Expanding opportunities

Annual and Sustainability Report 2020

sobi
rare strength

Contents

This is Sobi's Annual and Sustainability Report 2020. The audited Annual Report includes pages 34–91. The Sustainability Report is on pages 23–27 and 108–131 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.

Rare strength

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 treatments in the areas of haematology, immunology and specialty care.

15,261

Total revenue, SEK million

10 & 25%

Increase in haemophilia A and B patients respectively during 2020

- Two therapeutic areas – Haematology and Immunology – and products within Specialty Care
- Strong portfolios of on-market products and pre-market assets
- Our extended half-life 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 clinical research & development, and on patient access and commercialisation
- Global Head Office in Stockholm, Sweden, with offices in over 30 countries, delivering treatments to patients in more than 70 countries
- Sobi share (STO:SOBI) listed in the Large Cap segment of Nasdaq Stockholm

6,301

Adjusted EBITA, SEK million

1,509

Number of employees (FTE)

Strong suite of pre-market assets and strong portfolio of on-market products

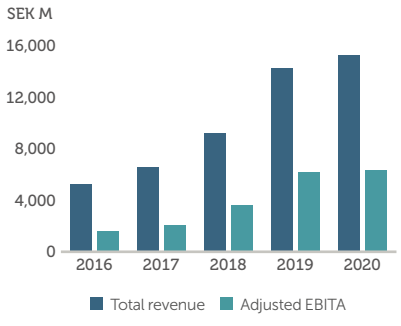
	Haematology	Immunology
Pre-market	BIVV001/efanesoctocog alfa[1] – haemophilia A Pegcetacoplan[2] – PNH	Gamifant/emapalumab – sHLH Gamifant/emapalumab – aGF Nirsevimab[3] – RSV Pegcetacoplan – ALS SEL-212[4] – chronic refractory gout
On-market	Elocta® – haemophilia A Alprolix® – haemophilia B Doptelet® – ITP, CLD	Kineret® – several indications Synagis® – RSV Gamifant® – pHLH

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.

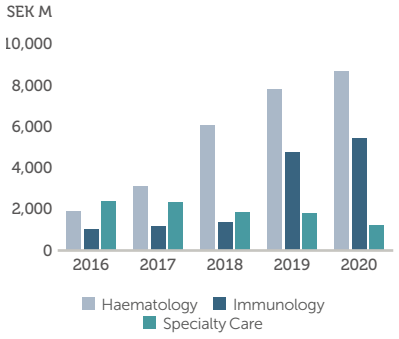
Solid revenue and double-digit growth in both core areas

Full-year revenue up 8 per cent at CER

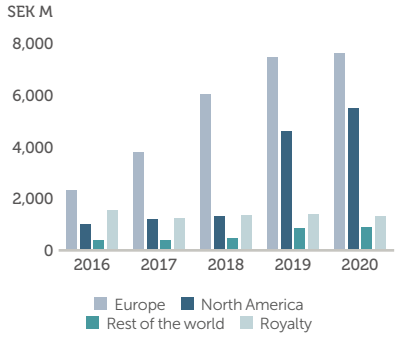
Total revenue and adjusted EBITA



Revenue per business area

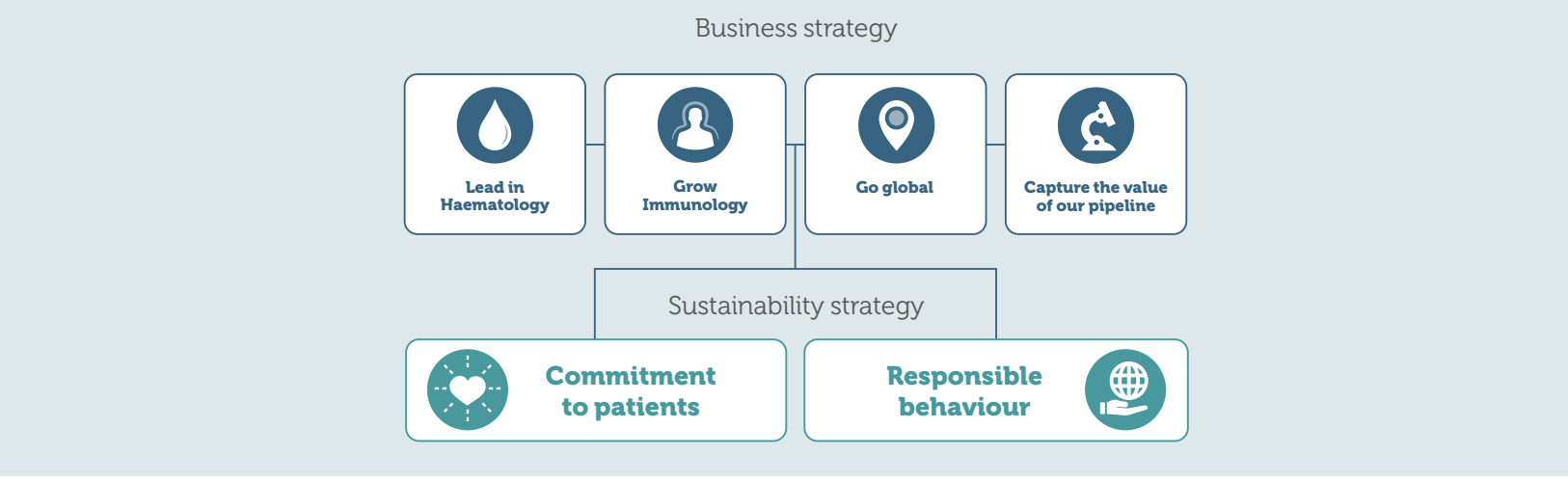


Revenue per geographic region



Year in brief

The COVID-19 pandemic had a significant effect on Sobi, and the rest of the world. Many stakeholder interactions moved online, operations adapted to the restrictions, and extraordinary efforts were made to get medicines to patients in lockdown. Despite these circumstances, Sobi made significant progress in all strategy areas.



	Continued solid patient growth was seen in the haemophilia area, although the pandemic affected sales, with fewer surgeries and lower levels of patient activity leading to lower consumption of replacement factor. Read more, p 12
	Doptelet was brought to Europe with the product launch for chronic liver disease (CLD) and approval for the treatment of chronic immune thrombocytopenia (ITP). Read more, p 12–13
	Sobi signed a collaboration agreement with Apellis for the development and commercialisation of systemic pegcetacoplan, a targeted C3 therapy, outside the US. The companies will jointly advance systemic pegcetacoplan in five parallel registrational programmes. Read more, p 21–22
	Sobi and Selecta signed a strategic licensing agreement for SEL-212, a phase 3-ready novel treatment for chronic refractory gout. SEL-212 subsequently entered the phase 3 study. Read more, p 20–21
	Presence in the Asia-Pacific expanded beyond China with the establishment of offices in Japan and Australia. In Russia, the offering to patients was expanded with the launch of Elocta (to be sold as Eloctate). Read more, p 18–19
	Sobi and Sanofi renewed their 2014 commitment to the World Federation of Hemophilia Humanitarian Aid Program, and pledged a further 500 million international units (IU) of extended half-life replacement clotting factor therapy. Read more, p 14, p 23–25
	Sobi launched a Responsible Sourcing Programme, including the introduction of a Partner Code of Conduct, and sustainability screening and management. Read more, p 22–25

8%
Revenue growth at CER

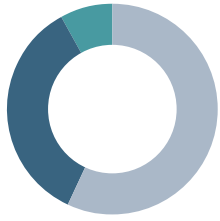
41%
Adjusted EBITA margin

Significant progress in all strategy areas.

Revenue per geographic region

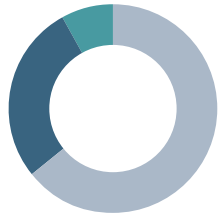
Europe 50% North America 36%
Rest of the world 6% Royalty 8%

Revenue per business area



Haematology 57% Immunology 35%
Specialty Care 8%

EBITA per business area



Haematology 64% Immunology 28%
Specialty Care 8%

Key figures

SEK M	2016	2017	2018	2019	2020
Total revenue	5,204	6,511	9,139	14,248	15,261
Gross profit	3,651	4,657	6,723	10,913	12,036
Gross margin[1], %	70	72	74	77	79
Operating expenses	2,518	3,057	3,601	6,430	7,575
EBITA[1]	1,543	2,053	3,571	5,933	6,700
Adjusted EBITA[1,2]	1,543	2,053	3,571	6,145	6,301
EBIT	1,133	1,600	3,122	4,533	4,818
Profit/loss for the year	802	1,149	2,148	3,304	3,245
Earnings per share, before dilution, SEK	2.99	4.27	8.97	11.29	11.01
Earnings per share, before dilution, SEK adjusted[1,2,3]	2.99	4.27	8.97	11.89	9.66
Cash flow from operations	343	1,333	2,090	3,634	5,214
Equity per share[1,2,3] SEK	19.8	24.6	33.1	56.4	66.5
Equity assets ratio, %	54	61	53	37	42
No. of employees (full-time equivalents)	760	800	902	1,335	1,509

1. Alternative Performance Measures (APMs).
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 in 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.

Thoughtful pathway to growth

Sobi is accelerating its growth trajectory and aims for revenue of SEK 25 billion by 2025.

In 2020, we continued to take major steps in the transformation of the company and expanded beyond our traditional stronghold in haemophilia. We achieved solid growth during the year, and broadened the foundation of the company to align with our ambition of becoming a global leader in rare diseases.

Milestones

Our launch products are becoming meaningful contributors to the overall financials of the Group. We continue to increase the scale of absolute growth for Doptelet in a difficult launch environment, and our market share in the chronic immune thrombocytopenia (ITP) market was around 7 per cent by the end of 2020.

With Gamifant, we experienced more than 50 per cent volume growth, while our sales growth was solid due to the positive impact of the previous year's price decreases on access and affordability.

We responded well to the ongoing COVID-19 crisis. We made certain that we could take care of patients by ensuring supply and implemented the necessary precautionary measures to protect our employees. Our global supply team avoided interruptions to supply for customers of all our core products.

Interest in Kineret remains strong, and we saw two publications in The Lancet Rheumatology on its utility. We expect to see more research into the effects of Kineret, particularly in the area of hyperinflammation.

Alprolix, Kineret and Synagis performed well. The pandemic affected sales of Elocta, mainly due to restrictions on physical activity resulting in reduced individualised consumption at patient level. On the other hand, Elocta proved very competitive against other therapies as we continued to gain significant patient numbers and increase our share of patients.

Not everything has gone according to plan. It is fair to say that our launch products were affected by the reduction in face-to-face interactions with healthcare professionals. The negative opinion on emapalumab for primary HLH in Europe and the phase 3 data for Doptelet in CIT surprised both us and key experts in the field.

Yet as an agile organisation, we were able to turn these setbacks into strengths. We see broader potential for emapalumab in other indications and outside Europe, and we are excited about Doptelet's global sales potential in chronic liver disease (CLD) and ITP. We embraced a multi-channel approach to sales and marketing, and are placing more importance on the scientific dissemination of knowledge via our medical-scientific liaison officers.

In addition, our licensing agreements with Selecta for SEL-212 and with Apellis for pegcetacoplan will open significant opportunities over the next three years.

Strategy for growth

To maintain our strategy for growth, we are building on the foundation of pipeline development in our two core therapeutic areas and the further internationalisation of the company. This strategy will position Sobi well to achieve our ambition of SEK 25 billion in revenue by 2025.

- We expect to achieve the primary growth from our launch products and late-stage pipeline in the US and Europe, mostly from Doptelet, Gamifant, pegcetacoplan, SEL 212 and BIVV001. Around 60–70 per cent of our future growth will come from this products.
- The second-largest growth driver will be our development in international markets. In particular, Russia, China, Japan, Central & Eastern Europe, and our Middle East-North Africa (MENA) region are expected to contribute 20–30 per cent to our total growth.
- Our existing core business will generate the earning foundation that allows us to embark on this ambitious growth strategy. It is not expected to be the main source of business growth.

We believe that our increasingly global footprint will enable us to forge new strategic alliances with numerous small to mid-size partners.

In the shorter term, we expect significant progress in our pipeline during 2021, including approval of pegcetacoplan in PNH. History has taught us to

»2021 will be a pivotal year as we build the company for mid-term success and invest in our portfolio, especially in R&D, infrastructure and launches.«

be patient, and although we know that approvals are not always predictable, we are optimistic.

We will be stepping up our R&D investment to properly develop our 12 late-stage projects in the years ahead, and maintaining our focus on late-stage assets which have a greater probability of success in the near to mid-term. And we will continue to broaden the company with acquisitions and partnerships, bringing in both on-market assets and late-stage projects.

Financial strength essential

In financial terms we are healthy, with strong earnings and topline, and a low leverage ratio. This financial health is vital for our transformation, and a prerequisite when pursuing acquisitions.

2021 will be a pivotal year as we build the company for mid- and long-term success and invest in our portfolio, especially in R&D, infrastructure and launches. The success that we hope 2021 will build may not be immediately visible, but it will transform Sobi over the coming five years.

Sustainability core to our business

I see sustainability, directly linked to our vision of transforming lives, as a key factor for the company's future. We have a great team working with a range of environmental, social and governance (ESG) issues that are high on the corporate agenda, and our commitment to the principles of the UN Global Compact remains firm. We have made great strides towards achieving our ambitions over the past two years, and I am glad to see the recognition we have received. We are in a unique position to improve health globally in our focus areas, and responsible practices throughout our business will help us grow stronger and become more sustainable.

Great pride

It became even more obvious during the COVID-19 pandemic: working at Sobi is more than just a job for my colleagues and for me.

It is an opportunity to make a difference for people living with rare diseases.

Our Global Engagement Survey, our first on this scale, provided important feedback on how we are performing as an employer. The overall results were positive but also identified areas for improvement.

2020 was a year like no other. I have been deeply impressed by how the entire organisation stepped up across the board, from ensuring supply, to ensuring we get a fair share in very competitive markets against new entrants. The individual efforts of every one of my 1,500 colleagues make all the difference.

As we cannot influence the impact of the pandemic, we focus on what we can influence at Sobi.

We will further upgrade our commercial effectiveness across the globe, strengthen our new entities in the International area, and drive the development and launch of our pipeline products.

I am proud of the rare strength we have shown as we pursue our vision of leading the world in providing innovative treatments that transform the lives of people with rare diseases.

Guido Oelkers
Chief Executive Officer

Rare diseases

While each rare disease may affect relatively few people, together the 6,000[1] identified rare diseases are thought to affect 300 million people.

High unmet medical need

Up to 70 per cent of identified rare diseases affect children and 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.

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 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 for many during 2020[2].

Much focus has been placed on the high costs of treating rare diseases. However, leaving conditions untreated leads to higher costs for patients, health systems, social services and governments. A lack of appropriate treatment and care also leaves rare disease patients and carers 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 medicinal products (OMP), and many drug candidates 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.

1. www.nature.com/articles/s41431-019-0508-0
2. www.sobi.com/en/press-releases/rare-disease-day-2021-pandemic-illuminates-every-day-social-obstacles-living-rare

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

Sobi, together with pharmaceutical trade associations, is engaging with different stakeholders from the European Commission, EU Parliament and others as part of the Commission's ongoing review of incentives for orphan medicinal product (OMP) and paediatric medicines. While the preliminary evaluation did not elaborate on any policy changes to come, it did highlight the fact neither of these regulations provides adequate support for development in areas with the greatest unmet medical needs. The review's interim report further indicates that any future response to the shortcomings and challenges identified should strike a balance between incentives for innovation on one hand, and availability and access for orphan and paediatric patients on the other.

Sobi believes that without the right incentives, or if current incentives are downgraded, 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

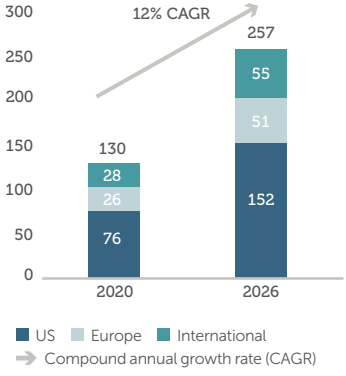
In 2020, the size of the orphan drugs market was USD 130 billion (adjusted) and is projected to reach USD 257 billion by 2026, with a compound annual growth rate (CAGR) of 12 per cent[1]. This is double the growth forecast for the non-orphan market.

Sobi established operations in China, Japan and Australia during 2020, and expanded in Russia, as part of its strategy for geographical expansion. Due to the extensive unmet medical needs in these countries, they represent significant growth potential.

Raising rare voices

Sobi has important, long-standing relationships with EURORDIS (Rare Diseases Europe), NORD (the National Organization for Rare Diseases) and the rare disease community. Sobi's participation in the EURORDIS Round Table of Companies, the Black Pearl Awards, ECRD and further contributions towards NORD and EURORDIS events are helping to elevate the voice of the rare disease community.

Orphan drug market, USD Bn



Source: EvaluatePharma®

What is a rare disease?

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

Worldwide orphan drug market growth

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

Great need outside EU and US: More than 250 million people outside the US and EU are thought to be affected by rare diseases. Of these, an estimated 60 per cent are children*.

* Source: Profound

Attractive opportunity: Rare disease therapeutic 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, 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 biological nature, and are less attractive targets for biosimilars because of the small patient population.

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 and payers in order to transform the lives of people living with rare diseases.

From clinical research to patient
Sobi's value chain spans from clinical research and development to patient access and commercialisation. Our strengths include evaluating and developing clinical projects, commercialisation and bringing treatments to patients as quickly as possible.

Partnership and cooperation
Our strengths combine with those of our collaboration partners to shape opportunities for value creation in the rare disease landscape. 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.

Patient access and commercialisation
Cross-functional teams bring together our many disciplines. By bringing in patient access specialists as early as possible into development projects, approval applications and pricing negotiations, for example, we are speeding up the delivery of treatments to patients.

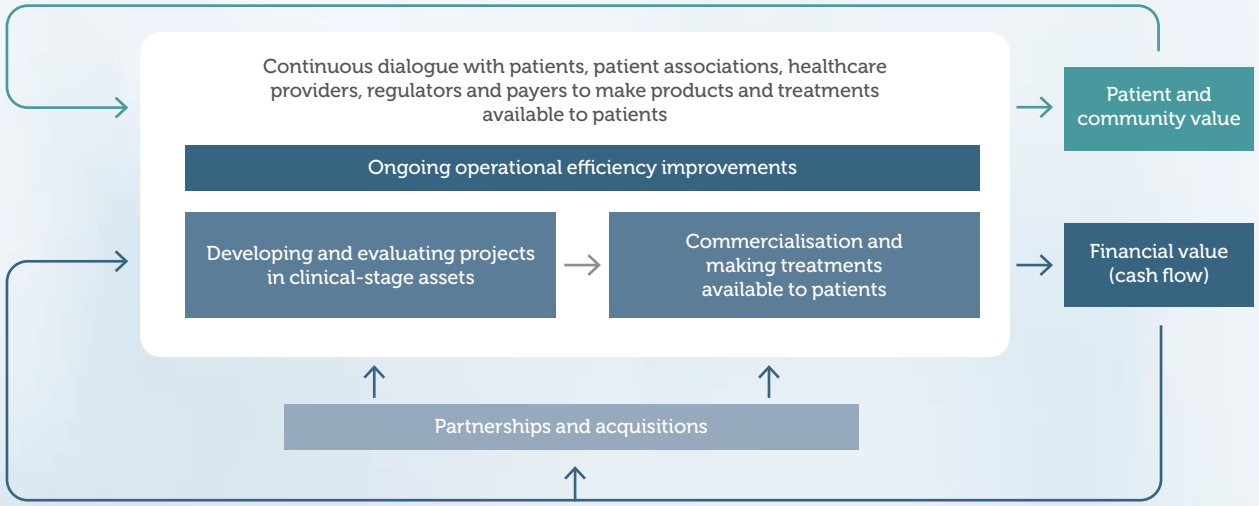
Our commercial, medical and R&D teams work with healthcare professionals, external researchers and other stakeholders to increase understanding of patients' and healthcare professionals' changing needs. This provides insight into needs that we continuously feed back into the system to improve our treatments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

Responsible pricing is vital in ensuring 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: 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

The strategy we established in 2017 remains firm, with refinements reflecting the evolution of the company.

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

Our 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 leading company within Haematology. We will continue to expand access to our extended half-life factor replacement treatments Elocta and Alprolix, reaching more people with haemophilia A and B in more countries.

In 2021, we will launch Elocta (as Eloctate) in Russia. We see BIVV001 as a future growth driver, with the potential to change the treatment paradigm within haemophilia A. Within the larger scope of Haematology, we are expanding access to Doptelet, taking it to new markets and new indications. We are planning for a launch of pegcetacoplan in PNH, expanding the non-haemophilia segment of our Haematology portfolio.

We will continue to grow in Immunology. Work will intensify in order to maximise the value of our existing products, for Kineret and Gamifant in new markets and new indications, and we will continue to seek promising candidate treatments. Research into pegcetacoplan in indications within neurology and nephrology will continue.

We will continue our geographical expansion to become a global company. Following our expansion into the Asia-Pacific in 2020, with offices established in China, Japan and Australia, and an increased presence in Russia, we are now examining other potential markets in South-East Asia and Latin America.

Business strategy

Sustainability strategy

And we will continue to capture the value of our R&D pipeline by concentrating on late-stage assets that address unmet medical needs and have significant market potential. With 12 planned programmes focused on six products, we expect to see more than 30 launches in key geographies over the coming years. We continue to seek additional attractive assets.

Sustainable access
Our sustainability strategy is closely linked to the business and based on two priorities – our commitment to patients and our responsible behaviour.

By expanding our geographical reach, investing in the development of novel products 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.

If we are successful in our operations, we will positively impact the communities we serve.

Haematology

Haematology is now established as one of Sobi's two therapeutic areas, building on our success in haemophilia and creating a platform for long-term growth.

57%
of total revenue

4,377
EBITA, SEK M

Covering more than 100 benign and malignant disorders of the red and white blood cells, platelets and coagulation system, haematology includes the diagnosis, treatment and prevention of diseases of the blood and bone marrow as well as the immunological, haemostatic (blood clotting) and vascular systems. The science of haematology profoundly affects the understanding of many diseases.

In 2020, the scope of this therapeutic area expanded from haemophilia to include Doptelet (avatrombopag), an orally administered, second-generation thrombopoietin receptor agonist (TPO-RA) used in the treatment of thrombocytopenia (low platelet count), which can be administered without dietary restrictions.

We are excited about the opportunities this provides for increasing our presence across the haematology spectrum within rare diseases. Despite increased competition, challenges in access and additional pressure on prices, we see extensive potential for patients and physicians to use and benefit from our therapies in this area.

Elocta and Alprolix

Elocta and Alprolix, our market-leading extended half-life factor replacement products for haemophilia A and B, continued to perform strongly. Replacement therapy is fundamental in many treatment areas: the replacement of a missing hormone, enzyme, nutrient or protein allows patients to achieve a normalised state. Factor replacement remains the mainstay of treatment for haemophilia – by replacing the missing factor, people with haemophilia can take control of their condition, and their treatment can be individualised to suit their situations and lifestyles.

Haemophilia

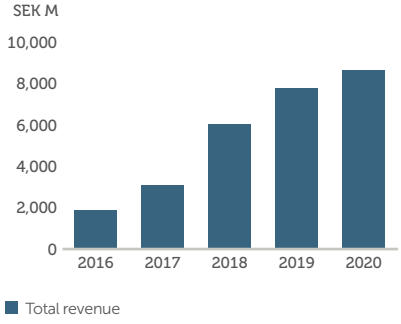
A bleeding disorder in which the blood does not clot properly. More than 400,000 people globally are estimated to have haemophilia, while only around 25 per cent receive adequate treatment[1]. Haemophilia is caused by lack of a coagulation factor, factor VIII in haemophilia A and factor IX in haemophilia B. Appropriate management aims to help people with haemophilia to live full, healthy and active lives.

1. www.hemophilia.org/About-Us/Fast-Facts

Thrombocytopenia

A condition resulting from low levels of blood platelets. It can arise from either decreased production of platelets, for example due to chronic liver disease, or through increased destruction of platelets, as in the case of Immune thrombocytopenia.

Total revenue, Haematology

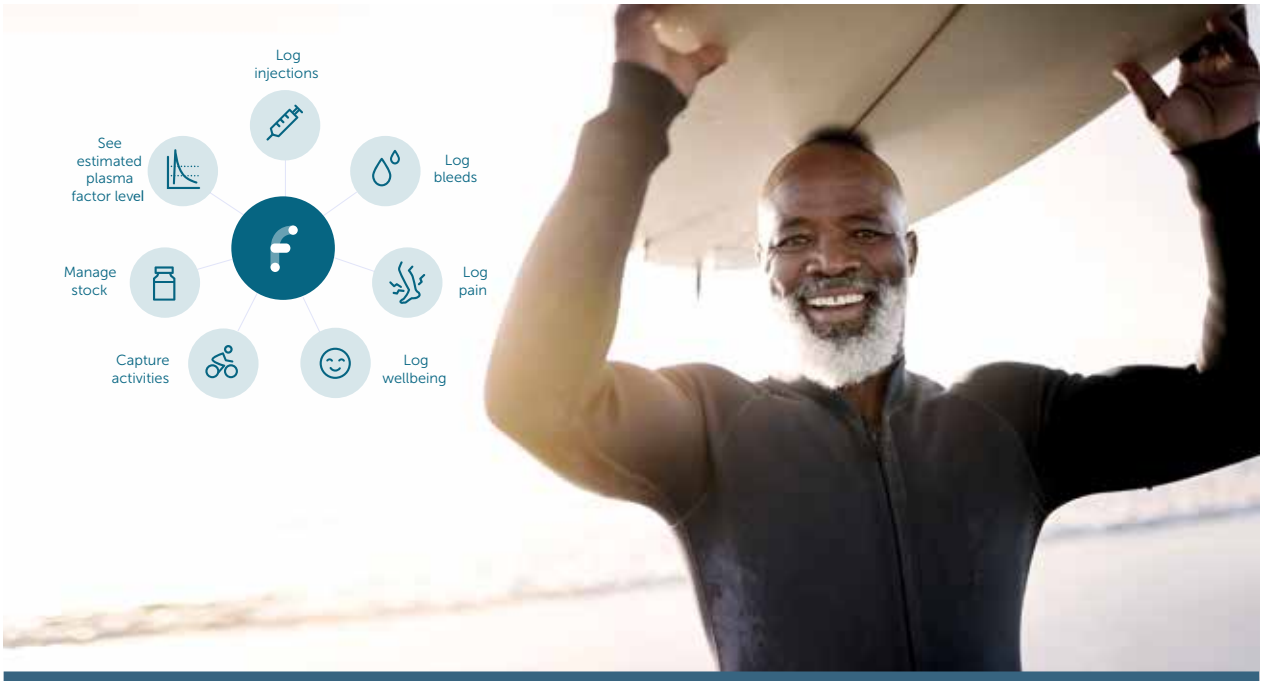


Revenue per product, Haematology

SEK M	2019	2020	Change at CER
Elocta	4,508	4,585	3%
Alprolix	1,463	1,705	18%
Royalty[1]	1,373	1,301	–3%
Doptelet	34	587	>100%
Manufacturing[2]	376	481	28%
Total	**7,755**	**8,660**	**13%**

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

Florio®



Sobi's subsidiary Florio develops next-generation digital products for patients and healthcare professionals that capture and visualise disease- and treatment-related data. Its first product florio HAEMO, designed to monitor haemophilia therapy, was co-created with patients and health-care professionals to provide more insights into patient treatment based on real-time data. The CE-marked digital medical device consists of an app for people with haemophilia, and a dashboard for their treating physicians.

Florio HAEMO allows patients to easily document their treatment and strengthens the relationship between patients and doctors.

Since launching in April 2020, florio HAEMO has expanded to more than 20 countries and 20 languages. User feedback from both doctors and patients has been excellent.

Florio continues to develop the app in co-creation with doctors and patients, adding functionality such as data export and analysis, a caregiver mode and many more useful features. An app for children with haemophilia was launched in late 2020.

Florio continues to develop digital products for patients and healthcare professionals in line with Sobi's development portfolio.

Doptelet picks up speed

Doptelet is a thrombopoietin receptor agonist (TPO-RA) used to treat low blood platelet counts (thrombocytopenia) in adults.

Doptelet has performed well in the US in its two approved indications: chronic immune thrombocytopenia (ITP) and chronic liver disease (CLD). In ITP, Doptelet has a market share of around 7 per cent, and the aim is to become a market leader. In CLD, adjustments to strategy increased the rate of growth, with teams successfully engaging with decision makers at key treatment centres regarding treatment protocols. The CLD market in the US is valued at USD 400–500 million, and the only real competition to Doptelet is platelet transfusions.

In Europe, Doptelet was launched in CLD in the UK, Ireland, Austria and Denmark in Q4. Doptelet was approved for the treatment of ITP in the EU in January 2021 and is launching during 2021.

In June 2020, we announced together with Sanofi that we would renew and extend our commitment to the WFH Humanitarian Aid Program, fulfilling our 2015 pledge to donate up to 1 billion international units (IU) of replacement factor for humanitarian use.
Read more in Sustainability, page 24.

COVID-19

The pandemic posed a challenge to sales growth. During lockdowns and restrictions, people with haemophilia reduced their levels of activity, which in turn reduced demand for factor. A fall in the number of surgical procedures also impacted sales for all treatments. However, we continued to see growth in patient numbers, particularly among people shifting from standard half-life treatments.

Our multichannel approach to meeting clients, including the use of virtual platforms, has proved successful. In the Middle East, a series of regular webinars provided an opportunity for healthcare professionals to discuss challenges and developments in a professional yet less formal manner.

The use of virtual meetings in the haemophilia community has also brought increased levels of participation albeit with fewer opportunities for informal discussions. In 2020, the World Federation of Hemophilia's virtual conference attracted 8,551 participants, compared with the normal figure of around 5,000.

Growth across Europe

Markets across Europe continued to show growth despite challenges from COVID-19. Changes to regulations and new tender rounds opened up new patient segments, and Elocta and Alprolix remained the market-leading factor replacement treatments in several countries.

In the Middle East, some patient cohorts were switched from on-demand treatment to weekly prophylaxis with Elocta, reducing the treatment burden while improving protection.

In Russia, Sobi is preparing for the launch of our haemophilia A treatment, which will be known there as Eloctate.

In all markets, we see that COVID-19 has placed additional pressure on healthcare budgets, and we expect increased price pressure in several markets.

BIVV001/efanesoctocog alfa

Together with Sanofi, we are proud to see positive results from the clinical study programme assessing BIVV001 as a potential treatment for haemophilia A. We see potential for BIVV001 to advance the treatment of people with haemophilia A by normalising factor levels for a significant part of the treatment interval.
Read more in R&D, page 20.

Immunology

With three on-market products, and strengthened by new licensing agreements for pre-market assets, Immunology has performed strongly during its first full year as a therapeutic area for Sobi.

Our immune system protects us from disease. Yet sometimes it can malfunction, underreacting or overreacting to a real or perceived threat. Immunology has long been at the heart of what we do at Sobi, and over many years we have been building up extensive expertise and experience.

COVID-19

The therapeutic area, like much in society, was affected by the COVID-19 pandemic.

The impact stretched across all Sobi regions, with a primary effect being a decline in activities at medical level. Many procedures and treatments were postponed or cancelled, and restrictions on interactions affected sales. The sales teams around the Sobi territories adapted by using a multi-channel digital approach to maintain contact with clients and stakeholders.

Addressing unmet medical need

We see our expansion into new territories where we can address unmet medical needs as good news for patients, for physicians and for Sobi. And we continue to bring in pre-market assets such as SEL-212 to strengthen our portfolio as we prepare for launch in coming years. Read more in R&D, pages 20–21.

Kineret

Kineret (anakinra) grew strongly in both the EU and North America. With its long history in clinical practice, it is recognised as an effective treatment for several indications, with a strong safety profile. As the COVID-19 situation stabilises during 2021, we look forward to continuing our examination of future indications and markets.

The drug has been well received by the market since its launch in 28 EU countries for the Still's disease indication, covering adult onset Still's disease and systemic juvenile idiopathic arthritis, during 2019-2020.

In 2020, Kineret was also approved in the EU for treatment, in combination with colchicine if appropriate, of familial Mediterranean fever, a rare disease on a global scale but affecting up to one person in 200 among certain ethnic groups with Mediterranean heritage.

35%

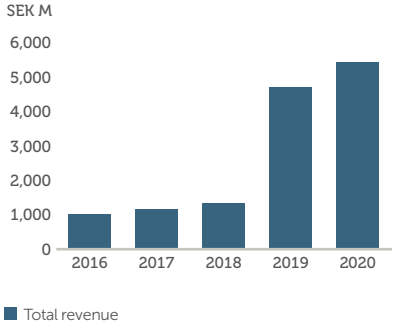
of total revenue

1,902

EBITA, SEK M

Strong interest in the potential of Kineret as a treatment for COVID-19-induced SARS (severe acute respiratory syndrome) and CSS (cytokine storm syndrome), as featured in prestigious publications such as The Lancet Rheumatology, has been gratifying to see. We will continue to support investigator-sponsored studies into the use of Kineret in this area. It is not often that products from a rare disease company

Total revenue, Immunology



Revenue per product, Immunology

SEK M	2019	2020	Change at CER
Kineret	1,571	2,079	35%
Synagis	2,594	2,726	5%
Gamifant	542	609	16%
Total	4,706	5,415	16%

make headline news in the mainstream media, and we are honoured to be able to help in the fight against COVID-19. Read more in R&D, pages 20–21.

Synagis and RSV

Respiratory syncytial virus (RSV) is a common and highly contagious seasonal virus contracted by nearly all babies by the age of two. In most, 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 highly seasonal virus, which has a major effect on sales of Synagis. The vast majority of sales take place during RSV season: the fourth and first quarters of each year.

Synagis performed well overall in 2020 despite a low incidence of RSV in the fourth quarter as a consequence of the COVID-19 pandemic, with social distancing and reduced international travel affecting the RSV season.

Outstanding efforts by the Synagis team in the US, including extensive public awareness and educational activities, were able to extract growth from a mature therapy.

»RSV is the leading cause of hospitalisation in infants aged less than one year in the United States.«

In 2020, distribution of Synagis was transferred from a wholesaler model to a specialty distribution model; six new specialty pharmacies were contracted and a new patient-support hub partner was introduced. All these systematic changes were conducted smoothly ahead of the 2020–2021 season, putting Synagis in a better position for long-term success.

Gamifant/emapalumab

Emapalumab, approved in the US under the name Gamifant as the only treatment for primary haemophagocytic lymphohistiocytosis, continued to see steady patient growth. Sales totalled SEK 609 M.

The European Commission's Committee for Medicinal Products for Human Use (CHMP) confirmed its negative opinion of emapalumab as a treatment for primary HLH at a re-examination in November. Sobi remains convinced of the medicine's safety and efficacy in this indication, and will seek approval in primary HLH in countries outside the EU; an application for approval in pHLH in China has been granted priority review there. We also continue to investigate emapalumab's potential as a treatment for other forms of HLH. It is also under investigation for other indications, including graft failure after haemopoietic stem cell transplant. See more in R&D, pages 20–21.

8%
of total revenue

564
EBITA, SEK M

Specialty Care

As well as playing a key role in the health of people living with HT-1, Orfadin is now the first pharmacological treatment approved for people living with AKU.

Sobi continues as the market leader to support those living with hereditary tyrosinaemia (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 has been approved in the US, the EU and several other markets for the treatment of HT-1, in combination with dietary restriction of tyrosine and phenylalanine.

In scientific collaboration with experts and prescribers, Sobi completed a 15-year follow-up study, the OPAL study, with 315 patients across 17 European countries and 77 sites studying the long-term outcomes during standard clinical practice. Over the study period, Orfadin treatment in HT-1 patients with a median treatment duration of 11.2 years (range 0.7–28.4 years) was shown to have a good safety profile and be well tolerated with sustained efficacy. The study adds insights to further ensure that optimal management of HT-1 patients with Orfadin is maintained throughout life.

Generic competition has had an effect, with lower revenue mainly due to price decreases, but Orfadin has retained its role in the management of HT-1.

High unmet medical need

In 2020, the European Commission approved Orfadin as the first pharmacological treatment for adults with alkaptonuria (AKU). The unmet medical need is high as previous treatment options have been limited to treating the symptoms of the disease.

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 of people in need is expected to be higher.

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

The development of Orfadin for the treatment of AKU was enabled by the work carried out within the DevelopAKUre programme, an international research consortium, initiated by the AKU Society and clinical experts. The DevelopAKUre consortium received financial support through the European Commission's 7th Framework Programme.

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

1. Zatkova A, Ranganath LR, and Kadasi L. Alkaptonuria: Current Perspectives. Appl Clin Genet. 2020; 13: 37–47. doi: 10.2147/TACG.S186773

Geographical expansion

Sobi continues to expand into new geographies. We see significant unmet need in regions outside our current territories, and are committed to reaching more patients with our medicines.

As a rare disease company, we serve a relatively small proportion of the population and concentrate on areas of high unmet medical need. Expanding our geographical presence allows more people living with rare diseases to access our therapies and takes Sobi into new markets with major growth potential.

Our objective for 2025 is to reach twice as many patients with our medicines, with an established presence in selected new markets, and partnerships to serve others. We are planning at least 18 launches in markets outside the EU and North America within the same timeframe, and expect the International division to account for 15 per cent of Sobi's revenue.

In the second half of 2020, operations were established in Japan and Australia, following expansion into China, and we increased our presence in Russia.

In Europe, all countries have been brought under a single umbrella organisation. This allows Sobi to have three regional groupings: Europe, North America and International. The International grouping includes all countries outside of North America and 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 are the second and third-largest pharmaceutical markets, respectively, in the world.

As well as continuing to grow in Europe, the Middle East and North Africa, we have seen significant expansion in North America. Operations there have grown from 54 to 457 employees (FTE) in just over three years. This includes 446 in the US, the single largest rare disease market in the world, and Sobi's largest affiliate (including Dova).

Geographic expansion also requires extensive logistical infrastructure to maintain Sobi's high standards for the production of biological pharmaceuticals, delivery, pharmacovigilance, quality assurance and serialisation.

China

Sobi had 12 staff in China at the end of 2020, in administration, regulatory and medical affairs.

The rare disease landscape in China is developing rapidly, with increasing attention and awareness from the government since 2018 and a major patient community drive to increase access to orphan medicines.

To address the unmet medical needs of roughly 17 million patients with rare diseases in China, the Chinese National Medical Products Administration has been carrying out reforms, including:

- Clinical study data from abroad can be submitted for the Chinese registry of rare disease drugs approved overseas
- Shortening the review and approval process
- Extension of clinical data exclusivity, ranging from six to 12 years.

Despite the relatively low number of patients with each rare disease, the "long tail" of the market provides major volumes that can be attractive for a company with the specialist expertise and infrastructure required.

Japan

In Japan, rare diseases have been largely neglected in the past, with healthcare focusing more on 'lifestyle' conditions such as diabetes, hypertension and high cholesterol. But awareness of rare diseases and orphan drugs has increased after recent approvals.

The birth ratio in Japan is only 1.36, so society places great importance on protecting children. This means that there is both momentum for addressing the unmet medical need, and opportunities for commercial growth.

The Japanese Ministry of Health, Labour and Welfare has requested that anakinra be developed and submitted for approval in the country, and Sobi is currently working on this request.

At 31 December 2020, Sobi had six staff in Japan.

