Focus on **rare diseases**

Annual and Sustainability Report 2019

sobi
rare **strength**

Contents

This is Sobi's Annual and Sustainability Report 2019. The audited Annual Report includes pages 32–92. The Sustainability Report is found on pages 22–25, 40–45 and 110–119 and consists of the Company and the Group's legally required sustainability report according to the Annual Accounts Act, 6 chap. 11. The report also constitutes our reporting to the UN Global Compact, Communication on Progress.

Rare strength

An international biopharmaceutical company specialising in rare diseases
We bring something rare to rare diseases – the strength of focus, the power of partnership and the agility to innovate. We believe in the potential of the people we are dedicated to serving.

This is Sobi

At Sobi, we are transforming life for people with rare diseases. As an international biopharmaceutical company, we provide access to innovative treatments in the areas of haematology, immunology and specialty care.

- Two therapeutic areas – Haematology and Immunology – and a portfolio of products within Specialty Care
- A strong portfolio of on-market products, and an extensive portfolio of pre-market assets
- Our extended half-life factor replacement treatments Elocta® and Alprolix® are the most prescribed treatments for haemophilia A and B respectively in several markets
- We put our focus where we can have the greatest impact, in late-stage research and development, and in patient access and commercialisation
- Global Head Office in Stockholm, Sweden, with offices in more than 30 countries, delivering treatments to patients in more than 70 countries
- The Sobi share (STO:SOBI) is listed in the Large Cap segment on Nasdaq Stockholm.

14,248
Total revenue, SEK million

1,335
Number of employees (FTE)

35%
Increase in haemophilia patients

6,145
Adjusted EBITA, SEK million

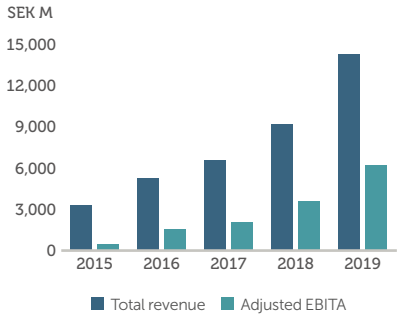
With the acquisitions made over the past two years our pre-market portfolio has never been stronger.

	Haematology	Immunology
Pre-market	Avatrombopag[1] – CIT, ITP (EU) BIVV001[2] – haemophilia A BIVV002[3] – haemophilia B	Emapalumab[4] – secondary HLH Emapalumab[4] – new indications Anakinra[5] – indication expansion Nirsevimab[6] (MEDI8897) – RSV
On-market	Elocta – haemophilia A Alprolix – haemophilia B Doptelet®[1] – ITP (US), CLD	Gamifant®[4] – primary HLH (US) Synagis® – RSV (US) Kineret®[5]

1. Avatrombopag – approved as Doptelet for thrombocytopenia in chronic immune thrombocytopenia (ITP) and chronic liver disease (CLD) in the US. Approved in EU for CLD but not yet launched. Under investigation for chemotherapy-induced thrombocytopenia (CIT).
2. Developed in collaboration with Sanofi.
3. Sobi has elected to add the BIVV002 programme to the collaboration agreement with Sanofi but has not yet opted in.
4. Emapalumab – approved as Gamifant in the US for primary haemaphagocytic lymphohystiocytosis (HLH).
5. Anakinra – approved as Kineret in the US and in the EU for several autoinflammatory diseases.
6. Nirsevimab (MEDI8897), a follow-on compound to Synagis for respiratory syncytial virus (RSV).

