60.

Sustainability risk management
Sobi's 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, and sustainability risks have been included in the overall risk mapping. The risk assessment and the results of the 2021 risk management process are described in detail on pages 39–41. The Risk Management function reports the risk status to the Executive Committee, and to the Board of Directors. As part of the risk management process, the company's critical flows are identified, and business continuity plans are implemented.

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 sustainability performance, goals and strategy. Sobi is committed to transparency in sustainability performance and progress.

Sobi is preparing to include analysis and reporting according to the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD). Regarding the EU Taxonomy Regulation, for 2021, Sobi has carried out an analysis of to what extent the company's economic activities meet the criteria set out in the Taxonomy Regulation. The analysis showed that Sobi's core business, which is commercialising, development and manufacturing of pharmaceutical products, is not an economic activity that is included in the Taxonomy Regulation yet. Therefore, Sobi's share of eligible turnover as defined by the Taxonomy Regulation, is 0%. Sobi will continue to closely follow the development of the Taxonomy Regulation in coming years.

The Sustainability Report has been approved by Sobi's auditors in line with requirements in the Swedish Annual Accounts Act.

Sustainability strategy

Sobi's sustainability strategy helps deliver on the vision of transforming the lives of people living with rare diseases and will be crucial to execution of the business strategy. Progress in sustainability performance will also deliver value to Sobi's stakeholders and society in general. The sustainability strategy is based on two priorities – commitment to patients and responsible behaviour – and includes nine sustainability commitments. Each priority is linked to the UN Sustainable Development Goals (SDGs) and is connected to targets perceived as business-critical. The sustainability strategy is based on Sobi's commitment to transparency and the realisation of the 2030 Agenda as expressed by the UN SDGs and the Paris Agreement.

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 realisation of the SDGs via specific targets.

Commitment to patients and the SDGs

Sustainable Development Goals	Sustainable Development targets	Action and ambitions	Progress	Read more
SDG 3 Good health and wellbeing	3.2 End preventable deaths of newborns and children under 5 years of age	Promote life expectancy by expanding access to paediatric treatments	Synagis (palivizumab) is the only approved medicine for the prevention of serious lower respiratory tract infections caused by RSV in high-risk infants.	p 16
			More institutions in the US have begun using Gamifant for treating primary HLH, and the medicine was approved in the UAE during 2021.	p 16
			Kineret approved in Russia for CAPS and Still's disease (adults and children from eight months and 10 kilo)	p 20
	3.4 Reduce premature mortality from non-communicable diseases	Increase number of R&D programmes in rare diseases and areas of high medical need	Approximately ten projects focused on five medicines and aiming for more than 60 launches in key geographies.	p 11
			The approval of Kineret in the EU for treatment of COVID-19 related pneumonia in adult patients with risk of developing severe respiratory failure was preceded by a landmark phase 3 study, SAVE-MORE.	p 15
			Ongoing R&D programme centred around complement C3 inhibitor pegcetacoplan to broaden development outside first approved indication of PNH into other diseases and patient groups, in collaboration with Apellis.	p 21–22
	3.8 Achieve universal health coverage	Continue 10-year commitment to the WFH Humanitarian Aid Program	Since the initial pledge, over 18,800 people with haemophilia have been treated with factor donated by Sobi and Sanofi.	p 24
		Contribute to cost-support programmes	Continued support of Kineret OnTrack and Orfadin4U support programmes in the United States.	p 108
	3b Support R&D and make vaccines and medicines available for all	Increase number of first-in-class medicines in R&D pipeline	Five medicines in the pipeline with novel mechanisms of action or first-in-class.	p 24
		10–15% of revenue in R&D spend	R&D spend 13% of revenue in 2021	p 34
		Expand medicines' global market reach	Distribution agreement expands access to 7 markets in Latin America.	p 24
			Increased market availability of most Sobi medicines.	p 123–124
SDG 10 Reduced inequalities	10.3 Equal opportunity	Expand rare disease and orphan drug innovation pipeline	Pegcetacoplan investigations outside first approved indication	p 21–22
SDG 16 Peace, justice and strong institutions	16.7 Inclusive, participatory and representative decision-making	Include patient and healthcare representatives in decision-making	International patient councils for insights into design of clinical trials and trial protocols.	p 110
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, and is a long-term sponsor of several patient organisations.	p 9 & p 110
			Membership in PSCI.	p 115
	Science and technology innovation for recovery from COVID-19	Provide treatment to investigator sponsored studies (ISS) and conduct own studies to support use in COVID-19	Kineret approved in the EU for treatment of COVID-19 in adult patients with pneumonia who are at risk of developing severe respiratory failure after results from the investigator-sponsored SAVE-MORE study.	p 6 & p 15

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 treatments for rare diseases in areas of unmet medical need.

Sobi's pipeline is focused on innovative and differentiated medicines, enabling a step change in therapy in cases of unmet medical need where there is no treatment available. Innovation is essential for realising the vision of being a global leader in rare diseases. Sobi's medicines are developed and evaluated for multiple indications and an integrated lifecycle management approach is applied. Sobi is also exploring possibilities within digital health through for example Florio, companion diagnostics and genetic screening to optimise treatment outcomes.

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 treatments 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 (ICH) Guideline for Good Clinical Practice (GCP) 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 area of rare diseases 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 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 clinicaltrials.gov. All clinical studies are registered and reported, and the complete and accurate 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 (ISS) can play in expanding knowledge related to Sobi's medicines and their associated disease areas. In an ISS, 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 drug material, 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 and therapy development is a potentially sensitive area and internal standard operating procedures (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 contracts only 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.

Expanded access to treatment

Sobi's growth strategy and market expansion enables more patients to access treatments. Regulatory approvals are necessary for commercialisation in new markets. Sobi has set an ambitious target to expand operations and access to treatments into Asia, the Pacific and South America which will broaden access to treatments outside existing markets. Sobi also has a partnership strategy to serve currently underserved markets.

During 2021, five of six of Sobi's main medicines were made available in a total of 12 new markets. For a review of current approval and reimbursement status in markets, see the Market availability table on pages 123–124.

To increase access to treatment, 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.

Medicine delivery programmes to support people living with haemophilia are currently in place in Saudi Arabia, Italy and Spain. In the United States, Sobi has been running the patient support programmes Kineret OnTrack 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 treatments in the US.

Pricing and reimbursement

Following regulatory approval, pricing and reimbursement are key factors in patient access; these 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, creating 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 treatment. Sobi works continuously to develop data that reflects 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.

Ethical R&D focused on medical need – Ambitions

- Committed R&D budget for rare diseases
- Increase number of R&D programmes in rare diseases and areas of high medical needs
- Use orphan drug regulations to shorten time to patient
- Increase number of clinical studies with Sobi's products
- Support investigator-sponsored studies

In some markets, patient access to treatments 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 overall attention and resources to the evaluation of applications for therapies which, if approved, could provide significant improvements in the safety or efficacy of the treatment, 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 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 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.

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 (World Federation of Hemophilia) 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 that are 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 international units (IU) of factor therapy for humanitarian aid, thereby fulfilling the 2014 pledge to donate up to an unprecedented 1 billion IU over a 10-year period. This agreement came into effect in January 2021.

Since the 2014 pledge, more than 588 million IU of factor have been donated and 18,881 people with haemophilia were treated with factor donated by Sobi and Sanofi. Both companies are recognised by the WFH as Founding Visionary Contributors to the Program.

Training and workshop interactions organised by the WFH continued in digital format in 2021 due to the COVID-19 pandemic. This resulted in a further increase in the number of attending healthcare providers and other important stakeholders in donation countries compared to previous years. This supports the envisaged future multi-channel approach of donation country interactions by the WFH. Despite the continuous impact of the COVID-19 pandemic, the number of newly treated patients and newly treated patients on prophylaxis could be increased in 2021 compared to the previous two years through targeted WFH initiatives.

Actions to ensure continued access to treatment during the COVID-19 pandemic

Supply-chain continuity

In 2021, Sobi's product supply chain was not challenged by lockdowns as in 2020 and did not encounter any stock-out situations resulting in interrupted treatment to patients. Sobi was able to manage increased, unforecast demand.

The key factors for continuous supply of Sobi medicines are strong partner relationships through the production and warehouse network, precise supply planning and close communication around demand management.