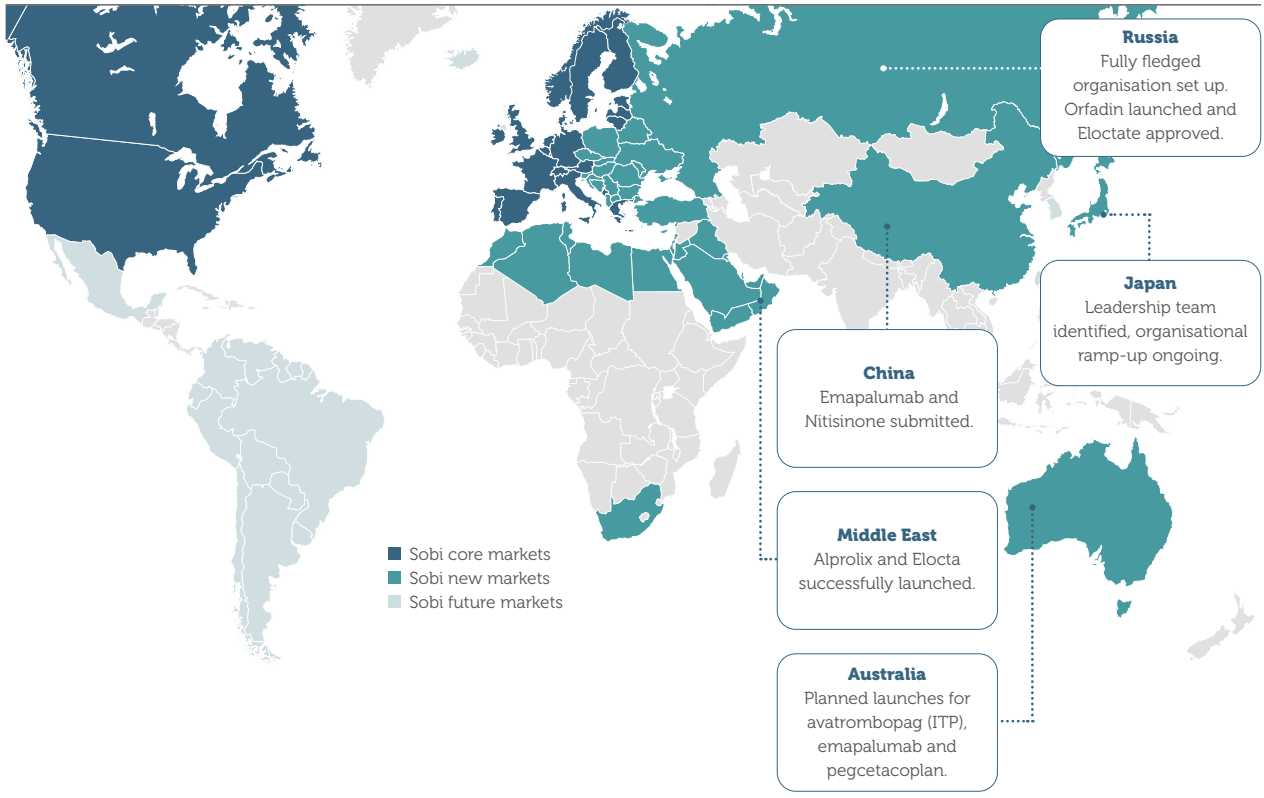
Both China and Japan generally require that medicines submitted for approval have been studied in local populations, contributing to greater scientific understanding of the challenges facing ethnic populations. In China, medicines with an urgent clinical need that have recently been approved overseas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

Russia

Sobi has expanded its presence in Russia. Our extended half-life treatment for haemophilia A, to be sold there under the name Eloctate, has been approved, and Orfadin has been launched as a treatment for HT-1.

Elsewhere, Sobi opened a new subsidiary in Australia in Q4 and sees further potential for growth there.

We are expanding our market presence outside Europe and North America



Sobi's markets

	Haematology	Immunology	Specialty Care
USA	Doptelet	Synagis Gamifant Kineret	Orfadin Kepivance®
Europe	Elocta Alprolix Doptelet	Kineret	Orfadin Tegsedi®, Waylivra® Partner Products
Middle East	Elocta Alprolix Doptelet	Kineret Gamifant (NPU)[1]	Orfadin Tegsedi, Waylivra
Rest of the world	Doptelet[2]	Kineret	Orfadin

See pages 127–128 for full details.

1. NPU – Named patient use.
2. Outlicensed in China.

»Our objective for 2025 is to reach twice as many patients, with an established presence in selected new markets, and partnerships to serve others.«

Capturing the value of our pipeline

Sobi now has six products under development, with 12 programmes planned to allow more than 30 launches in coming years.

R&D activities and the licensing agreements reached in 2020 changed the pipeline in terms of both volume and nature, and created a nexus between the areas of haematology and immunology.

Sobi continues to invest strongly in R&D, adding studies in phase 2 and 3. Several pipeline assets are being investigated in multiple indications, mitigating the risk inherent in orphan drug research.

A leadership transition took place in September, with Ravi Rao taking over as Chief Medical Officer and Head of R&D.

The COVID-19 pandemic had a moderate impact on clinical studies, including recruitment. In response to a request from the investigating authority in Italy, Sobi launched the Immuno-101 proof-of-concept study to evaluate the efficacy and safety of anakinra and emapalumab for the treatment of hyper-inflammatory syndrome, one of the most serious complications associated with severe COVID-19. The study expanded to the US, but was later terminated due to improvements in the standard of care for COVID patients and the impact this would have on study design.

However, 18 external, randomised controlled trials of anakinra in moderate-severe COVID-19 are ongoing or planned. Sobi is supporting 10 investigator-sponsored studies across the US and EU.

Haematology

BIVV001/efanesoctocog alfa

BIVV001 is an investigational factor VIII therapy – built on Fc-fusion technology with added von Willebrand factor domains and XTEN® polypeptides – designed to provide near-normal factor levels and higher bleed protection in a once-weekly prophylactic treatment regimen for haemophilia A.

Normal factor levels allow high levels of physical activity with low bleeding risk.

With two major phase 3 studies underway, BIVV001 is expected to be submitted for approval in the US in 2022. A study in pediatric patients is ongoing prior to submission in the EU. Sobi and Sanofi are collaborating on the development and commercialisation of BIVV001.

Doptelet /avatrombopag

A second-generation oral thrombopoietin receptor agonist (TPO-RA), Doptelet has been approved in the US for the treatment of immune thrombocytopenia (ITP) and chronic liver disease (CLD) by increasing platelet numbers. It is the only once-daily oral TPO-RA approved for the treatment of ITP without dietary restrictions, and exhibits no hepatoxicity.

Launched in the EU for CLD in Q4, Doptelet was approved in the EU in Q1 2021 for chronic ITP. It is also approved in China for CLD, and has been submitted for approval in both indications in a further two countries outside the EU, Russia and Switzerland.

The topline results from the phase 3 study in solid tumour cancer patients with chemotherapy-induced thrombocytopenia (CIT) were released in October. Although avatrombopag increased platelet counts relative to placebo as expected, the study did not meet the composite primary endpoint. The results continue to undergo examination.

Immunology

Nirsevimab/MEDI8897

Nirsevimab, a single-dose monoclonal antibody (mAb) under development by AstraZeneca and Sanofi for passive immunisation of a broad infant population against respiratory syncytial virus (RSV), showed a significant reduction in medically-attended lower respiratory tract infections (LRTI) and hospitalisations caused by (RSV) in healthy preterm infants in a positive phase 2b study published in the New England Journal of Medicine. Sobi holds the rights to 50 per cent of US earnings, mitigating the risk of future potential revenue reductions for Synagis.

SEL-212

Under a strategic licensing agreement with Selecta, SEL-212 is under investigation as a potential once-monthly treatment option for patients with chronic refractory gout. Sobi is responsible for development, regulatory and commercial activities in all markets with the exception of China. The phase 3 programme for SEL-212 is being run by Selecta and funded by Sobi.

A novel product candidate combining Selecta's tolerogenic ImmTOR™ immune tolerance platform and a therapeutic uricase enzyme (pegadricase), SEL-212 has been designed to provide sustained control of serum uric acid levels in patients with chronic refractory gout and may be particularly beneficial in patients with gouty tophi.

In the phase 2 COMPARE study, SEL-212 showed a numerically higher response rate than pegloticase on the

primary endpoint during months 3 and 6 combined, but did not meet the primary endpoint of statistical superiority. The data supported the commencement of the phase 3 clinical programme involving two double-blind, placebo-controlled phase 3 clinical studies (DISSOLVE I and DISSOLVE II) of SEL-212 for the treatment of chronic refractory gout. Topline data is expected in the second half of 2022.

Kineret/anakinra

Sobi continues to study the potential of anakinra in several indications, and continues to see great external interest in the drug.

Kineret was approved in the EU in April for the treatment of familial Mediterranean fever. FMF is a rare genetic disorder that causes recurrent episodes of fever typically accompanied by pain in the abdomen, chest, or joints.

Kineret has been approved in the US as a treatment for deficiency of interleukin-1 receptor antagonist (DIRA), a rare and life-threatening autoinflammatory disease.

Overlap between Haematology and Immunology

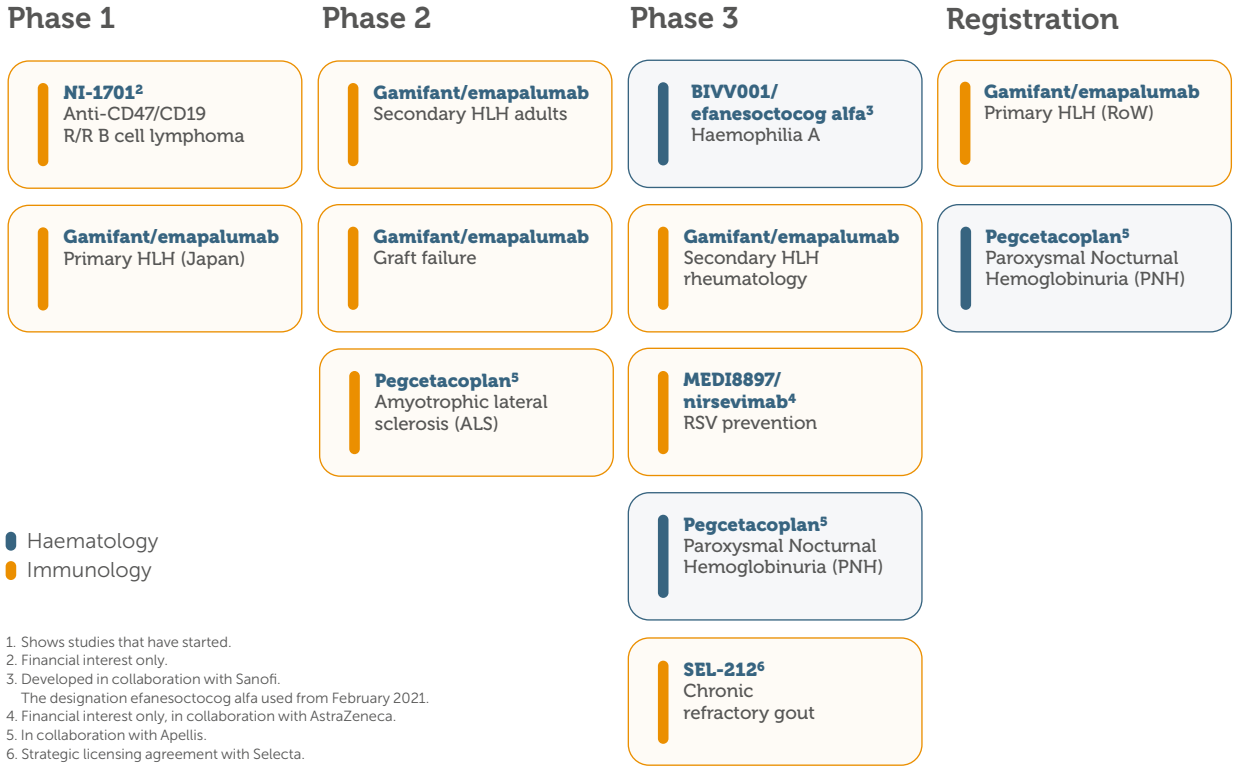
Gamifant/emapalumab

Emapalumab, marketed in the US as Gamifant, is the only treatment approved to target and neutralise interferon-gamma (IFNγ) – a major proinflammatory cytokine. Approved in the US as a treatment for primary HLH (haemophagocytic lymphohistiocytosis), emapalumab is under investigation for three further indications: secondary HLH, haemopoietic stem cell transplant (HSCT) graft failure, and graft versus host disease (GvHD).

The European Commission's Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion for the use of emapalumab as a treatment for primary HLH in Q4. Sobi sees significant unmet medical need in this indication and has therefore either submitted or will submit emapalumab for approval in primary HLH in several non-EU jurisdictions. We believe there is potential in other related indications on the spectrum between primary (genetic) and secondary (acquired) HLH, including rheumatological and infectious HLH.

We also see potential in the area of precision medicine. HSCT graft failure can be detected within days of the procedure through raised levels of the biomarker CXCL9. Sobi has entered into a partnership with bioMérieux for the development of a companion diagnostic to rapidly measure CXCL9.

Our innovation pipeline[1]



1. Shows studies that have started.
2. Financial interest only.
3. Developed in collaboration with Sanofi.
   The designation efanesoctocog alfa used from February 2021.
4. Financial interest only, in collaboration with AstraZeneca.
5. In collaboration with Apellis.
6. Strategic licensing agreement with Selecta.

»Several pipeline assets are being investigated in multiple indications, mitigating the risk inherent in orphan drug research.«

Pegcetacoplan

Pegcetacoplan is an investigational, targeted C3 therapy designed to regulate excessive complement activation, which is involved in the pathology of a broad range of disorders including various autoimmune and immune diseases. By targeting C3, pegcetacoplan modulates a key component of the complement system.

Under the licensing agreement with Apellis for ex-US development and commercialisation rights to systemic pegcetacoplan, marketing applications for the treatment of paroxysmal nocturnal haemoglobinuria (PNH) were submitted to the FDA and EMA based on positive results from the phase 3 PEGASUS study. Top-line results from the phase 3 PRINCE study, evaluating pegcetacoplan in treatment-naïve patients with PNH, are expected in the first half of 2021. A file was also submitted for PNH in Australia.

Sobi will also lead development activities for cold agglutinin disease and for haematopoietic stem cell transplantation-associated thrombotic microangiopathy (HSCT-TMA). Apellis is leading further studies in the areas of nephrology and neurology; the first patient was dosed in the potentially registrational study of amyotrophic lateral sclerosis (ALS) in November.

Specialty Care

Orfadin/nitisinone

During 2020, the European Commission approved the indication extension of Orfadin for the treatment of alkaptonuria (AKU) in adult patients, making Orfadin the first pharmacological treatment approved for AKU, a rare disease with high unmet medical need.

The development of Orfadin for the treatment of AKU was enabled by the DevelopAKUre programme, an international research consortium including researchers, patient groups and Sobi. DevelopAKUre was initiated by the AKU Society and clinical experts, and received funding from the European Commission.

Sustainability

Our commitment to providing access to treatment for people with rare diseases is not only our company vision but also our main contribution to sustainable development.

Sobi's sustainability strategy is focused on two main areas, aimed at transforming lives for people living with rare diseases:

• Supporting the rare disease community through our **commitment to patients**, working actively by enabling connectedness, ensuring sustainable and secure access to care, and giving a voice to patients. A strong pipeline and expanded access through geographical growth are key elements of our commitment, which puts patient safety first by adhering to the highest pharmaceutical standards

• **Acting responsibly** in everything we do, through high research standards, business ethics and policies aimed at creating a sustainable organisation with the purpose of serving the community. We show our commitment to sustainability by measuring and mapping our emissions, setting ambitions and targets, and working together with our partners to reduce our environmental footprint.

Sobi is a signatory of 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 willingness to contribute to the realisation of Agenda 2030 and the Paris Agreement.

Commitment to patients

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

R&D focused on medical need

In 2020, our R&D portfolio was expanded to include more drug candidates and investigations in multiple indications, 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 13–15 per cent of revenue for 2021–2022.

Six products are currently involved in 12 development programmes; five medicines in the pipeline either have novel mechanisms of action or are first-in-class.

Where orphan drug regulations can shorten time to patient, they will be used, as was the case when the FDA granted a priority review designation for pegcetacoplan for the treatment of paroxysmal nocturnal haemoglobinuria (PNH).

The development strategy also includes exploring innovative approaches that help optimise treatment outcomes. In the digital health area, Sobi's subsidiary Florio launched the digital medical device florio HAEMO and the florio HAEMO kids app. Within precision medicine, Sobi's partnership with bioMérieux aims to develop a companion diagnostic to detect HSCT graft failure. We are also exploring the potential of genetic screening to gain deeper insights into patient care in HLH.

12
programmes in rare diseases

5
novel mechanisms of action

Patient access

In 2020, we expanded the potential for access to treatments in three new markets, by establishing and enlarging operations in China, Japan and Australia.

We also took part in many events advocating for support for people living with rare diseases. At one such event, we joined EUCOPE (European Confederation of Pharmaceutical Entrepreneurs) at the World Pharma Pricing, Market Access & Evidence Congress 2020 to discuss how to evaluate innovation.

Humanitarian aid

In 2020, we announced an extension of our support for the World Federation of Hemophilia (WFH) 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.

Since the initial pledge, more than 538 million IU have been donated and over 17,330 people with haemophilia have been treated with factor donated by Sobi and Sanofi. Both companies are recognised by the WFH as Founding Visionary Partners of this programme.

By providing a more predictable and sustainable flow of treatment, the WFH programme allows patients to receive consistent and reliable access to therapy and care. In addition, educational programmes for treaters and patients are critical for developing domestic capacities to improve diagnosis and treatment monitoring, and enabling long-term sustainable change.

Realising that donations do not provide sustainable or long-term access to treatment, we strive to transform donations to access within the regulated healthcare system where possible.

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

17,330 people reported treated in 43 countries	Over 198,000 acute bleeds treated	Over 2,960 surgeries, including limb-saving	538 million IU of factor donated

Community engagement

At the 10th European Conference on Rare Disease & Orphan Products (ECRD) in May 2020, the rare disease community voiced the need to be included in efforts to achieve Universal Health Coverage (UN SDG3, Good health and Well-being), as well as efforts to ensure non-discrimination on the basis of health or disability status (SDG 10, Reducing Inequalities). Sobi aims to support the achievement of these goals in collaboration with the patient community.

In 2020, Sobi supported several social media and online communities as well as networking events and patient summits specifically addressing the COVID-19 situation. Informational tools and materials for patient caregivers and healthcare personnel to facilitate knowledge sharing were part of this support.

Knowledge sharing

Each rare disease is so uncommon that knowledge about the disease is also rare, often leading to delayed diagnosis. Understanding the experience of living with a rare disease can provide important information and increased knowledge about disease burden and treatment options.

Sobi regularly attends scientific meetings to share medical advancements and to take part in discussions to enhance the practice of medicine. We also arrange advisory boards to seek advisor input into key clinical and scientific questions, continuing to develop our medicines to meet unmet needs. The challenges of COVID-19 were met by the widespread adoption of virtual meetings and webinars, and online events.

Sobi is a long-term supporter 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's annual support to 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.

Focus on patient safety

The patients we serve are among the most vulnerable. Many are children with a rare disease they will have to live with for the rest of their lives. Working with rare diseases adds another dimension to patient safety, because less information is available than for more widespread illnesses, and skilled 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.

Responsible behaviour

We aim always to act ethically and expect the highest standards of ethical behaviour from our employees. In return, we offer a healthy workplace with continuous professional development opportunities.

Our five core values – Care, Ownership, Urgency, Partnership and Ambition – aim to ensure that more patients benefit from our therapies, now and in the future.

Caring for our employees

Our workforce is essential for our ability to deliver on our strategy. Over the course of 2020, we welcomed over 400 individuals to Sobi, and finished the year with more than 1,500 highly skilled employees in more than 30 countries around the world.

During the year, the COVID-19 pandemic greatly impacted employees across the world. Sobi protected the health and safety of employees by promoting working from home and allowing only business-critical international travel. For employees who were needed physically in the workplace, necessary distancing and safety precautions, such as additional personal protection equipment (PPE), flexible working hours and office attendance planning were implemented.

To retain a high level of employee engagement during the pandemic, Sobi worked extensively to enhance the digital workplace and communication tools, and used surveys to understand perceived challenges and involve employees in Sobi's future.

Engagement survey

In 2020, a Global Engagement Survey was conducted with over 85 per cent of employees responding. Employee engagement was on par with the industry, strongly correlated to high employee competence-fit and patient focus.

Positive relationships with our employees support their development, wellbeing and job satisfaction, and we are proud to offer a safe, healthy and inclusive workplace with equal development opportunities for all.

No tolerance for corruption

Responsible behaviour is promoted through the company values and Code of Conduct. In 2020, a new, updated Code of Conduct was launched and made available for internal as well as external stakeholders. The whistleblower hotline was also extended to include external parties.

In 2020, a geographic shift increased Sobi's risk exposure to new markets in Asia and Russia. Organic growth also continued, with new employees joining the company. In line with these changes, policies, systems and training are continuously reviewed to ensure our high standards are maintained.

97 per cent of Sobi's employees completed the Code of Conduct training in 2020.

50%

reduction of Sobi's CO_2 emissions since 2016

>30

countries

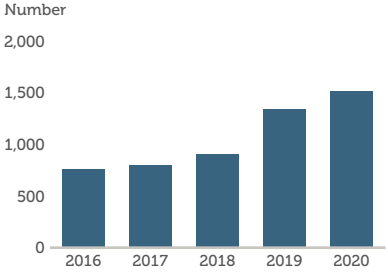
Responsible sourcing

With a largely outsourced supply chain, we rely on sustainable and robust suppliers to produce, package and distribute our products. Sobi's application to join the Pharmaceutical Supply Chain Initiative (PSCI) was approved in January 2020.

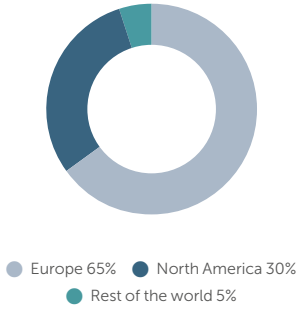
The Responsible Sourcing Programme, introduced in 2019, was implemented across Sobi during 2020. This includes the Partner Code of Conduct, which is available in several languages on Sobi's

Employees

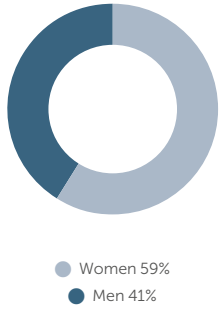
Number of employees



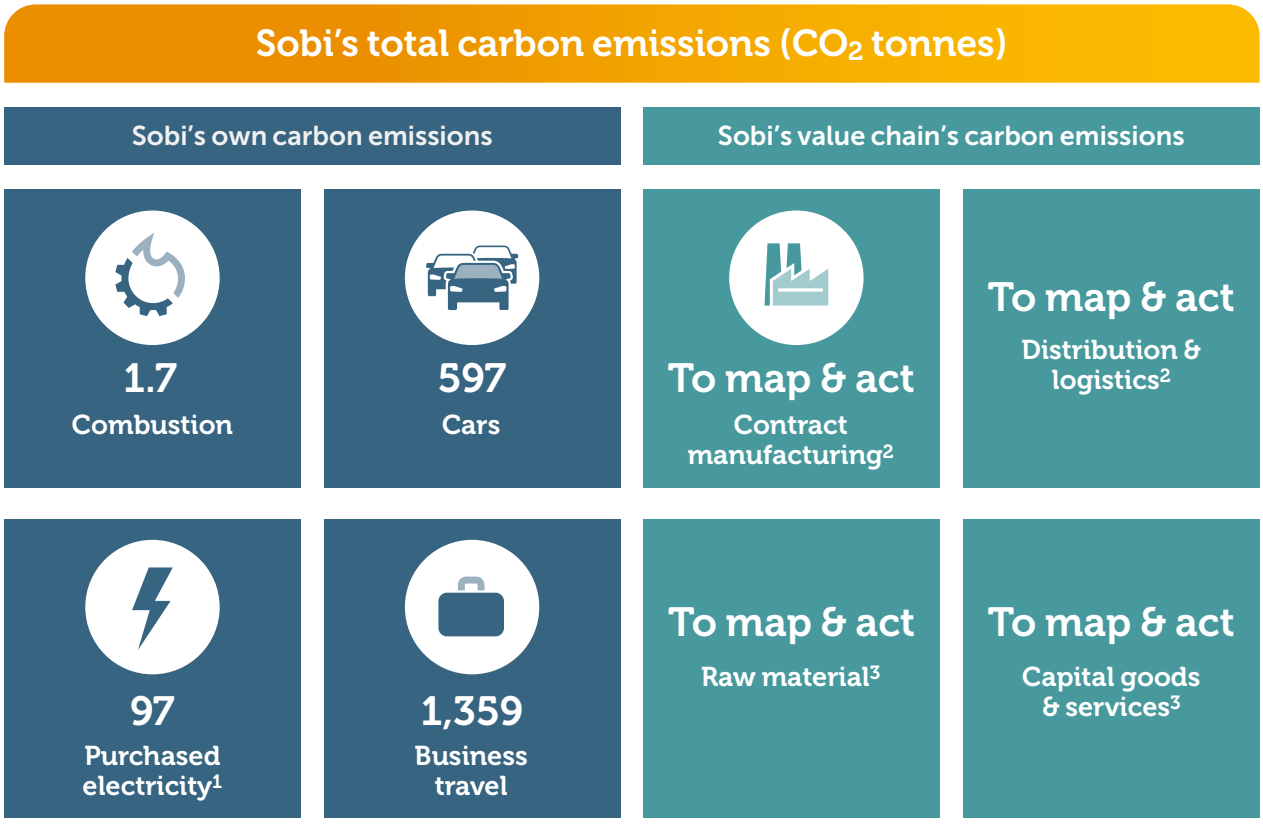
Geographical distribution



Gender distribution



Sobi's greenhouse gas emissions



Direct and indirect emissions (Scope 1, 2 and parts of Scope 3)
1. Calculation methods have been adjusted. See Sustainability notes p 122.

Other indirect emissions (rest of Scope 3), in the value chain to be mapped by 2022.
2. Hybrid method based on supplier direct reporting will be used
3. GHG-protocol calculations based on spend will be used

website, and risk-based screening of suppliers for compliance with management, labour, human rights, and environmental standards.

Reducing our environmental footprint

Sobi's direct Scope 1 and indirect Scope 2 emissions from our own operations are limited. In 2020, we expanded our reporting practice to include all global operations (leased premises and vehicles).

We have most control over our own operations, and by avoiding, reducing and substituting we are aiming to achieve net zero emissions from our sites and ground fleet by 2030.

The direct emissions derived from the Parent Company's operations have been reduced by 50 per cent since 2016. All electricity consumed at the Stockholm facility was produced from a mix of certified renewable energy sources. The impact of our offices, laboratory and manufacturing facility is described in detail on pages 123–124.

Due to our business model, we can assume that most of our impact on the environment is a result of the activities we source from our contract manufacturers, and the logistics in our supply chain and for the distribution of our products. The greenhouse gas (GHG) emissions derived from sourced activities are classified as indirect Scope 3 emissions.

While the reduction of indirect Scope 3 emissions could have a significant impact, this is also where we have the least control. By 2022, Sobi intends to fully map and calculate the indirect emissions from our supply chain and prioritise the most significant reduction opportunities with Scope 3 emission targets.

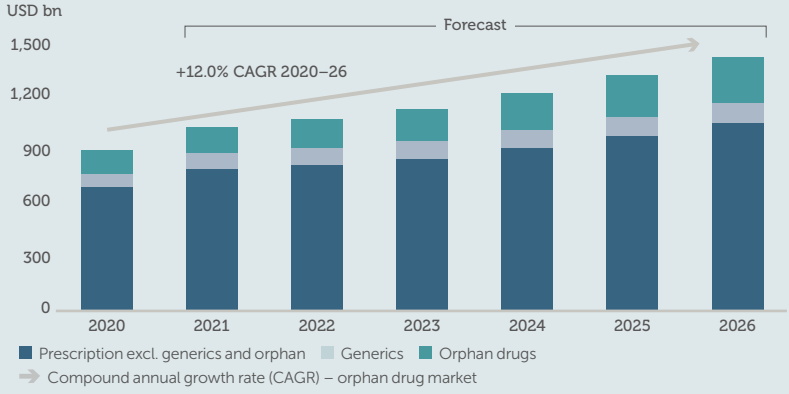
We will focus on areas of producer responsibility. In 2021, as a part of our Responsible Sourcing Programme, we will start communicating our ambitions to suppliers, integrating emissions reporting in business follow-ups and working together with our partners to reduce emissions wherever we can.

Sobi investment case

With a solid financial position and significant potential in our portfolio of pre-market and on-market products, Sobi is well positioned for continued international expansion and profitable growth in an attractive market.

Well positioned in a fundamentally attractive market

Worldwide orphan drug sales & share of prescription drug market (2020–2026).



Source: EvaluatePharma

Sobi is a global player in the rare-disease market, which is characterised by high unmet medical needs. The cost of developing a treatment for a rare disease is high in proportion to the number of patients; such a medicine therefore generally commands a higher price and has a shorter time to market than other pharmaceuticals. Rare disease therapies are also less likely to face generic competition, limiting price pressure.

Read more on page 8.

Strong pre-market pipeline

Sobi has built a strong pre-market pipeline through the continued development of core assets, partnerships and by acquiring promising late-stage assets. External growth is essential for the strategy and Sobi continues to evaluate opportunities. The medium-term focus is on the current pre-market portfolio which has potential to offer significant organic growth opportunities.

Read more on page 20.

	Haematology	Immunology
Pre-market	BIVV001/efanesoctocog alfa[1] – haemophilia A Pegcetacoplan[2] – PNH	Gamifant/emapalumab – sHLH Gamifant/emapalumab – aGF Nirsevimab[3] – RSV Pegcetacoplan – ALS SEL-212[4] – chronic refactory gout

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

Geographical expansion

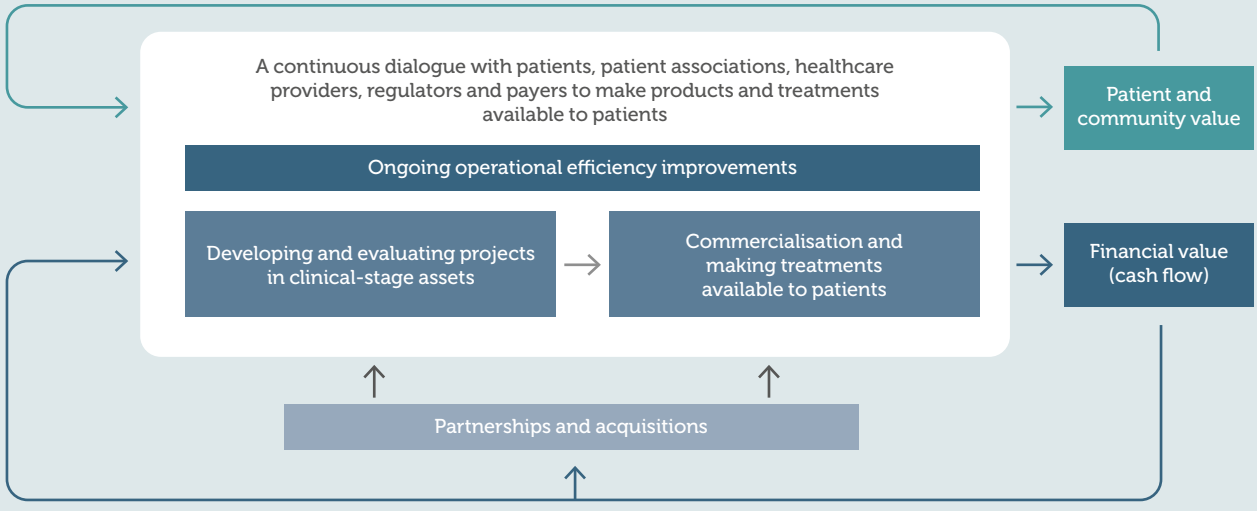
Sobi is represented in more than 30 markets across Europe, North America, the Middle East, Russia and Asia. There is significant potential to expand our global position, with focus on the 15 largest markets representing a majority of the global market for rare diseases. With more late-stage candidates and more on-market products for which we hold the global rights, global expansion should allow us to maximise the growth potential of our portfolio.

Read more on page 18.

Commercial excellence is our core competence

Our core competence is late-stage clinical development and commercialisation, which opens up for co-development opportunities. Commercial excellence refers to our skills and experience, competence and the networks required to launch innovative rare-disease and niche medicines for sustainable patient access.

Read more on page 10.



Cash flow and financial position support growth

Sobi has a strong cash conversion rate, which has enabled investments in on-market products and late-stage assets in the R&D portfolio as well as in focused acquisitions. The ambition is to further strengthen cash flow and profitability in the commercial portfolio, and to drive development projects to market launch over the next five years. Sobi has good financial capacity based on a strong operational cash flow which enables debt-financed external growth followed by quick reduction of debt.

The share

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

In 2020 the highest price paid was SEK 240.8 on 23 September, and the lowest was SEK 127.8 on 17 March. Sobi's market capitalisation at year-end 2020 was SEK 50.5 billion. Over 2020, the share price increased by 7.1 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 2020, trading on Nasdaq Stockholm accounted for over 70 per cent of the total turnover.

Average daily total turnover in Sobi shares was 987,486 on Nasdaq Stockholm. In 2020, a total of 248.8 million shares were traded, corresponding to a value of approximately SEK 45.5 billion.

Share capital

At 31 December 2020, the total number of ordinary shares outstanding, excluding shares in treasury, comprised 294,896,839. All issued shares are ordinary shares and carry one vote per share.

At year-end, the share capital was SEK 166,710,655, distributed between 303,815,511 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 eight active share programmes, all vesting within three years. The programmes represent a total maximum of 2,343,465 shares, or 0.8 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 33,816 (25,226). The largest shareholder, Investor AB, held 35.4 per cent (35.9) of the shares. Swedish legal entities, including institutions and funds, held 64.9 per cent (59.3) of the shares. Shares held by Swedish Orphan Biovitrum AB (publ) at year-end totalled 8,918,672 common shares.

During the year 599,530 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 2020. For more information about Sobi's dividend policy, please refer to the Corporate Governance Report.

Largest shareholders at 31 December 2020[1]

SHAREHOLDERS	Number of A shares	Share capital, %	Share votes, %
Investor AB	107,594,165	35.4	35.4
Morgan Stanley Smith Barney LLC, W9	24,196,377	8.0	8.0
Swedbank Robur Fonder	14,825,497	4.9	4.9
Fjärde AP-fonden	13,783,356	4.5	4.5
State Street Bank and Trust Co, W9	12,421,288	4.1	4.1
Handelsbanken fonder	9,278,636	3.0	3.0
Swedish Orphan Biovitrum AB (publ.)	8,918,672	2.9	2.9
AMF - Försäkring och Fonder	5,833,337	1.9	1.9
HSBC bank PLC, W8IMY	5,205,063	1.7	1.7
Cbny-Norges Bank	3,931,645	1.3	1.3
Lannebo fonder	3,870,000	1.3	1.3
JP Morgan Chase Bank NA	3,518,678	1.2	1.2
JP Morgan Bank Luxembourg S.A.	2,803,912	0.9	0.9
SEB Investment Management	2,798,301	0.9	0.9
BNY Mellon NA (former Mellon), W9	2,619,708	0.9	0.9
Total 15 largest shareholders	**221,598,635**	**72.9**	**72.9**
Other	82,216,876	27.1	27.1
Total	**303,815,511**	**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	2016	2017	2018	2019	2020
A shares	1,240,305	784,589	900,760	778,920	987,486

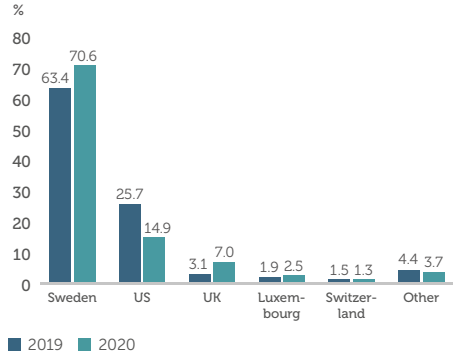
Source: Nasdaq

Shareholder categories

31 DECEMBER 2020	% of capital
Foreign shareholders	29.7
Swedish shareholders	70.3
whereof	
Institutions	64.9
Natural persons	5.3

Source: Euroclear.

Shareholders by country

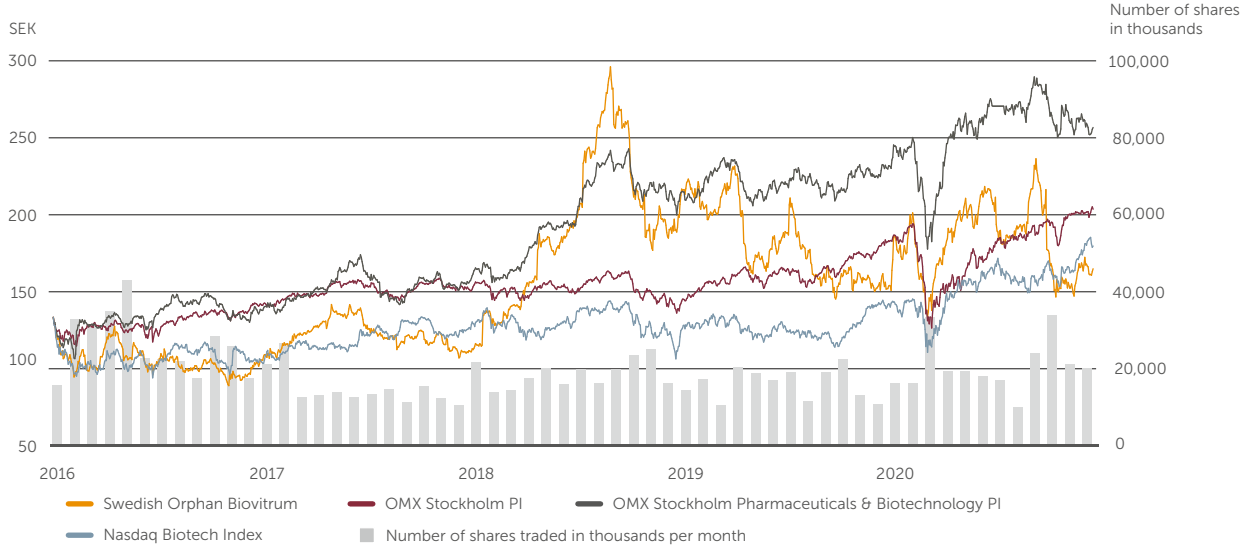


Source: Euroclear.

Key data per share

SEK	2016	2017	2018	2019	2020
Earnings/loss per share	2.99	4.27	8.97	11.29	11.01
Equity per share	19.8	24.6	33.1	56.4	66.5
Market price, Series A-share, 31 Dec., last paid price	106.7	112.3	193.0	154.5	166.1
P/E ratio	35.7	26.3	21.5	13.7	15.1
Number of shares at 31 Dec.	272,010,948	272,507,708	273,322,117	299,977,839	303,815,511

Sobi share price and trading volume 2016–2020



Five-year summary – Group development

	2016	2017	2018	2019	2020
Income statement, SEK M					
Operating revenue	5,204	6,511	9,139	14,248	15,261
Gross profit	3,651	4,657	6,723	10,913	12,036
EBITDA[1]	1,574	2,086	3,607	6,121	6,830
EBITA[1]	1,543	2,053	3,571	5,933	6,700
EBITA adjusted[1,2]	1,543	2,053	3,571	6,145	6,301
EBIT (operating profit)	1,133	1,600	3,122	4,533	4,818
Profit/loss for the year	802	1,149	2,418	3,304	3,245
Capital, SEK M					
Total assets	9,974	10,903	17,183	45,658	48,283
Capital employed[1]	5,880	6,716	9,048	33,560	34,777
Equity	5,365	6,701	9,040	16,930	20,206
Cash and cash equivalents	786	1,478	2,999	737	404
Net debt (+)/net cash (–)[1]	–289	–1,478	–2,999	15,404	13,748
Cash flow, SEK M					
Cash flow from operating activities before changes in working capital	642	1,431	2,341	5,300	5,398
Cash flow from operating activities	343	1,333	2,090	3,634	5,214
Cash flow from investing activities	–158	–139	–575	–21,686	–3,964
Cash flow from financing activities	–308	–500	–1	15,780	–1,570
Change in cash and cash equivalents	–123	694	1,514	–2,271	–320
Key figures, %					
Gross margin[1]	70	72	74	77	79
EBITA margin[1]	30	32	39	42	44
EBITA margin adjusted[1,2]	30	32	39	43	41
Return on capital employed[1]	19.3	23.8	34.5	13.5	14
Return on equity[1]	16.0	19.0	30.7	25.4	17
Equity ratio[1]	54	61	53	37	42
Debt/equity ratio[1]	86	63	90	170	139
Share ratio, SEK					
Earnings/loss per share	2.99	4.27	8.97	11.29	11.0
Equity per share[1]	19.8	24.6	33.1	56.4	66.5
Cash flow per share[1]	–0.5	2.6	5.6	–7.8	–1.1
Cash flow from operating activities per share[1]	1.3	5.0	7.8	12.4	17.7

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.

Reporting

Contents

Directors' Report

The Board of Directors and the CEO of Swedish Orphan Biovitrum AB (publ.), organisation number 556038-9321, submit the following annual report and consolidated financial statements for financial year 2020.