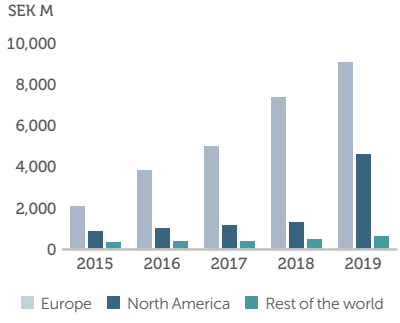
Recent acquisitions provide better balance

Total revenue and adjusted EBITA

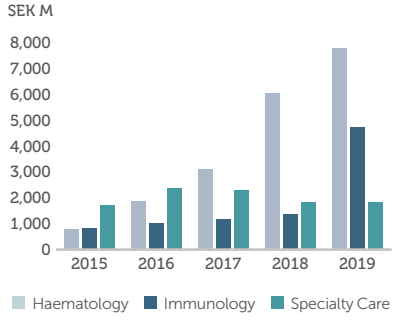


The creation of a strong second leg in Immunology balances our success in haemophilia, while expansion in North America during 2019 strengthens our revenue base outside Europe.

Revenue per geographic region



Revenue per business area



Year in brief

Our growth journey continued at speed during 2019 as significant acquisitions drove the ongoing transformation of the company. A sharper R&D focus, broader geographical footprint and two strong therapeutic areas position us well for continued strong growth.

We continue to deliver on our strategy

	Sobi completed the acquisition of Synagis, significantly expanding operations in the US.
	Sobi acquired emapalumab and related assets, giving Sobi access to additional competence within the immunology field.
	Sobi discontinued its early-phase R&D operations in order to focus on late-stage R&D projects within the core areas of haematology and immunology.
	Sobi acquired Dova Pharmaceuticals, creating a global growth platform in haematology. The acquisition provided Sobi with Doptelet (avatrombopag), a second-generation small-molecule thrombopotein receptor (TPO) agonist used in the treatment of thrombocytopenia by increasing platelet count.
	Sobi entered into an expanded agreement with Sanofi to exercise early opt-in for the development and commercialisation of BIVV001, an investigational extended half-life factor VIII therapy with the potential to provide extended protection from bleeds with once-weekly dosing for people with haemophilia A.
	The first patient was dosed in the phase 3 study with BIVV001 for the treatment of haemophilia A.
	The FDA grants orphan drug designation for avatrombopag as a candidate for the treatment of chemotherapy-induced thrombocytopenia (CIT).
	Sobi established a presence in Asia with office and staff in China.

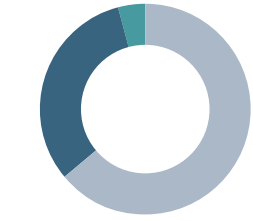
56%

Revenue growth

72%

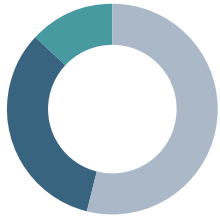
Adjusted EBITA growth

Revenue per geographic region



Europe 64% North America 32%
Rest of the world 4%

Revenue per business area



Haematology 54% Immunology 33%
Specialty Care 13%

» The year ended on a high note with strong organic growth as well as new assets added to the portfolio. «

Key figures

SEK M	2015	2016	2017	2018	2019
Total revenue	3,228	5,204	6,511	9,139	14,248
Gross profit	2,007	3,651	4,657	6,723	10,913
Gross margin[1], %	62	70	72	74	77
Operating expenses	1,861	2,518	3,057	3,601	6,430
EBITA[1]	433	1,543	2,053	3,571	5,933
Adjusted EBITA[1,2]	433	1,543	2,053	3,571	6,145
EBIT	146	1,133	1,600	3,122	4,533
Profit/loss for the year	83	802	1,149	2,418	3,304
Earnings per share, SEK	0.31	2.99	4.27	8.97	11.29
Earnings per share, SEK adjusted[1,2,3]	0.31	2.99	4.27	8.97	11.89
Cash flow from operations	507	343	1,333	2,090	3,634
Equity per share[1,2,3] SEK	17.3	19.8	24.6	33.1	56.4
Equity assets ratio, %	56	54	61	53	37
Dividend	0	0	0	0	0
No. of employees (full-time equivalents)	702	760	800	902	1,335

1. Alternative Performance Measures (APMs).
2. EBITA full-year 2019 excluding non-recurring items; transaction costs related to the acquisition of Dova of SEK 92 M, restructuring costs of SEK 157 M and gain from divestment of SOBI005 of SEK 37 M.
3. EPS full-year 2019 excluding impairment of intangible assets of SEK 18 M related to restructuring.