Expand access to treatment – Ambitions

- Increase geographical reach of operations
- Continual medicine launches in areas of rare diseases in key geographies
- Support Managed Access[1]
- WHF Humanitarian Aid Program
  – 2015–2019 – 500 million IU donated
  – 2020–2025 – 500 million IU to be donated

1. Managed Access describes areas regularly known as compassionate use, expanded access and other similar programmes.

Patient-centricity & community engagement
Sobi's patient community engagement is based on three elements: enabling connectedness, ensuring sustainable access to care, and giving a voice to patients to express their care-related needs.

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 Healthcare Interactions Policy.

Sobi is a long-term sponsor of patient organisations such as the European and North American rare disease organisations EURORDIS and NORD respectively, the World Federation of Hemophilia (WFH) and the European Haemophilia Consortium. Sobi contributes to the European Haematology Association (EHA) and the Histiocytosis Association, and also supports local patient organisations such as the Irish Platform for Patient Organisations, Science and Industry (IPPOSI) and the AKU Society. An annual summary of support provided to patient organisations is published on www.sobi.com.

Sobi recognises the importance of integrating the patient voice into R&D and clinical studies to ensure that future medicines adhere to patient needs and that the patient community is consulted in the early stages of clinical development. In 2021, Sobi organised international patient councils to deliver insights into how clinical studies and study protocols should be designed, for three upcoming studies. The insights enable Sobi to choose patient-reported outcomes more appropriately for the targeted patient populations, to design more patient-friendly forms and information materials for study participants, and to adapt 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 disease areas such as haemophilia, ITP, PNH, HLH, FMF, AKU and refractory gout.

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, supporting a range of projects and programmes that seek to create positive change.

Community engagement – Ambitions

- Support patient connectedness
- Give patients a voice

Knowledge contribution to enhance the practice of medicine
Sobi is committed to contributing to 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 the Healthcare Interactions Policy. Sobi participated in several international scientific meetings as well as local events in 2021.

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.

Safety surveillance, pharmacovigilance, continues across the product 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 drug 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 all employees, consultants and vendors to ensure that all safety information – such as adverse events, product complaints and incorrect use – in relation to Sobi's medicines is reported.

By adhering to pharmaceutical standards, Sobi strives to provide safe medicines that meet the high-quality standards of the pharmaceutical field.

Product quality regulations
As part of the pharmaceutical industry, Sobi works in a heavily regulated environment. Therefore, it is essential that Sobi meets all regulations, and acts in compliance with Good Manufacturing Practices (GMP), Good Distribution Practices (GDP), Good Clinical Practice (GCP) and Good Pharmacovigilance Practice (GVP) including the dossier requirements of all countries in which our 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 product release management; this process includes the evaluation of medicine testing and the manufacturing steps. In the EU, product release management is carried out by a Qualified Person (QP). The Qualified Person for Pharmacovigilance (QPPV) is responsible for drug 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 product integrity
Sobi works to improve patient safety through updated product 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 marketing authorisation holder (MAH), and for Investigational Medicinal Products (IMP) 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 product quality and compliance risks for products 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. Standard operating procedures are in place to ensure timely updates to product 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 products. All Sobi medicines are serialised and given unique identification codes. Sobi's medicines have not yet been subject to falsification.

Patient safety – Ambitions

- All Sobi employees undergo training in patient safety
- No critical or major incidents of product recall
- No incidents of incorrect labelling

Responsible behaviour

As a company, Sobi works to always ensure responsible behaviour in the role of employer, as a business and towards the communities in which Sobi operates. Sobi supports employees to act and make decisions reflecting corporate principles. Ambitions are aligned with the United Nations Sustainable Development Goals (SDGs) and Sobi contributes to the SDGs through several company targets.

Responsible behaviour and the SDGs

Sustainable Development Goals	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	93% of Sobi operations tracking use & source of energy in new global digital reporting platform. Renewable energy sourced for offices and facilities in Sweden, Denmark and Switzerland.	p 119 (E2)
			Sobi encourages suppliers to switch to renewable energy. Among suppliers tracked in EcoVadis, 56% report use of renewable energy.	p 122 (G5)
		Transition to 100% hybrid/electrical car fleet by 2030	97% of Sobi operations now reporting car fleet footprint. 12% of car fleet hybrid/electrical. Parent car fleet reporting a considerably reduced footprint.	p 118 (E1)
SGD 8 Decent work and economic growth	8.8 Safe and secure work environments	Ambition for zero workplace incidents	A new and improved digital reporting system implemented and training carried out.	p 113
			The number of injuries reported increased, due to changed reporting principles.	p 121 (S6)
SDG 12 Responsible consumption and production	12.1 Implement programmes on sustainable production	Implement the Sobi Responsible Sourcing Programme in supplier relationship management	Partner Code of Conduct part of supplier contracts. EcoVadis assessment conducted on prospective and current partners. Important practices monitored.	p 115 & p 122 (G5)
	12.4 Achieve the environmentally sound management of chemicals and all wastes throughout their life cycles	Comply with REACH legislation	Sobi maintains REACH authorisation for the use of Triton X-100. Detailed analyses were carried out in 2021.	p 116
		Environmental assessments of products		
		Increase data collection on waste to enable reduction of waste volumes	10 new countries reporting waste in 2021, covering 57% of Sobi operations. Process for reuse and recycling of IT equipment expanded to more Sobi markets.	p 120 (E7)
SDG 13 Climate action	13.2 Integrate climate change measures	Apply TCFD risk analysis and adopt climate strategy in response.	Sustainability risks included in overall risk mapping	p 39–41, p 106
		Complete Scope 1, 2 and 3 reporting with targets	Targets for Scope 1 and 2 set. Numbers reported from 93% of Sobi operations, new digital reporting tool implemented.	p117, p 118 (E1)
			Enhanced Scope 3 data collection and reporting with target planned for 2022.	p117, p 118 (E1)
SDG 16 Peace, justice and strong institutions	16.4 Combat organised crime	Zero incidents of product counterfeiting	100 % serialisation of products to prevent counterfeiting.	p 111
	16.5 Anti-corruption and bribery	Zero incidents of bribery or corruption	New Corporate Compliance Committee, awareness initiatives conducted. 14 cases reported via hotline and investigated.	p 114
			96% completion rate in anti-bribery and anti-corruption training.	p 122 (G6)

Sobi keeps employees safe and healthy, and helps them develop
Sobi relies on its people to deliver on business strategy and strives to always be a responsible employer.

Employee survey
Sobi has committed to performing regular all-employee surveys, including pulse surveys to monitor employee satisfaction, inclusion and engagement.

A full Global Engagement Survey was conducted in 2020 and a pulse survey in 2021. The latest Global Engagement survey had a response rate of 87 per cent including all employees and full-time consultants in wholly owned subsidiaries. The employee engagement score was 73 (benchmark 74), on par with the industry.

Subsequent workshops throughout the organisation identified areas for development in three main areas: culture, career opportunities and work-life balance. Culture is considered an aspect important to maintain and nurture during the organisation's growth and strategic shift. Career opportunities are also valued, and there is a continued wish that opportunities for career development be recognised in the expanding business strategy.

Work-life balance was adversely impacted by the COVID-19 pandemic, especially in the early phases, as shown by the 2020 pulse survey. Actions were taken to improve the workload situation, and already in the Engagement Survey of September 2020 the situation had improved. A second COVID pulse survey in 2021 showed improved employee wellbeing.

Follow-up actions during 2021 focused on managing employee wellbeing during the pandemic and working to develop the principles and set-up of a future, post-pandemic Sobi workplace. The 2021 Global Engagement Survey was postponed until 2022 as a result of the public offer for Sobi in 2021.

Development, training and compensation
For Sobi, highly skilled and high-performing teams are key to meeting the 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 training which helps managers practise leadership skills, identify their own strengths and development areas, and learn from their peers. It is run two to three times per year, targeting all new managers and those identified for managerial positions.

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. To support employee evaluation and development, a talent management process is used. 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 product training. Employees are assigned training based on 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.

Competitive terms of employment are a prerequisite for recruiting and retaining highly qualified and skilled people. Sobi offers competitive salaries and benefits, individually determined and adapted to the local labour market. All employees (with the exception of North American and Asian-based employees due to tax reasons) are offered long-term incentive programmes as described in Note 10, page 67.

Health and safety
Sobi enforces a global Health and Safety Policy. Occupational health and safety (OHS) management is integrated into operational control as part of daily work. OHS should be regularly addressed at meetings and any OHS aspects regarding activities considered. Managers are responsible for addressing any concerns raised. The joint management-worker health and safety committee operates from head office and includes representatives from all operations. The committee meets quarterly and reports to the Executive Committee.