Highlights 2020

Financial highlights

- Total revenue of SEK 15,261 M (14,248), an increase of 7 per cent.
- The gross margin was 79 per cent (77).
- EBITA was SEK 6,700 M (5,933).
- Adjusted EBITA was SEK 6,301 M (6,145), an increase of 3 per cent, corresponding to an adjusted EBITA margin of 41 per cent (43). Adjusted EBITA excludes a positive impact of SEK 399 M from reversal of the Contingent Value Right (CVR) liability. See page 36 under operating profit for more information.
- Profit for the year totalled SEK 3,245 M (3,304), representing earnings per share of SEK 11.01 (11.29), adjusted earnings per share amounted to SEK 9.66 (11.89).
- Cash flow from operating activities was SEK 5,214 M (3,634).

Business highlights

- Sobi concluded the strategic licensing agreement with Selecta Biosciences, Inc. related to the product candidate SEL-212, a potential treatment for chronic gout.
- Sobi and Apellis entered into a collaboration, whereby Sobi has paid USD 250 M to Apellis, for global co-development and ex-US commercialisation of systemic pegcetacoplan in rare diseases with an urgent need for new treatments.
- Doptelet® (avatrombopag) was approved by the European Commission in January 2021 for the treatment of ITP.
- Sobi launched Doptelet in Europe.
- Orfadin® (nitisinone) was approved by the European Commission in October 2020 for the treatment of AKU.
- Sobi signed a new distribution agreement with Akcea regarding sales of the products Tegsedi® and Waylivra®.
- Sobi established operations in Japan and Australia.
- Emapalumab received a negative opinion from the CHMP in Europe for the treatment of primary HLH.
- Results from the phase 3 study with Doptelet for the treatment of CIT were published. As expected, avatrombopag increased platelet counts compared with a placebo, but the study did not meet the combined primary endpoint of avoiding a platelet transfusion.

Sobi's operations

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

In 2020, revenue was generated by:

- Sales in Europe and rest of the world of the proprietary products Elocta® and Alprolix®, and royalty revenue from Sanofi's sales of Eloctate® and Alprolix
- Global sales of the proprietary products Doptelet, Kineret® and Orfadin.
- Sales in the US of the proprietary products Gamifant® and Synagis®.
- Sales in Europe and rest of the world of products for which Sobi holds distribution and/or licensing agreements.
- Manufacturing of the drug substance for ReFacto AF®/Xyntha® for Pfizer.

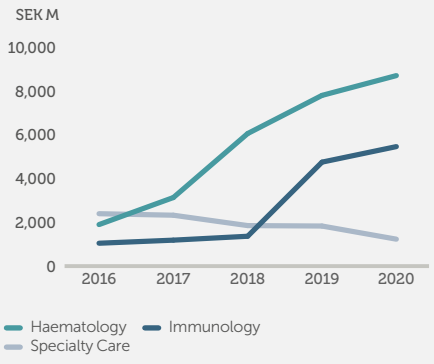
Key figures

SEK M	2020	2019
Total revenue	15,261	14,248
Gross profit	12,036	10,913
Gross margin[1]	79%	77%
EBITA[1]	6,700	5,933
EBITA adjusted[1]	6,301	6,145
EBITA margin[1]	44%	42%
EBITA margin adjusted[1]	41%	43%
Profit for the year	3,245	3,304
Earnings per share, before dilution, SEK	11.01	11.29
Earnings per share, before dilution, adjusted SEK[1]	9.66	11.89

1. Alternative Performance Measures, see Definitions on page 136.

See page 32 for a five-year summary of revenue, expenses and earnings.

Five-year revenue trend



Total revenue
In 2020, total revenue amounted to SEK 15,261 M (14,248), an increase of 7 per cent (8 per cent at CER).

Revenue by business area
Haematology
Revenue for Haematology amounted to SEK 8,660 M (7,755), an increase of 12 per cent (13 per cent at CER).

Sales of Elocta amounted to SEK 4,585 M (4,508), an increase of 2 per cent (3 per cent at CER). Patient growth continued, but sales were adversely impacted by lower consumption per patient due to the COVID-19 pandemic, as well as unfavourable price adjustments and order patterns.

Sales of Alprolix amounted to SEK 1,705 M (1,463), an increase of 17 per cent (18 per cent at CER). The sales growth was driven by underlying patient growth, but this was adversely impacted by lower consumption per patient due to the prevailing pandemic.

Sales of Doptelet amounted to SEK 587 M (34 for the 12 November–31 December period of 2019) including a milestone revenue of SEK 87 M related to marketing approval for the CLD indication in China.

Royalty revenue amounted to SEK 1,301 M (1,373), derived from Sanofi's sales of Eloctate and Alprolix.

Manufacturing revenue for ReFacto amounted to SEK 481 M (376), an increase of 28 per cent.

The current manufacturing agreement for ReFacto AF/Xyntha is valid until 31 December 2025.

Immunology
Revenue for Immunology totalled SEK 5,415 M (4,706), an increase of 15 per cent (16 per cent at CER).

Sales of Kineret amounted to SEK 2,079 M (1,571), an increase of 32 per cent (35 per cent at CER). The strong trend for Kineret has continued, with double-digit growth, driven by strong underlying demand in all regions. Sales were also positively impacted by the use of Kineret for treating COVID-19 patients.

Sales of Gamifant amounted to SEK 609 M (542), an increase of 12 per cent (16 per cent at CER). The number of patients continued to rise, but sales was offset by a slightly lower price.

Sales of Synagis amounted to SEK 2,726 M (2,594 for the 23 January–31 December period of 2019). The RSV season was very mild with almost no RSV reported across the US in the fourth quarter, largely thought to be a result of COVID-19 measures such as social distancing and travel restrictions, resulting in weak underlying demand for Synagis. However, previously implemented efficiency measures, improved dose adherence and a new distribution system partly offset the negative effects of the milder RSV season.

Specialty Care
Specialty Care revenue amounted to SEK 1,186 M (1,787), a decrease of 34 per cent (–33 per cent at CER).

Annual sales of Orfadin amounted to SEK 665 M (827). The decrease was attributable to generic competition for Orfadin and subsequent price erosion.

Revenue for other Specialty Care products amounted to SEK 521 M (959). The decrease is related to product divestment.

Gross profit
Gross profit totalled SEK 12,036 M (10,913), representing a gross margin of 79 per cent (77). The increase in gross margin was driven by a favourable product mix and ceased royalty obligations.

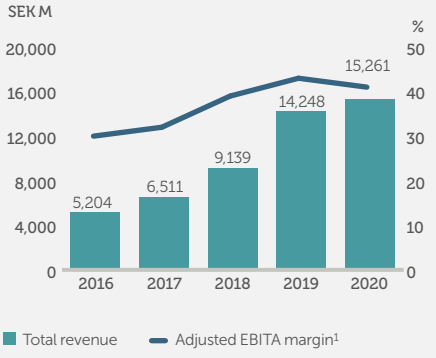
Operating expenses
In 2020, operating expenses increased to SEK 7,575 M (6,430).

Sales and administrative expenses excluding amortisation and write-downs, amounted to SEK 4,099 M (3,535). The expenses increased due to the inclusion of the Dova business, launch preparations for Doptelet and geographic expansion in Asia.

Research and development expenses amounted to SEK 1,594 M (1,495). The increase reflects spending related to programmes for emapalumab, avatrombopag, SEL-212 and pegcetacoplan.

Operating expenses also include expenses of SEK 114 M (80) for the long-term incentive programmes. Cash flow will not be affected

Total revenue and adjusted EBITA margin[1]



Revenue by business area

SEK M	2020	2019
Haematology	8,660	7,755
Immunology	5,415	4,706
Specialty Care	1,186	1,787
Total revenue	15,261	14,248

1. Alternative Performance Measures, see Definitions on page 136.

by the share-based programmes until they expire, and then in the form of social security contributions.

Other operating income and expenses amounted to SEK 357 M (50). Operating revenue for the year mainly pertains to the reversal of SEK 399 M for the CVR liability, see also under Operating profit.

Operating profit

Operating profit before amortisations and write downs on intangible assets (EBITA) amounted to SEK 6,700 M (5,933), corresponding to a margin of 44 per cent (42). Adjusted EBITA was SEK 6,301 M (6,145), corresponding to a margin of 41 per cent (43). Adjusted EBITA excludes 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-transferrable 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 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. Consequently, the corresponding liability on the balance sheet was reversed, positively impacting other operating income by SEK 399 M. Adjusted EBITA for 2019 excludes transaction costs of SEK 92 M related to the acquisition of Dova, restructuring costs of SEK 157 M and a gain of SEK 37 M from the divestment of SOBI005.

For operating profit by segment, see Note 5.

Amortisation and write-downs of intangible assets amounted to SEK 1,882 M (1,401). The increase was mainly attributable to amortisation of product and marketing rights related to Synagis, Gamifant and Doptelet.

Operating profit (EBIT) totalled SEK 4,818 M (4,533), an increase of 6 per cent.

Net financial items

Net financial items totalled SEK −601 M (−286), including exchange rate losses of SEK −115 M (−31) driven by high volatility in currency rates. The year-on-year increase is mainly attributable to new borrowings and liabilities arising from acquisitions completed in 2019.

Tax

Total tax amounted to SEK −972 M (−942), of which SEK −1,125 M (−449) pertained to current tax and SEK 153 M (−494) to deferred tax. The Group's effective tax rate was 23.1 per cent (22.2). See also Note 15 and 20.

Profit

Profit for the year totalled SEK 3,245 M (3,304). Earnings per share, before dilution, amounted to SEK 11.01 (11.29).

Revenue by business area

SEK M	2020	2019	Change
Elocta	4,585	4,508	2%
Alprolix	1,705	1,463	17%
Royalties	1,301	1,373	−5%
Doptelet	587	34	>100%
Manufacturing	481	376	28%
Haematology	**8,660**	**7,755**	**12%**
Kineret	2,079	1,571	32%
Synagis	2,726	2,594	5%
Gamifant	609	542	12%
Immunology	**5,415**	**4,706**	**15%**
Specialty Care	**1,186**	**1,787**	**−34%**
Total revenue	**15,261**	**14,248**	**7%**

Revenue by region

SEK M	2020	2019	Change
Europe	7,620	7,468	2%
North America	5,483	4,586	20%
Rest of the world	857	821	4%
Other[1]	1,301	1,373	−5%
Total	**15,261**	**14,248**	**7%**

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	2020	2019	2018	2017	2016
Total revenue	15,261	14,248	9,139	6,511	5,204
Cost of goods sold	−3,225	−3,335	−2,415	−1,854	−1,554
Research and development expenses	−1,594	−1,495	−1,090	−908	−778
Operating profit (EBIT)	4,818	4,533	3,122	1,600	1,133
Net financial items	−601	−286	−40	−68	−85
Profit for the year	3,245	3,304	2,418	1,149	802
Earnings per share, SEK	11.01	11.29	8.97	4.27	2.99
Earnings per share after dilution, SEK	10.90	11.22	8.93	4.25	2.98
Number of shares, 000s	303,816	299,978	273,322	272,508	270,390
Equity/assets ratio[1]	42%	37%	53%	61%	54%

1. Alternative Performance Measures, see Definitions on page 136.

Cash flow and investments
Cash flow from operations before changes in working capital was SEK 5,398 M (5,300). Working capital affected cash flow by SEK –184 M (–1,666), driven by inventory build-up partially offset by sales related accruals.

Cash flow from investing activities was SEK –3,964 M (–21,685) and includes the investments for pegcetacoplan of SEK –2,198 M and SEL-212 of SEK –977 M. The 2019 figure includes the acquisition of Synagis and Dova.

Cash flow from financing activities amounted to SEK –1,570 M (15,780). During the year, repayments of loans were possible due to the strong cash flow from the day-to-day operations.

Financial position
At 31 December 2020, cash and cash equivalents and amounted to SEK 404 M (737).

At 31 December 2020, undrawn committed credit facilities amounted to SEK 4,320 M (3,959) and drawn facilities totalled SEK 14,234 M (16,243). These comprise total credit facilities of EUR 1,540 M and SEK 3,000 M, and an overdraft of SEK 250 M. In 2020, the maturity of one credit facility of EUR 190 M was extended by one year to 2022. During the year, one undrawn credit facility of SEK 1,000 M expired. See Note 3 for more information about maturity structure. At 31 December 2020, net debt was SEK 13,748 M (15,404).

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 16 and 28.

Equity
At 31 December 2020, consolidated shareholders' equity was SEK 20,206 M (16,930).

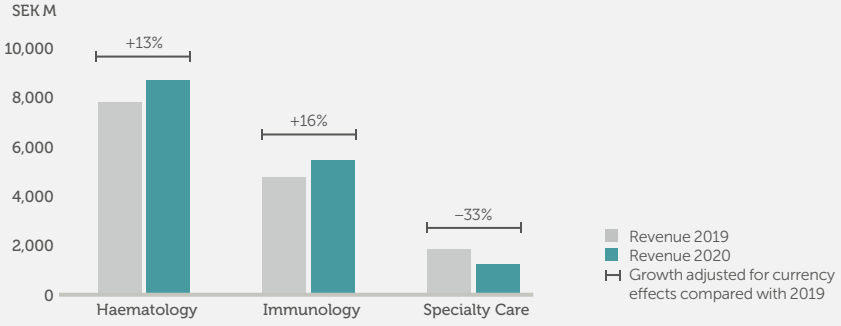
Parent Company
The Parent Company's business model is to develop, register, distribute and market drugs for rare diseases.

Total revenue amounted to SEK 13,968 M (12,991) and operating profit totalled SEK 5,833 M (4,536). Profit for the year totalled SEK 3,406 M (1,118), including excess depreciation of SEK –107 M (–400) and Group contributions of SEK –1,583 M (–2,766).

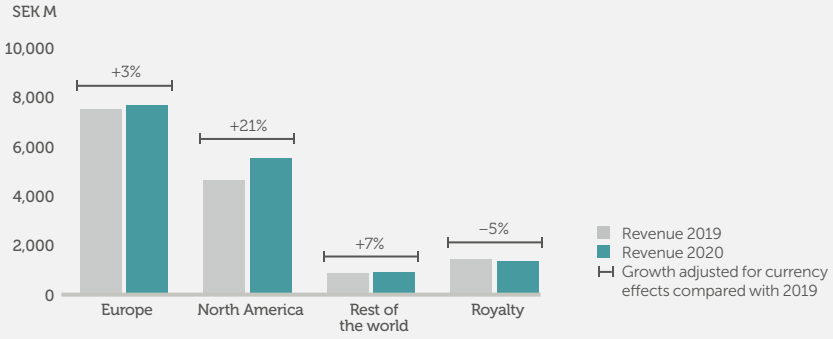
Investments in fixed assets amounted to SEK –3,760 M (–673) of which SEK –2,198 M pertained to pegcetacoplan and SEK –977 M to SEL-212.

At 31 December 2020, cash and cash equivalents amounted to SEK 240 M (431). At 31 December 2020, equity amounted to SEK 17,200 M (13,534).

Revenue by business area



Revenue by region



Development

Sobi's pipeline projects include development programmes, primarily in the areas of Haematology and Immunology. Sobi is also conducting a number of projects to gather evidence for the company's existing products.

During the year, Sobi entered into agreements with Selecta and Apellis. Under the licensing agreement with Selecta for the product candidate SEL-212, 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. Under the agreement with Apellis, Sobi obtained the rights to global development and ex-US commercialisation of systemic pegcetacoplan.

The development of BIVV001 (efanesoctocog alfa), currently a phase 3 study conducted jointly with Sanofi, continued during the year. BIVV001 is a factor haemophilia A therapy under development and is a new class of FVIII replacement therapy that has shown the potential to provide high sus-

tained levels of factor VIII (FVIII) activity for most of the week with once-weekly dosing. BIVV001 is the first von Willebrand-independent FVIII therapy in clinical development and has the potential to transform replacement therapy for people with haemophilia A.

Clinical programmes with the aim of studying new applications for anakinra and emapalumab are also ongoing.

Development events during the year

Partnership with Apellis

Under the agreement with Apellis, the companies will jointly advance systemic pegcetacoplan in five parallel registrational programmes, of which three are ongoing in haematology (PNH), nephrology (C3G/IC-MPGN) and neurology (ALS). The remaining two haematology studies (CAD and HSCT-TMA) are planned to start up in 2021.

Sobi and Apellis announced positive topline results from the phase 3 PEGASUS study at week 48. Patients with paroxysmal nocturnal hemoglobinuria (PNH) who were treated with pegcetacoplan, a targeted C3 therapy that is under development, showed sustained and clinical improvements. The safety profile of pegcetacoplan was consistent with previously reported data and no new safety signals were identified.

Sobi and Apellis announced that the first patient had been dosed in the potentially registrational phase 2 MERIDIAN study. The study is evaluating pegcetacoplan in approximately 200 adults with sporadic amyotrophic lateral sclerosis (ALS).

Doptelet approved in the EU for the treatment of ITP

Doptelet was approved by the European Commission in January 2021 for the treatment of primary chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (such as corticosteroids and immunoglobulins).

The CHMP adopted a negative opinion for emapalumab for the treatment of primary HLH in Europe

The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use, the CHMP, adopted a negative opinion recommending the refusal of a marketing authorisation for emapalumab in Europe for the treatment of primary haemophagocytic lymphohistiocytosis (HLH) in children under 18 years of age. The decision confirms the initial opinion adopted by the CHMP in July 2020 that was re-examined at Sobi's request.

Data from several studies presented at the American Society of Hematology (ASH) annual meeting

Sobi's commitment to people living with rare diseases was reflected in 12 congress presentations (oral/poster) related to five different therapies as follows:

- Final results for efficacy and safety of Elocta and Alprolix in previously untreated patients (PUPs) with haemophilia A and B, respectively, were presented in partnership with Sanofi
- An overview of the design of the phase 3 study (XTEND-1) with BIVV001 was presented. BIVV001 is under development in partnership with Sanofi
- Efficacy and safety data for Doptelet in patients with chronic immune thrombocytopenia (ITP) was presented
- Data for emapalumab was reported in three presentations, mostly data from the pivotal phase 2/3 study with analyses confirming the study's primary endpoint, supporting flexible dosing and a favourable safety profile for the use of emapalumab in patients with primary hemophagocytic lymphohistiocytosis (HLH)
- Sobi's partner Apellis presented data from eight congress presentations supporting the efficacy and safety of pegcetacoplan, a targeted C3 therapy for patients with paroxysmal nocturnal hemoglobinuria (PNH).

SmPC for Alprolix updated following favourable efficacy and safety data in paediatric treatment

The European Commission approved an update of the Summary of Product Characteristics (SmPC) for Alprolix to include additional information regarding use among previously untreated patients (PUPs) with haemophilia B. Alprolix is now the only extended half-life factor IX (FIX) product with safety and efficacy data in PUPs included in the SmPC. The data reinforces Alprolix's favourable safety profile for use in all age groups.

Emapalumab's efficacy confirmed by sensitivity analysis presented at the European Society of Immunodeficiencies (ESID) in 2020

Results from the sensitivity analysis from the pivotal phase 2/3 study (NCT01818492) with emapalumab in patients with primary HLH were presented at the 19th meeting of the European Society of Immunodeficiencies (ESID). Analyses of the efficacy of emapalumab in primary HLH using various definitions of treatment response all support the study's primary endpoint of a 63 per cent overall response rate (ORR) in patients with insufficient response to standard of care. The results from the pivotal study were published in the New England Journal of Medicine in May 2020.

Sobi presented topline results from the phase 3 study with avatrombopag in patients with chemotherapy-induced thrombocytopenia (CIT)

Sobi presented topline results from its phase 3 study with avatrombopag, an oral thrombopoietin (TPO) receptor agonist, in solid tumour cancer patients with chemotherapy-induced thrombocytopenia (CIT). Although platelet counts (thrombocytes) increased in avatrombopag-treated patients compared with placebo-treated patients as expected, the study did not meet the combined primary endpoint in terms of avoiding a platelet transfusion, a 15 per cent or more chemotherapy dose reduction, and a four-day or longer delay in the chemotherapy cycle. In the intention to treat (ITT) population (complete analysis), 69.5 per cent of avatrombopag-treated patients and 72.5 per cent of placebo-treated patients responded to the primary endpoint (p=0.72). In the per protocol (PP) population, 85.0 per cent of avatrombopag-treated patients and 84.4 per cent of placebo-treated patients responded to the primary endpoint (p= 0.96).

Partnership with Selecta
During the year, Sobi signed a strategic licensing agreement with Selecta under which Sobi is responsible for the development, as well as regulatory and commercial activities in all markets outside China, of the product candidate SEL-212. Selecta will conduct the phase 3 study on behalf of Sobi. SEL-212 is a combination of Selecta's tolerogenic ImmTOR immune tolerance platform and a therapeutic uricase enzyme (pegadricase), designed to reduce immunogenicity and treat chronic gout with monthly dosing.

Topline data from the phase 2 COMPARE study with SEL-212 was announced in 2020. The study compared the efficacy of SEL-212 with the uricase enzyme approved in the US, pegloticase (Krystexxa®), for the treatment of chronic gout. All data was consistent with stronger performance of SEL-212 versus pegloticase. Although the primary endpoint was not achieved, the underlying data is positive and supports the commencement of the phase 3 DISSOLVE programme.

The first patient was randomised in the first phase 3 study with SEL-212. The phase 3 clinical programme consists of two double-blind, placebo-controlled studies with SEL-212: DISSOLVE I and II. Topline data is expected in the second half of 2022. A Biologics License Application (BLA) for SEL-212 is expected to be submitted to the U.S. Food and Drug Administration (FDA) in the first quarter of 2023.

Orfadin approved in the EU for the treatment of AKU
Orfadin was approved by the European Commission for the treatment of adult patients with alkaptonuria (AKU).

The New England Journal of Medicine (NEJM) published positive final results from the phase 1/2a study of BIVV001 in patients with severe haemophilia A
NEJM published positive final results from a phase 1/2a study of BIVV001 in patients with severe haemophilia A. Results from the phase 1/2a study showed that a single dose of BIVV001 achieved high sustained factor activity and a three to four-fold increase in half-life compared with conventional factor VIII replacement therapies.

Sobi presented data at the ISTH Virtual Congress to highlight the company's commitment to advancing rare haematology treatments
Sobi presented data at the ISTH Virtual Congress (International Society on Thrombosis and Haemostasis) in 2020 strengthening evidence for the efficacy and safety of Elocta and Alprolix for haemophilia A and B. In addition, pharmacokinetic data on BIVV001 and data for Doptelet in treatment for thrombocytopenia within chronic liver disease (CLD) and chronic immune thrombocytopenia (ITP) were presented.

Sobi's subsidiary, Florio GmbH, launched a new digital platform to improve quality of life for people with haemophilia
In 2020, via its subsidiary Florio GmbH, Sobi launched Florio®, a digital medical device designed to improve quality of life for people with haemophilia. Florio consists of a smartphone app that can be combined with a wearable device and a web-based dashboard for physicians, allowing patients to track, monitor and share their health data in real-time with their healthcare teams to enable personalised care. The new technology is intended to enable meaningful discussions between physicians and people living with haemophilia, aimed at reducing the uncertainty around treatment so that patients with haemophilia can lead full and active lives. Florio is being developed with extensive input from both healthcare professionals and people with haemophilia, further supporting Sobi's long term commitment to the community.

Other information

Changes in Management
In 2020, Ravi Rao was appointed as Head of Research & Development, Chief Medical Officer.

At 31 December 2020, 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 Haematology: Philip Wood

Head of International: Norbert Oppitz

Head of Europe: Sofiane Fahmy

Head of Medical & Scientific Affairs: Armin Reininger

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

Head of Technical Operations: Anne Marie De Jonge Schuermans

Head of Communication & Investor Relations: Paula Treutiger

During the year, Amy Pott and Milan Zdravkovic stepped down from the Executive Committee and left Sobi. In the first quarter 2021, Duane H. Barnes, Head of North America, Mahmood Ladha, Head of Business Development and Daniel Rankin, Head of Global Portfolio and Product Strategy (GPPS), were appointed to the Executive Committee, and Philip Wood left. See pages 106–107 for current Executive Committee.

Sustainability Report
Sobi has, in accordance with the Annual Accounts Act, Chapter 6, Section prepared the statutory sustainability report as a separate report which can be found on pages 23–27 and 108–131. 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 97–103.

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. 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 conditions for these 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 2020, no breaches of the conditions were reported by either of the facilities. The company also has an import permit for animal by-products from the Swedish Board of Agriculture, and a permit for handling flammable products. 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 2020, Sobi's share capital amounted to SEK 166,710,655, distributed between 303,815,511 shares, with a par value per share of about SEK 0.55. At 31 December 2020, the total number of ordinary shares outstanding, excluding shares in treasury, comprised 294,896,839, each carrying one vote. At 31 December 2020, Investor AB was Sobi's largest single shareholder with a total of 107,594,165 shares, representing 35.4 per cent of the votes and 35.4 per cent of the capital.

Share conversions
The Annual General Meeting (AGM) on 13 May 2020 authorised Sobi's Board to resolve on an issue of class-C shares, and to repurchase all class-C shares issued in order to hedge the long-term incentive programmes. The AGM also resolved to approve the Board's proposed transfer of shares.

At 31 December 2020, Sobi held 8,918,672 ordinary shares in treasury, with a par value per share of about SEK 0.55, totalling SEK 4.9 M. The shares represent about 2.9 per cent of the total share capital. The shares have been acquired through conversion of class-C shares for the purpose of being allotted to the employees covered by Sobi's share-based programmes. In accordance with the conditions for the programmes, 599,530 treasury shares were distributed to the employees during 2020. The par value per share of these shares was about SEK 0.55, totalling SEK 0.3 M and representing about 0.2 per cent of the total share capital. See Note 10 for more information about Sobi's outstanding share-based programmes at the end of 2020.

All class-C shares issued in 2020 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 page 30.

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 2020 will be presented to the 2021 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:

SEK K	
Share premium reserve	9,023,392
Retained earnings	3,803,035
Profit for the year	3,406,312
Total	**16,232,739**

The Board of Directors proposes no dividend for the 2020 financial year.

The Board proposes that the share premium reserve, retained earnings and profit for the year, SEK 16,232,739 K to be carried forward.

Events after the balance-sheet date

Doptelet approved in the EU for the treatment of chronic immune thrombocytopenia (ITP)
Doptelet was approved in the EU for the treatment of chronic immune thrombocytopenia (ITP) in adult patients with insufficient response to previous treatment. Chronic ITP is a rare autoimmune disorder characterised by low blood platelet counts.

Kineret approved in Russia for the treatment of CAPS
Kineret was approved in Russia by the Ministry of Health of the Russian Federation for the treatment of Cryopyrin associated periodic syndromes (CAPS).

Financial outlook for 2021

The outlook for 2021 is expressed at January 2021 closing exchange rates. The negative currency impact on 2021 performance is expected to be 5–7 per cent on revenues and 6–8 per cent on EBITA compared to average full year 2020 exchange rates.

Revenue for 2021 is expected to be in the range of SEK 14,000–15,000 M. At constant exchange rates this range corresponds to a revenue growth between –2.5 and 4.5 per cent.

EBITA margin is expected to be in the range of 30–35 per cent of revenue.

R&D expenses as a share of revenue are expected to grow to 13–15 per cent reflecting increased investments in SEL-212 and pegcetacoplan, and support for our 12 late-stage programmes.

Risk management

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 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, measured and reported to Sobi's risk management function. Sobi's risk management function presents an aggregated risk scenario 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.

Key risk areas

The main business-related risks are summarised below. The risks are not ranked, but categorised and described.

Pandemics and other external events

External events such as pandemics, natural disasters, war and so forth affect Sobi and place demands on active and agile crisis and risk management, something that Sobi further developed during the COVID-19 pandemic.

Risk	Risk description	Management and comments
Risk of inability to deliver	Increased demand for Sobi's products places higher demands on delivery capacity and logistics chains.	Sobi works continuously to strengthen its partner relationships with good communication and clear delivery plans. During the pandemic, Sobi strengthened its efforts to build up resources, and to secure delivery capacity and product availability.
Risk of access to raw materials, manufacturing capacity and packaging materials	Sobi is affected by change and obstructions to global product flows. Increased vaccine manufacturing is competing with Sobi's needs in terms of access to raw materials, manufacturing capacity and packaging materials.	
Risk of postponed non-essential health services and lower demand for Sobi's drugs	Overburdened hospitals have led to the postponement of other non-essential health services, which is affecting Sobi's patients and demand for Sobi's products, and making access to prescribing physicians difficult. Lockdowns make patient access to medicines difficult. Social distancing has reduced the incidence of other infectious diseases, affecting demand for some of Sobi's products.	Sobi works closely with patient organisations to strengthen information, provide training and increase opportunities for home delivery. There is a strong focus on securing access to high-quality care during the pandemic. Sobi is exploring digital tools that could make contact with care services easier.

Strategic risks

Sobi's ambition is to bring new products to market that meet major unmet medical needs and have strong commercial potential, and to continue developing existing products.

Risk	Risk description	Management and comments
Delays or failures in research pipeline	Development of a new drug all the way to market launch is a capital-intensive, complex and risky process. The probability of reaching the market increases as the project advances through the development process.	Sobi currently has a number of projects in clinical development. New products/programmes were acquired following a proof of concept, which reduces the risk of late failure. The research portfolio is well-balanced, where a number of products are being studied for several indications, which increases the probability of approval.
Obtain approval for drug candidates	Prior to launch, a drug must meet the strict requirements on quality, safety and efficacy that are expected by the regulators. Failure can lead to a delayed or cancelled launch. Clinical evidence requirements are often beyond the company's control.	Sobi has strong relationships with stakeholders among patients and healthcare to identify medical needs with the aim of ensuring that clinical trials correspond to the needs of the regulators and the community for evidence.
Intellectual property protection and patents	Risk that Sobi is not granted or can maintain intellectual property (IP) protection, including patents. Sobi's success will largely depend on these types of protection.	Sobi has a number of valuable patents and patent applications that are handled by recognised experienced and established patent attorneys. Sobi has a designated person to monitor patents in all markets.

Operational risk

Sobi's supply chain is largely outsourced, and contract manufacturing currently takes place in Europe and the US. The focus lies on meeting high standards for pharmaceuticals and ensuring that the size of our supplier network meets our needs.

Risk	Risk description	Management and comments
Ability to attract new employees and develop existing personnel	Sobi operates in a competitive market where employees are the company's most valuable asset. If we cannot attract employees who can contribute with a range of skills and experience, we could be at risk of losing efficiency.	Sobi works to promote good working conditions, leadership and competitive terms of employment. Positive relationships with our employees support development, well-being and job satisfaction, which in turn creates pride among employees and strengthens the Sobi brand.
Collaborations and partnerships	The strategy includes collaboration agreements with other pharmaceutical companies regarding development and launch of some of Sobi's products. There is a risk of limited influence for Sobi, since these partners have considerable decision-making power when it comes to determining the type of work and resources that will be invested in the projects. This could lead to delays in the development and launch of new products.	Clear information flows are essential for successful partnerships. Sobi establishes Joint Steering Committees in all partnership agreements to ensure regular coordination and information sharing.
Quality and availability of contract manufacturing	Sobi's supply chain is largely outsourced, and contract manufacturing currently takes place in Europe and the US. Sobi is dependent on the Good Pharmaceutical Practice (GMP/GDP) compliance of its partners' facilities, and that they are maintained and available.	The focus lies on ensuring that the size of our supplier network meets our needs. Sobi applies a non-conformance management system, and corrective and preventive actions related to Good Pharmaceutical Practice (GxP). Good relationships, clear expectations and well-developed forecasts create opportunities for securing access and delivery.
Violation of environmental, social and governance (ESG) criteria	Sobi is responsible for ensuring compliance with basic sustainability requirements. Non-compliance could cause supply chain disruptions and prevent Sobi from participating in public tenders applying sustainability requirements.	Sobi applies a responsible sourcing programme to ensure that suppliers comply with basic sustainability requirements. Sobi is a member of the Pharmaceutical Supply Chain Initiative (PSCI) to collaborate with and influence the pharmaceutical sector in a positive direction.

Commercialisation and business environment

The approval and subsidisation of medical treatments is completely dependent on external evaluations, which affects the possibility of gaining market access.

Risk	Risk description	Management and comments
Pricing of orphan drugs	In many countries, the market is increasingly affected by cost-awareness in healthcare, which is pushing prices down. Marketing authorisation does not guarantee that the products will be granted pricing or subsidisation approval in the national or regional healthcare systems. A decline in revenue could have a considerable adverse effect on Sobi's operations, earnings and financial position.	Sobi applies a value-based pricing model based on the perceived value of the product that shows clear benefits and the medical needs. In addition, Sobi applies country-specific strategies. By working with most stakeholders throughout the entire development process, we are aiming to anticipate market needs and the demands that will be imposed on the product by paying agencies in the event of authorisation.
Use and recommendation of Sobi's drugs	The use of drugs is affected by regulatory guidelines, recommendations, studies and market acceptance among physicians, patients and procurement organisations. The degree of market acceptance for the company's products depends on a number of factors, of which the vast majority are beyond the company's control.	By working with stakeholders throughout the entire development process, we are aiming to anticipate market needs and the demands that will be imposed on the product by regulators and prescribers in the event of authorisation, and that they will meet the demands that arise over time.
Competition	Sobi's competitors include international pharmaceutical, biotechnology and specialty pharmaceutical companies. Some competitors have considerable financial, technical and human resources, as well as substantial manufacturing, distribution, sales and marketing capacity.	Sobi has unique expertise in orphan drugs. Sobi's operations have been adapted to meet market expectations and needs in such areas as medical expertise, geographic presence and community contacts.
Product counterfeiting	Risk of Sobi's drugs meeting competition from illegally produced drugs and the availability of pirated products in some distribution channels.	Sobi's products have not yet been exposed to pirating. To minimise the risk of counterfeiting, all of Sobi's distribution processes comply with Good Distribution Practice. All of Sobi's products are serialised and have a unique identifier.

Financial and reporting risk

Sobi's financial risk consists of risk areas that largely affect Sobi's financial reporting. Financial and reporting risks includes financial risk, accounting risk, reporting risk and tax risk.

Risk	Risk description	Management and comments
Financial risk	Financial risks refers to the potentially negative impact of financial risk factors. Sobi's main risk factors are currency, liquidity, re-financing, interest-rate, credit and capital risk.	Financial risk management is presented in Note 3.
Accounting risk	The Group makes estimates and assumptions concerning the future, as well as accounting judgements, which could result in accounting risks.	Significant accounting judgements, and the estimates and assumptions entailing a considerable risk of material adjustment to carrying amounts, are presented in Note 4.
Reporting risk	As a growing multi-national group, Sobi may be faced by the challenge of providing a true and fair view in its financial reporting or that reporting is not submitted in time.	The main task of Sobi's Treasury function is to ensure correct and timely financial reporting. This is mainly achieved with clear and communicated accounting rules and reporting processes, joint accounting and reporting systems, as well as analysis and monitoring.
Tax risk	As a multi-national group, Sobi may be affected by changes in policy decisions, changes in local tax laws and other international agreements in all countries and jurisdictions in which the Group operates. These could include internal pricing changes, taxes targeted at the industry or new regulations for local ownership.	Sobi's proactive efforts to manage tax risk include: • Completed tax-compliance processes • Close collaboration between the Group's tax function and subsidiaries • Engaging external experts when required

Compliance risk

Sobi has 1,500 employees in more than 30 countries. Prioritised areas include a strong company culture, high standards of ethics and integrity, and good working conditions.

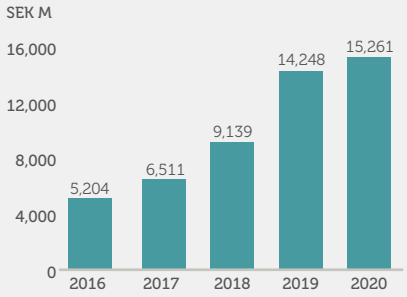
Risk	Risk description	Management and comments
Patient and customer integrity	Risk that the personal data processed by Sobi's business units is not protected could lead to personal data leaks and affect Sobi's credibility.	Sobi agrees to protect the personal integrity of every individual whose personal data the company process. Sobi has a firmly established GDPR process with policies, an updated structure for personal data processing and a designated Data Protection Officer.
Cyber security	As a global organisation, Sobi's IT environment is subject to threats, such as virus and hacking attacks. Cyber attacks could lead to loss of data, regulatory sanctions and lack of trust in the company if sensitive data is leaked to the public.	Stable IT environments, reliable protection and robust infrastructure are essential for the company's operations. Sobi applies a combination of modern security controls with policies, processes and recurring campaigns and training to ensure a stable environment. All processes are continuously developed and updated to ensure that Sobi's IT can prevent, identify and respond to cyber threats and hacking attacks.
Patient safety and ethics	There is a significant risk of poor patient safety and ethical values in research when large parts of the operations are outsourced. It is vital that all research involving people, such as clinical studies, is based on precise, evidence-based evaluations by clinical experts in collaboration with regulators, independent ethical committees and stakeholders. Monitoring and following up the safety profiles of all drugs is a prerequisite for keeping the products on the market.	Sobi collaborates with contract research organisations (CROs) and these collaborations are characterised by mutually applied high standards and processes. All of Sobi's clinical studies are conducted and reported in accordance with applicable laws and Good Clinical Practice (GCP). Sobi complies with the European Medicines Agency's (EMA) policy on the publication of data for medicinal products for human use. Sobi manages a worldwide service for adverse reactions reporting and provides regular training for employees in patient safety.
Anti-corruption, anti-competition, an ethical approach and collaboration	Collaborations with stakeholders are important for sharing of knowledge and experience of rare diseases. A risk of corruption exists in activities where Sobi interacts with healthcare.	Sobi takes a zero-tolerance approach to bribery, which is supported by Sobi's Code of Conduct and Global Anti-Corruption Policy. Both have been incorporated into appropriate business processes. See page 118 for a detailed description of Sobi's anti-corruption efforts.

Consolidated statement of comprehensive income

SEK M	Note	2020	2019
	1–4		
Total revenue	5	15,261	14,248
Cost of goods sold		–3,225	–3,335
Gross profit		**12,036**	**10,913**
Selling and administrative expenses		–5,981	–4,935
Research and development expenses		–1,594	–1,495
Other operating income	7	401	68
Other operating expenses	8	–44	–18
Operating profit	6, 9, 10, 11, 12, 16, 17, 29	**4,818**	**4,533**
Financial income	13	1	5
Financial expenses	14	–602	–291
Net financial items		**–601**	**–286**
Profit before tax		**4,217**	**4,247**
Income tax	15	–972	–942
Profit for the year[1]		**3,245**	**3,304**
Other comprehensive income[2]	25		
Items that cannot be reclassified into profit or loss			
Remeasurement on defined-benefit plan (net of tax)		–3	–4
Fair value of financial investments (net of tax)		9	–
Total		**6**	**–4**
Items that can be reclassified into profit or loss			
Translation differences		–434	–97
Net investment hedges (net of tax)		246	–
Cash flow hedges (net of tax)		130	42
Total		**–58**	**–55**
Other comprehensive income		**–52**	**–57**
Comprehensive income for the year[2]		**3,193**	**3,247**
Earnings per share	25		
Earnings per share, SEK		11.01	11.29
Earnings per share, SEK, adjusted[3]		9.66	11.89
Earnings per share after dilution, SEK		10.90	11.22
Earnings per share after dilution, SEK, adjusted[3]		9.56	11.81

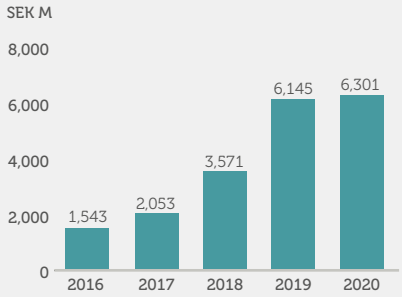
1. Everything attributable to Parent Company shareholders.
2. Under the revised version of IAS 1, all changes in equity not arising from transactions with owners are recognised on the consolidated statement of comprehensive income. Translation differences are entirely related to the consolidated net assets of subsidiaries in foreign currency.
3. Alternative performance measures, see Definitions on page 136.

Total revenue



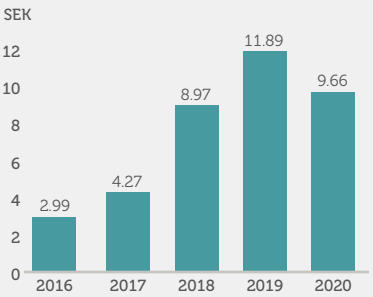
Total revenue
Revenue for the 2020 amounted to SEK 15,261 M (14,248), up 7 per cent.

Adjusted EBITA[3]



Adjusted EBITA for the year rose 3 per cent to SEK 6,301 M compared with 2019.