Increasing speed

The transformation of Sobi accelerated during 2019, with the acquisition of Dova Pharmaceuticals, the closing of the Novimmune acquisition and the first year of Synagis sales, as well as significant progress with our core brands Elocta, Alprolix and Kineret. In addition, we have been able to advance important assets in our pipeline.

2019 was a rewarding year in which we made major progress in every area of our strategy. We ended the year as a stronger company with a broader geographical footprint and exceptional value in both our on-market and pre-market portfolios.

We are proud to have access to five material growth drivers in our portfolio. These have the potential to transform the outlook of our company based on launch performance and indication expansion, see below.

Our success during 2019 led to total revenue of SEK 14,248 M, up 56 per cent on 2018 (48 per cent at CER), and adjusted EBITA[1,2] of SEK 6,145 M. Organic growth adjusted for Synagis and Doptelet amounted to 20 per cent.

We now have two core therapeutic areas, Haematology and Immunology, both of which are growing strongly.

1. Alternative Performance Measures (APMs), see page 122.
2. EBITA full-year 2019 excluding non-recurring items; transaction costs related to the acquisition of Dova in Q4 of SEK 92 M, restructuring costs of SEK 157 M in Q2 and gain from divestment of SOBI005 in Q1 of SEK 37 M.

Haematology

While extending the scope of our former haemophilia business to the broader area of Haematology, we believe in the strengths of our existing core products Elocta and Alprolix. The continued strong growth for both products justifies our belief that factor replacement remains a mainstay of treatment for haemophilia, and I am confident that we will continue to grow significantly in haemophilia based on greater patient access and internationalisation.

Our decision to opt in early to the development of BIVV001, a novel investigational factor VIII therapy, shows our ongoing commitment to the field of haemophilia. Promising early data shows the potential for BIVV001 to provide extended protection from bleeds with once-weekly dosing for people with haemophilia A.

We completed our acquisition of Dova Pharmaceuticals in November, reinforcing our Haematology portfolio with the Dova asset Doptelet which is used in the treatment of thrombocytopenia by increasing platelet count. We look forward to bringing this important medicine to more people around the world.

Immunology

In Immunology, we have created a strong second leg to balance our outstanding success in haemophilia. All three products in our Immunology portfolio performed well during 2019.

- We completed our acquisition of emapalumab and all related assets, and integrated the emapalumab organisation into Sobi during 2019. Launched in the US at the beginning of 2019 as Gamifant, emapalumab has performed well. Sales have however been volatile during this period, which is common for products in ultra-rare diseases. Gamifant is currently under investigation in other markets and in other indications including secondary HLH.
- Synagis is flourishing under our care. After we acquired the US rights, and the entire Synagis team agreed to join Sobi, we strengthened the field force during 2019, and intensified efforts to extend protection against RSV to even more children.
- Kineret continues to deliver double-digit growth in both North America and the EMENAR region (Europe, Middle East, Northern Africa and Russia). Extensive scientific interest in potential new indications shows that it holds much promise for years to come.

Key growth drivers

1. Gamifant – in launch phase in primary HLH (haemophagocytic lymphohistiocytosis) in the US, phase 3 in secondary HLH, and further internationalisation.
2. Doptelet – launch phase in chronic liver disease (CLD) and immune thrombocytopenia (ITP) in the US, phase 3 in chemotherapy-induced thrombocytopenia (CIT), and further expansion into international markets.
3. Kineret – expanding into new indications and improving absolute growth.
4. BIVV001 – phase 3 study now under way. Sobi has the rights for Europe, the Middle East and North Africa.

»With several launches in new markets and new indications to accelerate our growth journey, 2020 will be when we turn potential into value for our stakeholders.«

Geographical expansion

We have long seen North America as a strategically important market for Sobi. Including the additions of Dova and Synagis, we have built our workforce in the US and Canada from 54 to 420 in just two years, giving us the scale we need to build our position in the largest rare disease market in the world.