Investigating and identifying the cause(s) of an accident, dangerous situations or near-misses makes it possible to take action to prevent a similar occurrence in the future. All employees are required to report OHS-related incidents to management, and managers have a duty to ensure that legislative reporting requirements and internal reporting processes are followed.

In 2021, a new and improved digital reporting system was implemented, and training carried out to highlight the importance of reporting and follow-up.

Diversity and equality
Every employee is offered equal opportunities regardless of ethnicity, age, gender, religion, sexual orientation or physical abilities. Sobi's guidelines clearly prohibit discrimination and sexual harassment. In the US, a Diversity, Equity & Inclusion programme has been initiated, including an Employee Resource Group, manager training on inclusion and belonging as well as unconscious bias training.

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.

Caring for our employees – Ambitions

- Perform annual employee engagement survey
- Offer all employees annual performance and career development discussions
- Zero-tolerance for discrimination and sexual harassment
- No workplace accidents leading to lost workdays

Creating a safe working environment during COVID-19

COVID-19 has impacted employees across the world both privately and professionally.

Actions taken to ensure a safe working environment included more flexible working hours, initiatives to ensure necessary distancing and safety precautions such as additional personal protection equipment (PPE), desk dividers, information signs and office attendance planning. International travel restrictions have been applied since March 2020, allowing only business-critical international travel.

Sobi conducted a global COVID-19 employee pulse survey (response rate 85 per cent) in June that showed strong employee engagement and an eagerness to influence working conditions.

Zero tolerance for corruption

Sobi's Code of Conduct provides a framework for responsible and appropriate conduct. It has been approved by the Board of Directors 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. 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. A fully digital version of the Code of Conduct is available for both employees and external audiences (www.coc.sobi.com).

Sobi promotes high ethical standards by supporting a corporate culture that embraces open discussions of ethics both in our operations and among key stakeholders.

Compliance

Sobi's compliance programme is aimed at managing risks before they arise; it 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 training and communication include general and topic-specific e-learning, videos and articles on Sobi's intranet, InsideSobi. In 2021, a global Ethics and Integrity Week was conducted to further underline Sobi's commitment to compliance. The event included interviews and live events with senior management, the launch of a quarterly compliance newsletter, and other local awareness activities including townhalls, compliance awards and gamification.

The Global Compliance Governance Charter ensures management oversight of the compliance programme, including a governance structure with compliance committees, clear compliance accountability at different levels of the organisation and a network of compliance subject-matter experts in the countries. 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 of Directors.

The compliance programme is developed continuously through annual development roadmaps. Since 2021, all Executive Committee members have a designated compliance primary point of contact.

Sobi employees are encouraged to report potential misconduct or unethical behaviour openly to line management, Human Resources, Corporate Compliance or the Legal Department, or by using the Sobi Compliance Hotline, a whistleblowing hotline run by a third party to allow for the possibility of anonymous reporting. 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 the Corporate Compliance Department and subject to investigation according to Sobi's Investigation Policy and followed up with the appropriate remediation measures. During 2021, the Corporate Compliance Committee consisting of the CEO, the CFO, the General Counsel and the Chief Compliance Officer took over the oversight of compliance investigations. This ensures both non-retaliation against whistleblowers, and organisational fairness in regard to how sanctions are applied. In 2021, 14 cases were reported via the hotline. To capture all cases, events reported outside the system can also be entered by proxy. More details on page 122, 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 widespread use of third parties throughout the pharmaceutical value chain. Sobi works actively to prevent any form of corruption.

Sobi's Anti-Corruption Policy, 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 of 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 training. In 2021, 95 per cent of eligible employees were trained in the Sobi Code of Conduct and 96 per cent in Anti-Bribery and Anti-Corruption (ABAC). 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.

Considering the risk of exposure to corruption and Sobi's zero-tolerance policy, significant efforts are made to promote the reporting of suspected corruption incidents. Sobi's Compliance Hotline has a dedicated reporting section for potential bribery and corruption concerns to facilitate reporting.

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 with relevance for corruption prevention are: Policy on Anti-Corruption Due Diligence on Third Parties, Group Authority Policy, Global Expense Policy, Procurement Policy and Risk Management Policy.

Sobi's Healthcare Compliance (HCC) 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 HCC programme is an important tool for ensuring that all interactions and value transfers remain legal and can withstand external scrutiny, 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. A compliance monitoring plan is adopted and executed on an annual basis, involving sample testing and 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 EFPIA Code, US Sunshine Act and national transparency laws, and are made public on an annual basis on www.sobi.com. Sobi publishes Transfers of Value to healthcare providers in 36 markets across Europe (including Russia and Ukraine), Asia and the Middle East, and the United States. In 2021, Fair Market Value methodology was revised to ensure that Sobi's rates for provided services remain in line with continuously updated market standards.

Responsible marketing and sales
Sobi is committed to employing high ethical standards of sales and marketing practice worldwide, in line with our 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.

Data privacy
Data privacy is part of Sobi's Code of Conduct and a prioritised area across Sobi. It is important that our customers, clinical study subjects, employees and others we interact with can trust that Sobi processes personal data in a responsible and secure manner.

Sobi has implemented a data privacy programme in order 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, requiring all staff to report suspected and confirmed personal data breaches immediately to Sobi's DPO. The DPO assesses all cases and ensures that appropriate actions are taken.

Responsible sourcing
Sobi's manufacturing is to a large extent outsourced, and as a consequence, a large part of the sustainability impact occurs outside Sobi's own operations. Sustainable and responsible sourcing is therefore a critical process, outlined in the Sobi Responsible Sourcing Programme. The programme consists of three main pillars: alignment of values and principles; risk assessment and qualification; performance management and monitoring.

Sobi's Partner Code of Conduct (PCoC), 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 current partners, and performs due diligence and screening for compliance with management, labour and human rights and environmental standards through the evaluation tool provided by sustainability rating specialist firm EcoVadis. 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 or have a score <40 in any theme are encouraged to improve their score, and improvement activities are identified.

By end of 2021, the scored supplier average was 55.8, an acceptable performance level that can be contributed to Sobi's geographic footprint as well as supply base maturity, and represents an average improvement of 4 points for those scored before. Sobi's primary focus has been its external manufacturing partners and logistics partners. A majority of these companies are performing well across all topics included in the assessment. For 2022, individual company targets will be set based on identified improvement needs. Among our indirect material suppliers, we have good coverage in the majority of categories identified as high risk and are making progress in the remaining categories. This will be a priority in 2022.

Since 2020, Sobi has been part of the Pharmaceutical Supply Chain Initiative (PSCI). The 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. For Sobi, it is a valuable means to increase reach of onsite audit results within high-risk supplier categories and geographies.

Responsible sourcing is an integrated part of Sobi's supply chain strategy, owned and managed by the indirect procurement department, in close cooperation with the Sustainability function. Members from both procurement departments undergo regular training in responsible sourcing.

Third-party due diligence
Sobi's commitment to preventing bribery and corruption in connection with business activities around the world extends to third parties engaged to perform services on Sobi's behalf. In accordance with Sobi's Anti-Corruption Policy, Sobi conducts appropriate risk-based anti-corruption due diligence of third parties ("TPDD") to identify and mitigate bribery and corruption risks and address any "red flags" prior to engagement of third parties. Third parties in scope for TPDD are re-evaluated periodically. Sobi contracts include standard compliance with laws clauses and related anti-corruption protections.

Compliance – Ambitions

- All employees to undergo regular e-learning training with the following required for all employees: Code of Conduct, Anti-corruption and anti-bribery, Data privacy, and Product safety training
- Zero tolerance for bribery
- No major violations of data privacy
- Transparent reporting of monetary transactions to healthcare professionals and organisations
- Secure minimum performance and drive improvement through responsible sourcing programme
- Conduct ESG due diligence and promote the responsible business conduct of suppliers

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 our operations.

Sobi's carbon footprint is caused by energy consumption in pharmaceutical manufacturing, business travel, supply chain logistics and the distribution of our medicines. Environmental impacts from production and the 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 standard operating procedures and in the environmental compliance programme, which aims to improve control of the environmental impact of production. Energy and water consumption in Sobi's production facility is continuously assessed with the aim of improving environmental performance.

In 2021, Sobi further expanded reporting practices by introducing a common digital reporting platform for all global operations and entities.