Adjusted earnings/share[3]

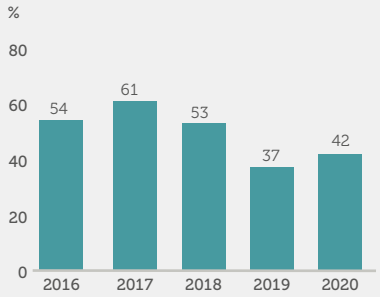


Consolidated balance sheet

SEK M	Note	31 Dec 2020	31 Dec 2019
ASSETS	1–4		
Non-current assets			
Intangible assets	16	38,791	37,412
Tangible assets	17	534	518
Financial assets	19	179	50
Deferred tax assets	20	611	354
Total non-current assets		**40,115**	**38,335**
Current assets			
Inventories	21	3,053	1,772
Accounts receivable	22	3,756	3,736
Other receivables	22	465	530
Prepaid expenses and accrued income	23	490	548
Cash and cash equivalents	24	404	737
Total current assets	26	**8,168**	**7,323**
TOTAL ASSETS		**48,283**	**45,658**
EQUITY AND LIABILITIES			
Equity			
Share capital		167	165
Other contributed capital		9,816	9,697
Other reserves	25	–253	–202
Retained earnings		7,232	3,965
Profit for the year		3,245	3,304
Equity attributable to Parent Company shareholders		**20,206**	**16,930**
Liabilities			
Non-current liabilities			
Borrowings	27	10,137	16,141
Deferred tax liabilities	20	3,464	3,726
Lease liabilities	9	308	320
Provisions	29, 30	252	179
Other liabilities, non-interest-bearing	28	3,473	2,620
Total non-current liabilities	26	**17,634**	**22,987**
Current liabilities			
Borrowings	27	4,015	–
Accounts payable		569	681
Tax liabilities		518	281
Lease liabilities	9	111	99
Other liabilities, non-interest-bearing	28	1,302	1,641
Accrued expenses and deferred income	31	3,928	3,039
Total current liabilities	26	**10,443**	**5,741**
TOTAL EQUITY AND LIABILITIES		**48,283**	**45,658**

Related to pledged assets and contingent liabilities. See Note 32.

Equity/ratio[1]



Net debt (+)/net cash (–)

SEK M	2016	2017	2018	2019	2020
Borrowings	497	–	–	16,141	14,152
Cash and cash equivalents	786	1,478	2,999	737	404
Net debt (+)/net cash (–)	**–289**	**–1,478**	**–2,999**	**15,404**	**13,748**

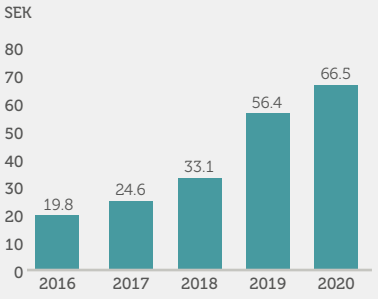
1. Alternative performance measures, see Definitions on page 136.

Consolidated statement of changes in equity

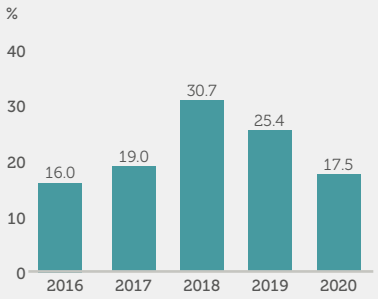
SEK M	Share capital	Other contributed capital	Other reserves[1]	Retained earnings	Total equity
Opening equity, 1 Jan 2019	150	5,069	–144	3,965	9,040
Comprehensive income					
Profit for the year	—	—	—	3,304	3,304
Other comprehensive income					
Remeasurement on defined-benefit plan (net of tax)	—	—	–4	—	–4
Translation differences	—	—	–97	—	–97
Cash flow hedges (net of tax)	—	—	42	—	42
Total comprehensive income	—	—	–57	3,304	3,247
Shareholder transactions					
Issue of shares	15	4,498	—	—	4,513
Share-based compensation to employees	—	80	—	—	80
Share-based compensation to employees tax effect[2]	—	50	—	—	50
Total shareholder transactions	15	4,628	—	—	4,642
Closing equity, 31 Dec 2019	165	9,697	–202	7,270	16,930
Opening equity, 1 Jan 2020	165	9,697	–202	7,270	16,930
Adjusted opening balance for post employment-benefits from prior years[3]	—	—	—	–45	–45
Tax on adjusted opening balance for post employment-benefits from prior years[3]	—	—	—	7	7
Comprehensive income					
Profit for the year	—	—	—	3,245	3,245
Other comprehensive income					
Remeasurement on defined-benefit plan (net of tax)	—	—	–3	—	–3
Remeasurement of equity instruments (net of tax)	—	—	9	—	9
Translation differences	—	—	–434	—	–434
Net investment hedges (net of tax)	—	—	246	—	246
Cash flow hedges (net of tax)	—	—	130	—	130
Total comprehensive income	—	—	–52	3,245	3,193
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	9,816	–253	10,476	20,206

1. For a specification of other reserves, see Note 25.
2. During the period, the Parent Company was granted additional tax deductions for incentive programmes ending in 2013–2018. The additional deductions relate to the difference between the market value of allotted shares and recognised IFRS 2 expense.
3. Refers to post employment-benefits, mainly in Switzerland not previously included at Dec 2019.

Equity/share[4]



Return on equity[4]



Return on equity
Return on equity was 17.5 per cent.

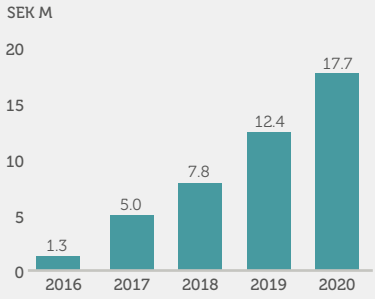
4. Alternative performance measures, see Definitions on page 136.

Consolidated cash flow statement

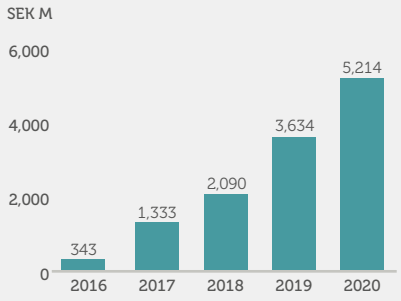
SEK M	Note	2020	2019
Operating activities			
Profit for the year		3,245	3,304
Adjustments for non-cash items		2,153	1,995
Cash flow from operating activities before changes in working capital		**5,398**	**5,300**
Cash flow from changes in working capital			
Decrease (+) / Increase (–) in inventories		–1,306	–459
Decrease (+) / Increase (–) in operating receivables		175	–2,428
Increase (+) / Decrease (–) in operating liabilities		947	1,221
Cash flow from operating activities		**5,214**	**3,634**
Investing activities			
Business acquisitions[1]	16, 17	–	–12,880
Investments in intangible assets[2]	16	–3,811	–9,709
Investments in tangible assets	17	–41	–37
Investments in financial assets[3]	19	–120	–
Disposal of intangible assets[4]	16	–	941
Disposal of tangible assets	17	8	–
Cash flow from investing activities		**–3,964**	**–21,685**
Financing activities			
Borrowings	27	13,575	19,422
Repayment of borrowings		–15,027	–3,548
Repayment of leasing		–118	–94
Cash flow from financing activities		**–1,570**	**15,780**
Change in cash and cash equivalents		**–320**	**–2,271**
Cash and cash equivalents at beginning of year		**737**	**2,999**
Exchange difference in cash and cash equivalents		**–13**	**9**
Cash and cash equivalents at end of year		**404**	**737**

1. Relates to the acquisition of Dova and emapalumab in 2019.
2. The largest investments during the year were pegcetacoplan of SEK –2,198 M and SEL-212 of SEK –977 M. The largest investments in 2019 were SEK 13,869 M related to Synagis, with a cash flow impact of SEK –9,051 M, and SEK 1,817 M related to acquisition of the development and commercial rights to BIVV001 in Sobi's territory, with a cash flow impact of SEK –490 M.
3. Relates to shares in Selecta Biosciences, Inc.
4. 2019 relates to the sale of Priority Review Voucher (PRV), acquired in the business acquisition of emapalumab, and the divestment of SOBI005.

Cash flow from operating activities/share[4]



Cash flow from operating activities[5]



5. Alternative performance measures, see Definitions on page 136.

Consolidated cash flow statement, cont.

Supplemental disclosures to the consolidated cash flow statement

SEK M	Note	2020	2019
Interest paid and received			
Interest received		1	5
Interest paid		−333	−114
Income tax paid		−918	−520
Adjustments for non-cash items			
Amortisation and impairment of intangible assets	6, 16	1,882	1,401
Depreciation and impairment of tangible assets	6, 17	141	188
Cost of share programmes[1]		114	80
Deferred tax	20	−153	411
Elocta and Alprolix[2]		−101	−454
Currency effects		520	333
Reversal of the CVR liability[3]		−399	—
Interest expense[4]		122	53
Other items		27	−16
Total		**2,153**	**1,995**

1. IFRS 2 expense related to the share programmes that is recognised in equity.
2. Relates to royalty revenue used to settle the liability to Sanofi, and interest expense related to the liability to Sanofi.
3. For more information about the reversal of the CVR liability, see page 33.
4. Refers mainly to interest expenses related to additional purchase prices.

Parent Company income statement

SEK M	Note	2020	2019
	1–4		
Total revenue	5	13,968	12,991
Cost of goods sold		–3,134	–3,177
Gross profit		**10,834**	**9,814**
Selling and administrative expenses		–4,174	–4,220
Research and development expenses		–923	–1,110
Other operating income	7	96	62
Other operating expenses	8	–	–10
Operating profit	6, 9, 10, 11, 12, 16, 17	**5,833**	**4,536**
Financial income	13	663	348
Financial expenses	14	–469	–287
Net financial items		**194**	**61**
Profit/loss after financial items		**6,027**	**4,597**
Group contributions, net		–1,583	–2,766
Excess depreciation		–107	–400
Appropriations		**–1,690**	**–3,166**
Profit before tax		**4,337**	**1,431**
Tax on profit for the year	15	–931	–313
Profit for the year		**3,406**	**1,118**

Parent Company statement of comprehensive income

SEK M	2020	2019
Items that cannot be reclassified into profit or loss		
Remeasurement of equity instruments (net of tax)	9	–
Items that can be reclassified into profit or loss		
Cash flow hedges (net of tax)	130	44
Other comprehensive income	**139**	**44**
Comprehensive income for the year	**3,545**	**1,161**

Parent Company balance sheet

SEK M	Note	31 Dec 2020	31 Dec 2019
ASSETS	1–4		
Non-current assets			
Intangible assets	16	10,205	5,572
Tangible assets	17	64	65
Financial assets			
Participations in Group companies	18	7,676	7,676
Receivables from Group companies		15,312	18,389
Other financial assets	19	176	47
Deferred tax assets	20	24	22
Total non-current assets		**33,457**	**31,772**
Current assets			
Inventories	21	2,527	1,533
Current receivables			
Accounts receivable	22	731	2,402
Other receivables	22	405	449
Receivables from Group companies		3,947	1,286
Prepaid expenses and accrued income	23	430	499
Cash and cash equivalents	24	240	431
Total current assets		**8,280**	**6,601**
TOTAL ASSETS		**41,737**	**38,373**

SEK M	Note	31 Dec 2020	31 Dec 2019
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital		167	165
Statutory reserve		800	800
Total restricted equity		**967**	**965**
Unrestricted equity			
Share premium reserve		9,024	8,905
Retained earnings		3,803	2,547
Profit for the year		3,406	1,118
Total unrestricted equity		**16,233**	**12,569**
Total equity		**17,200**	**13,534**
Untaxed reserves			
Excess depreciation		3,091	2,984
Total untaxed reserves		**3,091**	**2,984**
Liabilities			
Non-current liabilities			
Borrowings	27	10,137	16,141
Liabilities to Group companies		157	–
Provisions	30	82	84
Other liabilities, non-interest-bearing	28	2,475	1,273
Total non-current liabilities		**12,851**	**17,499**
Current liabilities			
Borrowings	27	4,015	–
Accounts payable		398	574
Liabilities to Group companies		1,674	1,358
Tax liabilities		467	230
Other liabilities, non-interest-bearing	28	727	623
Accrued expenses and deferred income	31	1,314	1,570
Total current liabilities		**8,595**	**4,356**
TOTAL EQUITY AND LIABILITIES		**41,737**	**38,373**

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 2019	**150**	**800**	**4,277**	**2,503**	**7,731**
Comprehensive income for the year	—	—	—	1,161	1,161
Shareholder transactions					
Issue of shares	15	—	4,498	—	4,513
Share-based compensation to employees	—	—	80	—	80
Share-based compensation to employees tax effect[2]	—	—	50	—	50
Total shareholder transactions	**15**	**—**	**4,628**	**—**	**4,643**
Closing equity, 31 Dec 2019	**165**	**800**	**8,905**	**3,665**	**13,534**
Opening equity, 1 Jan 2020	**165**	**800**	**8,905**	**3,665**	**13,534**
Comprehensive income for the year	—	—	—	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**

1. See specification of equity instruments measured at fair value.
2. During the period, the Parent Company was granted additional tax deductions for incentive programmes ending 2013–2018. 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 166,711 distributed between 303,815,511 ordinary shares with a par value of about SEK 0.55 and one voting right. At the balance-sheet date, the company held 8,918,672 ordinary shares in treasury, corresponding to 2.9 per cent of the total number of shares in the company.

Other comprehensive income	Cash flow hedges	Equity instruments	Total
Opening balance, 1 Jan 2019	**–106**	**—**	**–106**
Gain/loss on remeasurement of hedging instruments recognised in equity	–79	—	–79
Tax on gain/loss on remeasurement of hedging instruments recognised in equity	17	—	17
Transferred to profit or loss for the period	135	—	135
Tax on transferred to profit or loss for the period	–29	—	–29
Closing balance, 31 Dec 2019	**–62**	**—**	**–62**
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 for the period	34	—	34
Tax on transferred to profit or loss for the period	–7	—	–7
Gain/losses on remeasurements of equity instruments recognised in equity	—	11	11
Tax effect on equity instruments	—	–2	–2
Closing balance, 31 Dec 2020	**68**	**9**	**77**

Parent Company cash flow statement

SEK M	Note	2020	2019
Operating activities			
Profit for the year		3,406	1,118
Adjustments for non-cash items		1,550	3,201
Cash flow from operating activities before changes in working capital		**4,957**	**4,318**
Cash flow from changes in working capital			
Decrease (+) / Increase (–) in inventories		–994	–462
Decrease (+) / Increase (–) in operating receivables		2,316	–15,758
Increase (+) / Decrease (–) in operating liabilities		–1,258	–1,796
Cash flow from operating activities		**5,021**	**–13,698**
Investing activities			
Acquisition in subsidiaries		–	–4,201
Investments in intangible assets[1]	16	–3,633	–658
Investments in tangible assets	17	–15	–15
Investments in financial assets	19	–120	–
Disposal of intangible assets	16	8	28
Cash flow from investing activities		**–3,760**	**–4,846**
Financing activities	27		
Borrowings		13,575	19,422
Repayment of borrowings		–15,027	–3,208
Cash flow from financing activities		**–1,452**	**16,214**
Change in cash and cash equivalents		**–191**	**–2,331**
Cash and cash equivalents at beginning of year		**431**	**2,762**
Cash and cash equivalents at end of year		**240**	**431**

Supplemental disclosures to cash flow statement – Parent Company

SEK M	Note	2020	2019
Interest paid and received			
Interest received		387	230
Interest paid		–343	–128
Income tax paid		–747	–435
Adjustments for non-cash items			
Group contributions, unpaid		1,583	2,766
Depreciation/amortisation and impairment of assets	6, 16, 17	347	381
Cost of share programmes[1]		68	54
Excess depreciation		107	400
Elocta and Alprolix[2]		–92	–454
Interest		60	30
Currency effects		–565	10
Other items		35	14
		1,550	**3,201**

1. IFRS 2 expense related to the share programmes that is recognised in equity.
2. Pertains to royalty revenue used to settle the liability to Sanofi, and interest expense related to the liability to Sanofi.

1
2

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 (IFRSs) 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 have been rounded to the nearest million. 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 2020

The revised standards and interpretations applied by the Group as of 1 January 2020 are described below.

– IFRS 3 – Business combinations. The definition of business combinations has been changed. The criteria for classifying an acquisition as a business combination are that it must include, at a minimum, an input and a substantive process that together significantly contribute to the creation of outputs. It is also clarified that this must be based on what has been acquired in its condition at the acquisition date and not on what can be paid by a market player. The changes also include an optional concentration test to simplify the assessment of whether an acquired set of activities is an asset or a business. The changes have not affected the consolidated financial statements, but may impact future periods in the event of acquisitions.

– IAS 1 – Presentation of Financial Statements, and IAS 8 – Accounting Policies, Changes in Accounting estimates and Errors. The changes have been introduced to ensure that the definition of 'material' is consistent across all IFRS and to clarify some aspects of the definition. The new definition states that information is material if omitting, misstating or obscuring it could reasonably be expected to influence the decisions that the primary users of general purpose financial statements make on the basis of those financial statements, which provide financial information about a specific reporting entity. The change specifically clarifies the concept of obscuring material information and the meaning of primary users of general purpose financial statements. In addition, the International Accounting Standards Board (IASB) has updated other standards and guidance that contain a definition of material or that refer to material to ensure consistency.

In 2020, Sobi adjusted the ingoing balance in equity – retained earnings, for non-included pension obligations from preceding years, mainly from Switzerland. The comparative periods in the consolidated financial statements have not been adjusted due to the size of the amount. Refer also to the consolidated statement of changes in equity and Note 29 for more information.

No other new or revised standards and interpretations applied since 1 January 2020 have had any effect on the consolidated financial statements.

New or revised accounting policies that will come into effect after 2020

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

Segment reporting

Sobis operations are organised into three business areas, Haematology, Immunology and Speciality Care. As from 1 January 2020, these business areas form the basis for the Group's segment reporting. 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 decisions about overall resource allocation and for assessing the performance of the operating segment. Sobi has identified its chief operating decision-maker as the Group's CEO. The internal reporting to the CEO uses three segments that represents Sobi's three business areas. See Note 5.

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 the controlling influence 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 identified 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 in profit or loss as a financial expense and the remining change of the remeasurement is recognised as other operating income/expense.

The difference between the fair value of the purchase price 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 are 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.

Note 2, cont.

Foreign currency

Functional and reporting currency

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

Transactions and balance-sheet items

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

Translation of foreign subsidiaries

The assets and liabilities of foreign subsidiaries are measured in their respective functional currency, meaning in the primary economic environment in which the company operates. For Sobi's foreign subsidiaries, all assets, provisions and other liabilities are translated into the Group's reporting currency (SEK) using the closing day rate, and all resulting exchange differences are recognised in other comprehensive income and accumulated in the separate component of equity – translation differences. All items in profit or loss are translated using the average rate for the year.

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 rate.

Net investment in foreign operations

Exchange differences resulting from the translation of a foreign operation's net investment and the associated effects of net investment hedging are recognised in a separate component of other comprehensive income. On the disposal of a foreign operation, the accumulated amount of the exchange differences relating to that foreign operation, less any hedging, shall be reclassified from other comprehensive income to profit or loss as a component of capital gain or loss.

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 out-licensing revenue and milestone payments. 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 directly when the licence fee is received, or allocated over its estimated useful life. In 2020, milestone payments received amounted to SEK 87 M (–) related to approval of the CLD indication in China.

Service fees comprise consideration for sales and marketing services related to some partner products during a contractual term. Revenue is recognised over time. When the Group has an obligation to carry out research and development assignments and the consideration pertains to services provided by the Group, the consideration is recognised over time as the services are performed. Revenue from research collaborations is recognised in the period in which the work is performed.

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 2020, Sobi did not receive any government grants.

Other operating income/expenses

Other operating income and other operating 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 Note 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 utilized. Tax is recognised under Income tax in the statement of comprehensive income except for those items recognised in other comprehensive income or equity. See 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 case of considerations contingent upon future events, usually related to the achievement of certain regulatory and commercial milestones, product and marketing rights are initially recognised at fair value of paid purchase price and future contingent considerations plus transaction costs. Fair value is determined by totalling the payment obligations in connection with the acquisition. The future payments 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 at 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.

Licenses and patents

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

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 have 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 incurred when the relevant software is acquired and available for use. These costs are amortised over the estimated useful life of the software.

Costs associated with developing or maintaining software are recognised as an expense when 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 capitalized 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 probable 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

Land and buildings

- Buildings 20 years
- Land indefinite useful life

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 thus 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 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. Impairment testing of goodwill, product and marketing rights, and development projects are described in Note 16.

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 Note 16.

LEASES

Most of the Group'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

Note 2, cont.

low-value leases are excepted, which in all material respects comprise copying machines, printers and computers. Variable lease payments other than those that depend on an index or rate are recognised as an expense in the period in which they occur.

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

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

Properties	2–10 years
Vehicles	36–48 months

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

Sobi has a provision for site restoration related to restoration of the leased property Paradiset 14 when the lease expires. The company recognises this item as a provision on the balance sheet.

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

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 receivable 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 impairment 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 tied to future payments contingent on achievement of certain regulatory and commercial milestones. The fair value of contingent liabilities 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 the liability due to changed assumptions regarding future payments is recognised as a corresponding change in the related 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, 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 recognized in net financial items while other changes in fair value are recognised in profit or loss.

Note 2, cont.

Changes in the fair value of derivatives that are not included in an effective cash flow hedge or net investment hedge are recognised in profit or loss. Changes in the fair value of derivatives that are included in an effective cash flow hedge or net investment hedge are recognised in other comprehensive income.

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

Fair value hedges
Fair value hedges are only made with derivative instruments. When hedging fair value, derivatives are recognised in profit or loss together with changes in the fair value of the hedged item pertaining to the portion that is exposed to the hedged risk and included in the 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 balances of the 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 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 and earnings history.

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 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 first-class corporate bonds and mortgage bonds issued in the same currency that 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 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 classified as a financial expense.

Note 2, cont.

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. 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 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 shares.

A more detailed description of the long-term incentive programmes can be found in Note 10.

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

Leased assets
Leases are reported according to the exception allowed in RFR 2. For leases where the Parent Company is lessee this means that the right-of-use assets and liabilities are not recognized on the balance sheet. Costs under the lease are recognized in the income statement on a straight-line basis over the term of the lease. Lease incentives received are recognized as an integral part of the total lease expense, over the term of the lease.

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

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

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

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

3 Financial risk management

Financial risks and risk management
Through its operations, Sobi is exposed to various kinds of risks that may impact 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 objective of the Treasury Policy is to maintain a low level of financial risk and to manage risk safely.

Note 3, cont.

Financial risk factors

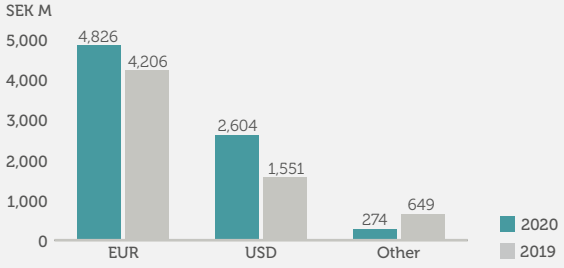
Currency risk – Transaction risk

Transaction risk arises when sales and purchasing transactions are denominated in other 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. The currency surplus in EUR is most significant as a large part of sales are denominated in EUR while purchasing is spread between several currencies. In the event of a 5 per cent depreciation of the SEK against other currencies, sales in 2020 would have increased SEK 696 M (677) and EBITA SEK 402 M (397).

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

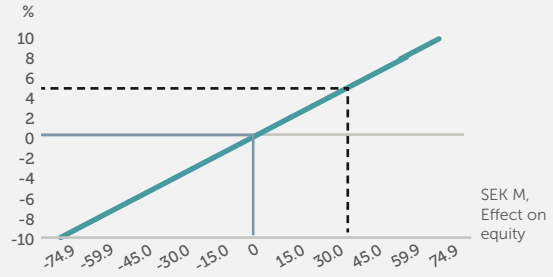


Currency risk – Translation risk

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. In 2020, translation risk decreased for Sobi mainly as a result of decreased net exposure in USD. 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 diagram of translation risk shows the Group's sensitivity to this risk. The diagram shows how the translation effect on consolidated equity would be negative if the SEK weakened, and vice versa. If the SEK, for example, were to depreciate 5 per cent against all currencies, the translation effect on consolidated equity would have been SEK –38 M (–249). The corresponding translation risk for Sobi´s financial assets and liabilities would have been 489 MSEK (878).

Translation risk

Currency change in SEK



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 maintain an appropriate liquidity reserve.

The liquidity reserve comprises bank balances, current investments and undrawn committed credit facilities. At 31 December 2020, the company's undrawn committed credit facilities totalled SEK 4,320 M (3,959). At 31 December 2020, SEK 14,234 M (16,243) of the facilities had been drawn. See the distribution in the table below.

Credit facilities, maturity structure

GROUP	2021	2022	2023	2024	Total
Credit facilities, undrawn	250	1,560	–	2,510	4,320
Credit facilities, drawn	4,015	3,570	3,363	3,287	14,234
Credit facilities, total	**4,265**	**5,130**	**3,363**	**5,797**	**18,554**

The following table shows the contractual, non-discounted cash flows from the Group's financial liabilities, divided according to the time remaining at the balance-sheet date until the contractual maturity date.

Maturity analysis

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	308	–	–
Contingent considerations	491	–	2,836	11,259
Non-contingent considerations	205	102	962	–
Total	**5,875**	**4,159**	**10,615**	**11,259**

AT 31 DECEMBER 2019, GROUP	Less than 1 year	Between 1–2 years	Between 2–5 years	More than 5 years
Derivatives[1]	60	–	–	–
Borrowings	–	6,953	9,290	–
Accounts payable	681	–	–	–
Leases	99	320	–	–
Contingent considerations	464	–	2,221	–
Non-contingent considerations	662	1,234	210	
Total	**1,966**	**8,508**	**11,721**	**–**

1. Included in other liabilities, non-interest bearing in the balance sheet.

The liabilities in the table are presented at nominal value according to an assessment of the contracts at 31 December 2020. 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 had a remaining fixed-rate period of one month.

The liabilities to Sanofi and AstraZeneca are non-interest bearing by agreement, but are discounted in the accounts and therefore incur an interest expense in accounting. There were no fixed-income derivatives outstanding at the balance-sheet date.

Interest-rate sensitivity is measured by assuming a constant interest-rate change of 1 percentage point. At 31 December 2020, such a change would have had an annual impact of SEK 132 M (146) on net financial items. At 31 December 2020, Sobi's interest-bearing liabilities amounted to SEK 14,152 M (16,141). The loans raised carry variable interest, which is deemed most favourable for Sobi.

Note 3, cont.

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 3,756 M (3,736), of which SEK 662 M (685) was overdue, see Note 22 for information about overdue accounts receivable. 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 2020, these amounted to SEK 71 M (69). Only a very limited volume of accounts receivable have been pledged.

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 risk
The goal of Sobi's capital structure is to generate high shareholder returns, value for other stakeholders, and to maintain an optimal capital structure in order to keep cost of capital at a reasonable level. The capital structure can be adapted to the needs that arise by, for example, paying dividends to shareholders, repaying capital to shareholders, issuing new shares or repaying debts.

The Group's equity/assets ratio forms the basis of the Group's capital structure assessment. At 31 December 2020, the equity/assets ratio was as follows:

GROUP	2020	2019
Equity	20,206	16,930
Total assets	48,283	45,658
Equity/assets ratio, %	41.8	37.1

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 hedging instrument's counterparty's credit risk

In 2020, Sobi had no hedging relationships associated with fair value hedges.

Sobi's hedging relationships at the end of 2020 and their effects on profit or loss during the year are presented below. In 2020, Sobi's total ineffectiveness was SEK 0 M (0).

Cash flow hedges 2020

Currency	Nominal value in MSEK	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 consider-ation	Highest probable inflows of USD	Foreign-exchange risk (Avista)	2021

Cash flow hedges 2019

Currency	Nominal value in MSEK	Hedging instrument	Hedged item	Hedged risk	Maturity interval
EUR	335	Borrowings	Highest probable inflows of EUR	Foreign-exchange risk (Avista)	2021–2023
USD	89	Non-contingent consider-ations	Highest probable inflows of USD	Foreign-exchange risk (Avista)	2020–2021

Net investment hedges 2020

Currency	Nominal value in MSEK	Hedging instru-ments	Hedged item	Hedged risk
USD	345	Contingent considerations	Net assets in USD	Foreign-exchange risk (Avista)

Net investment hedges 2019

Currency	Nominal value in MSEK	Hedging instru-ments	Hedged item	Hedged risk
USD	137	Contingent consideration	Net assets in USD	Foreign-exchange risk (Avista)

In 2020 and 2019, 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.

Note 4, cont.

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 December2020, sales related accruals amounted to SEK 2,158 M (1,032). See Note 5 and Note 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 2020, Sobi had not completed any business acquisitions considered as an asset acquisition.

Intangible assets

When intangible assets are acquired, including terms for additional considerations contingent upon future events, usually related to the achievement of certain regulatory and commercial milestones, assessments and assumptions are made to determine the initial acquisition value (fair value of paid purchase price and future considerations). 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 2020, Sobi's goodwill amounted to SEK 5,873 M (6,678). Performed testing during 2020 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 2020, Sobi's product and marketing rights amounted to SEK 32,307 M (30,139).

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, Gamifant and Doptelet were tested for impairment due to the negative opinion adopted by the CHMP for emapalumab in Europe for treatment of primary HLH in children under 18 years of age, and the results from the phase 3 study with Doptelet (avatrombopaq) and its efficacy in the treatment of CIT, respectively. Testing showed no indication of impairment. Refer also to Note 16. Product marketing rights that have not yet been amortised are tested, at least annually, for impairment 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 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 2020, impairment loss of SEK – M (–18) was related to the early-stage 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 2020, Sobi recognised deferred tax assets of SEK 611 M (354) and deferred tax liabilities of SEK 3,464 M (3,726). Non-capialised tax loss carry-fowards amounted to SEK 2,708 M (2,212). 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 valuing deferred tax. See Note 20 for more information about deferred taxes.

Financial liabilities

Contingent considerations

Sobi has financial liabilities related to contingent considerations attributable to business combinations and intangible assets acquired. At the end of 2020, recognised liability amounted to SEK 2,846 M (1,661) and total obligations amounted to SEK 14,587 M (2,685). The contingent considerations are usually related to future payments for 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 related 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. As of 1 January 2020, the Group's segment information will be based on these business areas.

Haematology segment: Revenue is generated from sales of Elocta, Alprolix and Doptelet. 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 generated from sales of Kineret, Synagis and Gamifant.

Specialty Care segment: Revenue is generated from sales of Orfadin, Kepivance and partner products 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 2020	Haematology	Immunology	Specialty Care	Group – other	Total
Revenue and EBITA per segment					
Revenue	8,660	5,415	1,186	–	15,261
EBITA[1]	4,377	1,902	564	–143	6,700
Adjusted EBITA	3,978	1,902	564	–143	6,301
Amortisation/depreciation	–652	–1,009	–179	–42	–1,882
Financial expenses	–	–	–	–602	–602
Financial income	–	–	–	1	1
Profit/loss after financial items	**3 725**	**893**	**385**	**–786**	**4,217**
Assets					
Goodwill	4,761	1,112	–	–	5,873
Other intangible assets	10,512	21,507	701	198	32,918
Total intangible assets	**15,274**	**22,619**	**701**	**198**	**38,791**

GROUP 2019	Haematology	Immunology	Specialty Care	Group – other	Total
Revenue and EBITA per segment					
Revenue	7,755	4,706	1,787	–	14,248
EBITA[1]	4,451	1,529	563	–610	5,933
Adjusted EBITA	4,451	1,529	563	–398	6,145
Amortisation/depreciation	–228	–942	–181	–50	–1,401
Financial expenses	–	–	–	5	5
Financial income	–	–	–	–291	–291
Profit/loss after financial items	**4,223**	**587**	**382**	**–448**	**4,247**
Assets					
Goodwill	5,536	1,142	–	–	6,678
Other intangible assets	11,961	17,762	857	153	30,735
Total intangible assets	**17,497**	**18,904**	**857**	**153**	**37,412**

1. EBITA 2020 excluding non-recurring items; other operating income related to reversal of the CVR liability of SEK 399 M. EBITA for 2019, excluding non-recurring items: transaction costs of SEK 92 M related to the acquisition of Dova, restructuring costs of SEK 157 M, and a gain of SEK 37 M from the divestment of SOBI005.

GROUP	2020	2019
Haematology		
Elocta	4,585	4,508
Alprolix	1,705	1,463
Royalties	1,301	1,373
Doptelet	587	34
Manufacturing	481	376
Total	**8,660**	**7,755**
Immunology		
Kineret	2,079	1,571
Synagis	2,726	2,594
Gamifant	609	542
Total	**5,415**	**4,706**
Specialty Care		
Specialty Care	1,186	1,787
Total	**1,186**	**1,787**
Total revenue	**15,261**	**14,248**

GROUP	2020	2019
Revenue – Gross-To-Net		
Product sales, gross	18,401	17,192
Contractual discounts	–1,243	–832
Statutory discounts	–3,849	–3,820
Tender-based discounts	–77	–64
Product returns	–44	–14
Cash discounts	–47	–20
Total discounts	**–5,260**	**–4,750**
Product sales, net	**13,141**	**12,441**
Manufacturing	481	376
Royalties	1,301	1,373
Milestone payment	87	–
Service fees	251	58
Total revenue	**15,261**	**14,248**

Note 5, cont.

PARENT COMPANY	2020	2019
Revenue - Gross-To-Net		
Product sales, gross	13,690	14,050
Contractual discounts	–543	–487
Statutory discounts	–1,211	–2,365
Total discounts	**–1,754**	**–2,852**
Product sales, net	**11,936**	**11,198**
Manufacturing	481	376
Royalties	1,301	1,373
Service fees	251	45
Total revenue	**13,968**	**12,991**

	Group		Parent Company	
	2020	2019	2020	2019
Total contract assets[1]				
Accounts receivable	3,756	3,736	731	2,402
Accrued royalties[2]	302	358	302	358
Total	**4,058**	**4,094**	**1,033**	**2,760**

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

Total contract liabilities

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

GROUP	Accrued contractual and tender-based discounts	Accrued refunds based on government and regulatory price changes	Accrued product returns	Accrued co-financing	Accrued cash and other discounts	Total
Opening balance, 1 Jan 2019	147	280	10	5	—	442
Reserves for current year	605	930	19	73	20	1,647
Adjusted reserves for prior years	1	–44	–2	–1	—	–46
Payments	–327	–623	–5	–38	–18	–1,011
Translation differences	–2	3	0	0	0	93
Closing balance, 31 Dec 2019	**424**	**546**	**22**	**38**	**2**	**1,032**
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**

Revenue and assets by segment and geographic area

	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	5,924	618	10,046	625	701	198	7,620[1]	16,868
North America	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**	**15,274**	**5,415**	**22,619**	**1,186**	**701**	**198**	**15,261[4]**	**38,791**

	Haematology		Immunology		Specialty Care		Group – Other	Total	
GROUP 2019	Revenue	Non-current assets	Revenue	Non-current assets	Revenue	Non-current assets	Non-current assets	Revenue	Non-current assets
Europe	6,037	10,299	501	5,671	930	857	153	7,468[1]	16,980
North America	34	7,198	4,046	13,233	506	—	—	4,586[2]	20,431
Rest of the world	311	—	159	—	351	—	—	821	—
Other[3]	1,373	—	—	—	—	—	—	1,373	—
Total	**7,755**	**17,497**	**4,706**	**18,904**	**1,787**	**857**	**153**	**14,248[4,5]**	**37,412**

1. Sales revenue from external customers amounted to SEK 4,400 M (2,004) in France, SEK 1,445 M (1,254) in Germany, and to SEK 720 M (616) in Sweden.
2. Sales revenue from external customers amounted to SEK 5,435 M (4,543) in the US.
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 1,960 M (4,458).
5. Sobi's largest customer accounted for approximately 12 per cent (5) of sales in 2020. The customer was reported under the Immunology and Specialty Care segments. See also Note 22 for more information about Sobi's customers.

Note 5, cont.

PARENT COMPANY	2020	2019
Revenue by geographic area[1]		
Europe[2]	7,174	6,677
North America[3]	4,799	4,266
Rest of the world	694	675
Other[4]	1,301	1,373
Total	**13,968**	**12,991**

1. The geographic distribution is based on where the customer is located.
2. Sales in Sweden amounted to SEK 720 M (616).
3. Sales revenue from external customers in the US amounted to SEK 1,247 M (2,594).
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	2020	2019
Depreciation/amortisation according to plan by type of asset		
Licences and patents	–38	–38
Product and marketing rights	–1,779	–1,305
Capitalised costs	–65	–39
Plant and machinery	–17	–22
Equipment, tools, fixtures and fittings	–18	–13
Right-of-use assets	–102	–90
Other non-current assets	–4	–2
Total	**–2,023**	**–1,508**
Impairment by type of asset[2]		
Licences and patents	–	–18
Plant and machinery	–	–32
Right-of-use assets	–	–30
Total	**–**	**–80**
Total depreciation/amortisation and impairment by type of asset	**–2,023**	**–1,588**
Depreciation/amortisation according to plan by type of function		
Cost of goods sold	–36	–34
Selling and administrative expenses	–1,974	–1,445
Research and development expenses	–13	–28
Total	**–2,023**	**–1,508**
Impairment by type of function[2]		
Cost of goods sold	–	–16
Selling and administrative expenses	–	–18
Research and development expenses	–	–47
Total	**–**	**–80**
Total depreciation/amortisation and impairment by type of function	**–2,023**	**–1,588**

PARENT COMPANY	2020	2019
Depreciation/amortisation according to plan by type of asset		
Licences and patents	–1	–3
Product and marketing rights	–262	–262
Capitalised costs	–65	–39
Plant and machinery	–13	–19
Equipment, tools, fixtures and fittings	–6	–7
Other non-current assets	–1	–1
Total	**–347**	**–331**
Impairment by type of asset[2]		
Licences and patents	–	–18
Plant and machinery	–	–32
Total	**–**	**–50**
Total depreciation/amortisation and impairment by type of asset	**–347**	**–381**
Depreciation/amortisation according to plan by type of function		
Cost of goods sold	–12	–11
Selling and administrative expenses	–336	–312
Research and development expenses	0	–8
Total	**–347**	**–331**
Impairment by type of function[2]		
Cost of goods sold	–	–16
Selling and administrative expenses	–	–18
Research and development expenses	–	–17
Total	**–**	**–50**
Total depreciation/amortisation and impairment by type of function	**–347**	**–381**

1. See Note 16 and 17 for further information.
2. For 2019, impairment losses pertained to one of the early-stage clinical programmes as well as tangible assets and right-of-use assets for properties used in early-stage R&D, since these were discontinued in 2019.

7 Other operating income

GROUP	2020	2019
Remeasurement contingent consideration[1]	399	–
Expenses re-invoiced to partners	–	8
Disposal of early-stage clinical programme	–	46
Other	2	14
Total	**401**	**68**

PARENT COMPANY	2020	2019
Expenses re-invoiced to Group companies	95	–
Expenses re-invoiced to partners	–	8
Exchange-rate gains[2]	1	8
Disposal of early-stage clinical programme	–	46
Total	**96**	**62**

1. Reversal of the CVR liability related to the acquisition of Dova in 2019, see Note 33 for more information.
2. Exchange-rate effects are recognised net as other operating income or other operating expense. In 2020, exchange rate effects generated a loss of SEK –42 M (–7) for the Group. For the Parent Company, exchange rate effects generated a gain of SEK 1 M (8), see Note 8.

8 Other operating expenses

GROUP	2020	2019
Exchange-rate losses[1]	–42	–7
Scrapping/disposal of non-current assets	–2	–12
Other	0	0
Total	**–44**	**–18**

PARENT COMPANY	2020	2019
Scrapping/disposal of non-current assets	–	–10
Total	**–**	**–10**

1. Exchange-rate effects are recognised net as other operating income or other operating expense. In 2020, exchange rate effects generated a loss of SEK –42 M (–7) for the Group. For the Parent Company, exchange rate effects generated a gain of SEK 1 M (8), see Note 7.

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 Sobis 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 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	Properties	Cars	Total
At 1 January 2019	**394**	**18**	**412**
Addition[1]	77	25	102
Depreciation and impairment[2]	–110	–10	–120
Divestments and disposals	0	–2	–2
Translation differences	2	0	3
At 31 December 2019	**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**

1. Of additional right-of-use assets of SEK 102 M in 2019, acquisitions accounted for SEK 10 M.
2. 2019 includes an impairment loss of SEK 30 M on right-of-use premises related to premises previously used for early-stage R&D, which the company discontinued in 2019.

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	2020	2019
At 1 January	**419**	**393**
Addition	119	113
Accumulated interest	7	6
Payments	–118	–94
Translation differences	–8	2
At 31 December	**419**	**419**
Non-current	308	320
Current	111	99

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

The following amounts were recognised in profit or loss:

GROUP	2020	2019
Depreciation and impairment of right-of-use assets[1]	–102	–120
Interest expense on lease liabilities	–7	–6
Costs attributable to short-term leases	–9	–6
Costs attributable to low-value leases	–1	–1
Costs attributable to variable lease payments not included in the measurement of the lease liability	–1	–
Total amount recognised in profit or loss	**–120**	**–133**
Amounts recognised in the cash flow statement		
Amortisation of lease liability	–118	–94
Short term leases	–9	–6
Low value leases	–1	–1
Variable lease payments not included in the measurement of the lease liability	–1	–
Total cash flow	**–129**	**–101**

1. 2019 includes an impairment loss of SEK 30 M on right-of-use premises related to premises previously used for early-stage R&D, which the company discontinued in 2019.

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 MINIMUM LEASE PAYMENTS

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

	Parent Company	
	2020	2019
Within 1 year	61	60
Between 1–5 years	218	226
Later than 5 years	27	–
Total	**306**	**286**
Rental payments for the year	60	61

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

	Parent Company	
	2020	2019
Within 1 year	0	0
Between 1–5 years	–	–
Later than 5 years	–	–
Total	**0**	**0**
Lease payments for the year	0	0

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

No. of employees[1]

GROUP	2020	of whom women, %	of whom men, %	2019	of whom women, %	of whom men, %
US	444	57	43	414	58	42
Sweden	438	64	36	435	66	34
Switzerland	148	64	36	128	66	34
Germany	80	56	44	51	59	41
UK	62	52	48	47	44	56
France	61	61	39	55	64	36
Italy	56	46	54	46	54	46
Spain/Portugal	44	66	34	37	63	37
United Arab Emirates	34	41	59	27	22	78
Central and Eastern Europe	30	49	51	25	49	51
Russia	22	77	23	4	75	25
Belgium/ Netherlands	21	41	59	22	45	55
Denmark	14	71	29	15	67	33
China	12	100	0	–	–	–
Canada	11	45	55	6	33	67
Austria	10	62	38	6	46	54
Finland/Baltics	7	57	43	8	50	50
Greece	7	71	29	4	75	25
Japan	6	50	50	–	–	–
Norway	4	75	25	5	80	20
Total	**1,509**	**59**	**41**	**1,335**	**60**	**40**

1. At 31 December 2020, the number of full-time employees was 1,509 people, while the number of employees at the same date was 1,568.

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	2020	2019
Board		
Men	4	5
Women	3	3
Total	**7**	**8**
CEO and other senior executives		
Men	8	8
Women	2	3
Total	**10**	**11**

GENDER COMPOSITION EMPLOYEES

59% ♀ ♂ 41%

Salaries, other remuneration and social security costs

GROUP AND PARENT COMPANY	2020 Salaries and remuneration	2020 Social security costs	2019 Salaries and remuneration	2019 Social security costs
Parent Company	477	250	577	273
(of which pension expense)	–	*(72)*	–	*(103)*
Subsidiaries	1,773	276	1,171	202
(of which pension expense)	–	*(96)*	–	*(58)*
Group, total	2,250	526	1,748	475
(of which pension expense)	–	*(168)*	–	*(161)*

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

	2020 Board and CEO	2020 Other employees	2019 Board and CEO	2019 Other employees
Parent Company				
Salaries and other remuneration	24	453	24	553
(of which bonus)	*(8)*	*(61)*	*(8)*	*(67)*
Subsidiaries				
Salaries and other remuneration	–	1,773	–	1,171
(of which bonus)	–	*(435)*	–	*(239)*
Group, total	24	**2,226**	24	**1,724**
(of which bonus)	*(8)*	*(496)*	*(8)*	*(306)*

Guidelines and remuneration 2020

The 2020 AGM resolved on remuneration guidelines for the company's senior executives as set forth below, that 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.

The guidelines' promotion of the Company's business strategy, long-term interests and sustainability

At Sobi we are transforming the lives of people affected by rare diseases. As a specialised international biopharmaceutical company, we provide access to innovative therapies in the areas of Haematology, Immunology and Specialty Care. We bring something rare to rare diseases – a belief in the strength of focus, the power of agility and the potential of the people we are dedicated to serving.

Sobi's vision is to be recognised as a global leader in providing innovative treatments that transform lives for individuals with rare diseases.

Sobi aim to have a strong correlation between Sobi's compensation elements, the long-term strategy and sustainability. To support our vision, we also have performance measures such as growth and profitability as we aim to create long-term sustainable value for people with rare diseases, shareholders, employees and other stakeholders.

For more information about the company's business strategy, see www.sobi.com.

A prerequisite for the successful implementation of the company's business strategy and safeguarding of its long-term interests, including sustainability, is that the company is able to recruit and retain highly qualified personnel. As an international company, Sobi employs the majority of its personnel outside Sweden. Remuneration of the Executive Committee is designed on a total

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

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, David Allsop and Hans GCP Schikan stepped down from their positions as ordinary Board members, and Staffan 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. During the financial year 2020, he did not act as Deputy CEO, so his remuneration is included among other senior executives.
5. 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

2019	Base salary/fees	Bonus	Pension expense	Other benefits	Share programmes	Total
Chair of the Board						
Håkan Björklund	1,542					1,542
Other Board members						
David Allsop	585					585
Annette Clancy	632					632
Matthew Gantz	677					677
Lennart Johansson	630					630
Helena Saxon	627					627
Hans GCP Schikan	677					677
Elisabeth Svanberg	585					585
Executive Committee, 2019						
Guido Oelkers, Chief Executive Officer	9,524	8,385	2,781	0	12 722[4]	33,412
Other senior executives (10–12 people)[2, 3]	43,840	18,225	5,796	5 701[5]	8 162[4]	81,727
Total	**59,319**	**26,610**	**8,577**	**5,701**	**20,884**	**121,092**

1. Other senior executives refers to Sobi's Executive Committee, which consisted of ten people in addition to the CEO at 31 December 2019. 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. Base salary and other benefits include severance pay of KSEK 4,951 to former senior executives, according to agreement.
3. Henrik Stenqvist was appointed Deputy CEO in 2018. During the financial year 2019, he did not act as Deputy CEO, so his remuneration is included among other senior executives.
4. The year's cost for Sobi is not to be equated with employee benefits.
5. Other benefits includes costs for relocation to senior executives.

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.

Types of remuneration
The remuneration shall be on market terms and may consist of the following components: 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.

Note 10, cont.

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 and 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 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 fixed base pay. To which extent the criteria for awarding annual short-term incentive has been satisfied shall be evaluated and determined by the Board upon the recommendation from the Compensation and 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 fixed base pay 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.

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. For more information about the Company's long-term share-related incentive plans, including the criteria which the outcome depends on, see www.sobi.com.

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

The pension premiums or allowance for pension shall amount to not more than 40 per cent of the member'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 fixed base pay.

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 equalization, 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 fixed base pay.

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 fixed 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 of decision 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 programs 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 competent personnel.

Remuneration of AGM-elected Board members is paid in accordance with a resolution adopted by the 2020 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
Each senior executive's area of responsibility, experience and performance is taken into account when determining the base salary. The base salary is reviewed every year.

Short-term variable pay
For the CEO, short-term variable pay in 2020 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

1. Earnings before interest, tax and amortisation.
2. A defined-contribution pension plan determines a percentage level of the employee's annual gross base salary as the contribution paid into the pension plan for each employee.

Note 10, cont.

capped at 60 per cent of base salary and based on financial and non-financial targets. The expected outcome is reviewed continuously throughout the year and reserves are adjusted monthly. The outcome of variable pay is assessed on each reporting date.

Retirement benefits
The CEO is entitled to a defined-contribution pension solution amounting to 30 per cent of base salary. In 2020, Sobi paid out a premium of KSEK 2,840. The retirement age is 65 years.

Other senior executives employed in Sweden are covered by the ITP plan with a retirement age at 65. They are also covered by a supplementary defined-contribution pension obligation of 27 per cent of pensionable salary, including ITP.

Incentive programmes
Sobi had four active share programmes at the balance-sheet date. To participate in the share programmes, employees must be permanently employed. All programmes run for three years. The company also has three active cash-based programmes for employees in the US. The 2017, 2018 and 2019 programmes run for four years, while the 2020 programme runs for three years.

10

Long-term incentive programmes
The 2017–2020 AGMs adopted the Board's proposal to establish long-term incentive programmes. The aim has been to create long-term commitment to Sobi, to offer participants the opportunity to share in 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 share-based remuneration programmes are described below.

The share programmes for 2017–2020 are structured according to similar principles.

The programmes have a three-year vesting period.

The programmes for the employees require a personal investment in Sobi shares, and matching shares may be allotted free of consideration.

The management programmes require no personal investment in Sobi shares, but performance shares are only allotted if the programme criteria are met.

The number of performance shares that employees are entitled to receive differs according to the organisational level.

One requirement for all programmes is that the employee must be permanently employed throughout the entire vesting period and, in the case of investment shares, that these are retained throughout the entire vesting period.

The performance targets for the management programme are that the share price increases by a certain percentage over a three-year period, and that actual annual sales during the vesting period meet or exceed the budget for annual sales.

The 2019 and 2020 AGM resolved to introduce a share and share option programme 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 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.

2017 Share Programmes (paid in 2020)
The 2017 Share Programmes expired in 2020. For 2017, the Board resolved that 91.82 per cent of the following performance and other vesting conditions had been achieved when the 2017 Share Programme for the CEO, senior executives and managers was redeemed on 19 May 2020. In the programme for senior executives and managers, 562,425 shares with a market value of SEK 119.7 M were allotted. For 60 per cent of the maximum number of 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 straight-line allotment of performance shares for 15–50 per cent. The performance was 86.37 per cent. For a maximum allotment of the remaining 40 per cent of performance shares, actual annual revenue during the vesting period must meet or exceed the budget for the annual revenue. The performance target was achieved for 2017, 2018 and 2019. In the all employee programme, 37,313 shares with a market value of SEK 7.5 M were allotted. Participants in the programme were allotted two matching shares for each saving share. To qualify for the allotment of matching shares, programme participants must have retained the saving shares they have acquired.

2017 Cash-based Programme (expired in 2020, paid out in 2021)
The 2017 AGM approved a long-term cash-based programme for all employees in the US and Canada. 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) were that the share price should increase by at least 10 per cent over a four-year period. The other performance target (50 per cent) was that sales in North America had to be at least 95 per cent per year in relation to the budget over a four-year period. The programme expired in 2020 and the outcome for share price performance was 0 per cent, while the outcome for sales was achieved.

2018 Share Programme
The 2018 AGM approved a long-term share programme covering the CEO, senior executives and managers, and a programme for other employees. Participation in the programme for other employees requires personal investment in Sobi's ordinary shares, referred to as "saving shares" in the programme.

After a three-year lock-up period: Participants in the management programme are allotted performance shares contingent upon a certain share price performance. For a maximum allotment of 60 per cent of performance shares, the price of Sobi's ordinary share, adjusted for any dividends, must increase by at least 50 per cent. If the share price, adjusted for any dividends, has increased by 15–50 per cent, the programme participants will receive a straight-line allotment of performance shares. For a maximum allotment of the remaining 40 per cent of performance shares, actual annual revenue during the vesting period must meet or exceed the budgets for the annual revenue. The performance target was achieved for 2018, 2019 and 2020. The maximum possible allotment of shares is 656,325. Participants in the all emplyee programme are allotted two matching shares for each saving share. To qualify for the allotment of matching shares, programme participants must have retained the saving shares they have acquired. The maximum possible allotment of shares is 34,650.

During the roll-out of the 2018 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 roll-out of LTI 2018B for these employees and new employees since the roll-out of LTI 2018A. The maximum possible allotment of shares in the management programme is 21,551, and 3,434 in the all employee programme.

2018 Share Programme

	Number of performance shares	Number of matching shares	Value in KSEK
CEO and other senior executives in the Group (7)	224,901	—	27,253
Total	224,901	—	27,253

2018 Cash-based Programme
The 2018 AGM approved a long-term cash-based programme for all employees in the US and Canada. 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 (50 per cent) is that the share price must increase by at least 10 per cent over a four-year period. The other performance target (50 per cent) is that sales in North America must be at least 95 per cent per year in relation to the budget over a four-year period.

2019 Share Programme
The 2019 AGM approved a long-term share programme covering the CEO, senior executives and managers, and a programme for other employees. Participation in the programme for other employees requires personal investment in Sobi's ordinary shares, referred to as "saving shares" in the programme.

Note 10, cont.

After a three-year lock-up period: Participants in the management programme are allotted performance shares contingent upon a certain share price performance. For a maximum allotment of 60 per cent of performance shares, the price of Sobi's ordinary share, adjusted for any dividends, must increase by at least 50 per cent. If the share price, adjusted for any dividends, has increased by 15–50 per cent, the programme participants will receive a straight-line allotment of performance shares. For a maximum allotment of the remaining 40 per cent of performance shares, actual annual revenue during the vesting period must meet or exceed the budgets for the annual revenue. The performance target was achieved for 2019 and 2020. The maximum possible allotment of shares is 742,951. Participants in the all employee programme are allotted two matching shares for each saving share. To qualify for the allotment of matching shares, programme participants must have retained the saving shares they have acquired. The maximum possible allotment of shares is 38,998.

2019 Share Programme

	Number of performance shares	Number of matching shares	Value in KSEK
CEO and other senior executives in the Group (9)	197,766	—	21,764
Total	197,766	—	21,764

2019 Share Option Programme
In May 2019, the AGM resolved that, in addition to the right to a long-term share programme, a share option programme would be launched in accordance with the Board's proposal covering the CEO and a maximum of 15 members of the Sobi Group's Executive Committee, and 15 pre-selected key individuals in the Sobi Group. The programme comprises 25 people. The total number of options issued was 1,454,718. The vesting period is three years, followed by a two-year redemption period. One condition for the granting of options is a strike price of SEK 180.65, corresponding to 105 per cent of the volume-weighted average price for the Sobi share (SEK 172.05). In addition, the performance target must be met – that the Sobi Group's actual 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 maximum value per share that may be obtained through the redemption of share options is limited to an amount that is five times the strike price. Should the share value exceed this level, the conditions must be recalculated. In the programme, those employees qualifying for options in Sweden may request that their share options be settled by the company making a cash payment corresponding to the excess amount of the closing price for the shareholders, compared with the strike price on the redemption date less any administrative expenses. Due to the possibility of such a choice for employees in Sweden, share options are classified as settled in cash for accounting purposes, in accordance with IFRS 2.

2019 Cash-based Programme
The 2019 AGM approved a long-term cash-based programme for all employees in the US and Canada. 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 (50 per cent) is that the share price must increase by at least 10 per cent over a four-year period. The other performance target (50 per cent) is that sales in North America must be at least 95 per cent per year in relation to the budget over a four-year period.

2020 Share Programme
The 2020 AGM approved a long-term share programme covering the CEO, senior executives and managers, and one programme for other employees. Participation in the programme for other employees requires personal investment in Sobi's ordinary shares, referred to as "saving shares" in the programme.

After a three-year lock-up period: Participants in the management programme are allotted performance shares contingent upon a certain share price performance. For a maximum allotment of 60 per cent of performance shares, the price of Sobi's ordinary share, adjusted for any dividends, must increase by at least 50 per cent. If the share price, adjusted for any dividends, has increased by 15–50 per cent, the programme participants will receive a straight-line allotment of performance shares. For a maximum allotment of the remaining 40 per cent of performance shares, actual annual revenue during the vesting period must meet or exceed the budgets for the annual revenue. The performance target was achieved for 2020. The maximum possible allotment of shares is 794,110. Participants in the all employee programme are allotted two matching shares for each saving share. To qualify for the allotment of matching shares, programme participants must have retained the saving shares they have acquired. The maximum possible allotment of shares is 51,446.

During the roll-out of the 2020 Share Programme, 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 programme, the Board decided to establish a long-term cash-based incentive programme instead.

2020 Share Programme

	Number of performance shares	Number of matching shares	Value in KSEK
CEO and other senior executives in the Group (9)	174,750	—	23,230
Total	174,750	—	23,230

2020 Share Option Programme
The AGM in May 2020 resolved that, in addition to the right to a long-term share programme, a share option programme would be launched in accordance with the Board's proposal covering the CEO and a maximum of 15 members of the Sobi Group's Executive Committee, and 15 pre-selected key individuals in the Sobi Group. The programme comprises 24 people. The total number of options issued was 1,363,514. The vesting period is three years, followed by a two-year redemption period. One condition for the granting of options is a strike price of SEK 213.86, corresponding to 105 per cent of the volume-weighted average price for the Sobi share (SEK 203.68). In addition, the performance target must be met– that the Sobi Group's actual 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 maximum value per share that may be obtained through the redemption of share options is limited to an amount that is three times the strike price. Should the share value exceed this level, the conditions must be recalculated. In the programme, those employees qualifying for options in Sweden may request that their share options be settled by the company making a cash payment corresponding to the excess amount of the closing price for the shareholders, compared with the strike price on the redemption date less any administrative expenses. Due to the possibility of such a choice for employees in Sweden, share options are classified as settled in cash for accounting purposes, in accordance with IFRS 2.

2020 Cash-based Programme
The 2020 AGM approved a long-term cash-based programme for all employees in the US and Canada. 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 (50 per cent) is that the share price must increase by at least 10 per cent over a four-year period. The second performance target (50 per cent) is that sales in North America must be at least 95 per cent in relation to the budget over a three-year period.

Note 10, cont.

Expensing of the 2018–2020 Share Programmes is calculated using the following parameters:

	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[2]	Fair value of performance share[3]	Expected employee turnover, %	Max. allotment of shares[1]	Forfeited shares in 2020
2018 Share Programme: All Employee	11 May 2018	11 May 2021	34,650	n/a	36	184.32	n/a	n/a	7	34,650	2,408
2018 Share Programme: Management	11 May 2018	11 May 2021	n/a	656,325	36	n/a	79.75	184.32	7	656,325	33,762
2018B Share Programme: All Employee	1 Nov 2018	1 Nov 2021	3,434	n/a	36	185.6	n/a	n/a	7	3,434	252
2018B Share Programme: Management	1 Nov 2018	1 Nov 2021	n/a	21,551	36	n/a	66.92	185.6	7	21,551	1,817
2019 Share Programme: All Employee	28 May 2019	28 May 2022	38,998	n/a	36	179.26	n/a	n/a	7	38,998	2,552
2019 Share Programme: Management	28 May 2019	28 May 2022	n/a	742,951	36	n/a	67.75	173.5	7	742,951	46,977
2020 Share Programme: All Employee	28 May 2020	28 May 2023	51,446	n/a	36	200.49	n/a	n/a	7	51,446	206
2020 Share Programme: Management	28 May 2020	28 May 2023	n/a	794,110	36	n/a	85.77	203.68	7	794,110	35,874

1. At 31 December 2020, there were 2,343,465 shares outstanding in the share programmes amounting to a theoretic value of SEK 294 M, representing a market value of SEK 389 M.
2. Fair value of performance shares related to share price performance, see under 2018, 2019 and 2020 Share Programmes above.
3. Fair value of performance shares related to revenue, see under 2018, 2019 and 2020 Share Programmes above.

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

11 Remuneration of auditors

GROUP	2020	2019
EY		
Auditing assignments[1]	–8	–9
Audit activities in addition to the auditing assignment	0	–1
Tax consultancy	–	0
Other services	0	0
Total EY	**–9**	**–10**

PARENT COMPANY	2020	2019
EY		
Auditing assignments[1]	–3	–4
Audit activities in addition to the auditing assignment	0	–1
Tax consultancy	–	0
Other services	0	0
Total EY	**–4**	**–5**

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	2020	2019
Raw materials and consumables	–2,778	–2,962
Other external costs	–3,044	–2,763
Employee benefit costs	–2,965	–2,452
Depreciation/amortisation and impairment[1]	–2,013	–1,588
Other operating expenses	–44	–18
Total	**–10,844**	**–9,783**

1. Increase in depreciation/amortisation during the year is due to assets acquired in 2019.

PARENT COMPANY	2020	2019
Raw materials and consumables	–2,759	–2,831
Other external costs	–4,380	–4,404
Employee benefit costs	–755	–891
Depreciation/amortisation and impairment	–337	–381
Other operating expenses	–	–10
Total	**–8,230**	**–8,517**

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

13 Financial income

GROUP	2020	2019
Interest income	1	5
Total	**1**	**5**

PARENT COMPANY	2020	2019
Interest income, Group companies	486	346
Interest income, other	0	2
Exchange-rate gains[1]	177	–
Total	**663**	**348**

1. Exchange-rate effects are recognised net and in 2020, generated a gain in the Parent Company and a loss in the Group. In 2019, this item was a loss in both the Parent Company and the Group. See also Note 14.

14 Financial expenses

GROUP	2020	2019
Interest expense, borrowings	−330	−182
Interest expense, other[1]	−124	−59
Exchange-rate losses[2]	−115	−31
Management costs	−32	−18
Other	−1	−1
Total	−602	−291

PARENT COMPANY	2020	2019
Interest expense, Group companies	−38	−11
Interest expense, borrowings	−330	−184
Interest expense, other[1]	−69	−30
Exchange-rate losses[2]	—	−42
Management costs	−31	−18
Other	−1	−1
Total	−469	−287

1. Includes interest expense for considerations.
2. Exchange-rate effects are recognised net and in 2020, generated a gain in the Parent Company and a loss in the Group. In 2019, this item was a loss in both the Parent Company and the Group. See also Note 13.

15 Income tax

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

GROUP	2020	2019
Current tax		
Current tax on profit for the year[1]	−1,133	−449
Prior year adjustments[1]	8	1
Total current tax recognised for the Group	−1,125	−449
Deferred tax		
Excess depreciation	−479	−805
Inventories	295	137
Sale of PRV (priority review voucher)	—	125
Acquired product rights	166	81
Other intangible assets	−4	−8
Tax loss carry-forwards	100	−43
Net investment hedges	64	—
Pharmaceutical tax	14	11
Other	−3	7
Total deferred tax recognised for the Group	153	−494
Total tax recognised for the Group	−972	−942

PARENT COMPANY	2020	2019
Current tax		
Current tax on profit for the year[1]	−944	−318
Prior year adjustments[1]	7	2
Total current tax recognised in the Parent Company	−938	−316
Deferred tax		
Other	7	4
Total deferred tax recognised for the Parent Company	7	4
Total tax recognised for the Parent Company	−931	−313

Reconciliation of effective tax

GROUP	2020	2019
Profit before tax	4,217	4,247
Tax at applicable tax rate for the Parent Company[2]	−902	−909
Tax effect, non-deductible/non-taxable items		
Remeasurement of contingent consideration (CVR)[3]	82	—
Utilisation of non-capitalised tax loss carry-forwards	—	49
Non-capitalised tax loss carry-forwards	−101	−73
Changed tax rate in Sweden[2]	−17	31
Difference foreign tax rates	8	0
Non-deductible expenses	−51	−49
Adjustment of tax prior years	8	1
Other	0	8
Total effective tax recognised for the Group	−972	−942

PARENT COMPANY	2020	2019
Profit before tax	4,337	1,431
Tax at applicable tax rate for the Parent Company[2]	−928	−306
Tax effect, non-deductible/non-taxable items		
Changed tax rate in Sweden[2]	0	0
Controlled Foreign Company taxation	—	−2
Non-deductible expenses	−9	−7
Adjustment of tax prior years	7	2
Other	—	1
Total effective tax recognised in the Parent Company	−931	−313

1. In addition to tax recognised in earnings, current tax of SEK 35 M (−12) 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 9 M (42) was recognised directly in equity, attributable to the Parent Company's long-term incentive programme (deferred tax of SEK 5 M (8) was also recognised directly in equity, see Note 20 for other deferred tax items).
2. The current tax rate for the Swedish Parent Company amounts to 21.4 per cent (21.4), but will be reduced to 20.6 per cent from 2021. Deferred tax was valued using the applicable tax rate for the period that reversal/resolution is expected to occur.
3. See also Note 33.

Non-capitalised tax loss carry-forwards

GROUP	2020	2019
Tax loss carry-forwards for which no deferred tax asset was recognised	2,708	2,212
Potential tax benefit	523	480

Of non-capitalised tax loss carry-forwards, SEK 1,291 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[5]	Ongoing capitalised costs[5]	Total
1 January–31 December 2019						
Opening cost	1,554	550	10,850	227	76	13,256
Investments[1]	—	3	15,686	74	260	16,023
Business acquisitions[2]	5,293	35	7,555	11	—	12,895
Disposals[3]	—	−16	—	−58	—	−74
Reclassification	—	—	—	3	0	3
Translation differences	−169	0	−88	0	—	−257
Closing cost	**6,678**	**572**	**34,003**	**258**	**336**	**41,846**
Opening accumulated amortisation and impairment	—	−418	−2,559	−120	—	−3,097
Amortisation	—	−38	−1,305	−39	—	−1,382
Impairment[4]	—	−18	—	—	—	−18
Disposals[3]	—	7	—	57	—	65
Translation differences	—	0	0	0	—	0
Closing accumulated amortisation and impairment	**—**	**−467**	**−3,864**	**−102**	**—**	**−4,434**
Closing carrying amount	**6,678**	**104**	**30,139**	**155**	**336**	**37,412**
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
Reclassification	—	—	—	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. Investments for the year are mainly related to pegcetacoplan, SEK 3,060 M and SEL-212, SEK 1,776 M. In 2019, investments mainly pertained to Synagis, SEK 13,689 M and BIVV001, SEK 1,817 M.
2. During the year, goodwill declined SEK 313 M related to adjustments to the acquisition analysis for Dova, see Note 33. In 2019, business combinations pertained to accrued goodwill of SEK 4,391 M related to Dova, and SEK 902 M related to the acquisition of emapalumab. Priority Review Voucher (PRV) was not classified as an intangible asset. In 2019, acquired product and marketing rights of SEK 7,555 M pertained to Doptelet.
3. In 2019, disposals pertained to licences and various IT projects.
4. In 2019, impairment pertained to an impairment loss on one of the early-stage clinical programmes.
5. Capitalised costs comprise IT projects and expenses to relocate manufacturing of active substance. Items under capitalised costs are amortised according to plan.

Specification of major intangible assets

SEK M	2020[1]	Amortisation rate, years	Remaining amortisation period, years
Synagis	12,574	20	18.1
Doptelet	5,910	15	13.9
Gamifant	3,802	20	18.0
Pegcetacoplan[2]	3,060	–	–
SEL-212[2]	1,776	–	–
Alprolix	1,297	20	14.2
Elocta	1,310	20	15.0
BIVV001[2]	1,868	–	–
Orfadin	630	15	4.4
Other – launched	526	3–15	5.0
Other – not yet launched	166	–	–
Total	**32,918**		

1. Reported net value.
2. Under development, amortisation has not yet started.

Note 16, cont.

PARENT COMPANY	Licenses and patents	Product and marketing rights	Capitalised costs[4]	Ongoing capitalised costs[4]	Total
1 January–31 December 2019					
Opening cost	54	4,776	220	75	5,125
Investments[1]	3	1,817	74	207	2,101
Disposals[2]	–16	–	–58	–	–74
Reclassification	–	–	3	0	3
Closing cost	**40**	**6,593**	**240**	**282**	**7,155**
Opening accumulated amortisation and impairment	–23	–1,185	–116	–	–1,325
Amortisation	–3	–262	–39	–	–304
Impairment[3]	–18	–	–	–	–18
Disposals[2]	7	–	57	–	65
Closing accumulated amortisation and impairment	**–37**	**–1,447**	**–98**	**–**	**–1,583**
Closing carrying amount	**3**	**5,146**	**141**	**282**	**5,572**
1 January–31 December 2020					
Opening cost	40	6,593	240	282	7,155
Investments[1]	–	4,849	–	113	4,961
Reclassification	–	–	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. Investments for the year are mainly related to pegcetacoplan, SEK 3,060 M and SEL-212, SEK 1,734 M. In 2019, investments mainly pertained to BIVV001, SEK 1,817 M and capitalised IT costs.
2. In 2019, disposals pertained to licenses and various IT projects.
3. In 2019, impairment pertained to an impairment loss on one of the early-stage clinical programmes.
4. Capitalised costs comprise IT projects and expenses to relocate manufacturing of active substance. Items under capitalised costs are amortised according to plan.

IMPAIRMENT TESTING OF INTANGIBLE ASSETS

Goodwill

The assessment of the value of the Group's goodwill is based on value in use of the smallest cash-generating unit. Sobi has three separate cash generating units – Haematology, Immunology and Speciality Care – to which goodwill is allocated. At 31 December 2020, Sobi's goodwill amounted to SEK 5,873 M (6,678). See Note 5 for goodwill split by cash generating unit.

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 the current product development and future 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, %	2020	2019
Growth rate beyond the initial five-year period	2	2
Discount rate before tax	10.0	10.2
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 per cent (6.6).
- 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.

Note 16, cont.

During the year, emapalumab was tested for impairment due to a negative opinion by the CHMP regarding the use of emapalumab for treating primary HLH in Europe. The impairment test indicates that there are good margins in the calculation but is dependent on future approvals and commercial success on markets outside Europe.

On 9 October 2020, Sobi announced the topline results from the phase 3 CIT study of avatrombopag, of which the primary endpoints were not met. Following the results of the study, an impairment test of the carrying amount for the intangible asset related to Doptelet was performed. The impairment test showed no impairment need. Doptelet has performed well during 2020 in the US in its two approved indications ITP and CLD. Further, Doptelet was approved in the EU for treatment of ITP in January 2021. At 31 December 2020 the reported value on the balance sheet was SEK 5,910 M.

The impairment model was based on a fifteen-year time horizon with no terminal value and a WACC of 8%. Annual peak sales were assumed at SEK 4,000–5,000 M. The fifteen-year period reflects a growth phase to peak revenue, with the outer years growth at a low single-digit growth, followed by a phase of double-digit decline. The impairment model was adjusted to remove all future revenue and operating expenses related to CIT. The main risk for impairment in the future, where reported value for Doptelet exceeds its recoverable amount, will be events that change the underlying launch assumptions or peak revenue estimates.

Impairment

There were no impairment losses in 2020. In 2019, an impairment loss of SEK 18 M was recognised for one of the early-stage clinical programmes, which affected the value of the intangible assets.

16

CONTRACTUAL COMMITMENTS RELATED TO INTANGIBLE ASSETS

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

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 2020, the value of BIVV001, which is recognised as an intangible asset, was SEK 1,868 M (1,817). For liabilities related to BIVV001, see Note 28.

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.

Alprolix

The liability for development and commercialisation of Alprolix was repaid in full in 2020.

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, Sobi will pay up to USD 135 M (approximately SEK 1.1 billion) based on annual net sales of Doptelet, calculated per calendar year. This obligation is recognised as a financial liability in Sobi's balance sheet.
- Under the licensing agreement with Astellas, Sobi will make additional milestone payments of up to USD 3 M (approximately SEK 25 M) to Astellas if certain regulatory milestones are achieved. In addition, Sobi will pay royalties to Astellas based on net sales of Doptelet.
- Under a contract with Eisai regarding commercial sales of Doptelet, Sobi will place some binding orders in the coming period. The minimum possible purchasing requirement is about USD 13 M (approximately SEK 106 M).

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 40 M (approximately SEK 343 M) in 2019 and 2020, and shall pay an additional USD 20 M (SEK 164 M) at the end of 2021. This obligation was recognised as a current financial liability on the balance sheet.

Provided that some terms related to sales of Synagis are met, an additional consideration of up to USD 470 M (approximately SEK 3.8 billion) may be payable as of 2026. Sobi may also pay USD 175 M (approximately SEK 1.4 billion) for the submission of a Biologics License Application (BLA) for MEDI8897 to the FDA. The agreement also includes possible net payments of about USD 110 M (approx. SEK 900 billion) on achievement of other MEDI8897 profit and development-related milestones. In this case, these will be paid as of 2023. At the end of 2020, Sobi has 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 licencing 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 5.1 billion). The purchase price of SEK 1,896 M for the acquired intangible and financial assets comprises the initial 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. Selecta will also be entitled to incremental double-digit royalties on future sales.

GROUP	Balance sheet at the agreement date
Intangible assets	1,767
Financial assets	120
Other liabilities, non-interest-bearing	954

Note 16, cont.

Pegcetacoplan
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 7.5 billion). The purchase price of SEK 3,060 M for the acquired intangible assets comprises the initial 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. Apellis will also be entitled to incremental double-digit royalties on future sales.

Sobi will pay USD 80 M (approximately SEK 655 M) to Apellis over a four-year period as consideration for R&D in accordance with the original development plan. These costs will be recognised as expenses in the period in which they occur.

GROUP	Balance sheet at the agreement date
Intangible assets	3,060
Other liabilities, non-interest-bearing	851

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 2019						
Opening cost	466	245	–	12	9	731
Change in accounting principle	–	–	412	–	–	412
Investments	18	16	92	–	3	129
Business acquisitions	19	3	10	3	–	35
Divestments and disposals	–19	–85	–2	–2	–	–108
Reclassification	–1	–2	–	4	–3	–2
Translation differences	0	1	2	–	–	3
Closing cost	**483**	**178**	**515**	**16**	**8**	**1,200**
Opening accumulated depreciation and impairment	–378	–212	–	–5	–	–594
Depreciation	–22	–13	–90	–2	–	–128
Impairment[1]	–32	–	–30	–	–	–62
Business acquisitions	–	0	0	–1	–	–1
Divestments and disposals	18	84	0	1	–	104
Reclassification	–	1	–	–1	–	–
Translation differences	–5	5	0	0	–	0
Closing accumulated depreciation and impairment	**–418**	**–135**	**–120**	**–8**	**–**	**–682**
Closing carrying amount	**65**	**43**	**395**	**8**	**8**	**518**
1 January–31 December 2020						
Opening cost	483	178	515	16	8	1,200
Investments	3	17	121	5	15	162
Divestments and disposals[2]	–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[2]	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. Impairment pertained to impairment on plant and machinery, as well as right-of-use premises previously used for early-stage R&D which was discontinued during 2019.
2. Divestments and disposals for the year refer to plant and machinery used for early-stage R&D, which was discontinued in 2019.

The table above includes right-of-use assets, i.e. leased assets, due to the IFRS 16 reporting standard that came into effect on 1 January 2019. 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 2019					
Opening cost	458	202	5	9	674
Investments	11	1	—	3	15
Divestments and disposals	–18	–83	—	—	–101
Reclassification	—	0	—	–3	–3
Closing cost	**451**	**121**	**5**	**8**	**585**
Opening accumulated depreciation and impairment	–371	–189	–3	—	–562
Depreciation	–19	–7	–1	—	–27
Impairment[1]	–32	—	—	—	–32
Divestments and disposals	18	83	—	—	101
Closing accumulated depreciation and impairment	**–404**	**–113**	**–3**	**—**	**–520**
Closing carrying amount	**47**	**8**	**2**	**8**	**65**
1 January–31 December 2020					
Opening cost	451	121	5	8	585
Investments	—	—	—	15	15
Divestments and disposals[2]	–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[2]	49	1	—	—	49
Closing accumulated depreciation and impairment	**–369**	**–118**	**–4**	**—**	**–491**
Closing carrying amount	**40**	**13**	**2**	**9**	**64**

1. Impairment pertained to impairment on plant and machinery, as well as right-of-use premises previously used for early-stage R&D which was discontinued during 2019.
2. Divestments and disposals for the year refer to plant and machinery used for early-stage R&D, which was discontinued in 2019.

18 Participations in Group companies

PARENT COMPANY	2020	2019
Cost		
Opening balance	8,853	4,652
Investment[1]	—	4,201
Closing balance	**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. The Parent Company had no investments in Group companies during the year. In the sub-group, Swedish Orphan Biovitrum International AB has created two new subsidiaries, Swedish Orphan Biovitrum Japan Co.,Ltd in Japan, and Swedish Orphan Biovitrum Pty Ltd in Australia. In 2019, investment of SEK 4,201 M pertained to the investment in Sobi US Holding Corp. related to the acquisition of Dova.

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[3]
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, Parma, 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			
Novimmune B.V. 27278836, Amsterdam, Netherlands			
Florio GMBH, HRB 249347, Munich, Germany			
Sobi Pharma (Guangzhou) Company Limited, 91440101MA5D2D0A6G, Guangzhou, 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			
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
Sobi, Inc EIN 68-0682244, Delaware, USA	1,000	100	7
Swedish Orphan Biovitrum s.r.o, 28171276, Prague, Czech Republic[2]	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	4,201,329
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. The remaining portion is owned by Swedish Orphan Biovitrum International AB.
3. The carrying amount is given in KSEK.

19 Financial assets

GROUP	2020	2019
Cost		
Opening balance	50	55
Equity instruments[1]	131	—
Endowment policy	–3	0
Financial receivables	–1	2
Returned deposit	1	–3
Other	—	–5
Closing balance	**179**	**50**
Closing carrying amount	**179**	**50**

1. Equity instruments refer to the holding in Selecta Bioscience, Inc. The holding is measured at fair value through other comprehensive income. Investment for the year amounted to SEK 120 M and a gain of SEK 11 M was recognised in other comprehensive income.

GROUP	2020	2019
Equity instruments	131	—
Endowment policy	44	47
Deposits	2	1
Financial receivables	1	2
Total	**179**	**50**

PARENT COMPANY	2020	2019
Cost		
Opening balance	47	52
Equity instruments[1]	131	—
Endowment policy	–3	0
Fair value hedges	—	–5
Closing balance	**176**	**47**
Closing carrying amount	**176**	**47**

1. Refer to comments for the Group.

PARENT COMPANY	2020	2019
Equity instruments	131	—
Endowment policy	44	47
Total	**176**	**47**

20 Deferred tax assets and deferred tax liabilities

Deferred tax assets and tax liabilities

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**

GROUP 2019	Deferred tax assets	Deferred tax liabilities	Net
Excess depreciation	—	–1,338	–1,338
Inventories	318	—	318
Acquired product and marketing rights	—	–2,524	–2,524
Other intangible assets	53	—	53
Tax loss carry-forwards	47	—	47
Pharmaceutical tax	17	—	17
Other	54	—	54
Total	**489**	**–3,862**	**–3,372**
Offsetting	–136	136	—
Tax assets/liabilities, net	**354**	**–3,726**	**–3,372**

The Parent Company's total deferred tax assets amounted to SEK 24 M (22), and mainly comprised a deferred tax asset of SEK 12 M (13) related to pension provisions, a deferred tax asset of SEK 6 M (8) related to long-term incentive programmes, a provision of SEK 9 M (2) for expected credit losses on external and internal receivables, and a deferred tax liability of SEK –2 M (–) related to the market value of a financial asset. Deferred tax has been valued using enacted future tax rate in Sweden, see Notes 2 and 15.

Change in deferred tax

GROUP 2020	Amount at beginning of year	Recognised in profit or loss	Recognised in other comprehensive income	Recognised directly in equity	Increase through business acquisitions	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**	**94**	**–48**	**320**	**–2,853**

1. The year-on-year decrease of SEK 320 M in deferred tax for acquired product and marketing rights refers to a previously unrecognised deferred tax asset related to a liability in the acquisition analysis for Dova. See also Note 33.
2. 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.

GROUP 2019	Amount at beginning of year	Recognised in profit or loss	Recognised in other comprehensive income	Recognised directly in equity	Increase through business acquisitions	Amount at end of year
Excess depreciation	–532	–805	—	—	—	–1,338
Inventories	181	137	—	—	—	318
Sale of PRV (priority review voucher)	—	125	0	—	–125	0
Acquired product and marketing rights[1]	–263	81	–54	—	–2,288	–2,524
Other intangible assets	61	–8	—	—	—	53
Tax loss carry-forwards[2]	86	–43	3	—	—	47
Pharmaceutical tax	6	11	0	—	—	17
Other	28	7	0	9	10	54
Total	**–433**	**–494**	**–51**	**9**	**–2,404**	**–3,372**

1. The increase in acquired product and marketing rights is attributable product and marketing rights acquired during the year.
2. 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	2020	2019
Raw materials and consumables	21	13
Work in progress	1,929	775
Finished goods and goods for resale	1,103	985
Total	**3,053**	**1,772**

The cost of inventories recognised as an expense is included in cost of goods sold and amounted to SEK 2,778 M (2,962). Reported inventory includes a reserve for obsolete goods of SEK 443 M (390). During the period, the Group's inventories were written down by M 49 SEK (50).