Sobi trains its staff in EHS practices. In 2021, 95 per cent of eligible Sobi employees participated in the digital training.

Responsible handling of chemicals

All applicable chemical regulations are monitored closely and constitute an important aspect of Sobi's business. One example is the use of Triton X-100, a nonionic surfactant, in the ReFacto production process. Sobi has been granted REACH authorisation to handle Triton. The requirements include strict rules for cleaning filters and the treatment of waste. During 2021, detailed analyses of Triton handling were carried out to ascertain compliance with the requirements. An embankment around a floor drain was installed as a precautionary measure following an incident with a crack in the Triton filter that could have resulted in a larger leakage of Triton-contaminated water into the municipal wastewater system. The incident was proactively reported to the authorities.

Chemical regulations are extensive and continuously expanding; all handling of chemicals in our laboratory and manufacturing processes follows strict instructions. We perform continuous risk assessments and internal audits. In 2021, improvements were made in the areas of chemical control and follow-up of risk assessments. The Responsible Sourcing Programme is an important tool for influencing, managing and monitoring the sourcing and handling of chemicals in our supply chain.

Sobi's GHG emissions mapping (tonnes CO_2)

Emissions directly controlled by Sobi[1]

- **3.3** Direct emissions production facility
- **701** Direct emissions fleet cars
- **99** Purchased electricity
- **4,357** Business travel

Sobi's value chain emissions[2]

- To map & act — Contract manufacturing
- To map & act — Distribution & logistics
- To map & act — Raw material
- To map & act — Capital goods & services

1. Full scope 1 and scope 2 emissions, and scope 3 business travel. Details in sustainability notes, p 11.

2. Remaining scope 3 emissions to be mapped by 2022. Details in Sustainability notes, p 118.

Pharmaceuticals in the environment
The environmental hazards of a specific drug refer to its inherent properties, such as toxicity and ability to be broken down by nature. According to existing EU and US guidelines on environmental risk assessments of medicinal products, 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 not therefore 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 treatments, Orfadin and Doptelet, and they are considered to be of low risk to the environment.

Direct GHG emissions (Scope 1 and 2)
Sobi's direct emissions occur from our commercial operations in 33 countries with 33 offices as well as our biological production facility (reported as Manufacturing/Haematology) in Stockholm, Sweden, and our legacy laboratory in Geneva, Switzerland.

Sobi is committed to substantially reducing emissions from sites and the ground fleet by 2025 and aims to reach net zero emissions and use 100 per cent renewable energy by 2030. All of the electricity consumed at the Stockholm facilities comes from a mix of certified renewable energy sources. In 2021, a new digital reporting platform was introduced and 93 per cent of Sobi operations worldwide, measured as share of employees, reported all or some energy data. The details of impact from the global operations are described in detail on page 118.

Indirect GHG emissions (Scope 3)
Sobi's main scope 3 impact currently measured is employee travel, mainly air travel but also the use of employee-owned cars.

All production of commercial medicines is outsourced to contract manufacturers.

Sobi has obtained limited emissions data from contract manufacturers (Category 1 Scope 3 emissions for Sobi) and is working to expand the reporting to include all major contract manufacturers and logistics partners (Category 4 and 9 Scope 3 emissions for Sobi). In 2021, suppliers were not included in the Scope 3 reporting.

The remaining emissions from raw materials, packaging, capital goods and services will be calculated using industry-specific guidance on spend from the GHG Protocol, and priorities set based on identified reduction opportunities. Sobi will aim to apply the boundaries "from cradle to customer", meaning reporting on areas upstream in the value chain, Sobi's own activities, and up to and including the delivery of sold goods to wholesalers or partners. Emissions calculations will not cover a full consumer lifecycle analysis as the prescription and use of our medicines is beyond our control.

In 2021, as part of Sobi's Responsible Sourcing Programme, ambitions were communicated to suppliers, and progress reporting and target reviews were integrated into regular business follow-ups.

The details of mapped scope 3 emissions are described in detail on page 118.

Business travel
Sobi started reporting on business travel emissions in 2019 and all global operations were included by 2021.

Business travel numbers include a Sobi-leased car fleet (formally Scope 1) as well as employee-owned cars, and air and ground travel (Scope 3). In the current mapping, the impact from employee mobility is by far the biggest contributor to Scope 1 and Scope 3 emissions respectively. The practice of car management and policy is dependent on local regulations and culture. Local car policies and changes in the design of car lease set-ups have been implemented to promote electric and hybrid cars, and steps taken to incentivise charging at the office and at home. Currently, 12% of the car fleet is hybrid or electric.

A significant shift has been made to virtual internal and external meetings as well as scientific congresses, which has reduced the need for travel. Sobi has accelerated the implementation of modern workplace technology across the entire organisation. The 2021 impact from air travel was lower than in 2019, an effect related both to the continuing COVID-19 pandemic as well as changed working routines.

Development of emissions-reduction targets

Target year	Topic	Ambitions
2022	Emissions – Scope 3	Map emissions in supply chain (CMO, distribution) – set baseline and reduction targets
2025	Emissions – Scope 1 and 2	Reduce operational GHG footprint by 50% from 2015 baseline
2030	Emissions – Scope 1 and 2	Reduce operational GHG footprint to net zero emissions
		Shift to 100% renewable energy
2030	Emissions – Scope 3	Set reduction target in 2022
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 prevent generation of waste.

In Sweden, Sobi has an established process for reuse and recycling of IT equipment via a certified technology lifecycle management service partner. This process was extended to Sobi's operations worldwide in 2021, including training of local teams.

Sustainability Notes

Sobi updated its materiality assessment process in 2021. For a detailed description of stakeholder groups and outcomes of the assessment, see page 105. The materiality assessment identified the most important topics for Sobi's sustainability strategic focus and reporting.

Economic performance

In 2021, revenue growth was 7 per cent with revenue of SEK 15,529 M. Adjusted EBITA was SEK 5,575 M, resulting in an adjusted EBITA margin of 36 per cent for the full year. Cash flow from operations totalled SEK 5,470 M.

Direct economic value generated

SEK M	2021	2020
Revenue	15,529	15,261
Operating costs	8,288	7,575
Employee wages and benefits	2,481	2,250
Payments to providers of capital	302	249
Payments to government[1]	1,124	918
Community investments[2]	17	20

Calculation is based on the consolidated statement of comprehensive income.

1. Includes corporate income tax (CIT) 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.
2. 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 www.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 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 international units (IU) of factor therapy for humanitarian use, thereby fulfilling the 2014 pledge to donate one billion IU over a 10-year period. The agreement came into effect in January 2021.

Sobi's impact is reported in accordance with the WFH's impact report for the Humanitarian Aid Program and is the result of Sobi's and Sanofi's contribution to the Program.

Number	2021	2020	2019
Total MIUs[1] delivered	588	499	449
Total patients treated (cumulative)	18,881	17,329	17,223
Acute bleeds treated	31,528	21,900	42,881
Surgeries	412	470	355
Number of workshop attendees	1,468	691	250

1. 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 on page 110 and on the website www.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 datapoints and geographies have been added in 2021.

Sobi aims to report comprehensively on supply chain emissions by 2022.

E1. GHG Emissions

GHG emissions (CO_2) (tonnes)

(tonnes)	2021	2020	2019	2018	2017
GRAND TOTAL	5,215	3,096	4,326	1,326	1,207
Scope 1 (direct emissions)					
Production facility	3.3	1.7	2.2	3	3
Fleet cars (Parent)	32	88	98	129	153
Fleet cars (Subsidiaries)	669	509	–	–	–
Total scope 1	**704**	**599**	**100**	**132**	**156**
Scope 2[1] (indirect emissions)					
Heating (Parent)	63	61	82	119	129
Cooling (Parent)	0	0	0	0	0
Electricity (Parent)	0.3	0.02	0.02	0.02	–
Heating (Subsidiaries)	16.4	–	–	–	–
Cooling (Subsidiaries)	0	–	–	–	–
Electricity (Subsidiaries)	19.1	–	–	–	–
Total emissions (Subsidiaries)	35.5	36	–	–	–
Total scope 2	**99**	**97**	**82**	**119**	**129**
Scope 3 (indirect emissions)					
Business travel – flight, taxi (Parent)	647	295	971	981	830
Business travel – flight (Subsidiaries)	2,452	1,064	3,099	–	–
Business travel – cars (Subsidiaries)	1,258	977	–	–	–
Heating (Parent)	22.5	43	74	94	92
Cooling (Parent)	0	33	0	0	0
Electricity (Parent)	0.2	0.01	0.01	0	0
Heating (Subsidiaries)	8.2	–	–	–	–
Cooling (Subsidiaries)	0	–	–	–	–
Electricity (Subsidiaries)	25	–	–	–	–
Total emissions (Subsidiaries)	33	17	–	–	–
Total scope 3	**4,412**	**2,400**	**4,144**	**1075**	**922**

1. Scope 2 emissions calculated using both market- and location-based components.

Comments GHG emissions

Emissions include data from Sobi's global operations. "Parent" is defined as the biological manufacturing facility and the Sweden corporate headquarters, and "Subsidiaries" constitute the Sobi global offices. Total Scope 1 and 2 emissions for 2020 and 2021 cannot be compared with prior years due to the expansion to include all global operations and changes in reporting processes in 2021 which meant changes in emission factors used. The evolution Is visible through inclusion of more emission components over the years. Additionally, due to the pandemic, both 2020 and 2021 are atypical years.

In 2021, 93 per cent of Sobi facilities worldwide (measured as share of employees) reported all or some energy data, while 97 per cent of Sobi operations reported travel and fleet car data. This data also includes employee-owned cars used for business purposes. The majority of reporters for leased car data have not split between business and private travel. Travel emissions are impacted both from an increasing number of reporting entities and decreased travel due to the COVID-19 pandemic. The mix of leased cars reported in Scope 1 remains at 12 per cent for electric or hybrid cars, while the total number of leased cars has increased in 2021 due to the expanded geographical scope.

Emission factors used

With the deployment of global reporting, work has commenced to align emission factors. Where credible sources of market-based emission factors are available, these have been used. For other emissions, location-based principles have been applied.

Aspect	Source
Location-based emissions	IEA 2021
District heating	Swedish average
District cooling	Stockholm Energi, miljönyckeltal 2020
Fossil fuel (production facility Sweden)	Energimyndigheten 2020
Business travel	Local travel agency reports NTM Emission factor (2018)
Leased cars	WLTP
Private cars	Car manufacturer data

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.

In 2021, energy consumption was tracked completely or partially in 93 per cent of Sobi's sites (as measured by share of employees). Renewable energy is sourced for offices and facilities in Sweden, Denmark and Switzerland.

Energy consumption (facilities' energy use)

MWh	2021	2020	2019	2018	2017
Electricity	8,440	8,318	7,518	7,694	7,852
of which renewable	8,042	8,318	7,518	7,694	7,852
Heating	2,391	2,133	2,550	2,596	2,690
of which renewable	2,268	1,770	2,015	2,051	1,991
Fossil fuel (oil)[1]	9.6	5.6	7.2	10.0	8.4
Cooling	2,121	2,902	3,059	3,167	2,793
Total	**12,962**	**13,359**	**13,134**	**13,467**	**13,343**

1. 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. In mid 2019, the process to test the generator was made more efficient and the time spent was cut in half, as were emissions.

E2.2 Total amount of energy indirectly consumed

Energy-saving possibilities are regularly evaluated at the production facilities in Stockholm, Sweden. As a result of the implementation of a global reporting platform in 2021, it will be possible to track indirect energy consumed and influence sourcing of energy. Sobi targets to switch to 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)

	2021	2020	2019	2018	2017
Energy (MWh)	5,958	6,597	5,867	6,313	6,480
Revenue manufacturing (SEK M)	445	481	376	436	559
MWh/SEK M	13.4	13.7	15.6	14.5	11.6

E4. Water use

Water consumption data includes Sobi's head office and production facilities in Stockholm, Sweden and for the first time also offices outside Sweden. Water consumption is regularly followed up in relation to internal performance indicators. In 2021, 46% of Sobi operations reported on water usage.

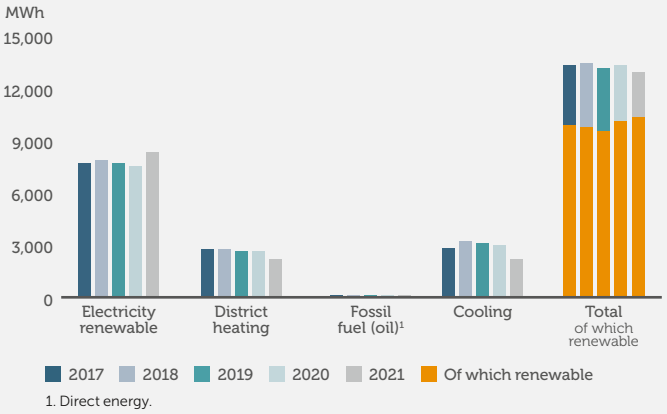
Water consumption

m³	2021	2020	2019	2018	2017
Purchased water	53,728	56,725	31,776	57,374	45,913

In the production facility, water consumption is regularly followed up in relation to internal performance indicators. In 2020, an incorrect reading of water consumption for the head office was adjusted, resulting in a considerably higher reading compared with previous years. In 2021, a validation of the reading was conducted. Laboratory activities performed at the corporate headquarters were discontinued In 2019. Historic figures are therefore most probably considerably higher.

Water in the production facilities is not reclaimed, but warm water is recycled from the production of steam to extract heating and cooling.

Energy consumption



1. Direct 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 the best of our knowledge, there were no confirmed incidents resulting in administrative and judicial sanctions for failure to comply with environmental laws and/or regulations in 2021.

E6. Climate oversight and risk mitigation

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 and risk-assessment process.

Sobi is working to fulfil the EU Taxonomy Regulation and recommendations from the Task Force on Climate-related Financial Disclosure (TCFD), with the aim of adapting the company's climate-related financial disclosures to evolving reporting practice. Sobi's direct and indirect climate-related risks and opportunities were part of the overall risk process in 2021 (see p 39). At this point in time, it is Sobi's understanding that none of our economic activities are covered by the technical screening criteria in the EU Taxonomy Regulation so far released.

E7. Waste

Waste reporting is mainly based on Sobi's head office and production facilities in Stockholm, Sweden but includes limited data from operations outside Sweden with 10 new countries reporting in 2021, and data now covering 57% of global Sobi operations. Because of this, numbers are increasing. Several entities have limited possibilities to report per fraction, but the reporting system will provide increased focus on the waste topic.

From 2021, numbers are also split between production and office, to better represent the different types of activities and possibilities both to implement waste reduction measures and report. Non-hazardous waste has in general decreased in recent years as a result of several measures, including digitalisation of deviation management and changes to available archive spaces.

Used IT equipment is now 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.

Office and production site waste

Tonnes	2021	2020	2019	2018	2017
Total amount of waste	**55.5**	**35**	**39**	**42**	**72**
Production	36	–	–	–	–
Office	19.4	–	–	–	–
Non-hazardous waste					
Recycling	7.9	5	6	–	–
Reuse	0.3	0	0.6	–	–
Combustion with energy recovery	20.3	16	17.5	–	–
Other treatment	0	0	0.6	–	–
Landfill[1]	1.9	1	0.2	0.1	0.1
Total non-hazardous	**30.4**	**22**	**24.3**	**24**	**50**
Hazardous waste					
Recycling	13.8	6	5	–	–
Reuse[2]	0.5	1	–	–	–
Combustion with energy recovery	3.0	0	0	–	–
Other treatment	1.9	7	8.6	–	–
Landfill[3]	5.7	0	0	–	–
Total hazardous	**25**	**13**	**14**	**18**	**22**

1. A limited amount of Sobi's waste cannot be recycled and is therefore sent to landfill. The waste is mostly construction related.
2. IT equipment sent for repurposing, a system expanded to cover all Sobi markets, except Asia, Middle East and Russia.
3. 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 2021, 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. In terms of number of employees, Sobi grew organically in 2021.

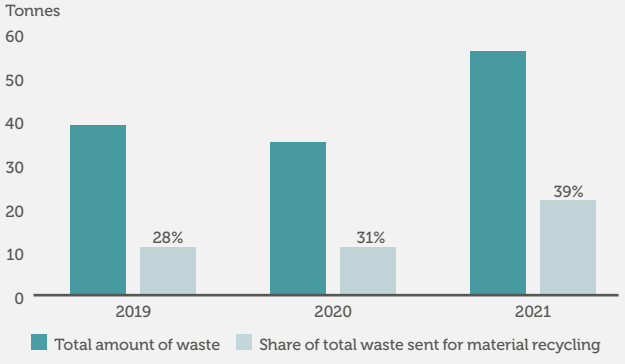
To the best of our knowledge, there were no confirmed incidents resulting in administrative or judicial sanctions for failure to comply with laws and/or regulations in the social and economic area in 2021.