PARENT COMPANY	2020	2019
Raw materials and consumables	21	13
Work in progress	1,929	775
Finished goods and goods for resale	577	745
Total	**2,527**	**1,533**

The cost of inventories recognised as an expense is included in cost of goods sold and amounted to SEK 2,759 M (2,831). Reported inventory includes a reserve for obsolete goods of SEK 440 M (389). During the period, the Group's inventories were written down by M 48 SEK (36).

22 Accounts receivable and other receivables

GROUP	2020	2019
Accounts receivable	3,827	3,804
Minus: Provision for credit losses	−71	−69
Accounts receivable, net	**3,756**	**3,736**
Tax assets	25	35
Other receivables	440	495
Total other receivables	**465**	**530**
Total accounts receivable and other receivables	**4,221**	**4,266**

PARENT COMPANY	2020	2019
Accounts receivable	747	2,410
Minus: Provision for credit losses	−16	−8
Accounts receivable, net	**731**	**2,402**
Tax assets	10	27
Other receivables	396	422
Total other receivables	**405**	**449**
Total accounts receivable and other receivables	**1,136**	**2,851**

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 2020, the Group's overdue receivables amounted to SEK 662 M (685), of which SEK 71 M (69) is included in the provision for credit losses. Actual credit losses of SEK 0.7 M (0.8) were charged to profit for the year, of which SEK 0.6 M (0.3) was attributable to the Parent Company.

Changes in the provision for credit losses are as follows:

Expected credit losses

GROUP	2020	2019
At beginning of year	−69	−70
Provision for credit losses	−14	−24
Reversed provisions	12	25
At end of year	**−71**	**−69**

PARENT COMPANY	2020	2019
At beginning of year	−8	−8
Provision for credit losses	−9	−22
Reversed provisions	1	22
At end of year	**−16**	**−8**

Maturity structure

GROUP	2020	2019
Not past due	3,094	3,051
Past due 1–30 days	505	459
Past due 31–90 days	93	130
Past due 91–120 days	8	53
Past due > 121 days	56	43
Total	**3,756**	**3,736**

PARENT COMPANY	2020	2019
Not past due	565	2,246
Past due 1–30 days	135	141
Past due 31–90 days	20	13
Past due 91–120 days	1	2
Past due > 121 days	11	0
Total	**731**	**2,402**

Note 22, cont.

Recognised amounts per currency for accounts receivable and other receivables

GROUP	2020	2019
CHF	67	136
EUR	919	1,003
GBP	109	117
SEK	747	807
USD	2,316	2,138
Other currencies	63	64
Total	**4,221**	**4,266**

PARENT COMPANY	2020	2019
CHF	62	85
EUR	277	238
SEK	740	807
USD	2	1,662
Other currencies	56	61
Total	**1,136**	**2,851**

23 Prepaid expenses and accrued income

GROUP	2020	2019
Accrued royalty revenue[1]	302	358
Other prepaid expenses	186	190
Total	**490**	**548**

PARENT COMPANY	2020	2019
Accrued royalty revenue[1]	302	358
Other prepaid expenses	127	141
Total	**430**	**499**

1. These are classified as contract assets under IFRS 15, no significant changes between the years.

24 Cash and cash equivalents

	2020		2019	
GROUP	Fair value	Carrying amount	Fair value	Carrying amount
Cash and cash equivalents	404	404	737	737
Total	**404**	**404**	**737**	**737**

	2020		2019	
PARENT COMPANY	Fair value	Carrying amount	Fair value	Carrying amount
Cash and cash equivalents	240	240	431	431
Total	**240**	**240**	**431**	**431**

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

22
23
24

25 Equity

Other reserves	Translation differences	Cash flow hedges	Net investment hedges	Financial investments	Defined-benefit pension plans and similar plans	Total
Other reserves 1 Jan 2019	–12	–106	–	–	–26	–144
Translation differences	–97	–	–	–	–	–97
Hedging instruments:						
Gain/loss on remeasurement of hedging instruments recognised in equity	–	–132	52	–	–	–80
Tax on gain/loss on remeasurement of hedging instruments recognised in equity	–	28	–10	–	–	18
Transferred to profit or loss for the period	–	135	–	–	–	135
Tax on transfers to profit or loss for the period	–	–29	–	–	–	–29
Gain/loss on remeasurement of defined-benefit pension plans and similar plans	–	–	–	–	–4	–4
Tax on gain/loss on remeasurement of defined-benefit pension plans and similar plans	–	–	–	–	0	0
Other reserves 31 Dec 2019	**–110**	**–104**	**42**	**–**	**–30**	**–202**
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 for the period	–	34	–	–	–	34
Tax on transfers to profit or loss for the period	–	–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**

At year-end, Sobi's share capital was SEK 167 M, distributed between 303,815,511 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 8,918,672 ordinary shares in treasury at the balance-sheet date. The own shares item corresponds to 2.9 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 shares held in treasury.

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.

	2020	2019
Earnings attributable to Parent Company shareholders (in KSEK)	3,244,521	3,304,479
Weighted average number of ordinary shares outstanding (000s)	294,658	292,649
Weighted average number of ordinary shares outstanding after dilution (000s)	297,640	294,528
Earnings per share (SEK per share)	11.01	11.29
Earnings per share, adjusted (SEK per share)[1, 2]	9.66	11.89
Diluted earnings per share (SEK per share)	10.90	11.22
Diluted earnings per share, adjusted (SEK per share)[1, 2]	9.56	11.81
Number of ordinary shares	303,815,511	299,977,839
Number of ordinary shares (in treasury)	8,918,672	5,678,099
Number of ordinary shares (excluding shares held in treasury)	294,896,839	294,299,740
Number of ordinary shares after dilution	306,797,549	301,857,247
Average number of ordinary shares (excluding shares held in treasury)	294,658,136	292,649,020
Average number of ordinary shares after dilution (excluding shares in treasury)	297,640,174	294,528,428

1. Alternative performance measures, see Definitions page 136.
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.

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 2020				
Assets on the balance sheet				
Accounts receivable	3,756	–	–	3,756
Endowment policy	–	44	–	44
Derivatives[1]	–	117	–	117
Equity instruments	–	–	131	131
Cash and cash equivalents	404	–	–	404
Total	**4,160**	**162**	**131**	**4,453**
31 December 2019				
Assets on the balance sheet				
Accounts receivable	3,736	–	–	3,736
Endowment policy	–	47	–	47
Derivatives[1]	–	57	–	57
Cash and cash equivalents	737	–	–	737
Total	**4,473**	**104**	–	**4,577**

	Liabilities measured at amortised cost	Liabilities measured at fair value through profit or loss	Total
31 December 2020			
Liabilities on the balance sheet			
Borrowings	14,152	–	14,152
Lease liabilities	419	–	419
Derivatives[2]	–	269	269
Accounts payable	569	–	569
Contingent considerations	2,845	–	2,845
Non-contingent considerations	1,191	–	1,191
Other liabilities	94	–	94
Total	**19,270**	**269**	**19,540**
31 December 2019			
Liabilities on the balance sheet			
Borrowings	16,141	–	16,141
Lease liabilities	417	–	417
Derivatives[2]	–	60	60
Accounts payable	681	–	681
Contingent considerations	1,273	388	1,661
Non-contingent considerations	2,002	–	2,002
Other liabilities	146	–	146
Total	**20,661**	**448**	**21,109**

1. Of the 2020 derivatives, SEK 117 M (57) 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. Of the 2020 derivatives, SEK 269 M (60) 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.

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.

Fair value measurements using significant unobservable inputs (level 3).
The table below shows the significant unobservable inputs used to measure fair value in level 3 instruments. In 2020, Sobi had no liabilities categorised within level 3.

	Fair value				Effect on fair value of	
	2020	2019	Expected cash flow	Discount rate	Discount rate +1%	Nominal cash flow +10%
Contingent consideration	—	388	417	5 %	–5	39

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

AT 31 DECEMBER 2019	Level 1	Level 2	Level 3[1]	Total
Financial assets measured at fair value through profit or loss				
Derivatives held for trading	—	–4	—	–4
Endowment policies	—	—	47	47
Contingent consideration	—	—	–388	–388
Total	**—**	**–4**	**–341**	**–345**

1. Due to results from the phase 3 study with Doptelet for the treatment of CIT, Sobi does not expect the conditions of the CVR to be met. The liability was subsequently reversed, which had a positive impact of SEK 399 M on other operating income during 2020. 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 2020, the net value of derivatives recognised on the balance sheet was SEK –151 M (–4).

27 Borrowings

Sobi has credit facilities of EUR 1,540 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 2022. During the year, one undrawn credit facility of SEK 1,000 M expired. In addition to these, Sobi has an overdraft of SEK 250 M with a repayment period of one year. For further information about maturity structure, see Note 3.

GROUP AND PARENT COMPANY	2020	2019
Non-current liabilities to banks and credit institutions	10,137	16,141
Current liabilities to banks and credit institutions	4,015	—
Total	14,152	16,141

Specification per currency, translated to SEK M

GROUP AND PARENT COMPANY	2020	2019
Currency		
EUR	7,377	7,669
SEK	2,918	5,398
USD	3,857	3,074
Total	14,152	16,141

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

GROUP	2020	2019
Non-current		
Liability to Sanofi[1]	1,163	1,273
Liability to Eisai[2]	993	1,177
Liability to Selecta[1]	773	—
Liability to Apellis[1]	539	—
Liability to AstraZeneca[2]	—	170
Other	5	—
Total	3,473	2,620
Current		
Liability to Sanofi[2]	—	475
Liability to Eisai[2]	41	—
Liability to Selecta[1]	81	—
Liability to Apellis[1]	265	—
Liability to AstraZeneca[2]	157	178
CVR[3]	—	388
Derivatives	269	60
VAT	322	394
Other	167	146
Total	1,302	1,641

Note 28, cont.

PARENT COMPANY	2020	2019
Non-current		
Liability to Sanofi[1]	1,163	1,273
Liability to Selecta[1]	773	—
Liability to Apellis[1]	539	—
Other	—	—
Total	**2,475**	**1,273**
Current		
Liability to Sanofi[2]	—	475
Liability to Selecta[1]	81	—
Liability to Apellis[1]	265	—
Derivatives	269	60
Other	112	88
Total	**727**	**623**

1. Contingent considerations.
2. Non-contingent considerations
3. See Note 26.

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, at exercise of the opt-in right, estimated to be USD 280–290 M less USD 50 M that has already been paid. The obligation was recognised as a non-current liability, non-interest-bearing on the balance sheet and amounted to SEK 1,163 M (1,273) at 31 December 2020.

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. At 31 December 2020, the obligation was recognised as a non-current liability, non-interest-bearing of SEK 993 M (1,177) and a current liability, non-interest-bearing of SEK 41 M (-) on the balance sheet.

Selecta
On 28 July, Sobi concluded the strategic licensing agreement for the SEL-212 product candidate with Selecta Biosciences, Inc. Sobi 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. 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. At 31 December 2020, the obligations were recognised as a non-current liability, non-interest bearing of SEK 773 M (-) and a current liability, non-interest-bearing of SEK 81 M (-) on the balance sheet.

Apellis
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 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. At 31 December 2020, the obligations were recognised as a non-current liability, non-interest-bearing of SEK 539 M (-) and a current liability, non-interest-bearing of SEK 265 M (-) on the balance sheet.

AstraZeneca
Acquisition of the rights to Synagis included a contract for Sobi to pay USD 60 M in addition to an up-front consideration to AstraZeneca. At 31 December 2020, an amount of USD 20 M remained payable. This obligation is recognised as a current liability, non-interest-bearing on the balance sheet and at 31 December 2020, amounted to SEK 157 M (178).

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 2020 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 that include salary, previously earned pension and expected remaining period of service. In 2021, expected contributions for ITP 2 plans insured through Alecta amount to SEK 20 M (24). 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 2020, Alecta's surplus in the form of the collective funding ratio was 148 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 expenses, 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 2020, the plans covered 157 employees (114) of whom all were active.

Other
At 31 December 2020, the liability recognised for other defined-benefit pension plans was SEK 21 M. Other pension obligations are attributable to France, Italy, Norway and Sweden.

Note 29, cont.

SEK M	2020	2019
Present value of funded obligations	349	227
Fair value of plan assets	–220	–145
Deficit in funded plans	129	83
Present value of unfunded obligations	15	–
Net	**144**	**83**

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

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			
Current service costs	–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.

1 JANUARY–31 DECEMBER 2019	Present value of obligations	Fair value of plan assets	Total
At beginning of year	**–39**	**32**	**–7**
Acquired pension liability Switzerland 2019[1]	–174	104	–69
Amount in profit or loss			
Current service costs	–6	–	–6
Interest expense	–1	–	–1
Interest income	–	0	0
Amount in cash flow			
Contributions from employees	–2	2	0
Contribution into plans from employer	–	6	6
Payment from the plans	1	–2	–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	–	1	1
Changed financial assumptions	–5	0	–5
Experience-based assumptions	–3	2	–2
Translation difference	1	–1	0
At end of year	**–227**	**145**	**–83**

1. Related to the acquisition of emapalumab, see Note 33.

Net obligation per country

	2020	2019[1]
Sweden	0	1
Italy	3	–
Norway	6	10
France	12	–
Switzerland	123	72
Total	**144**	**83**

1. Reported values are not adjusted for the pension plans that were not taken into account at end of 2019.

Actuarial assumptions at the balance-sheet date

AVERAGE FOR PENSION PLANS	2020	2019
Discount rate, %	0.3	1.2
Expected annual salary increase, %	1.9	2.0
Pension increases	0.9	0.9
Remaining life expectancy after retirement age, male, years	18.1	20.8
Remaining life expectancy after retirement age, female, years	22.2	23.4

Demographic assumptions

Mortality assumptions correspond to the Swedish Financial Supervisory Authority's recommendations, which came into effect on 31 December 2007 for the Swedish pension plan. Mortality assumptions are based on the BVG2015 mortality table for the Swiss pension plan, RG48 for the Italian pension plan and K2013 BE for the Norwegian pension plan. The retirement age is set at 65 years except in Switzerland, where the retirement age for women starts at 64 years.

Distribution by plan assets

	2020	Quoted, %	2019	Quoted, %
Equity funds	75	100	19	100
Interest-bearing securities	67	100	64	100
Properties	40	–	19	–
Other funds	27	–	43	–
Other	11	–	–	–
Total	**220**	**65**	**145**	**57**

Note 29, cont.

Sensitivity analysis

	2020	2019
Pension obligation under current assumptions	364	227
Discount rate –0.5%	396	249
Discount rate +0.5%	339	205
Salary decrease –0.5%	357	220
Salary increase +0.5%	371	235
Life expectancy after retirement –1 year	359	221
Life expectancy after retirement +1 year	366	231

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 2021 financial year, contributions to plans for post-employment benefits are expected to be SEK 22 M (16). The weighted average duration of the obligation is an estimated 19.2 years (19.1).

Risks

Through its defined-benefit pension plans, the Group is exposed to a number of risks. The most significant risks are described in the 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	
	2020	2019	2020	2019
Provision at beginning of year	**179**	**97**	**84**	**80**
Endowment policy[1]	–2	0	–2	–
Provision, milestone obligations[2]	12	0	–	0
Restoration reserve[3]	0	–	0	0
Changes in pension obligations	61	79	–	4
Other	1	2	–	0
Provisions at 31 December	**252**	**179**	**82**	**84**

	Group		Parent Company	
	2020	2019	2020	2019
Endowment policy[1]	44	47	44	47
Provision, milestone obligations[2]	23	11	–	–
Restoration reserve[3]	34	34	34	34
Pension obligations	144	86	3	3
Other	6	2	–	–
Provisions at 31 December	**252**	**179**	**82**	**84**

1. For corresponding assets, see Note 19.
2. Provision under licensing agreement with Astella related to Doptelet. For a more detailed description, see Note 16.
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	
	2020	2019	2020	2019
Non-current portion	249	179	82	84
Current portion	3	2	–	–
Total provisions	**252**	**179**	**82**	**84**

31 Accrued expenses and deferred income

GROUP	2020	2019
Sales-related	2,158	1,032
Employee-related	572	581
Royalties	207	230
R&D	194	181
Co-Promotion	191	277
Inventory-related	164	188
Other	442	550
Total	**3,928**	**3,039**

PARENT COMPANY	2020	2019
Sales-related	226	157
Employee-related	257	265
Royalties	189	226
R&D	179	172
Co-Promotion	191	277
Inventory-related	116	157
Other	156	316
Total	**1,314**	**1,570**

32 Pledged assets and contingent liabilities

GROUP	2020	2019
Pledged assets		
Endowment policy	44	47
Other pledged assets	2	1
Total	**46**	**48**

PARENT COMPANY	2020	2019
Pledged assets		
Endowment policy	44	47
Total	**44**	**47**

PARENT COMPANY	2020	2019
Contingent liabilities		
Guarantee commitment	26	24
Total	**26**	**24**

Guarantees for 2020 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 subsidiary in question may hold.

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 Acquisitions

Dova

Sobi completed the acquisition of Dova 12 November 2019. Following the completion of Sobi's tender offer to purchase all of the outstanding shares of Dova for USD 27.50 per share plus one non-transferable contingent value right (CVR) entitling Dova's previous shareholders to an additional USD 1.50 per share, conditional upon the FDA's approval of Doptelet for the treatment of chemotherapy-induced thrombocytopenia (CIT). As a result of the phase 3 study regarding Doptelet for use in CIT, Sobi estimates that the conditions for the CVR will not be met. Therefore, the CVR liability was reversed positively impacting the profit for the period of SEK 399 M.

Through the acquisition, Sobi received access to Dova's commercial product Doptelet. Dova became an indirect wholly owned subsidiary of Sobi through the aquisition.

If Dova had been included in the Group throughout 2019, sales would have increased by SEK 121 M and EBITA decreased by SEK 472 M. Transaction costs of SEK – M (92) were paid and are included under administrative expenses in the income statement, and are part of operating cash flow on the cash flow statement.

The purchase price allocation (PPA) was completed in 2020, and in connection with it, the value of deferred tax assets was adjusted upwards by SEK 320 M related to the liability to Eisai, which has been assessed as deductible. Goodwill and other liabilities and provisions were adjusted by SEK –313 M and SEK –7 M, respectively.

GROUP	Final PPA
Agreed purchase price	8,414
Contingent Value Right (CVR)	404
Consideration transferred	**8,818**
Assets	
Intangible assets	7,555
Other assets	61
Cash	444
Total assets	**8,060**
Other liabilities and provisions[1]	–1,694
Deferred tax[1]	–1,626
Total liabilities[1]	**–3,320**
Total identifiable net assets at fair value[1]	**4,740**
Goodwill[1,2]	4,078
Consideration transferred	**8,818**
Analysis of cash flows in acquisition	
Contingent consideration purchase price (CVR)	–404
Net cash acquired with the business	–444
Acquisition of business, net of cash	**7,969**

1. Updated values during 2020.
2. Recognised goodwill is mainly attributable to securing know-how and employees with cutting-edge expertise for future development, and earning potential related to follow-up indications for Doptelet.

Emapalumab

18 July 2019, Sobi completed the acquisition of emapalumab and related assets and liabilities.

As part of the acquisition of emapalumab, Sobi obtained:

- All emapalumab-related assets, including intellectual property (IP), patent rights, data and know-how.
- All employees involved in the clinical and biopharmaceutical development of emapalumab.
- Options for the shared financial rights of the immuno-oncology product candidates NI-1701 and NI-1801.
- A priority review voucher (PRV) in the FDA's expedited review programme for companies investing in orphan drugs, which reduces application fees for future products and shortens the review period. In September 2019, the PRV was sold for a total consideration of USD 95 M.

The acquisition consideration amounted to CHF 515 M (SEK 4,911 M), of which CHF 400 M was already committed under the exclusive license agreement for emapalumab.

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Note 33, cont.

GROUP	Final PPA
Agreed purchase price	4,914
Redemption of previous commitment[1]	–3,802
Deferred tax	469
Consideration transferred	**1,581**
Assets	
Intangible assets	88
Tangible assets	19
Inventories	34
Priority Review Voucher (PRV)[2]	892
Cash	3
Total assets	**1,037**
Liabilities	
Other liabilities and provisions	–245
Deferred tax	–113
Total liabilities	**–358**
Total identifiable net assets at fair value	**679**
Goodwill[3]	902
Consideration transferred	**1,581**
Analysis of cash flows in acquisition	
Net cash acquired with the business	–3
Cash paid	4,914
Acquisition of business, net of cash	**4,911**

1. Refers to a prior commitment of 400 MCH under the exclusive license agreement for emapalumab and was recognised as a current liability.
2. The PRV was sold in September 2019.
3. Recognised goodwill is mainly attributable to securing know-how and employees with cutting-edge expertise for future development, and earning potential related to follow-up indications for emapalumab.

Sobi's costs did not increase after the acquisition of emapalumab and related assets and liabilities, compared with the periods after the acquisition of the global rights.

Transaction costs of SEK – M (18) were expensed and are included in administrative expenses in profit or loss and are part of operating cash flow on the cash flow statement.

GROUP	Dova	emapalumab	Total
Compilation of acquired assets and liabilities			
Goodwill[1]	4,078	902	4,980
Other intangible assets	7,555	88	7,643
Priority Review Voucher (PRV)	—	892	892
Other assets	61	53	114
Cash	444	3	447
Total assets[1]	**12,138**	**1,938**	**14,076**
Other liabilities and provisions[1]	–2,098	3,557	1,459
Deferred tax[1]	–1,626	–582	–2,208
Total liabilities[1]	**–3,724**	**2,975**	**–749**
Total acquired assets and liabilities	**8,414**	**4,913**	**13,327**
Net cash acquired with the business	–444	–3	–447
Acquisition of business net of cash	**7,969**	**4,911**	**12,880**

1. Updated values during 2020.

34 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.

35 Proposed appropriation of profit

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

KSEK	
Share premium reserve	9,023,392
Retained earnings	3,803,035
Profit for the year	3,406,312
Total	**16,232,739**

The Board of Directors proposes no dividend for the 2020 financial year.

The Board of Directors proposes that the share premium reserve, retained earnings and profit for the year, totalling KSEK 16,232,739 SEK, be carried forward.

36 Events after the balance-sheet date

Doptelet was approved in the EU for the treatment of chronic immune thrombocytopenia (ITP) in adult patients with insufficient response to previous treatment. Chronic ITP is a rare autoimmune disorder characterised by low blood platelet counts.

Kineret was approved in Russia by the Ministry of Health of the Russian Federation for the treatment of cryopyrin associated periodic syndromes (CAPS).

Refer also to the Director's Report for more information about COVID-19.

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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 4 May 2021 for adoption.

Stockholm, 25 March 2021

Håkan Björklund
Chair

Annette Clancy
Board member

Matthew Gantz
Board member

Lennart Johansson
Board member

Helena Saxon
Board member

Staffan Schüberg
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 26 March 2021
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 2020. The annual accounts and consolidated accounts of the company are included on pages 34–91 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 2020 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 2020 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 consolidated statement of comprehensive income and balance sheet for the group as well as the income statement and the balance sheet for the parent company.

Our opinions in this report on the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the parent company's audit committee in accordance with the Audit Regulation (537/2014) Article 11.

Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the 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 2020 the majority of (79% or SEK 38 246 M) 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: • obtained 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 2020 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 Notes 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 2020 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, 2020, the reported liabilities for contingent consideration amounted to SEK 4,036 M and SEK 2,821 M 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: • obtained an understanding of the Company's process for valuing contingent considerations, • review of material agreements including conditions for contingent considerations; • review of management's assessments and assumptions used to support the valuation of contingent considerations with a focus on the assumptions for which the valuation is most sensitive and • tested the Company's calculations for arithmetical correctness and consistency with reported values. We have also assessed the disclosures in the annual report.

Other Information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 2–32, 96, 104–107, 133–136. The remuneration report for the financial year 2020 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 2020 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 organisation 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.

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 2020 and have been the company's auditor since 8 May 2014.

Stockholm, 26 March 2021
Ernst & Young AB

Jonatan Hansson
Authorised Public Accountant

Letter from the chairman

Sobi continues to deliver on its strategy for long-term growth and value generation, advancing towards the vision of being recognised as a global leader in rare diseases.

Sobi has delivered on its strategy for growth since 2017, and the company continues to generate long-term value. Two highlights in 2020 were the important agreements regarding SEL-212 and systemic pegcetacoplan, both of which broaden the R&D pipeline and expand the geographical scope.

The Board supports Sobi by providing a clear governance structure, as well as expertise in crucial corporate decisions.

Clear governance is particularly important during times of rapid growth such as the one Sobi is experiencing today. Many people are joining the company, and it is expanding into new geographical markets and new medical areas. This growth means Sobi's products will become available to even more patients. But with these new opportunities come the responsibility of continuing to do business in the right way.

The Code of Conduct is a foundation stone for Sobi's governance structure. The new code approved by the Board and introduced in Q4 2020 will help Sobi deliver on the strategy and act responsibly as it expands. Available digitally for all employees and external stakeholders on www.sobi.com, the code is a compulsory part of the education package for every Sobi employee. Compliance with the Code of Conduct 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 January last year, Sobi introduced the Partner Code of Conduct. Sobi has committed to work only with partners who embrace standards of ethical behaviour consistent with Sobi's own.

Sobi 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.

2020 was a year like no other, and the COVID-19 pandemic had long-reaching effects on both Sobi and on the individuals who make up the company. 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.

I am confident that Sobi in 2021 will lay the foundation for reaching its ambition of SEK 25 billion in revenue in 2025.

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 Solna, Sweden. Sobi is listed on Nasdaq Stockholm. This report for the 2020 financial year is part of Sobi's Directors' Report and 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 without any deviations and has not breached the Nasdaq Stockholm 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 2020. 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, including 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 shareholders justifies any special measures for shareholders being able 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.

2020 AGM

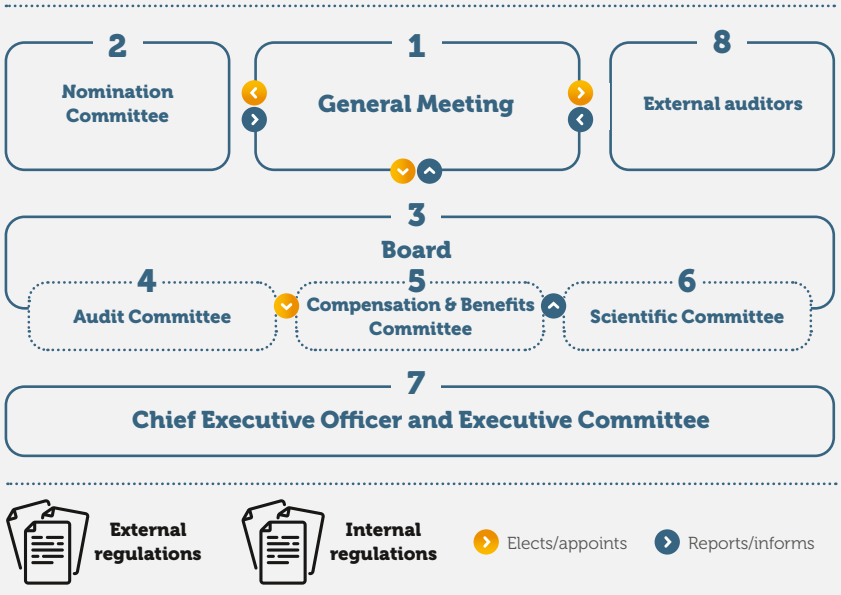
The AGM was held on 13 May 2020 in Stockholm. The Meeting was attended by 292 shareholders (385), in person or by proxy, representing 66.7 per cent (64.6) of the total number of votes. Lawyer Eva Hägg was elected to chair the meeting. The company's Chairman, CEO and auditor participated remotely.

The full minutes and information from the 2020 AGM are available at www.sobi.com.

Resolutions 2020 AGM

The following resolutions were inter alia adopted by the 2020 AGM:

- Re-election of six Board members
- Election of one new Board member
- Re-election of the Chair
- Re-election of Ernst & Young AB as auditor
- Remuneration of the Board and auditors
- Remuneration guidelines for senior executives
- Discharge from liability for the Board and CEO for the 2019 financial year
- Amendment of the Articles of Association



2021 AGM

The Annual General Meeting is held on Tuesday 4 May 2021. Due to the coronavirus and in order to reduce the risk of spreading the virus, the Board has decided that the Meeting should be conducted by way of postal vote pursuant to temporary legislation being in effect in 2021. This means that the Meeting will be held without the physical presence of shareholders, representatives or third parties. The shareholders will therefore only be able to exercise their voting rights by postal voting in advance of the Meeting.

Shareholders, share capital, the share and voting rights

At year-end, Sobi had a total of 33,816 (25,227) shareholders. Investor AB was the largest shareholder, with 35.4 per cent (35.9) of the share capital and 35.4 per cent (35.9) of the votes. The 15 largest shareholders accounted jointly for 70.8 per cent (78.1) of the share capital and 70.8 per cent (78.1) 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 13 May 2020 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 247,655 of Sobi's own shares in order to cover some expenses, mainly social security contributions, that may arise due to the 2017 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 2020, Sobi held 8,918,672 ordinary shares in treasury. In 2020, 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 30.

Dividend policy

One of Sobi's most important business objectives is to create long-term shareholder value. Sobi's Board bases its evaluation of 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 dividend's impact on liquidity.

The Board proposes that no dividend be paid for 2020. In the short term, the company intends to use accrued profits to finance the continued development and expansion of its operations.

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 composition of the Nomination Committee is to be announced at least six months before the AGM. The Nomination Committee observes the rules on the independence of Board members according to the Swedish Corporate Governance Code. The Nomination Committee's composition prior to the 2021 AGM was announced on 21 October 2020.

In the period up to the 2021 AGM, the Nomination Committee has 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 2021 AGM, the Nomination Committee held four 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, including proposals for Board members, the remuneration of Board and Committee members, auditor and auditor fees, and the 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, acquisitions, 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

Nomination Committee prior to the 2021 AGM

Name/Representing	Votes 31 Dec 2020, %	Votes 31 Dec 2019, %
Petra Hedengran (Chair of the Nomination Committee) Investor AB	35.4	35.9
Lennart Francke Swedbank Robur Fonder AB	4.9	4.7
Thomas Ehlin Fourth Swedish National Pension Fund (AP4)	4.5	3.2
Håkan Björklund Chair of Swedish Orphan Biovitrum AB (publ)	0.0	0.0
Total	44.8	43.8

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 2020 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 2020 AGM.

The 2020 AGM adopted the Nomination Committee's proposal that, as of the 2020 AGM, the Board should consist of seven AGM-elected members (six re-elected and one newly elected by the 2020 AGM) and two employee representatives appointed by the trade union organisations (plus two deputies for the employee representatives). Three of the seven AGM-elected members are women.

For more information about the Board, refer to pages 104–105.

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 100 shows the independence of Board members on the publication date of this report.

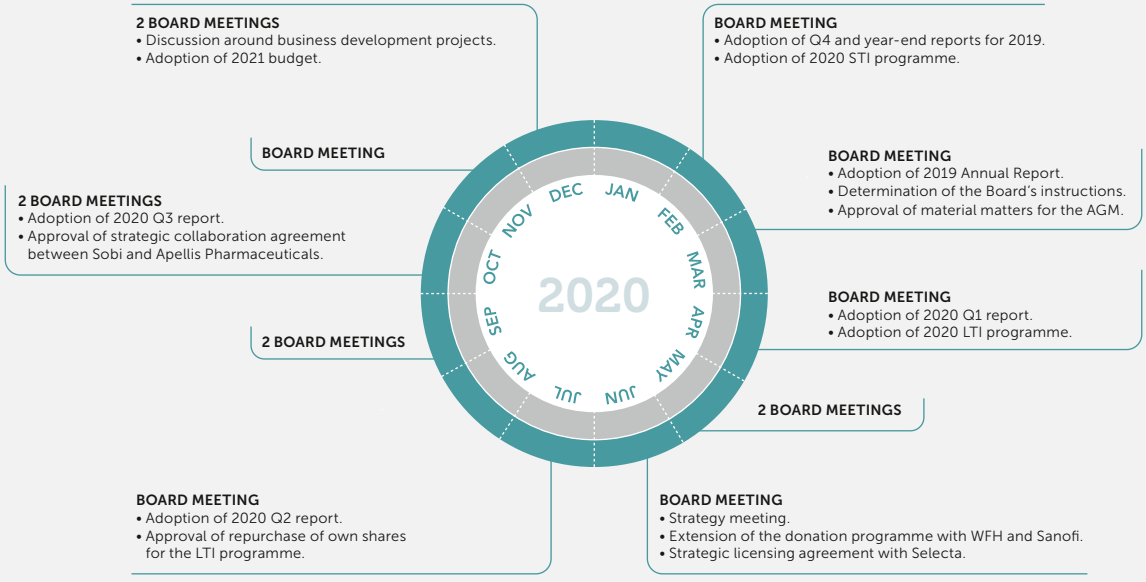
Chair of the Board

In addition to leading the Board's work, the Chair of the Board's duties include monitoring the company's performance and ensuring that any important matters are addressed if required, in addition to those already on the agenda. The Chair shall consult with the CEO on strategic matters, participate in important external relationships and represent the company in ownership issues. The Chair is also responsible for ensuring that the Board's work is regularly evaluated and that new Board members receive adequate training.

Number of meetings

In addition to the statutory Board meeting, the Board shall meet at least four to six 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. In 2021, the Board has scheduled a total of eight ordinary meetings.

Important events in Board work in 2020



In order to carry out effective board work, the Board has established three committees – 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.

Board work in 2020

In 2020, the Board held a total of 14 meetings, of which nine were scheduled in addition to the statutory meeting, and four were extra meetings. Sobi's CEO and President attends Board meetings, as does Sobi's General Counsel, who has served as secretary at the meetings. Other Sobi employees have attended in a reporting capacity. The number of extra Board meetings was motivated inter alia by discussions concerning business development projects. The matters addressed are shown in the illustration below. The Board members' attendance at Board meetings is presented in the table below.

Board fees

At the AGM on 13 May 2020, the Board resolved that for the period until the next AGM, a fee of SEK 490 K would be paid to each of the AGM-elected Board members except for the Chair, who would be paid a fee of SEK 1,500 K. The fees for Audit Committee work would be SEK 160 K to the Chair and SEK 100 K to each of the other members. Fees for the Compensation & Benefits Committee's work would be SEK 110 K to the Chair and SEK 60 K to each of the other members. Fees for Scientific Committee work would be SEK 110 K to the Chair and SEK 60 K to each of the other members. In 2020, Board fees of SEK 5,481 K were paid, including remuneration for committee work. It was further resolved that for each physical Board meeting, a fee of SEK 10 K would be paid to Board members residing in Europe but outside the Nordic region, and USD 3 K 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 2020, the evaluation took the form of individual discussions between the Chair and individual Board members. The evaluation was discussed at a Board meeting. 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. Sobi's Audit Committee consists of three members, all of whom are independent of management:

- Lennart Johansson (Chair)
- Helena Saxon
- Staffan Schüberg

Sobi's CFO serves as secretary of the Committee, but is not a member. Sobi's CEO attended the 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.

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

		Remuneration (KSEK)						Attendance[1]			
	Independence	Fees	Audit Committee	Compensation & Benefits Committee	Scientific Committee	Other[5]	Total	Board	Audit Committee	Compensation & Benefits Committee	Scientific Committee
David Allsop[2]	x	163	—	20	—	10	193	4/14	—	4/10	—
Håkan Björklund	x	1,500	—	110	—	—	1,610	14/14	—	10/10	—
Annette Clancy	x	490	—	—	110	10	610	13/14	—	—	4/4
Matthew Gantz	x	490	—	60	—	28	578	13/14	—	9/10	—
Lennart Johansson	[3]	490	160	—	—	—	650	14/14	6/6	—	—
Helena Saxon	[3]	490	100	60	—	—	650	14/14	6/6	10/10	—
Hans GCP Schikan[2]	x	163	33	—	20	10	227	5/14	3/6	—	2/4
Staffan Schüberg[2]	x	327	67	—	—	10	403	9/14	3/6	—	—
Elisabeth Svanberg	x	490	—	—	60	10	560	14/14	—	—	4/4
Pia Axelson	[4]	—	—	—	—	—	—	14/14	—	—	—
Erika Husing	[4]	—	—	—	—	—	—	2/14	—	—	—
Kristin Strandberg	[4]	—	—	—	—	—	—	12/14	—	—	—

1. The figures in the table show the totals for attendance/meetings. In 2020, the Board held a total of 14 meetings, of which nine were scheduled in addition to the statutory meeting and four were extra meetings. The Audit Committee held six meetings, the Compensation & Benefits Committee held 10 meetings and the Scientific Committee held four meetings.
2. At the AGM on 13 May, David Allsop and Hans GCP Schikan stepped down from their positions as ordinary Board members, and Staffan Schüberg was appointed new ordinary Board member.
3. Board member does not qualify as independent in relation to major shareholders.
4. Erika Husing was appointed to the Board as ordinary employee representative on 23 November 2020, when Kristin Strandberg ended her employment.
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.

Sobi's Head of HR serves as secretary of the Committee, but is not a member. The Compensation & Benefits Committee met 10 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 will be prepared and presented at the 2021 AGM for the shareholders' approval. The Board members' attendance and remuneration for committee meetings is presented in the table on page 100. 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. During the year, the Scientific Committee consisted of three members until Hans GCP Schikan stepped down from his positions as Board member and member of the Committee at the scheduled Board meeting in May 2020, and thereafter consisted of two Board members. All are independent of management:

- Annette Clancy (Chair)
- Elisabeth Svanberg

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 four 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 the committee meetings is presented in the table on page 100.

7. CEO/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 2020, the Executive Committee held one meeting every month. For more detailed information about the Executive Committee, see pages 106–107.

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 2021 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

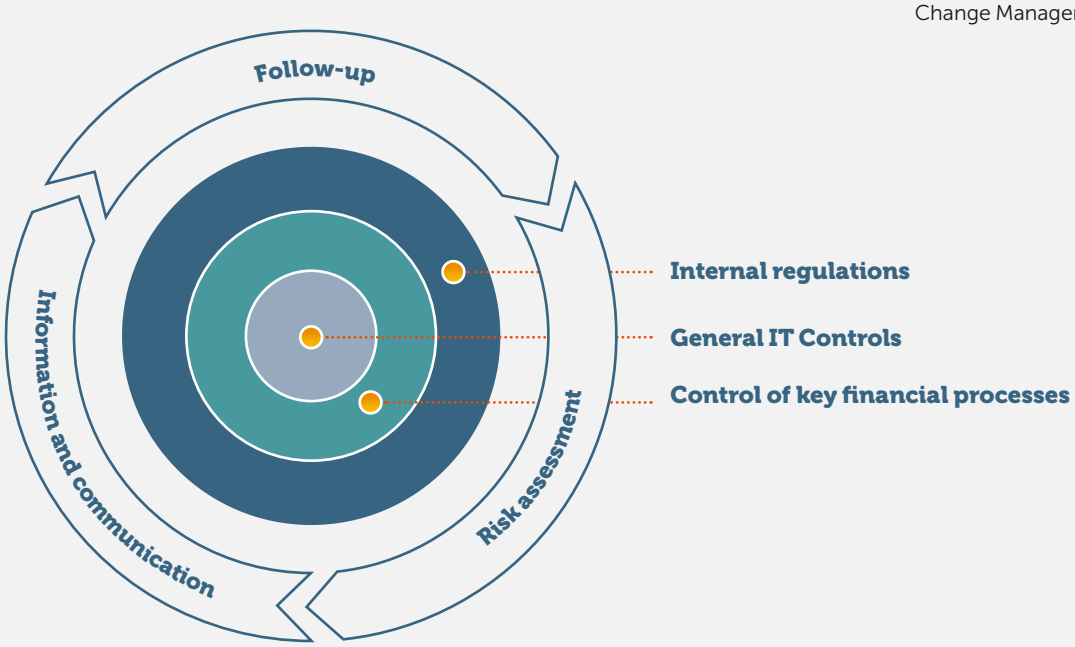
Effective risk assessment aligns Sobi's business opportunities and profits with shareholders' and other stakeholders' demands for stable, long-term value growth and control. The aim of Sobi's risk management process is to support the company's operations and create profitable business opportunities combined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

Material risks identified by Sobi are described on pages 41–43.

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, primary within 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 seperate internal audit function, for the time beeing, is not necessary.

Activities in 2020 that strengthened internal control

- Implementation of a new process for analysing Sobi's partners
- Implementation of the Partner Code of Conduct
- Implementation of a new contract management system
- Continued efforts to map processes for functions outside the finance function
- Implementation of control activities for the management of material risks identified
- Local visits by the internal control function to selected subsidiaries to provide support for the development of their internal control processes

Activities in focus for 2021 to further strengthen 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

Auditor's report on the corporate governance statement

To the general meeting of the shareholders of Swedish Orphan Biovitrum AB (publ), corporate identity number 556038-93211

Engagement and responsibility

It is the Board of Directors who is responsible for the corporate governance statement for the year 2020 on pages 97–103 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 statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2–6 the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the annual accounts and the consolidated accounts and are in accordance with the Annual Accounts Act.