S1. CEO remuneration

See Note 10 for information about CEO remuneration. See also the Remuneration Report available on the www.sobi.com website in connection with documentation for the 2022 Annual General Meeting.

Material recycling of waste

Share of total waste that is sent for material recycling



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 2021, Sobi grew slightly in number of employees and had a turnover rate of 15 (11) per cent due to voluntary terminations. The movement is believed to be caused partially by the job market shifts caused by the pandemic, and our growth in new geographies, but will be analysed more closely in 2022. Sobi did not introduce any furlough schemes or layoffs during the COVID-19 pandemic. Numbers below are headcount, fixed term employees excluded.

Year	New hires	Voluntary termination	Total number employees (end of year)
2021	364	235	1,588

S4. Gender diversity

Sobi has strong representation of women in management roles within STEM-related (Science, Technology, Engineering, and Mathematics) areas. Positions such as Head of Technical Operations, CIO, Head of R&D Operations, and Head of Project and Portfolio Management are all held by women.

	2021		2020		2019	
% per gender	Female	Male	Female	Male	Female	Male
Board	50	50	38	62	38	62
Executive Committee	8	92	18	82	27	73
Senior management[1]	40	60	42	58	–	–
All employees	59	41	59	41	60	40

1. Senior management – management positions reporting to Executive Committee.

Data includes permanent and fixed term employees

New hires diversity

Sobi increased the female share of new hires in 2021. The age profile of new hires reflects the industry and the company's need for highly qualified staff.

Split of new hires – gender and age [1]	<30	30–49	50–	Total 2021
Female	14	146	62	222
Male	9	100	44	153
Total new hires per age group	23	246	106	375

1. 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 child care.

Employees, contract type

Employees[1]		Total 2021
Permanent contract	An employee employed by Sobi without a predetermined end date.	1,536
Fixed-term contract	An employee employed by Sobi with a predetermined end date.	23
FTE consultants	Consultants acting as line staff and temporarily replacing a Sobi employee.	120

1. 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. Stronger emphasis was put on including accidents happening while commuting to and from the workplace, which has affected the total number reported.

For 2021, statistics include operations globally and include a measure on H&S committees.

Incidents	2021	2020	2019	2018	2017
No. of accidents	17	10	26	28	23
Lost workday injury (LWI)	4	0	0	1	0
Lost time incident rate LTFIR (LTIR)	6.37	0	0	(0.39)	0
% of employees[1] represented by H&S committees	53%	–	–	–	–

[1] calculated using headcount per unit.
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

Sobi applies a global Health & Safety Policy and Occupational Health & Safety (OHS) management is integrated into the company's overall management and business. Health and safety is addressed regularly at meetings and any OHS risks associated with activities are considered. Managers are responsible for addressing any concerns raised.

The joint management worker health and safety committee is based at the head office and consists of representatives from all operations. The committee meets quarterly and reports to the Executive Committee.

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, 2021, completion rates among eligible Sobi employees were 94 per cent–98 per cent.

Training title	Completion rate
Sobi all – Introduction	94%
Sobi all – Data Privacy & Information Security Training	97%
Sobi all – Anti-Corruption and Anti-Bribery Training	96%
Sobi all – Environment, Health and Safety Training	95%
Sobi all – GxP Introduction	95%
Sobi all – Patient Safety Core 2021	98%
Sobi all – Sobi Code of Conduct Training	95%

2021, Sobi started collecting data on locally managed training. Data gathered covered 55% of Sobi operations, where in total 2,360 hours of training was registered. Topics included leadership and personal development.

All employees completed their performance management process (PMP) in 2021. All managers and employees are encouraged to set up individual development plans, however the status is currently not possible to measure with confidence.

S9. Patient safety

To ensure and evaluate statutory compliance with quality and patient safety regulations, facilities are regularly inspected. In 2021, Sobi hosted eight inspections (2 GVP, 6 GMP). 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 2021.

S10. Marketing and labelling
In 2021, one incident of non-compliance with regulations and/or voluntary codes concerning product and service information and labelling was reported. This concerned a non-compliant banner on a web page, where view time was too short and font size too small according to the regulations. A fine was set to SEK 110 000.

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. Both documents are available on www.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. Both documents are available on www.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 pages 105–106 and 114.

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

	2021	2020	2019
Male	4	5	5
Female	4	3	3
Nationalities	3	4	4
30–50 years	1	0	1
Over 50 years	7	8	7
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.

In the Shareholding Guidelines, the Board recommends that the CEO and other members of the Executive Committee, within three years of their appointment, accumulate and hold Sobi shares equivalent to one annual gross base salary for the CEO, and 50 per cent of annual gross base salary for other members of 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. 39 per cent of Sobi's employees (Sweden, Austria, France, Italy, Spain) are covered by collective bargaining agreements.

Employees covered by collective bargaining

Percentage of employees in country or region	2021
Sweden	100
Europe[1]	30
North America[2]	0
Rest of the world	0
Total	**39**

1. Excluding Sweden
2. 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 www.sobi.com.

Since 2020, Sobi has been a formal associate member of the Pharmaceutical Supply Chain Initiative (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. At the end of 2021, the average score for rated suppliers was 55.8, a 4-point improvement on those rated previously. Three suppliers scored <40 using the EcoVadis CSR Rating Methodology. Sobi also encourages the implementation of key practices among its suppliers and tracks the implementation rate through the platform.

Proportion of suppliers reporting implemented practices	(%)
Actions on energy consumption & GHGs	88
Reporting on energy consumption or GHGs	81
Use of renewable energy	56
Audit or assessment of suppliers on CSR issues	75
Policy on anti-corruption	100
Active whistleblowing procedure	88

For more details about the Sobi Responsible Sourcing Programme, see p 115.

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 2021, 14 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.

95 per cent of Sobi's 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 page 114. R&D-related ethics principles are found in page 108.

G7. Data Protection
Sobi's data protection programme is described on page 115. 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 10 (16) internal reports of suspected personal data breaches during 2021 (2020), showing that there is an awareness within the company regarding integrity issues, and a continued readiness to report potential issues. The reports ranged from minor incidents such as emails sent to the wrong recipient to potentially more severe breaches. All incidents were investigated and corrective actions taken. One cases (two) were reported to the supervisory authority, as required by applicable data protection laws.

Market availability of Sobi products

Regulatory approvals and indications for Sobi's products vary according to geographical region. In addition to regulatory approval, local agreements on pricing and reimbursement are also required for the product to be fully available through regular healthcare pathways.

The table below shows the countries for which Sobi has been granted marketing authorisation (MA), including the indication, and whether market access is achieved through approved pricing and/or reimbursement (marked with x) or managed access programmes (MAP) or Named Patient Use (NPU). In the EU, the marketing authorisation approval and indication is valid for all EU member and EFTA states.

Sobi is commercialising the following proprietary products: Alprolix, Elocta/Eloctate, Doptelet, Gamifant, Kineret and Orfadin. As Sobi only holds the rights to Synagis in the US, Synagis is not included in the table. Sobi also commercialises Kepivance in the US. In 2021, Sobi received approvals for Aspaveli/Empaveli for PNH in the EU and Saudi Arabia but these have not yet been launched. In December of 2021, Kineret was recommended by the European Medicines Agency Committee for Medicinal Products as a tool for fighting COVID-19.

See the glossary on page 132 for a definition of the listed indications.

	Access to Sobi's products – *new in 2021					
Region	**Elocta[1]**	**Alprolix[1]**	**Doptelet[2]**	**Kineret**	**Gamifant**	**Orfadin**
EU and EFTA states	Haemophilia A	Haemophilia B	CLD/ITP	RA, CAPS, Still's, FMF		HT-1 & AKU
Austria	x	x	x*	x		x
Belgium	x	x	x*	x		x
Bulgaria	x	x		x		x
Croatia	x	x		x		x
Cyprus				x		
Czech Republic	x	x	x*CLD NPU	x		x
Denmark	x	x	x* ITP	x		x
Estonia	x			x		x
Finland	x	x	x*	x		x
France	x	x		x		x
Germany	x	x	x*	x		x
Greece	x	x		x		x
Hungary	x	x		x		x
Iceland				x		x*
Ireland	x	x	X	x		x
Italy	x	x	x* CLD	x		x
Latvia				x		
Liechtenstein	x	x		x		x
Lithuania				x		
Luxembourg	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	NPU	x		x
Slovenia	x	x		x		x
Spain	x	x*	x* CLD	x		x
Sweden	x	x	x* ITP	x		x

1. Sobi has final development and commercialisation rights in Europe, most Middle Eastern markets, North Africa and Russia.
2. Doptelet received approval for primary chronic immune thrombocytopenia (ITP) in January 2021.