Stockholm, March 26, 2021
Ernst & Young AB

Jonatan Hansson
Auktoriserad revisor

The Board

Håkan Björklund

Born 1956

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

Ph.D. from Karolinska Institutet

Other assignments: Chairman of OneMed. 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. Member of the Scientific Committee (Chair).

BSc Hons Pharmacology from Bath University

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

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

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. Founder and CEO of Acureon Pharmaceuticals. President and CEO of Hydrabiosciences Inc., VP Europe for Chiron's Biopharmaceutical Division and 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

Lennart Johansson

Born 1955

Board member since 2010. Member of the Audit Committee (Chair).

MBA from Stockholm School of Economics

Other assignments: Member of the management team and Senior Advisor at Patricia Industries (division of Investor AB). Chair of the Board of Bonesupport AB, board member of HI3G, Atlas Antibodies AB, Chalmers Ventures and Fastighets AB Tingshuset 13.

Previous positions: Chair of the Board of Vectura Fastigheter AB, CEO in b-business partners and Emerging Technologies AB. Board member of SAAB AB, IBX Group AB and Gambro Holding AB.

Independent of the company and its executive management: Yes

Independent in relation to major shareholders of the Company: No

Shares: 21,200

Helena Saxon

Born 1970

Board member since 2011. Member of the Audit Committee 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 and 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: 15,500

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 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

Elisabeth Svanberg

Born 1961

Board member since 2018. Member of the Scientific Committee.

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 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, Switzerland.

Independent of the company and its executive management: Yes

Independent in relation to major shareholders of the Company: Yes

Shares: 1,550

Pia Axelson

Born 1962

Employee representative

Board member since 2019. Deputy Board member 2019. Board member 2017. Deputy board member 2009. 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: 7,229

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: 25

Deputies for the employee representatives:
- Katy Mazibuko
- Linda Larsson

All shareholdings reported as per 31 December 2020.

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. Board member of Sartorius AG.

Previous positions: CEO BSN Medical GmbH, President & CEO Gambro, EVP Commercial Operations Nycomed, CEO Invida, Global Head of Healthcare DKSH, previous managerial roles at Aventis and preceding entities, Board member of Meda & Sartorius AG.

Shares: 213,223

Henrik Stenqvist

Chief Financial Officer

Born 1967

Employed since 2018

Degree in Finance and Business Administration from the University of Linköping

Other assignments: Board member of Midsona AB.

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

Shares: 28,000

Torbjörn Hallberg

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

Born 1969

Employed since 2018

Master of Laws from University of Lund

Previous positions: Vice President, General Counsel, Emerging Markets at Takeda Pharmaceuticals. Corporate Counsel, Nycomed Pharma. Corporate Counsel, Ferring Pharmaceuticals. Senior Associate/ Lawyer, Advokatfirman Lindahl.

Shares: 8,500

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 BIO - Biotechnology Innovation Organization; HLC - Healthcare Leadership Council.

Previous positions: President of UCB Inc and Head of US Operations, Amgen: Vice President & General Manager; Value, Access, Reimbursement and Patient Experience. Prime Therapeutics: Chief Operating Officer. Aetna Healthcare: Division President, Head of Pharmacy.

Shares: 0

Sofiane Fahmy

Head of Europe

Born 1972

Employed since 2013

Degree in Marketing, University of Paris XI France, 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 Roche.

Shares: 0

Anne Marie de Jonge Schuermans

Head of Technical Operations

Born 1972

Employed since 2018

PhD from Swiss Federal Institute of Technology Zurich (ETHZ); MSc. degrees in Agriculture & Natural Environment from Wageningen Agricultural University and in Environmental Management & Technology from the Ecole Polytechnique Féderale Lausanne (EPFL).

Previous positions: Vice President Global Supply Chain Operations & Strategic Partnerships, Vice President Global Manufacturing, Executive Board Member of Biogen International GmbH; more than 20 years of experience in the life-sciences industry from Biogen, Stryker and Novartis.

Shares: 0

Mahmood Ladha

Head of Business Development

Born 1964

Employed since 2019

MBA and BS from 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, Takeda/Nycomed as well as country management roles at Roche Pharmaceuticals and Aventis Pharma.

Shares: 12,000

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 Sobi, VP Chief of Staff to the CEO Sobi, Management consultant McKinsey & Company New York and Zurich, Group Leader University of Zurich.

Shares: 2,500

Ravi Rao

Head of Research & Development, Chief Medical Officer

Born 1967

Employed since 2020

MB BCh Cambridge University and PhD from Imperial College

Other assignments: Member of the Royal College of Physicians, London and an Honorary Member of the Faculty of Pharmaceutical Medicine.

Previous positions: Chief Medical Officer, Aeglea Biotherapeutics. Roles at GSK as Vice President, Global Medical Head, Immunology and Specialty Medicine Franchise, Vice President and Medicines Development Leader in Immuno-inflammation R&D. Group Medical Director, Immunology Clinical Development at Roche Pharmaceuticals. Academic rheumatologist at Imperial College and a post-doctoral fellow at Harvard University.

Shares: 0

Armin Reininger

Head of Medical and Scientific Affairs

Born 1957

Employed since 2017

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

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

Shares: 9,300

Paula Treutiger

Head of Corporate Communication & Investor Relations

Born 1967

Employed since 2019

Degree in Finance and Business Administration, Stockholm University

Previous positions: Director Corporate Communications & Investor Relations Medicover, Corporate Communications, IR and Sustainability Meda, Portfolio Manager Swedbank, VP Corporate Communications Gambro, Financial Analyst Carnegie and Alfred Berg.

Shares: 2,500

All shareholdings reported as per 31 December 2020.

Sustainability Report 2020

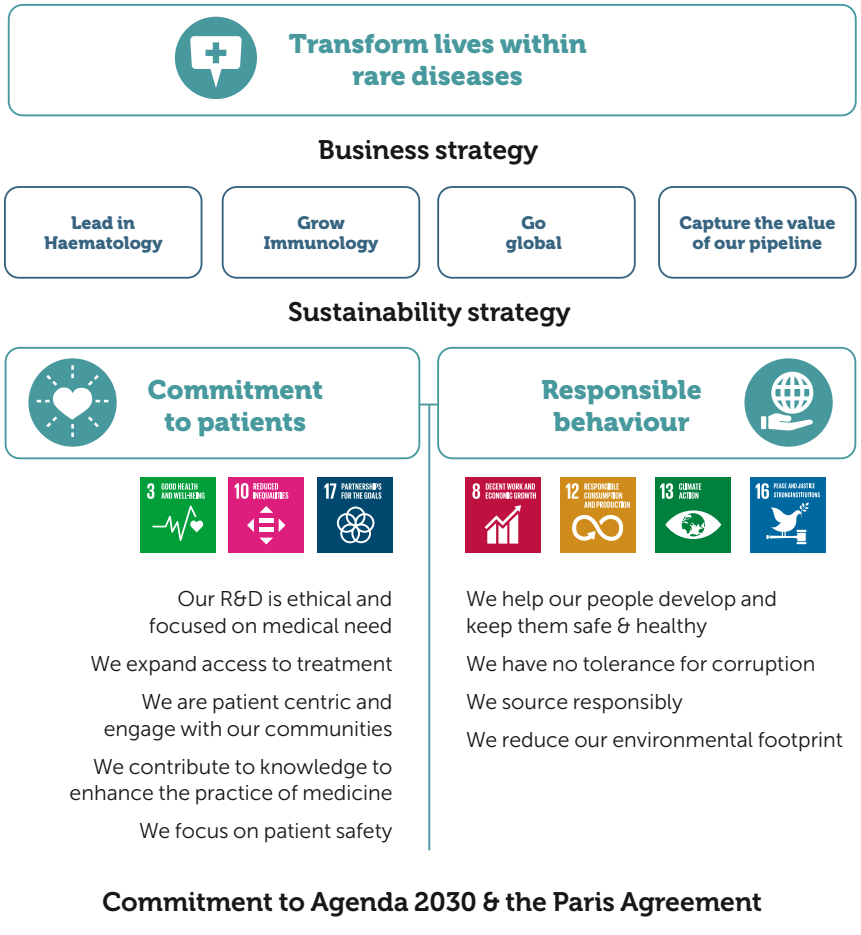
At Sobi our key contribution to sustainable development and our overall sustainability objective – to transform the lives of people living with rare diseases – is closely aligned with our vision and our operations.

Business model and sustainable growth

At Sobi, we are transforming the lives of people living with rare diseases. We provide access to innovative treatments in the areas of haematology and immunology. Sobi's business model (read more on page 10) spans from clinical research to patient access and international commercialisation.

Our sustainability strategy is closely linked to the business and based on two priorities – our commitment to patients and our responsible behaviour. By expanding our geographical reach, investing in the development of novel products and deepening our engagement in the areas of haematology and immunology, we can improve access to rare disease treatments for patients worldwide. If we are successful in our operations, we will positively impact the communities we serve.

Sobi is a signatory of the UN Global Compact, and we have integrated the ten principles of the Global Compact into our core business operations. We commit to operating in a way that contributes to achieving the UN Sustainable Development Goals (SDGs) and the Paris Agreement to address society's greatest challenges by 2030. We are in a unique position to improve health globally within our areas of focus and believe that aligning our business with the SDGs will help us to be stronger and more sustainable.



Material sustainability topics

Our material sustainability topics reflect those sustainability areas where our business has significant impact on our environment from the economic, environmental and social perspectives.

It is essential that we understand the outcome of our materiality assessment as it highlights sustainability topics that are important to our stakeholders and our strategy. In 2019, we performed a comprehensive materiality assessment including web surveys and targeted interviews with internal and external stakeholders such as employees, internal and external experts, owners, suppliers, partners and patient organisations. In 2020, we deepened the assessment by attending conferences, participating in ESG ratings and research, and following and reviewing new legislation.

Measures to address the patient perspective included attending the 10th European Conference on Rare Disease and Orphan Products, ECRD 2020, the largest, patient-led rare disease event for dialogue and learning shaping future rare disease policies. In November 2020, the European Commission communicated its Pharmaceutical Strategy for Europe which has an impact on our business and is aligned with our ambitions.

In 2020, governmental procurement bodies and tender processes have to a greater extent included sustainability requirements in order to be eligible to participate. Shareholders, institutional owners and banks have also increased expectations regarding Sobi's sustainability performance, reflected by an increased number of meetings with a sustainability focus.

The materiality assessment performed in 2019 remains in place, identifying the possibility to transform lives as Sobi's key long-term sustainability objective. The evolution of Sobi's corporate strategy, relying on sourced/acquired research and geographical expansion, has accentuated the need to focus on responsible partnerships and sourcing strategies. The material sustainability topics as defined through the materiality assessment and stakeholder dialogues are summarised in our sustainability strategy and its two priority areas:

- Commitment to patients
- Responsible behaviour

Sustainability governance

Management

Sobi's Board of Directors has overall responsibility for Sobi's sustainability performance, which is 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 Director of Sustainability is, on behalf of the Executive Committee, responsible for operationalisation and communication of the strategy in close collaboration with the business units.

Policies and responsibilities

All sustainability activities are driven by the sustainability strategy and based on the Code of Conduct and other sustainability-related policies. The Sobi Code of Conduct provides a framework for what Sobi considers to be responsible and appropriate conduct, and applies to all Sobi employees worldwide as well as temporary personnel. The most important practices and policies guiding Sobi's sustainability work and processes are listed below. Visit the website www.sobi.com for a list of policies governing sustainability-related areas.

Important responsibilities in terms of 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.
- Corporate Compliance, responsible for the implementation of anti-corruption and healthcare interaction policies, data privacy and the compliance hotline (whistleblower hotline).
- Technical Operations, which includes Procurement, is responsible for environmental compliance and performance regarding in-house operations, and for monitoring suppliers' and partners' adherence and development in accordance with the Responsible Sourcing Programme.
- Internal Control, which evaluates and improves processes for management, internal control and risk management.
- Business units, which are required to run the business in compliance with the Code of Conduct, realise the elements of the sustainability strategy and drive progress.

Sustainability-related policies

Commitment to patients	Responsible behaviour	
• Policy on Healthcare Interactions	• Anti-corruption policy	• Procurement Policy
• Good Pharmaceutical Practice including Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), Good Clinical Practice (GCP) and Good Pharmacovigilance Practice (GVP)	• Sobi Group Authority Policy	• Environmental Policy
	• Policy on Anti-Corruption Due Diligence on Third Parties	• Health and Safety Policy
	• Entertainment policy	• Policy on Processing of Personal Data
	• Policy on Healthcare Interactions	• Policy on Investigations
	• Communication Policy	
	• Insider Policy	
	• Finance Policy	

External recognition
Sobi's sustainability performance and progress is validated by external CSR specialist firm EcoVadis on an annual basis. Sobi also actively partakes in environmental, social and governance (ESG) evaluations with the aim of ensuring continuous improvement. The following sustainability rating agencies are rating our performance from an ESG perspective.

Sustainability Rating Agencies

Rating	2020	2019	2018
MSCI	A	A	A
Sustainalytics	26.4 medium risk	26.2 medium risk	
ISS	C High relative performance	C High relative performance	C High relative performance

Sustainability risk management
The Sobi risk management process is documented in the Sobi Group Risk Management Policy and the Sobi Group Risk Management Instructions.

Sobi applies a business risk-management approach where sustainability risks that may impede our ability to achieve set objectives are included. The organisation works actively to identify and address any uncertainties related to our ability to achieve our objectives. Identified risks are analysed using relevant values for the operations, enabling subsequent prioritisation on a commercial basis, whereby uncertainties and untapped opportunities around the company's strategy can be identified and managed. Sobi's Risk Manager reports the current risk status to the Executive Committee, and a review of this process is presented to the Board of Directors on a regular basis.

As part of the risk management process, the company's critical flows are identified and business continuity plans for these are implemented.

Sobi is following the development of the current Task Force on Climate-related Financial Disclosures (TCFD) recommendations and EU Taxonomy regulations. Our sustainability risks are presented on pages 41–43.

Sustainability reporting and communication

Sobi's sustainability reporting and communication aims to provide correct and relevant information regarding sustainability performance, goals and strategy to investors and stakeholders. We have committed ourselves to be transparent on our sustainability performance and progress.

Based on the outcome of the materiality assessment and the defined sustainability strategy, Sobi has identified material topics and their boundaries, taking into consideration reporting principles such as stakeholder inclusiveness, sustainability context, materiality and completeness.

Sobi's Sustainability Report has not been subject to external assurance. The Sustainability Report has been approved by Sobi's auditors in line with requirements in the Swedish Annual Accounts Act.

Sustainability strategy

The aim of the Sobi sustainability strategy is to deliver on the vision of transforming the lives of people living with rare diseases. It also aims to support Sobi's business strategy and deliver progress in terms of sustainability. The strategy is based on two priorities – our commitment to patients and our responsible behaviour – and includes nine sustainability commitments. Each priority is, in addition, linked to UN's Sustainable Development Goals (SDG) and targets that are perceived as critical for our business. The sustainability strategy is based on our commitment to always be transparent and our willingness to contribute to the realisation of Agenda 2030 and the Paris Agreement.

Commitment to patients

For Sobi, meaningful engagement and cooperation with the rare disease community is essential. Engaging with the rare disease community requires a specialised skill set and a high level of engagement. The community's collaborative commitment to reach common goals is important, as rare diseases are still undefined in many areas and cannot be charted in isolation.

We are in a unique position to improve health on a global scale for a number of small and often overlooked patient populations and we take action to contribute to 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, and significantly reduces the risk of RSV hospitalisation.	p 16
			Continued investments in expanding indications for Kineret (anakinra), approved in certain indications for children from 8 months of age.	p 15
			Continued efforts to ensure widespread sustainable access to Orfadin for children with HT-1. Regulatory filing in China.	p 17
	3.4 Reduce premature mortality from non-communicable diseases (NCDs)	Increase number of R&D programmes in rare diseases and areas of high medical need	12 late-stage programmes in our pipeline as of 31 December 2020	p 20–22
			Orfadin, the first pharmacological treatment approved for the ultra-rare disease AKU	p 17
	3.8 Achieve universal health coverage	Continue 10-year commitment to the WFH Humanitarian Aid Program	Signed additional 5-year contract for a total 1 billion IU donation.	p 24, 113
			To date, WFH donations have reached 17,329 patients in 43 countries.	p 113
		Contribute to cost-support programmes	Continued support of Kineret OnTrack and Orfadin4U support programmes in the US	p 112
		Support charities in under-developed and underserved areas	Medical grant to FYMCA Medical Ltd for continued rare disease education in developing countries.	p 114
	3b Support R&D and access to medicines for diseases	Increase number of first-in-class products in R&D pipeline	5 first-in-class products	p 24
		10–15% of turnover in R&D spend	R&D spend increased to 13–15% of revenue 2021–2022	p 24
		Expand products' global market reach	3 new indications approved 1 approval in a new market Expansion into China, Japan, Australia in 2020.	p 127–128 p 24
SDG 10 Reduced inequalities	10.3 Equal opportunity	Expand rare disease and orphan drug innovation pipeline	3 new partnerships for products with orphan drug status. 2 orphan drug designations for new indications of on-market products.	p 24
SDG 16 Peace, justice and strong institutions	16.7 Inclusive, participatory and representative decision-making	Include patient and healthcare representatives in decision-making	Co-developed patient support programmes, advocacy and evidence generation activities with patient advocacy groups.	p 113–114
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	Provided support to patient organisations as well as local patient organisations. Approved members of PSCI in January 2020.	p 113–114
	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	18 ongoing or planned, external, randomised controlled studies of anakinra in moderate-severe COVID-19. Sobi is supporting 10 ISS across the US and EU.	p 20, 112

Our R&D is ethical and focused on medical need
High-quality and ethical science is of the greatest importance to us and contributes to the expansion of treatments for rare diseases in areas of unmet medical need.

Sobi's pipeline has a tight focus on innovative and differentiated medicines, enabling a step change in therapy in cases of unmet medical need where there is no available treatment. Sobi intends to take leadership in medicine development within rare diseases. Sobi's products are already being developed and evaluated for multiple indications and an integrated life-cycle management approach is applied. Sobi is also exploring the possibilities of precision medicine in the use of digital health, companion diagnostics and genetic screening to optimise treatment outcomes.

Our research is founded on scientific and medical need, and the design of our studies and the studies we support enables a scientifically sound evaluation of the treatments we develop and provide.

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).

When conducting clinical studies, we make sure that we give participants comprehensive, easy-to-understand information so that they enrol only of their own free will and with informed consent. Patients also have the right to withdraw from a study without compromising the care they receive.

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 gaining consent, considerations for data privacy in small patient populations and research of genetic diseases. Through close collaboration with patient representatives, we act in the belief that this group should stand to benefit from the knowledge, practices or interventions that result from the research.

We conduct our research openly and publish clinical studies on clinicaltrials.gov. We register and report all our clinical studies and share the complete and accurate results of our clinical studies even if they show an outcome that is not beneficial for our business. Most clinical research is outsourced. Training on the medical aspects of the disease as well as processes and monitoring is done regularly for both our own and sourced personnel.

Sobi recognises the important role that investigator-sponsored studies (ISS) can play in expanding the knowledge related to Sobi's products and their associated disease areas. In an ISS, an investigator independently generates a research proposal, and Sobi provides support for the proposal if it is approved. Support can include drug material, expert advice, funding and more. The investigator serves as the study sponsor and assumes full responsibility for ensuring compliance with regulatory requirements.

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 external legislation, regulations and guidelines. Sobi does not currently conduct stem-cell research.

Where animal testing is necessary, it is carefully considered and justified, with the 3R (replacement, reduction and refinement) principles applied. Sobi does not perform in-house animal studies and contracts only from highly qualified suppliers.

We expand access to treatment
Sobi's growth strategy and market expansion enable us to reach more patients with our treatments and 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 over the coming five years which will broaden access to treatments outside our core markets. Sobi also has a partnership strategy to serve currently underserved markets.

For a review of current approval and reimbursement status in markets, see the table on pages 127–128.

A treatment is of value only if it reaches patients and physicians. One of the most powerful ways in which we work with the community is through patient access – ensuring rapid and sustainable access to treatment for people with rare diseases through the established healthcare system. Responsible pricing and reimbursement are essential components in enabling access.

Ensuring sustainable and secure access to care means that patients, caregivers and patient organisations can access the care they need when they need it without significant physical, social, financial or emotional burden. Some solutions created to support access include home nursing and product delivery programmes, telemedicine, patient navigation tools, culturally and linguistically adapted tools as well as adherence programs.

Product 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 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 on other treatments in the US.

Pricing and reimbursement
Pricing and reimbursement are two essential areas of patient access following regulatory approval. Each market has its own regulations and demands regarding approval of the proposed price and the degree to which reimbursement is provided.

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.

Sustainable reimbursement is achieved through evidence generation that enables the clinical and patient value of a treatment to be quantified. Sobi works continuously to develop data that reflects resolution of unmet medical need on both initial and ongoing bases.

Ethical R&D focused on medical need – Ambitions

- Committed R&D budget in rare diseases
- Increase number of R&D programmes in rare diseases and areas of high medical need
- Use orphan drug regulations to shorten time to patient
- Optimise treatment outcomes through innovative approaches
- Increase number of clinical studies on Sobi products
- Perform consultations of patients and payers to ensure endpoints and outcomes that are meaningful for payers and patients.
- Support investigator-sponsored studies

The EU Pharmaceutical Strategy aims to facilitate collaboration on unmet needs and evidence generation in joint meetings of existing committees/networks of regulators, health technology assessment (HTA) bodies and payers, involving key stakeholders in the development, authorisation and access to medicines for a life-cycle approach and improved availability and affordability. Sobi has pioneered and participated in these collaborations over many years and intends to continue doing so.

In some markets, patient access to treatments may be limited by the lack or complexity of reimbursement processes. We have several initiatives in place e.g. in the US to support patients and treaters to gain access, bridging the gap.

Acting with 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 that, if approved, would provide significant improvements in the safety or effectiveness of the treatment, diagnosis or prevention of serious conditions when compared with standard applications.

Sobi recognises that there may be instances 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 normally not available between completion of a clinical trial and regulatory approval or commercial availability. For such patients, upon an independent request from their treating physician and where legally permissible, Sobi considers making access of our medicines available via Managed Access Programmes[1]. Requests from treating physicians for Managed Access are assessed based purely on 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 products (Orfadin, Kineret and Gamifant) which is 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 World Federation of Hemophilia Humanitarian Aid Program helps address the lack of access to care and treatment by providing much-needed support for people with inherited bleeding disorders in developing countries.

By providing a more predictable and sustainable flow of humanitarian aid donations, the programme makes it possible for people living with haemophilia to receive consistent and reliable access to treatment and care. In addition, educational programmes for treaters and patients are critical initiatives helping to develop in-country capacities to improve diagnosis and treatment monitoring. In 2020, due to the COVID-19 pandemic, the training workshops were mainly conducted in a virtual setting, resulting in almost a three-fold increase in the number of attendees. While personal interactions are important, the WFH will evaluate how a multi-channel approach may further expand the reach and accessibility of training.

Since 2015, and renewed in 2020, Sobi and Sanofi have pledged to support of the WFH Humanitarian Aid Program with a total of 1 billion IU of factor therapy for humanitarian use over a ten-year period. See Sustainability Notes on page 122 for details on impact to date.

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

Supply-chain continuity

In 2020, our product supply chain withstood the challenges of the COVID-19 pandemic and there was no interruption to the safe and secure production, supply and logistics of Sobi products. Sobi – with its collaboration partners, contractual manufacturers and distribution network – has been able to manage the effects of the pandemic. This is a result of strong partner relationships, intensified communications and clear supply planning to secure product availability and manage fluctuating product demand.

Home delivery in Saudi Arabia during COVID-19 lockdown

Just as COVID-19 emerged, several major hospitals in Saudi Arabia switched haemophilia patients to Sobi products. The lockdown of the capital Riyadh meant patients outside the city were at risk of not receiving treatment. Sobi introduced a home delivery service in collaboration with local hospitals, pharmacies and Sobi supply chain/logistics, sending refrigerated trucks with products from Riyadh to 12 cities around Saudi Arabia.

COVID-19 educational material for haemophilia

Educational videos on COVID-19 were co-created with stakeholders from the haemophilia community, sharing insights, expertise and their experience on how best to manage haemophilia and maintain good health during the pandemic. There is a significant need to maintain exercise and adherence to prescribed treatment and support a healthy immune system.

Expand access to treatment – Ambitions

- Increase geographical reach of operations
- Ensure sustainable access to care
- Continuous product 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

Actions to ensure continued access to treatment after Brexit

Since 2018, Sobi has prepared for different possible outcomes of the Brexit Free Trade Agreement negotiations. The project has involved representatives from a multitude of functions. To ensure supply for patients in the UK, extra stock was organised in the UK and Sobi signed the UK Government's secured freight capacity for supply of medicines. When the UK left the EU on 1 January 2021, no patients experienced interruptions of product supply. Sobi is also well prepared for future regulatory changes.

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

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

Sobi supports connectedness so that patients, caregivers and patient organisations can connect to each other and the community, and to 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 also supports the European Haematology Association (EHA), The Irish Platform for Patient Organisations, Science and Industry (IPPOPI), The AKU Society, the Histiocytosis Association, AIArthritis Association, and other local patient organisations. A yearly summary of support provided to patient organisations is made public on www.sobi.com.

Sobi has been giving a voice to patients to express their needs related to care, offering a platform to build awareness and to advocate for their needs to be considered in current and future decisions related to care. This is done through patient advisory boards and involvement of patients in R&D and clinical study design to ensure we continue to develop our medicines to meet unmet needs, and by sharing patient stories. 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 refracorty gout.

Sobi also contributes to the wider community through collaborations with third parties. In 2020, Sobi entered into an agreement with QBE Europe to invest 25 per cent of our corporate insurance premium into investments with an additional social objective via Premiums4Good.

Community engagement – Ambitions

- Support patient connectedness
- Give a voice to patients

Knowledge contribution to enhance the practice of medicine
Within rare diseases, knowledge about each disease is rare too, and Sobi is committed to contributing to increased understanding, diagnosis and treatment of these underserved diseases. Sobi engages in advancement of knowledge by sponsoring and attending scientific meetings and arranging medical training designed to share medical advancements, and taking part in discussions to enhance the practice of medicine. Participation in medical events is governed by the Healthcare Interactions Policy. Sobi sponsored and participated in six international scientific meetings as well as several local events in 2020.

Sobi's annual support to 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.

For almost ten years, Sobi has been a sponsor of SSIEM, the Society for the Study of Inborn Errors of Metabolism. Sobi has taken part in the organisation's meetings, which offer a unique opportunity for the community to meet, train and learn from each other.

Sobi also provides a medical grant to FYMCA Medical Ltd for continued rare disease education and services in developing countries. The FYMCA programme aims to develop the skills of the healthcare personnel in diagnosing and managing metabolic diseases, as well as providing genetic counselling in countries where equipment and resources are not available.

Knowledge contribution – Ambitions

- Active participation and sponsorship of medical conferences
- Continued support of community-led initiatives to increase knowledge sharing

We focus on patient safety
By adhering to pharmaceutical standards, we strive to provide products that meet the high quality and regulatory expectations of the pharmaceutical field. The safety profile and monitoring of our products is of utmost importance.

Safety surveillance, pharmacovigilance, continues across the life cycle, allowing us to identify safety risks sooner so that we can mitigate them and minimise or avoid harm. For all our medicines, under development or on the market, we have systems in place for identifying and evaluating possible adverse drug effects. With a robust pharmacovigilance system, we continuously monitor the benefit/risk profiles of our products and ensure our alignment with the precautionary principle. Our Chief Medical Officer is accountable for the benefit and risk profiles of our products, providing medical oversight and enforcing risk assessment processes that help us make efficient and informed decisions about patient safety. Each product also has a dedicated safety team, which includes a responsible global safety physician.

As part of our commitment to patient safety we continue to improve the competence of our staff, and develop our processes, systems and tools. Annual training is provided for all employees to ensure that all safety information – such as adverse events, product complaints and incorrect use – in relation to our products is reported.

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 requirement in the regulatory dossier in all countries where our products are licensed, manufactured or sold.

Good Practice guidelines are maintained to monitor and ensure product safety and quality compliance during the products' life cycles. The Quality Assurance department is responsible for product release to the market; this process includes the evaluation of product testing and the manufacturing steps. In the EU, product release to the market is performed by a Qualified Person (QP). For drug safety (pharmacovigilance) the responsibility is held by the Qualified Person Pharmacovigilance (QPPV).

To ensure and evaluate compliance with current requirements, inspections of our facilities by regulatory authorities are performed regularly. In addition to external inspections, Sobi continuously monitors the performance of our suppliers and internal processes and operations.

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 recall is governed by standard operating procedures (SOP) and managed for all products for which Sobi is Marketing Authorisation Holder (MAH), and for Investigational Medicinal Products (IMP) in Sobi-sponsored clinical trials in cases when a product 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 to market and clinical studies, and a Recall Decision Body will take the decision on a recall together with the relevant regulatory authority or authorities.

Correct labelling is important to ensure proper use, and current and new safety information needs to be communicated consistently and promptly to authorities, prescribers, patients and within the organisation. SOPs are in place to ensure timely updates to Product Information and Patient Information Leaflets in the product 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 a growing worldwide problem. Governments all over the world are introducing regulations and systems to detect and prevent the distribution of counterfeit products. All Sobi products are serialised and given unique identification codes. Sobi's products have not yet been subject to falsification.

Patient safety – Ambitions

- All Sobi employees trained in patient safety
- No critical or major incidents of product recall
- No incidents of incorrect labelling

Responsible behaviour

At Sobi, we promote business ethics in everything we do by setting high ethical standards and providing policies to support employees by defining responsible behaviour. The aim is to build a sustainable organisation by enforcing compliance with our corporate principles, and by supporting a culture that promotes an open discussion of ethics in our operations. Through our actions, we take action to contribute to the SDGs via specific 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 and LED lighting	100% renewable energy at head office and manufacturing site in Sweden.	p 121
		Transition to 100% hybrid/electrical car fleet by 2030	Environmental limits and increased nominal value introduced in car policy for Sweden and Italy	p 121
SGD 8 Decent work and economic growth	8.8 Safe and secure work environments	Ambition for zero work-place incidents	Updated Health & Safety Policy. Reduced number of incidents in 2020.	p 117, 125
			Supplier requirements stipulated in Partner Code of Conduct.	p 119
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 in place.	p 119
			Responsible Sourcing Programme rolled out across the organisation.	
	12.4 Achieve the environmentally sound management of chemicals and all wastes throughout their life cycles	Comply with REACH legislation	Sobi granted REACH authorisation for the use of Triton X-100.	p 120
		Environmental assessments of products	Environmental assessments updated for Sobi's two small molecule treatments	
		Increase data collection on waste to enable reduction of waste volumes	Waste project initiated. Established process for reuse and recycling of IT equipment.	p 121
SDG 13 Climate action	13.2 Integrate climate change measures	Apply TCFD risk analysis and adopt climate strategy in response.	Strategy on environmental sustainability in place. Environmental policy updated with training.	p 120
		Complete Scope 1, 2 and 3 reporting with targets	Scope 1 and 2 reporting for whole organisation. Enhanced Scope 3 data collection and reporting with target set for 2022.	p 121—123
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 115
	16.5 Anti-corruption and bribery	Zero incidents of bribery or corruption	New Code of Conduct approved. Training distributed with a 97% completion rate.	p 118
			Healthcare Compliance structure strengthened and continued transparent reporting on monetary transactions and transfers of value.	
			Whistle-blower functionality made available to external parties.	

We help our people to develop and keep them safe & healthy
Sobi is a responsible employer. We rely on our people to deliver on our business strategy. Our social impact is derived from our commitment to patients as described in this report, but also through our interactions with our employees and the work opportunities and conditions we provide.

Employee survey
Sobi has committed to perform an annual all-employee survey, including pulse surveys to monitor employee satisfaction, inclusion and engagement.

In 2020, the Global Engagement Survey was conducted with a response rate of 87 per cent including all employees and full-time consultants in wholly owned subsidiaries. Employee engagement ranked on 73 (benchmark 74), on par with the industry.

Workshops throughout the organisation have identified areas for development in three main areas: culture, career opportunities and work-life balance. Culture is seen as an aspect important to maintain and nurture during the organisation's growth and strategic shift. Career opportunities are also valued, and while employees believe that their competence is a good match with their roles, there is a continued desire to develop to contribute even more and that opportunities for career development are recognised in the expanding business strategy. Finally, work-life balance was impacted negatively during the COVID-19 pandemic, as seen in many organisations last year. It was noted however that workload ranked better in the Engagement Survey in September 2020 than in the COVID Pulse Survey in June 2020, after which actions were taken to improve the workload situation.

Development, training and compensation
Sobi is a values-driven company with a scientific and patient-centric organisation. Highly skilled and high-performing teams have been identified as a key success factor for meeting our ambitious strategic objectives. This involves developing our methods to help managers, leaders and colleagues facilitate continuous growth. An example of a Sobi leadership training programme is the Sobi Management Toolbox training which is designed to develop Sobi's leadership population in the fundamentals of people management. The training, which is now available digitally, offers managers the opportunity to practise leadership skills, identify their own strengths and development areas, and learn from peers.

Sobi also offers regular business introduction sessions that are open to the whole company where corporate leaders present their respective areas.

Creating a safe working environment during COVID-19

COVID-19 impacted our employees across the world in a professional and private perspective.

Actions implemented 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 were applied March to December, 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 engagement from employees and an eagerness to influence working conditions.

All Sobi's employees receive regular performance and career development reviews. A talent management process was presented in 2020 to support employee evaluation and development. Sobi applies a 70:20:10 learning and development model: training opportunities are offered as part of the role (70), through interactions with others (20), and formal educational events (10).

All Sobi employees have access to the Sobi Learning Management system and are assigned training based on role, supported and documented by a training matrix system. The system also lists available business, management and product training, 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. In 2020, an online Learning Resource Guide was also made available to all employees.

Competitive terms of employment are a prerequisite for recruiting and retaining high-calibre people. We endeavour to offer competitive salaries and benefits, individually determined and adapted to the local labour market. All employees (with exception of North American and Asian based employees due to tax reasons) are offered long-term as described in Note 10.

Health and safety
Sobi enforces a global Health and Safety Policy. Occupational health and safety (OHS) management is integrated into overall activities and operational control as an ordinary 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 their employer; this is done through an electronic system. Managers are required to report serious incidents and significant OHS risks, and ensure that regulatory requirements and internal procedures for reporting of incidents are followed.

Diversity and equality
Every employee is offered equal opportunities regardless of ethnicity, age, gender, religion, sexual orientation or physical ability. Our guidelines clearly prohibit any sexual harassment. In the US, a Diversity, Equity & Inclusion programme was initiated, including an Employee Resource Group, manager training on inclusion and belonging as well as unconscious bias training.

In Sweden, our gender equality analysis carried out annually is designed to prevent discrimination and promote equal rights and opportunities. We carefully evaluate the results in collaboration with trade unions and act when needed. We also map roles and responsibilities proactively to ensure that salaries and development opportunities are provided in an equitable manner.

Caring for our employees – Ambitions

- Perform annual employee engagement survey
- All employees offered annual performance and career development discussions
- Zero-tolerance approach to discrimination and sexual harassment
- Target of no workplace accidents leading to lost workdays

We have no tolerance for corruption

Transparency and open dialogue about ethical issues form the foundation of strong collaborations. The Sobi Code of Conduct provides a framework for what Sobi considers to be responsible and appropriate conduct. It is 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 areas.

During the year, a fully digital version of the Code of Conduct (www.coc.sobi.com) was launched, accessible for both employees and external audiences, replacing the previous version. Topics include human rights, health in the workplace, freedom of association, zero tolerance of child and forced labour, patient and community interactions, product safety and quality, ethical research, anti-corruption, fair competition, handling of conflicts of interest, data privacy, intellectual property and environmental responsibility. The Code of Conduct has been translated into major languages and is supported with e-learning focusing on practical dilemmas.

We also promote high ethical standards by supporting a corporate culture that promotes open discussions of ethics both in our operations and among key stakeholders.

Sobi's 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 and legal protection. During 2020, the Sobi Compliance Hotline also became available for external audiences via a link on the company website. All reports made through the whistleblowing hotline are reviewed by the Corporate Compliance Department, are subject to investigation according to Sobi's Investigational Policy and are followed up with appropriate remediation measures as needed.

Compliance

Sobi's compliance programme aims to enable our business by handling risk before it arises; it follows the elements and principles for effective compliance programs established by regulators. Compliance is introduced to all new employees and included as a topic in induction programmes. As Sobi is expanding and entering into markets with higher risk, specific focus has been applied to introduce new markets to Sobi's compliance programme including on-site visits, training and increased monitoring of new service agreements.

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 the Board of Directors.

Anti-corruption

The pharmaceutical industry presents 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. We work actively to prevent any form of corruption.

Sobi's Anti-Corruption Policy, approved by the executive management, 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 nature of bribe, no offer or provision of facilitation payments, accurate bookkeeping and records, and ensuring that no gifts are made to public officials or to healthcare professionals. Risk assessments shall be carried out on a regular basis and risk-based due diligence procedures shall be carried out in respect of third parties.

Sobi's Internal Control function governs standards across the organisation, including the Risk Management Policy, the Authority Policy, conducting yearly walk-throughs and testing of previously mapped processes to identify changes in activities, risks and controls. Collaboration and audits with the Compliance department occur on a regular basis or when reason arises.

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. Additional training for specific audiences is defined in yearly 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 exposure related 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 Sobi's 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 to corruption prevention are: Policy on Anti-Corruption Due Diligence on Third Parties, Group Authority Policy, Entertainment Policy, Procurement Policy and Risk Management Policy.

We have an established Healthcare Compliance (HCC) programme including 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. All healthcare interactions are intended for the benefit of patients or to enhance the practice of medicine, and all interactions require 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. Findings are categorised, logged and reported.

Monetary transactions and transfers of value 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 our website, www.sobi.com. Sobi currently publishes Transfers of Value to healthcare providers in 33 markets across Europe (including Russia and Ukraine) and the US. In 2020, we launched an updated programme and system support for transparency reporting for increased effectiveness and rapid adaptation to new geographic areas.

Responsible marketing and sales

We are 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 are trained regularly.

The Policy on Healthcare Interactions guides promotional activity and provides relevant tools. The policy applies to 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 after each modification, by a cross-functional team of qualified representatives, and review and approvals are documented 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 on how to respond 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 assess if reporting to supervisory authorities and/or data subjects is required. In order to be able 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.

We source responsibly
To ensure sustainable and responsible sourcing, we launched the Sobi Responsible Sourcing Programme in January 2020, including the introduction of a Partner Code of Conduct and sustainability screening. Contracts include a requirement to comply with the Sobi Partner Code of Conduct. Sustainability screening of partners involves ensuring compliance with standards in the areas of governance, labour rights, human rights and environmental responsibility through EcoVadis third-party evaluation. Yearly assessment by EcoVadis is conducted for strategic suppliers in direct categories and for those in high-risk countries, in 2020 covering top 100 suppliers in spend.

In January 2020, Sobi's membership application to the Pharmaceutical Supply Chain Initiative (PSCI) was accepted, and requirements for supplier behaviour and performance have been aligned with the PSCI principles.

During the year, the Procurement department has been trained in responsible sourcing, and an assessment of supplier sustainability performance has been included as a qualifier in supplier selection. Suppliers that do not reach a total EcoVadis score of >40 or which have a score <40 in any theme will be further evaluated and encouraged to improve their score.

Sobi intends to expand the Responsible Sourcing Programme in 2021 to include a materiality and risk-based approach to sustainability audits, and introduction of continuous improvement plans and non-compliance procedures.

Sobi's human rights statement and statement against child and forced labour are included in the Partner Code of Conduct to address potential risks and manage compliance in the supply chain.

Third-party due diligence
Sobi's commitment to prevent bribery and corruption in connection with our 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 being mandatory for all employees: Code of Conduct, Anti-corruption and anti-bribery, Data privacy, and Product safety training
- Zero-tolerance approach to bribery
- No major violations of data privacy
- Transparent reporting of monetary transactions to healthcare professionals and organisations
- Deliver on Responsible Sourcing Programme
- Participate in supplier sustainability networks
- Conduct ESG due diligence and promote the responsible business conduct of suppliers

Reducing our environmental footprint

Our materiality assessment shows that our environmental and climate-related impact is limited. It can be broken down into direct and indirect impacts, through sourced activities both upstream and downstream and through activities caused by our operations.

Our carbon footprint arises from energy consumption during the production of products, business travel, logistics within the supply chain and the distribution of our products. Environmental impacts from production and the laboratories are mainly due to the use of energy, water, chemicals, generated waste and discharge of sewage.

Management of water and energy consumption, chemicals, waste and emissions have high priority in our production and laboratory facilities. More 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 from the production.

We continuously evaluate and monitor the energy and water consumption of our production facility. Sobi reports energy and water consumption annually and measures internal KPIs with the aim of improving environmental performance.

Sobi's current reporting practice covers Scope 1 and 2 for all our wholly own operations as well as Scope 3 for business travel.

Responsible handling of chemicals

All applicable chemical regulations are monitored closely and naturally constitute an important aspect of Sobi's business. A recent example is the use of Triton in the ReFacto production process. Triton X-100 is subject to REACH authorisation. It is not possible to replace Triton in the process, so Sobi applied for and was granted authorisation for its use. Strict requirements are applied on filter cleaning and waste handling to ensure that environmental discharge is avoided as far as possible.

Chemicals regulations are extensive and continuously expanding; all handling of chemicals in our laboratory and manufacturing processes therefore follows strict instructions. We perform continuous risk assessments and internal audits. The Responsible Sourcing Programme is an important tool to influence, manage and follow up sourcing and handling of chemicals in our supply chain.

Pharmaceuticals in the environment

The environmental hazards of a specific drug refer to its inherent properties, such as toxicity and its ability to be broken down by nature. According to existing EU and US guidelines on environmental risk assessments of medicinal products, biopharmaceuticals composed of for example proteins and peptides are not considered to have a significant negative environmental impact. A high percentage of Sobi's products are protein-based and are therefore considered

Sobi's total carbon emissions (CO_2 tonnes)

Sobi's own carbon emissions

1.7
Combustion

597
Cars

97
Purchased electricity[1]

1,359
Business travel

Sobi's value chain's carbon emissions

To map & act
Contract manufacturing[2]

To map & act
Distribution & logistics[2]

To map & act
Raw material[3]

To map & act
Capital goods & services[3]

Direct and indirect emissions (Scope 1, 2 and parts of Scope 3 in CO_2 tonnes)
1. Calculation methods have been adjusted to previous years.

Other indirect emissions (rest of Scope 3), in the value chain to be mapped by 2022.
2. Hybrid method based on supplier direct reporting will be used
3. GHG-protocol calculations based on spend will be used

not 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, nitisinone and avatrombopag, and they are considered to be of low risk to the environment.

Direct carbon emissions (Scope 1 and 2)
Sobi's direct emissions arise from our commercial operations in 30 countries with 20 offices as well as our biological production facility (reported as Manufacturing/Haematology) in Stockholm, Sweden, and our laboratory in Geneva, Switzerland.

Our direct operations are where we have the most control. We commit to substantially reducing emissions from our sites and ground fleet by 2025 by avoiding, reducing and substituting, and have the ambition to reach zero emissions by 2030. Electricity from renewable sources is currently sourced for offices and facilities in Sweden, Switzerland and Denmark. Mapping and review of energy sources as well as extent of use of LED lighting for local offices was initiated in 2020.

Indirect carbon emissions (Scope 3)
All production of our commercial products is outsourced to contract manufacturers. Sobi's supply chain sources production from CMOs in Europe and the US, with distribution to over 70 markets worldwide. Across our value chain (Scope 3), this is where reductions potentially could have the biggest impact but also where we have least control.

During 2020, Sobi participated for the first time in the PSCI Supplier Survey led by Ecodesk to collect Scope 1 and 2 emissions data from contract manufacturers.

Sobi intends to increase our awareness of our climate impact by mapping the supply chain by 2022, using surveys and other methods of direct reporting for CMOs as well as distribution and logistics services. Remaining emissions from raw materials, packaging, capital goods and services will be calculated using industry-specific guidance on spend from the GHG Protocol where possible. Sobi will aim to apply the boundaries "from cradle to customer", limiting reporting to areas within our producer responsibility - production, formulation, packaging and delivery of sold goods to wholesaler or partner. Emissions calculations will not cover a full consumer life-cycle analysis as the prescription and use of our products is beyond our control.

We will continue to use the Responsible Sourcing Programme and supplier relationship management to increase reporting coverage as well as influencing suppliers to participate in emission reductions with a focus on areas of our producer responsibility. The safe and timely delivery of our products will always be the primary consideration.

Development of climate-based targets

Target year	Topic	Ambitions
2022	Emissions – Scope 3	Map emissions in supply chain (CMO, distribution, waste and spend) – 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

Business travel
In 2020, Sobi expanded the reporting scope of business travel emissions to cover all global operations (in 2019, 80 per cent of operations were included) with the intention of setting a baseline year for business travel. However, in 2020 the COVID-19 pandemic had a substantial impact on business travel as Sobi limited all non-essential business travel from 15 March until the end of the year.

Business travel also includes a Sobi leased car fleet (Scope 1) as well as employee-owned cars (Scope 3). The practice of car management and policy is dependent on local regulations and culture. In Sweden and Italy, further sharpened environmental limits were introduced in 2020 for local car policies as well as the provision of an increased nominal value to include electric and hybrid cars. Charging facilities are available at offices in Italy, Belgium and Finland with economic compensation for the installation of charging facilities at employees' homes provided in Italy, UK, Ireland, Spain and Portugal. According to policies for the newly opened operations in Japan, only employees' public transport is compensated.

A significant shift has been made to transition to digital internal and external meetings as well as scientific congresses reducing the need for travel. Sobi has accelerated the implementation of modern workplace technology across the entire organisation.

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 2019, Sobi discontinued and moved the majority of the laboratory operations from the Solna head office. In 2020, all equipment was evaluated for further use within Sobi's operations. To further limit the volume of waste caused by this action and promote reuse, functioning laboratory equipment was sold to external parties.

Sobi has an established process for reuse and recycling of IT equipment in Sweden via a certified technology lifecycle management service partner. This process will extend to all Sobi's operations worldwide as of 2021.

Sustainability Notes

Sobi updated its materiality assessment process in 2020. For a detailed description of stakeholder groups and outcomes of the assessment, see page 109. The materiality assessment identified the most important topics for Sobi's sustainability reporting.

Economic performance

In 2020, revenue growth was 7 per cent with revenue of SEK 15,261 M. Adjusted EBITA was SEK 6,301 M, resulting in an adjusted EBITA margin of 41 per cent for the full year. Cash flow from operations totalled SEK 5,214 M.

Direct economic value generated

SEK M	2020	2019
Revenue	15,261	14,248
Operating costs	7,575	6,430
Employee wages and benefits	2,250	1,748
Payments to providers of capital	249	86
Payments to government[1]	918	520
Community investments[2]	20	23

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 employee's 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 June 2020, Sobi and Sanofi committed to an additional 500 million IUs to the initial donation, in support of the World Federation of Hemophilia (WFH) Humanitarian Aid Program, fulfilling the pledge to donate up to 1 billion IUs of coagulation factor to humanitarian aid between 2015–2025.

Sobi's impact is reported in accordance with the WFH's progress report for this programme and is the result of Sobi's and Sanofi's contribution to the programme.

Number	2020	2019	2018
Total M IUs[1] delivered	538	449	362
Total patients treated (cumulative)	17,329	17,223	16,885
Acute bleeds treated	21,900	42,881	37,896
Surgeries	470	355	461
Number of workshop attendees	691	250	240

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 the webiste www.sobi.com.

Environmental performance

The scope of Sobi's environmental impact reporting includes Sobi-owned biological manufacturing facility, headquarters in Sweden and international offices and business travel. Reporting for 2020 includes environmental data from subsidiaries, not previously included.

Sobi aims to report comprehensively on supply chain emissions by 2022.

E1. GHG Emissions

GHG emissions (CO_2) (tonnes)

	2020	2019	2018	2017	2016
Own activities (direct and indirect)					
Total	**3,096**	**4,326**	**1,326**	**1,207**	**1,331**
Scope 1 (direct emissions)					
Facilities' energy use	1.7	2,2	3	3	2.6
Fleet cars[1] (Parent)	88	98	129	153	167
Fleet cars[1] (Subsidiaries)	509	–	–	–	–
Total	**599**	**100**	**132**	**156**	**170**
Scope 2 (indirect emissions)					
Heating (Parent)[2]	61	82	119	129	130
Cooling (Parent)[2]	0	0	0	0	0
Electricity (Parent)[2]	0.02	0.02	0.02	–	–
Unspecified energy (Subsidiaries)	36	–	–	–	–
Total	**97**	**82**	**119**	**129**	**130**
Scope 3 (indirect emissions)					
Business travel - flight, taxi (Parent)	295	971	981	830	945
Business travel - flight (Subsidiaries)	1064	3099	–	–	–
Business travel - cars (Subsidiaries)	977	–	–	–	–
Heating (Parent)[2]	43	74	94	92	86
Cooling (Parent)[2]	3[3]	0	0	0	0
Electricity (Parent)[2]	0.01	0.01	0	0	0
Energy (Subsidiaries)	17	–	–	–	–
Total	**2,400**	**4,144**	**1075**	**922**	**1,031**

1. Includes fleet cars included in IFRS16 reporting of leased properties.
2. Parent company emissions adjusted from previous years' reporting in alignment with GHG-protocol. Energy at the head office is purchased indirectly through landlord.
3. Indirect effects of district cooling included in Scope 3 from 2020.

Scope 1 and 2 emissions include data from Sobi's global operations, defined as Parent for emissions from the biological manufacturing facility and headquarters in Sweden, and Subsidiaries for emissions from the international offices.

Scope 1 and 2 emissions from the Parent have reduced 47 and 53 per cent respective from 2016, 50 per cent in total. Total Scope 1 and 2 emissions for 2020 cannot be compared with prior years due to the expanded requirement to include all global operations. Scope 2 and 3 emissions from the Parent have gradually declined due to better energy mix from the supplier in Sweden and more efficient energy use.

In 2020, the reporting of business travel is complete covering all of Sobi's operations as well as employee-owned cars used for business purposes. Travel emissions decreased substantially during the year due to reduced travel during the COVID-19 pandemic. Sobi intended to set 2020 as a new base line year for calculation of total emission reductions, but due to the pandemic reported emissions are not representative of expected emissions.

Emission factors used

Aspect	Emission factor	Source
Electricity, Sweden	0.003 g CO_2/kWh	A mix of certified renewable energy sources
Cooling, Sweden	S2: 0 g CO_2/kWh S3: 1 g CO_2/kWh	Annual environmental report, District heating supplier
Heating, Sweden[1]	48.6 g CO_2/kWh	Annual environmental report, District heating supplier
Heating values fossil fuel consumption in facility, Sweden	35.82 GJ/m3	Emission factors and heating values 2020, Swedish Environmental Protection Agency (Naturvårdsverket)
Emission factor fossil fuel consumption in facility, Sweden	74.26 kg CO_2/GJ	Emission factors and heating values 2020, Swedish Environmental Protection Agency (Naturvårdsverket)
Air travel	—	Emission factors provided by flight operators and US Environmental Protection Agency
Car travel	—	Individual factors depending on type of car
Rail travel	—	Emission factors provided by different train operators

1. Emission factor for heating in Sweden was reduced due to the supplier's decommission of coal as energy source. The compensation made by the supplier is not included in Sobi's calculations.

E2. Energy use and mix

Energy consumption refers to all operations, including Sobi's contract and 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 2020, a mapping of energy sources for all offices was initiated. Renewable energy is sourced for offices and facilities in Sweden, Switzerland and Denmark.

In an effort to transition to more renewable energy in the company and employee car fleet, electrical cars are subsidised in Sweden, Italy, Norway, Finland, UK and Ireland. In Sweden, the nominal price was increased in 2020 to include electric and hybrid cars.

Energy consumption (facilities' energy use) (MWh)

	2020	2019	2018	2017	2016
Electricity	8,318	7,518	7,694	7,852	7,687
of which renewable	8,318	7,518	7,694	7,852	7,687
District heating	2,133	2,550	2,596	2,690	2,713
of which renewable	1,770	2,015	2,051	1,991	2,116
Fossil fuel (oil)[1]	5,6	7,2	10,0	8,4	8,8
Cooling	2,902	3,059	3,167	2,793	2,745
Total	**13,358**	**13,127**	**13,457**	**13,335**	**13,145**

1. Direct energy

E2.1 Total amount of energy directly consumed

The direct energy produced and consumed on-site (Scope 1 Facilities' energy use) is generated by an emergency generator that is tested every month. In mid 2019, the process to test the generator was made more efficient and the time spent was cut in half, as were the emissions.

E2.2 Total amount of energy indirectly consumed

Energy consumption is regularly followed up in relation to internal performance indicators. In 2020, energy consumption from the manufacturing of steam increased at the production site. The production of more steam was intentional and used to extend life duration of certain machinery.

Energy-saving possibilities are regularly evaluated at the production facilities in Stockholm, Sweden.

E3. Energy intensity

Total direct energy use for in-house manufacturing per output scaling factor.

Total direct energy use (MWh/SEK M)

	2020	2019	2018	2017	2016
Energy (MWh)	6,173	5,867	6,313	6,480	6,425
Revenue manufacturing (SEK M)	481	376	436	559	569
MWh/SEK M	12.8	15.6	14.5	11.6	11.3

E4. Water use

Water consumption refers to Sobi's head office and production facilities in Stockholm, Sweden. Water consumption is regularly followed up in relation to internal performance indicators.

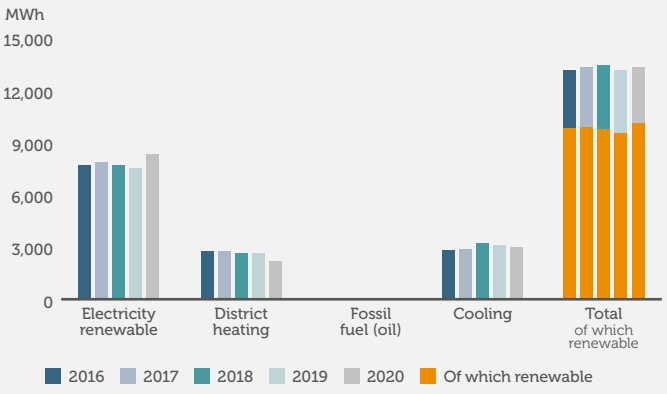
Water consumption

	2020	2019	2018	2017	2016
Purchased water	56,725	31,776	57,374	45,913	40,491
Reclaimed water	—	—	—	—	—
Total	**56,725**	**31,766**	**57,374**	**45,913**	**40,491**

In 2020, an incorrect reading of water consumption for the head office was adjusted, resulting in a considerably higher reading compared to previous years. During 2021, a validation of the reading will be conducted to certify proper reporting for actual consumption. The actual water consumption at the head office should most likely have decreased during 2020 compared to previous years, since the laboratory work performed there was discontinued in 2019.

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



E5. Environmental operations

The Environmental Policy emphasises the importance of management and states the basic overall principles and guidelines for managing environmental issues within Sobi.

To our knowledge, there have been no confirmed incidents resulting in administrative and judicial sanctions for failure to comply with environmental laws and/or regulations in 2020.

In an effort to reduce energy and water consumption by half at the Stockholm production site, several initiatives in 2014 reduced energy use by 45 per cent and water use by 60 per cent over a two-year period. The reductions achieved in 2014 remain in relation to production volumes (see Sobi's Annual Report 2016 and 2017 for details).

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 that are impacted by climate-related risks are continuously monitored as part of Sobis responsible sourcing programme and risk-assessment process.

Sobi is following the development of 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 will be assessed in accordance with the TCFD's recommendations in 2021. 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. We are continuously following the development of the EU Taxonomy Regulation and Sobi's operations do not make a substantial contribution, and do no significant harm, to the six environmental objectives established by the regulation.

E7. Waste

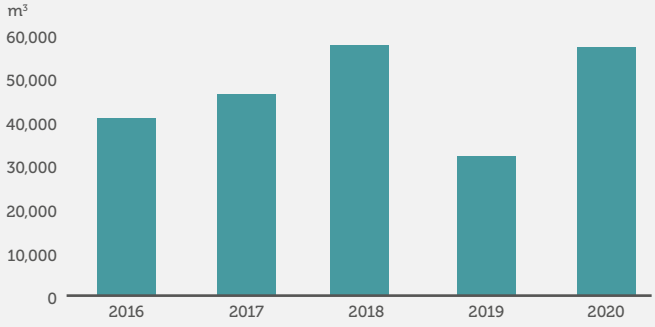
Waste reporting is based on Sobi's head office and production facilities in Stockholm, Sweden. Waste data does not include waste from marketing and sales offices outside Sweden. Non-hazardous waste has decreased as a result of several measures, including digitalisation of deviation management and changes to available archive spaces.

Office and production site waste (tonnes)

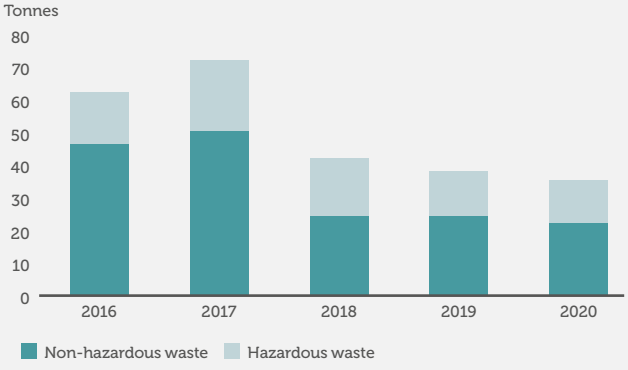
	2020	2019	2018	2017	2016
Total amount of waste	35	39	42	72	61
Non-hazardous waste					
Recycling	5	6	—	—	—
Combustion with energy recovery	16	17.5	—	—	—
Other treatment	0	0.6	—	—	—
Landfill[1]	1	0.2	0.1	0.1	0
Total	**22**	**24.3**	**24**	**50**	**46**
Hazardous waste					
Recycling	6	5	—	—	—
Reuse[2]	1	—	—	—	—
Combustion with energy recovery	0	0	—	—	—
Other treatment	7	8.6	—	—	—
Landfill	0	0	—	—	—
Total	**13**	**14.4**	**18**	**22**	**16**

1. A limited amount of Sobi's waste cannot be recycled and is therefore sent to landfill. The waste is non-hazardous and consists for example of insulation, bricks, ceramics and tiles. All waste is disposed of and treated by authorised companies.
2. IT-equipment sent for repurposing

Water consumption



Office and production sites waste



Social performance

In 2020, Sobi's commercial operations were based in Europe, North America, North Africa and the Middle East, and new offices were established in China, Japan and Australia. Biological manufacturing is based in Sweden with one laboratory facility in Switzerland. In terms of number of employees, Sobi grew organically in 2020.

To 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 2020.

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 the documentation for the 2021 Annual General Meeting.

S2. Gender pay ratio

In Sweden, our gender equality analysis is carried out annually and it is designed to prevent discrimination and promote equal rights and opportunities. We evaluate the results in collaboration with trade unions, and take action if necessary. We also map roles and responsibilities proactively to ensure fair and equitable salaries and development opportunities.

S3. Employee turnover

In 2020, Sobi had a turnover rate of 11 per cent due to voluntary terminations. Sobi did not introduce any furlough schemes or layoffs during the COVID-19 pandemic.

Year	New hires	Hires women	Hires men	Voluntary termination	Total number employees
2020	390	221	169	166	1509

S4. Gender diversity

Sobi has strong representation of women in management roles within STEM-related (Science, Technology, Engineering, and Mathematics) areas. Positions such as CIO, Head of Global Manufacturing and Infrastructure, Head of R&D Operations, and Head of Project and Portfolio Management are all held by women.

	2020		2019		2018	
%	Female	Male	Female	Male	Female	Male
Board	38	62	38	62	38	62
Executive Committee	18	82	27	73	18	82
Senior management[1]	42	58	–	–	–	–
All employees	59	41	60	40	59	41

1. Senior management - management positions reporting to Executive Committee.

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]	Male	Female	Sweden	Other Regions	Total 2020
Employees	615	894	438	1071	1509
Permanent contract	608	881	403	–	1491
Fixed-term contract	7	11	7	11	18
Substitute	1	1	1	1	2

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

S6. Injury rate

Total number of accidents includes those that did not lead to absence from work but that may have required medical care.

The number of incidents was lower in 2020, partly due to the closure of the laboratory facilities at the head office in 2019. For 2020, statistics include all operations globally. Up to 2019, the data only included reports from Sweden.

Incidents	2020	2019	2018	2017	2016
No. of accidents	10	26	28	23	22
Lost workday injury (LWI)	0	0	1	0	0
Lost time incident rate (LTIR)	0	0	0.39	0	0

LWI – Accidents that led to sickness absence (in addition to the day of the accident)
LTIR – Lost time incident rate per million hours worked

S7. Global Health and Safety

Sobi applies a global Health and Safety Policy and Occupational Health and 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 consist of representatives from all operations. The committee meets quarterly and reports to the Executive Committee.

S8. Training and education

All of Sobi's employees receive regular performance and career development reviews. Training documentation and performance management processes are digitalised.

All employees completed their performance management process (PMP) in 2020.

S9. Patient safety

To ensure and evaluate statutory compliance with quality and patient safety regulations, our facilities are regularly inspected. In 2020, Sobi hosted four inspections (3 GVP, 1 GMP). In addition to external inspections, Sobi continuously monitors the performance of our suppliers and internal processes and operations.

Sobi had no incidents of product recall in 2020.

S10. Marketing and labelling

In 2020, Sobi was sanctioned by the UK self-regulatory body PMCPA for one (1) instance of misleading advertising. The ad has since been removed.

No incidents of non-compliance with regulations and/or voluntary codes concerning product and service information and labelling were reported.

S11. Forced and Child Labour

Sobi's statement on forced and child labour is included in the Code of Conduct and Partner Code of Conduct (which applies specifically to the supply chain), both of which are available on www.sobi.com.

S12. Human rights

Sobi's human rights statement is included in the Code of Conduct and Partner Code of Conduct (which applies specifically to the supply chain), both of which are available on www.sobi.com.

Governance performance

Sobi promotes business ethics by setting high ethical standards in our operations globally. The aim is to create a sustainable organisation by building a culture of compliance with our corporate principles. The objective of maintaining ethical standards extends to our supply chain.

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

	2020	2019	2018
Male	5	5	5
Female	3	3	3
Nationalities	4	4	4
30–50 years	0	1	1
Over 50 years	8	7	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 Guideline 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 personal holdings in Sobi shares representing one annual gross base salary for the CEO, and 50 per cent of annual gross base salary for other members of the Executive Committee, and maintain these shares for the duration of their appointment as CEO or other Executive Committee member.

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. 40 per cent of Sobi's employees (Sweden, Austria, France, Italy, Spain/Portugal) are covered by collective bargaining agreements.

Employees covered by collective bargaining (%)

Region	2020
Sweden	100
Europe[1]	31
North America[2]	0
Rest of the world	0
Total	40

1. Excluding Sweden
2. US and Canada

G5. Supplier Code of Conduct

In 2019, Sobi introduced a Partner Code of Conduct for vendors, suppliers and partners. The Code is available on www.sobi.com.

In January 2020, Sobi became a formal associate member of the Pharmaceutical Supply Chain Initiative (PSCI) and during the year, participated in several PSCI working groups.

The sustainability assessment of 86 partners was monitored by EcoVadis.

- 3 suppliers scored <40 using the EcoVadis CSR Rating Methodology.
- No supplier scored <40 using the EcoVadis theme score of Labour Practices and Human Rights.

G6. Ethics and Anti-Corruption

Sobi's ethical standards statement is included in the Code of Conduct and Partner Code of Conduct (which applies specifically to the supply chain). Sobi's Anti-corruption Policy applies to all employees.

In 2020, five reports of alleged misconducted were reported to the Corporate Compliance Department. All cases were investigated and the appropriate corrective and disciplinary actions were taken where needed.

97 per cent of Sobi's workforce completed the Code of Conduct e-learning. 95 per cent completed the assigned anti-corruption training.

G7. Data Privacy

Please see page 119 for a high-level overview of Sobi's data privacy program. To allow for continuous improvements as well as complying 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 16 internal reports of suspected personal data breaches during 2020, showing that there is an awareness within the company regarding integrity issues, an inclination to report potential issues, and that there are open lines of communications enabling such reporting. The reports range from minor incidents such as e.g. emails sent to the wrong recipient to potentially more severe breaches. All incidents were investigated and corrective actions taken. Two cases were reported to the supervisory authority, as required by applicable data privacy legislation.

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). 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, 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.

See the glossary on page 134 for a definition of the listed indications.

	Access to Sobi's products – *new in 2020					
Region	**Alprolix[1]**	**Elocta[1]**	**Doptelet[2]**	**Kineret**	**Gamifant**	**Orfadin**
EU and EFTA states	Haemophilia B	Haemophilia A	CLD	RA, CAPS, Still's, FMF*[,3]		HT-1 & AKU*[,4]
Austria	x	x	x*	x		x
Belgium	x	x		x		x
Bulgaria	x	x		x		x
Croatia	x	x		x		x
Cyprus				x		
Czech Republic	x	x		x		x
Denmark	x	x	x*	x		x
Estonia		x		x		x
Finland	x	x		x		x
France	x	x		x		x
Germany	x	x		x		x
Greece	x	x		x		x
Hungary	x	x		x		x
Iceland				x		
Ireland	x	x	x*	x		x
Italy	x	x		x		x
Latvia				x		
Liechtenstein	x	x		x		x
Lithuania				x		
Luxembourg	x	x		x		x
Malta				x*		
Netherlands	x	x		x		x
Norway	x	x	x*	x		x
Poland	x	x		x		x
Portugal	x	x		x		x
Romania	x*	x*				x
Slovakia	x	x		x		x
Slovenia	x	x		x		x
Spain	x*	x		x		x
Sweden	x	x		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.
3. FMF – Familial Mediterranean Fever (FMF) indication approved in Europe 28 April 2020.
4. Adult patients with alkaptonuria (AKU) indication approved in Europe 22 October 2020.

Market availability of Sobi products, cont.

	Access to Sobi's products – *new in 2020					
Region	**Alprolix[1]**	**Elocta[1]**	**Doptelet[2]**	**Kineret**	**Gamifant**	**Orfadin**
Europe – other	Haemophilia B	Haemophilia A	CLD	RA, CAPS		HT-1
Russia		x*		x	x (MAP[2])	x
Switzerland	x	x		x		x
Turkey				x*		
United Kingdom	x	x	x*	x		x (HT-1 & AKU*)
Ukraine						x
North America	Not Sobi territory	Not Sobi territory				HT-1
Canada				RA, NOMID x		x
Mexico			x			x
United States[3]			CLD, ITP x	RA, NOMID x	pHLH x	x
Asia						HT-1
Bahrain	x			x		x
China	Not Sobi territory	Not Sobi territory	Out-licensed		submitted for approval	submitted for approval
Kuwait	x	x		x*	x*	
Israel	Not Sobi territory	Not Sobi territory		x + FMF*		x
Japan	Not Sobi territory	Not Sobi territory		x*		x
Jordan						x
Oman	x	x		x		
Palestine						x
Qatar	x	x		x		x
Saudi Arabia	x	x			x (MAP)	x
United Arab Emirates	x	x			x (MAP)	x (MAP)
Africa	Not Sobi territory	Not Sobi territory				HT-1
Algeria						x
Tunisia						x
South America	Not Sobi territory	Not Sobi territory				HT-1
Argentina						x
Chile						x
Australia	Not Sobi territory	Not Sobi territory		RA, CAPS, Still's x		x

1. Sobi has final development and commercialisation rights in Europe, most Middle Eastern markets, North Africa and Russia.
2. MAP - Managed access programme
3. In the US, Sobi also markets Synagis and Kepivance.

Global Reporting Initiative Index

Sobi's Sustainability Report 2020 is defined in the GRI Index below. Its main components are found in the following sections of the Annual and Sustainability Report 2020:

- Business Model is found on page 10.
- Description of sustainability approach is found on pages 108–121.
- Information on performance is reported in the Sustainability notes section, on pages 122–128.

This sustainability report has been prepared in accordance with the GRI Standards: Core option. It also fulfils the requirements on sustainability reporting in the Annual Accounts Act.

Sobi reports its sustainability performance on an annual basis, as part of the Annual and Sustainability Report. The indicators below have been selected on the basis of a materiality analysis, which is further described on page 109. All page references below refer to pages in Sobi's 2020 Annual and Sustainability Report or at www.sobi.com.

Our sustainability report serves as our UN Global Compact Communication on Progress report.

For questions regarding the Annual and Sustainability Report, please contact info@sobi.com.

GRI Standard	Disclosure		Page reference	Comment	UN Global Compact Principle
GENERAL DISCLOSURES – 102					
Organisational Profile					
	102-1	Name of the organisation	54, 97		
	102-2	Activities, brands, products, and services	12, 34, 36, 54		
	102-3	Location of headquarters	54, 97		
	102-4	Location of operations	21, 79		
	102-5	Ownership and legal form	30–31, 54, 97–98		
	102-6	Markets served	21, 34–36, 63		
	102-7	Scale of the organisation, including total number of employees, operations, net sales, and capitalisation	26, 32, 34–37		
	102-8	Information on employees and other workers	67		6
	102-9	Supply chain	119		
	102-10	Significant changes to the organisation and its supply chain	4, 34		
	102-11	Precautionary Principle or approach	109–110		
	102-12	External initiatives	7, 108, 116		
	102-13	Membership of associations	www.sobi.com		
Strategy and analysis					
	102-14	Statement from senior decision-maker	6–7, 96		
	102-15	Key impacts, risks, and opportunities	41–43, 109		
Ethics and Integrity					
	102-16	Values, principles, standards, and norms of behaviour	26–27, 109, 117–119		10
	102-17	Mechanisms for advice and concerns about ethics	118–119		
Governance					
	102-18	Governance structure	97–107, 109–110		
	102-19	Delegating authority	102–103, 109		
	102-22	Composition of the highest governance body and its committees	100–101		
Stakeholder Engagement					
	102-40	List of stakeholder groups	30, 109		
	102-41	Collective bargaining agreements	126		
	102-42	Identifying and selecting stakeholders	109		3
	102-43	Approach to stakeholder engagement	109		
	102-44	Key topics and concerns raised	109		

GRI Standard	Disclosure		Page reference	Comment	UN Global Compact Principle
Reporting methodology					
	102-45	Entities included in the consolidated financial statement	54–59		
	102-46	Defining report content and topic boundaries	54–59, 109		
	102-47	List of material topics	23, 108–109		
	102-48	Restatements of information	122–126		
	102-49	Changes in reporting	54, 109		
	102-50	Reporting period	97		
	102-51	Date of most recent report		April 2020	
	102-52	Reporting cycle	97, 110		
	102-53	Contact point for questions regarding the report	www.sobi.com		
	102-54	Claims of reporting in accordance with the GRI Standards	39, 129		
	102-55	GRI content index	129–131		
	102-56	External assurance	132		
GRI 103: MANAGEMENT APPROACH 2016					
	103-1	Explanation of the material topic and its boundary	108–121		1, 2, 6, 7, 8, 9, 10
	103-2	The management approach and its components	108–121		1, 2, 6, 7, 8, 9, 10
	103-3	Evaluation of the management approach	108–126		1, 2, 6, 7, 8, 9, 10
SPECIFIC DISCLOSURES – GRI 200: ECONOMIC					
GRI 200: Economic performance 2016					
	201-1	Direct economic value generated and distributed	122		
GRI 203: Indirect economic impacts 2016					
	203-2	Significant indirect economic impacts	122		
GRI 205: Anti-corruption 2016					
	205-1	Operations assessed for risks related to corruption	118–119		10
	205-2	Communication and training about anti-corruption policies and procedures	118–119		10
	205-3	Confirmed incidents of corruption and actions taken	126		10
GRI 206: Anti-competitive behaviour 2016					
	206-1	Legal actions for anti-competitive behaviour, anti-trust, and monopoly practices	126		
SPECIFIC DISCLOSURES – GRI 300: ENVIRONMENTAL					
GRI 302: Energy 2016					
	302-1	Energy consumption within the organization	122–124		
	302-3	Energy intensity	123		
	302-4	Reduction of energy consumption	122–124		
GRI 303: Water and effluents 2018					
	303-1	Water withdrawal by source	123–124		
GRI 305: Emissions 2016					
	305-1	Direct (Scope 1) GHG emissions	122		7, 8
	305-2	Indirect (Scope 2) GHG emissions	122		7, 8
	305-3	Other indirect (Scope 3) GHG emissions	122		
	305-4	GHG emissions intensity	123		
GRI 306: Effluents and waste 2016					
	306-2	Waste by type and disposal method	121, 124		8
GRI 307: Environmental compliance 2016					
	307-1	Non-compliance with environmental laws and regulations	124		
GRI 306: Supplier environmental assessment 2016					
	308-1	New suppliers that were screened using environmental criteria	119, 126		

GRI Standard	Disclosure		Page reference	Comment	UN Global Compact Principle
SPECIFIC DISCLOSURES– GRI 400: SOCIAL					
GRI 401: Employment 2016					
	401-1	New employee hires and employee turnover	125		6
GRI 403: Occupational Health and Safety 2018					
	403-1	Occupational health and safety management system	117		
	403-2	Hazard identification, risk assessment, and incident investigation	117		
	403-9	Work-related injuries	125		
GRI 404: Training and Education 2016					
	404-2	Programs for upgrading employee skills and transition assistance programs	117		
	404-3	Percentage of employees receiving regular performance and career development reviews	125		6
GRI 405: Diversity and Equal Opportunity 2016					
	405-1	Diversity of governance bodies and employees	125, 126		
GRI 413: Local Communities 2016					
	413-1	Operations with local community engagement, impact assessments, and development programs	112–114, 122		1
GRI 414: Supplier Social Assessment 2016					
	414-1	New suppliers that were screened using social criteria	119, 126		2
GRI 416: Customer Health and Safety 2016					
	416-1	Assessment of the health and safety impacts of product and service categories	114–115		
GRI 417: Marketing and Labelling					
	417-1	Requirements for product and service information and labelling	114–115		
	417-2	Incidents of non-compliance concerning product and service information and labelling	125		
	417-3	Incidents of non-compliance concerning marketing communications	125		
GRI 418: Customer Privacy 2016					
	418-1	Substantiated complaints concerning breaches of customer privacy and losses of customer data	126		
GRI 419: Socioeconomic Compliance 2016					
	419-1	Non-compliance with laws and regulations in the social and economic area	125		

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 2020 on pages 23–27 and 108–131 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 26, 2021
Ernst & Young AB

Jonatan Hansson
Authorized Public Accountant

2021 Annual General Meeting

2021 Annual General Meeting
Swedish Orphan Biovitrum AB (publ) will hold its Annual General Meeting (the "Meeting") on Tuesday, 4 May 2021. Due to the coronavirus and in order to reduce the risk of spreading the virus, the Board has decided that the Meeting should be conducted by way of postal vote pursuant to temporary legislation being in effect in 2021. This means that the Meeting will be held without the physical presence of shareholders, representatives or third parties. The shareholders will therefore only be able to exercise their voting rights by postal voting in advance of the Meeting.

To participate
Shareholders who wish to participate in the Meeting by postal voting 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 Monday, 26 April 2021, and must give notice of participation no later than Monday, 3 May 2021, by casting its postal vote so that the postal voting form is received by Euroclear Sweden AB no later than that day.

A special form must be used for the postal vote. The form for postal voting will be available on the company's website www.sobi.com latest three weeks before the Meeting. The postal voting form is considered as the notification of participation at the Meeting. Further instructions and conditions can be found in the postal voting form.

Nominee shares
Shareholders whose shares are registered in the name of a nominee through the trust department of a bank or similar institution must, in addition to giving notice of participation in the Meeting by casting its postal vote, re-register its shares in its own name, so that the shareholder is listed in the presentation of the share register as per 26 April 2021. 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 registration that have been made by the nominee no later than 28 April 2021 will be taken into account in the presentation of the share register.

Proxy
If the shareholder votes in advance by proxy, a dated written power of attorney shall be enclosed with the form. A proxy form in Swedish and English will be held available on the company's website, www.sobi.com, and will also be sent to shareholders who request it and who inform the company of their postal address. The power of attorney is valid for one year from the issue thereof or such longer period of time stated in the power of attorney, however not more than five years. If the shareholder is a legal entity, a certificate of incorporation or a corresponding document, not older than one year, shall be enclosed with the form.

Financial calendar 2021

January – March Interim Report	4 May
Annual General Meeting	4 May
January – June Interim Report	21 July
January – September Interim Report	28 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.

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Glossary

AKU
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 approved in the EU, Iceland, Kuwait, Liechtenstein, Norway, Saudi Arabia and Switzerland, as well as in Australia, Brazil, Canada, Japan, New Zealand, the United States and other countries, for the treatment of haemophilia B.

Amyotrophic lateral sclerosis (ALS)
A devastating neurodegenerative disease that results in progressive muscle weakness and paralysis due to the death of nerve cells, called motor neurons, in the brain and spinal cord.

BIVV001/efanesoctocog alfa
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.

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.

Chemotherapy-induced thrombocytopenia (CIT)
A common side effect of chemotherapy that results in a low number of platelets.

Chronic immune thrombocytopenia (ITP)
A rare autoimmune bleeding disorder characterised by a low number of platelets, affecting approximately 60,000 adults in the United States.

Chronic liver disease (CLD)
Liver disease becomes chronic when it has been present for more than 6–12 months without signs of resolution. Chronic liver disease can be inherited (genetic) or caused by a variety of factors such as viruses, auto-immunity, obesity and alcohol use.

Cold agglutinin disease (CAD)
A 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.

Doptelet (avatrombopag)
A second-generation small-molecule thrombopoietin receptor (TPO) agonist used in the treatment of thrombocytopenia by increasing platelet count.

EHL
Extended half-life, which means that the circulation in the body is prolonged. Sobi's haemophilia treatments, Elocta and Alprolix, are EHL products.

Elocta (efmoroctocog alfa)
A recombinant, EHL clotting factor VIII therapy approved in the EU, Iceland, Kuwait, Liechtenstein, Norway, Saudi Arabia and Switzerland for the treatment of haemophilia A. It is also approved in Australia, Brazil, Canada, Japan, New Zealand, the United States and other countries, where it is known as ELOCTATE®.

EMA
European Medicines Agency.

Familial Mediterranean Fever (FMF)
Familial Mediterranean Fever (FMF) is a genetic autoimmune disorder that causes recurrent episodes of fever together with abdominal, chest or joint pain.

FDA
The US Food and Drug Administration.

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.

Haemophagocytic lymphohistiocytosis (HLH)
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.

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.

Hereditary tyrosinaemia type 1 (HT-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.

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.

IC-MPGN/C3G
IC-MPGN and C3G are 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 (IL-1) is a key mediator of inflammation and driver of autoinflammatory diseases.

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 (MEDI8897)
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. MEDI8897 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.

Paroxysmal nocturnal haemoglobinuria (PNH)
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.

Pegcetacoplan
An investigational, targeted C3 therapy designed to regulate excessive complement activation, which can lead to the onset and progression of many serious diseases.

Real-world evidence
Real-world evidence is gained by examining how approved medicines and treatments are working in the healthcare system. Real-world evidence studies use observational data such as electronic medical records, insurance claims information and patient surveys. Real-world analyses can assess how various treatments impact actual patient outcomes.

Rheumatoid arthritis (RA)
Rheumatoid arthritis (RA) is 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
SEL-212 is 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.

WFH
World Federation of Hemophilia, an international not-for-profit organisation.

Definitions

CER
Constant exchange rate.

Earnings per share
Profit/loss divided by the average number of shares.

EBIT
Earnings before interest and tax (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
Operating 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
International Financial Reporting Interpretations Committee.

Alternative performance measures

Financial measures not defined according to IFRS
Sobi uses certain financial measures in the 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 therefore not be regarded as substitutes for measures defined according to IFRS. The following key ratios 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 outstanding shares.

Cash flow per share
Changes in cash and cash equivalents divided by the weighted average number of outstanding shares.

Debt-to equity ratio
Relative 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 average number of ordinary shares.

EPS after dilution, SEK adjusted
Profit for the period, adjusted, divided by average number of ordinary shares after dilution.

Equity per share
Equity divided by the number of ordinary shares.

Equity ratio
Shareholders' equity as a proportion of total assets.

Net debt (+)/Net cash (-)
Borrowings less cash and cash equivalents.

Organic growth, % CER
Total revenue adjusted for Synagis and Doptelet measured at CER compared with previous period.

Return on capital employed
Earnings before interest and tax (EBIT)/capital employed.

Return on equity
Profit/loss after tax as a percentage of average 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 flat-rate tax of 21.4 per cent has been used.

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.

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