Market availability of Sobi products, cont.

	Access to Sobi's products – *new in 2021					
Region	**Elocta[1]**	**Alprolix[1]**	**Doptelet[2]**	**Kineret**	**Gamifant**	**Orfadin**
Europe – other	Haemophilia A	Haemophilia B	CLD/ITP	RA, CAPS, Stills, FMF	pHLH	HT-1
Russia	x			x (not RA)	x (MAP2)	x
Switzerland	x	x	x*	x		x
Turkey				x*		
United Kingdom	x	x	x CLD	x		x (HT-1 & AKU)
Ukraine						x
North America	Not Sobi territory	Not Sobi territory	CLD/ITP	RA, NOMID	pHLH	HT-1
Canada				x		x
Mexico			x			x
United States			x	x + DIRA	x	x
Asia	Haemophilia A	Haemophilia B		RA, CAPS, Stills, FMF		HT-1
Bahrain				NPU		x
China	Not Sobi territory	Not Sobi territory	Out-licensed			
Kuwait	x	x		NPU	x*	
Israel				x		x
Japan	Not Sobi territory	Not Sobi territory				x
Jordan				NPU		x
Oman	x	x		NPU		
Palestine						x
Qatar	x	x		NPU		x
Saudi Arabia	x	x	x*	NPU	x (MAP)	x
United Arab Emirates	x	x		NPU	x (MAP)	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
Chile				NPU		x
Australia (Oceania)	Not Sobi territory	Not Sobi territory		CAPS, sJIA x		x

1. Sobi has final development and commercialisation rights in Europe, most Middle Eastern markets, North Africa and Russia.
2. Doptelet received approval for primary chronic immune thrombocytopenia (ITP) in January 2021.

GRI Content Index

The Sobi Sustainability Report 2021 has been prepared in accordance with the GRI Standards: Core option. It also fulfils the requirements on sustainability reporting outlined in the Swedish Annual Accounts Act.

Sobi reports its sustainability performance on an annual basis, in the Annual and Sustainability Report. The indicators below have been selected based on a materiality analysis, further described on page 105. All page references below refer to pages in Sobi's 2021 Annual and Sustainability Report or the company webpage www.sobi.com.

The sustainability report also serves as the Sobi UN Global Compact Communication on Progress (COP) report. For questions regarding the Annual and Sustainability Report, please contact info@sobi.com.

The pages identified in the GRI Index below refer mainly to the following sections of the Annual and Sustainability Report 2021

Business Model, strategy and description of activities on pages 10–20.

A description of the Sobi approach to sustainability is found on pages 23–27 and 104–117.

A report on the 2021 performance is found in the Sustainability notes section, on pages 118–124.

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GRI Standard	Disclosure		Page reference	UN Global Compact Principle
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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 2021 on pages 23–27 and 104–127 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, March 31, 2022
Ernst & Young AB

Jonatan Hansson
Authorized Public Accountant

2022 Annual General Meeting

2022 Annual General Meeting
Swedish Orphan Biovitrum AB (publ) will hold its Annual General Meeting (the "Meeting") on Tuesday, 10 May 2022.

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 2 May 2022 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 2 May 2022. 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 4 May 2022 will be taken into account in the presentation of the share register.

Additional instructions will be stated in the Notice convening the Annual General Meeting, which will be published in April.

Financial calendar 2022

January – March Interim Report	28 April
Annual General Meeting	10 May
January – June Interim Report	19 July
January – September Interim Report	27 October

The Annual Report can be downloaded in PDF format from www.sobi.com, as well as previous annual reports, interim reports and press releases.

Definitions

CER
Constant exchange rates.

Earnings per share
Net income divided by the average number of shares.

EBIT
Earnings before interest and taxes (operating income).

Full-time equivalent (FTE)
A unit that indicates the number of hours worked by an employee on a full-time basis, used to make workloads comparable across various contexts.

Gross profit
Total revenue less cost of goods sold.

Gross margin
Gross profit as a percentage of total revenue.

Gross to net
Operating revenue less mandatory and contractual price reductions.

IFRIC
The International Financial Reporting Interpretations Committee.

Alternative performance measures

Financial measures not defined according to IFRS
Sobi uses certain financial measures in interim and annual reports that are not defined according to International Financial Reporting Standards (IFRS). The company considers that these measures provide valuable supplementary information for investors 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. The following financial measures are not defined according to IFRS.

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.

EBITA
Earnings before interest, tax and amortisation.

EBITA adjusted
EBITA less non-recurring items.

EBITA margin, %
EBITA as a percentage of total revenue.

EBITA margin adjusted, %
EBITA adjusted as a percentage of total revenue.

EBITDA
Earnings before interest, tax, depreciation and amortisation.

EPS, SEK adjusted
Profit for the period, adjusted, divided by the weighted average number of ordinary shares.

EPS after dilution, SEK adjusted
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.

Equity ratio
Shareholders' equity as a proportion of total assets.

Net debt (+)/Net cash (–)
Borrowings less cash and cash equivalents.

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.

Weighted Average Cost of Capital (WACC)
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 21.4 per cent has been used.

Alternative performance measures

SEK M unless otherwise stated	2021	2020	2019	2018	2017
Total revenue	15,529	15,261	14,248	9,139	6,511
Total cost of goods sold	−3,484	−3,225	−3,335	−2,415	−1,854
Gross profit	**12,045**	**12,036**	**10,913**	**6,723**	**4,657**
Gross margin	**78%**	**79%**	**77%**	**74%**	**72%**
EBIT (operating profit)	3,733	4,818	4,533	3,122	1,600
Plus amortisation and impairment of intangible assets	1,841	1,882	1,401	449	441
EBITA	**5,575**	**6,700**	**5,933**	**3,571**	**2,053**
Plus depreciations and impairment of tangible assets	165	141	188	36	33
EBITDA	**5,740**	**6,841**	**6,121**	**3,607**	**2,086**
EBITA margin	**36%**	**44%**	**42%**	**39%**	**32%**
Non−recurring items[1]	–	−399	211	–	–
EBITA adjusted	**5,575**	**6,301**	**6,145**	**3,571**	**2,053**
EBITA margin adjusted	**36%**	**41%**	**43%**	**39%**	**32%**
Profit for the period	2,679	3,245	3,304	2,418	1,149
Non-recurring items[1, 2]	–	−399	174	–	–
Profit for the period, adjusted	2,679	2,846	3,479	2,418	1,149
Average number of ordinary shares (excluding shares in treasury)	295,051,119	294,658,136	292,649,020	269,523,784	269,020,363
Average number of ordinary shares after dilution (excluding shares in treasury)	296,799,459	297,640,174	294,528,428	270,603,665	270,003,546
EPS, SEK adjusted	**9.08**	**9.66**	**11.89**	**8.97**	**4.27**
EPS after dilution, SEK adjusted	**9.03**	**9.56**	**11.81**	**8.93**	**4.26**
Shareholders' equity	23,203	20,206	16,930	9,040	6,701
Total assets	48,661	48,283	46,568	17,183	10,903
Equity ratio	**48%**	**42%**	**37%**	**53%**	**61%**
Number of ordinary shares	307,114,495	303,815,511	299,977,839	273,322,117	272,507,708
Number of ordinary shares after dilution	308,862,835	306,797,549	301,857,247	274,365,601	269,975,826
Equity per share, SEK	**75.6**	**66.5**	**56.4**	**33.1**	**24.6**
Equity per share after dilution, SEK	**75.1**	**65.9**	**56.1**	**32.9**	**24.8**

1. 2020 refers to; reversal of the CVR liability of SEK 399 M. 2019 refers to; transaction cost 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.
2. 2020 refers to; reversal of the CVR liability of SEK 399 M. 2019 refers to; transaction cost related to the acquisition of Dova of SEK 92 M, restructuring costs of SEK 175 M including impairment of intangble assets of SEK 18 M, gain from divestment of SOBI005 of SEK 37 M and, related tax effects of SEK 55 M.

Glossary

AKU, Alkaptonuri
A serious, multifaceted, debilitating and slowly progressive disease affecting approximately 1 in every 250 000 to 1 million people. Also known as black bone disease or black urine disease.

Alprolix (eftrenonacog alfa)
A recombinant, EHL clotting factor IX therapy for treatment of haemophilia B.

ALS, Amyotrophic lateral sclerosis
A devastating neurodegenerative disease that results in progressive muscle weakness and paralysis due to the death of nerve cells, motor neurons, in the brain and spinal cord.

CAD, Cold agglutinin disease
A severe, chronic, rare blood disorder that currently has no approved therapies and impacts around 10,500 people across the United States and Europe. People living with CAD may suffer from chronic anaemia, transfusion requirements, and an increased risk of life-threatening thrombotic events such as stroke.

CAPS, Cryopyrin-associated periodic syndromes
Constitutes a group of rare autoinflammatory diseases with an incidence estimated to be 1:1,000,000 worldwide. CAPS is characterised by uncontrolled overproduction of interleukin-1 (IL-1) which induces a number of inflammatory responses such as fevers, rash, joint pain, headaches, conjunctivitis and many other symptoms.

CIT, Chemotherapy-induced thrombocytopenia
A common side effect of chemotherapy that results in a low number of platelets.

CLD, Chronic liver disease
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.

Doptelet (avatrombopag)
A second-generation small-molecule thrombopoietin receptor (TPO) agonist used in the treatment of thrombocytopenia by increasing platelet count.

Efanesoctocog alfa (BIVV001)
A novel, investigational factor VIII therapy designed to extend protection from bleeds with prophylactic dosing once-weekly or longer apart for people with haemophilia A. Builds on Fc-fusion technology by adding a region of von Willebrand factor and XTEN polypeptides to potentially extend its time in circulation.

EHL, Extended half-life
Means that the circulation in the body is prolonged. Sobi's haemophilia treatments, Elocta and Alprolix, are EHL products.

Elocta/Eloctate (efmoroctocog alfa)
A recombinant, EHL clotting factor VIII therapy a for the treatment of haemophilia A.

EMA
European Medicines Agency.

Familial Mediterranean Fever (FMF)
A genetic autoimmune disorder that causes recurrent episodes of fever together with abdominal, chest or joint pain.

FDA
The US Food and Drug Administration.

FMF, Familial Mediterranean Fever
A genetic autoimmune disorder that causes recurrent episodes of fever together with abdominal chest or joint pain.

Gamifant (emapalumab)
An anti-interferon-gamma (IFNγ) monoclonal antibody (mAb), approved by the FDA for the treatment of primary haemophagocytic lymphohistiocytosis (HLH), a life-threatening syndrome of immune activation, and which is under investigation for other indications.

Gout
An autoinflammatory disease that causes intensely painful flares and debilitating inflammatory arthritis due to deposition of pro-inflammatory monosodium urate (MSU) crystals in synovial fluid and other tissues.

Haemophilia
A rare, genetic disorder in which the ability of a person's blood to clot is impaired. 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. Both occur more rarely in females. People with haemophilia experience bleeding episodes that may cause pain, limited mobility, irreversible joint damage and life-threatening haemorrhages.

HLH, Haemophagocytic lymphohistiocytosis
A rare and life-threatening syndrome of extreme immune activation. The primary form (inherited) of the disease mainly occurs in infants and young children and the secondary form (acquired) of the disease is acquired from or associated with autoimmune diseases or malignancy.

HSCT-TMA
A rare blood disease that can be a fatal complication of a bone marrow transplant or HSCT. In HSCT-TMA, microscopic blood clots form in small blood vessels, leading to organ damage.

HT-1, Hereditary tyrosinaemia type 1
People with HT-1 have problems breaking down an amino acid called tyrosine. Toxic by-products are formed and accumulate in the body, which can cause liver, renal and neurological complications.

IC-MPGN/C3G
Rare, debilitating kidney diseases that affect around 18,000 people in the United States and Europe. There are no approved therapies for the diseases, and symptoms include blood in the urine, dark foamy urine due to the presence of protein, swelling, and high blood pressure.

IL-1, Interleukin-1
A key mediator of inflammation and driver of autoinflammatory diseases.

ITP, Chronic immune thrombocytopenia
A rare autoimmune bleeding disorder characterised by a low number of platelets, affecting approximately 60,000 adults in the United States.

Kineret (anakinra)
A recombinant protein drug that blocks the biological activity of interleukin-1α and β (IL-1α and IL -1β) by binding to IL-1 type 1 receptors (IL-R 1), expressed in a variety of tissues and organs, thereby blocking the IL-1 signalling. IL-1 is a key mediator of inflammation and a significant contributor to autoinflammatory diseases.

MAH, Marketing authorisation holder
The company in whose name the marketing authorisation has been granted and who is responsible for all aspects of the product.

Nirsevimab
A single dose extended half-life anti-RSV F-monoclonal antibody (mAb) being developed for the prevention of lower respiratory tract infections (LRTI) caused by RSV in all infants entering their first RSV season and children with chronic lung disease or congenital heart disease entering their first and second RSV season. Is being developed for passive immunisation of a broad infant population, and engineered to have a long half-life so that only one dose will be needed for the entire RSV season.

NOMID
Neonatal-onset multisystem inflammatory disease, the most severe form of CAPS, also associated with chronic meningitis, hearing loss, craniofacial abnormalities, bone lesions and increased mortality.

Orfadin (nitisinone)
A drug used to treat hereditary tyrosinaemia type 1 (HT-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.

Orphan drugs
Medicinal products targeting rare, life-threatening diseases or disorders in very small patient populations. They are called "orphan drugs" because, under normal market conditions, there is little incentive for the pharmaceutical industry to develop a treatment for such a small patient population. Revenues would not be expected to meet the extremely high costs of bringing such a treatment to market. Governments often provide economic incentives to encourage companies to develop and market medicines for rare diseases.

Pegcetacoplan
An investigational, targeted C3 therapy designed to regulate excessive complement activation, which can lead to the onset and progression of many serious diseases.

PNH, Paroxysmal nocturnal haemoglobinuria
A rare, chronic, life-threatening blood disorder characterised by the destruction of oxygen-carrying red blood cells through extravascular and intravascular haemolysis. Persistently low haemoglobin can result in debilitating symptoms such as severe fatigue, haemoglobinuria, and difficulty breathing (dyspnoea), and can require frequent transfusions.

RA, Rheumatoid arthritis
A chronic autoimmune and inflammatory disorder that primarily affects joints.

RSV, Respiratory syncytial virus
A common virus and the most common cause of lower respiratory tract infections (LRTI) in young children. The RSV season usually occurs from early autumn until late spring and peaks during the winter.

SEL-212
A novel combination product candidate designed to sustain control of serum uric acid levels in patients with chronic refractory gout. SEL-212 consists of pegadricase, co-administered with ImmTOR, designed to mitigate the formation of anti-drug antibodies.

Still's disease
An autoinflammatory disease that affects both children and adults, characterised by persistent high spiking fevers, recurring rashes and arthritis. Still's disease is also known as systemic-onset juvenile idiopathic arthritis (SJIA) or adult-onset Still's disease (AOSD).

Synagis (palivizumab)
Indicated for the prevention of serious lower respiratory tract infections (LTRI) caused by respiratory syncytial virus in infants and young children at high risk of RSV disease. RSV is the most prevalent cause of LRTI among infants and young children. Synagis is an RSV F-protein inhibitor monoclonal antibody (mAb) that acts as prophylaxis against serious RSV disease. It is the only medicine approved for the prevention of serious RSV disease.

Tegsedi (inotersen)
A self-administered subcutaneous treatment for the treatment of polyneuropathy of hATTR amyloidosis in adults.

Waylivra (volanesorsen)
A treatment for the treatment of genetically confirmed familial chylomicronaemia syndrome (FCS).

WFH
World Federation of Hemophilia, an international not-for-profit organisation.

Forward-looking statements

This report includes forward-looking statements. Actual results may differ from those stated. Internal factors such as the successful management of research programmes and intellectual property rights may affect future results. There are also external conditions such as the economic climate, political changes and competing research programmes that may affect Sobi's results.

Production: Sobi in cooperation with Hallvarsson & Halvarsson.
Printing: Göteborgstryckeriet. Photos: Martin Botvidsson, Petter Karlberg, Paulina Westerlind, Stock images/Getty, World Federation of Hemophilia, Sobi.

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