With the addition of Gamifant and Doptelet to our portfolio, we have two new products with a global scope, which will allow us to expand into new territories and new indications. The establishment of our office in China in early 2020 is the first step of our exploration of the Asian market.

In a shift in our research & development, we took the decision to discontinue early research and focus instead on late-stage development. Combined with our acquisitions over the past few years, we now have a strong late-stage pipeline. These pre-market assets should allow us to maintain a high pace of launches in new indications and new markets over the coming years, which also delivers on our mission and sustainability commitment to enable access to treatments.

With our strong revenue growth, and as profitability generated by both new and established products continues to generate substantial cash flow, we expect to expand both organically and through acquisition. Investments in 2019 were debt-financed but given the strong cash-flow generation we should be able to restore our financial position quickly.

Revenue for the full-year 2020 is expected to be in the range of SEK 15,000–16,000 M, reflecting expected double-digit growth in each of the two core businesses, Haematology and Immunology. EBITA is expected to be in the range of SEK 5,500–6,300 M, including the development and launch of Doptelet which will affect EBITA negatively by around SEK 500 M in 2020.

I am pleased to confirm that we continue to support the ten principles of the United Nations Global Compact in the areas of human rights, labour, environment and anti-corruption, and that we are committed to making the Global Compact and its principles part of our strategy, culture and daily operations.

Yes, 2019 was an exciting year, but not without its challenges. I wish to thank everyone working at Sobi for their efforts every day to make a difference for people with rare diseases. I am proud to be part of this team.

2019 was a year of transformation for Sobi. As our growth journey continues, I see 2020 as a year when we turn potential into value for our stakeholders. With COVID-19 posing a major challenge for societies around the world, we will continue to do our best to protect the interests of the many people around the world who rely on us. Our ambition is that investments in 2020 will lay the foundations for continued annual double-digit growth in Haematology and Immunology in the medium term. In the slightly longer term, both Doptelet and Gamifant have the potential to generate peak sales of more than USD 500 M.

Guido Oelkers
Chief Executive Officer

The rare disease market

There are thought to be around 6,000 rare diseases, affecting a total of 300 million people around the world[1]. Yet around 95 per cent of rare diseases still do not have any approved treatment option[2].

High unmet medical need

An estimated 75 per cent of identified rare diseases affect children, often with a devastating effect on life expectancy and quality of life. Around 30 per cent of children diagnosed with a rare disease will not live to see their fifth birthday.

The severe nature of many rare diseases often leads to high levels of distress for patients and their families, with an accompanying high treatment burden.

Many rare diseases are inherited rather than acquired, and involve a defect in the genes that instruct our bodies how to work[3]. As a result, the body may fail to produce an essential enzyme or protein, for example, or immune defences may attack its own systems.

Because they are often genetic disorders, rare diseases tend to be lifelong. In such cases, treatment often focuses on resolving the problems caused by the defective gene, alleviating symptoms and allowing the person to live a more normal life.

Many physicians may never have seen a specific rare condition before and, as a result, many cases can go undiagnosed for years.

Rare challenges

The rare disease landscape presents specific scientific, medical and commercial challenges. These include understanding the biology of little-known diseases, developing the complex biopharmaceutical processes to manufacture a drug, designing and running clinical studies in extremely small patient populations, navigating new regulatory pathways, and working with healthcare professionals to improve diagnosis of diseases that most doctors may see only once in a lifetime.

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

Fast track

Because of the challenges, and the high unmet medical need in most rare diseases, government authorities such as the US Food & Drug Administration (FDA) and the European Medicines Agency (EMA) have put measures in place to encourage pharmaceutical companies to develop treatments for rare diseases and reduce the time it takes for the treatments to reach patients.

In small studies, the process can be accelerated if a candidate treatment demonstrates transformative results for study patients. Both the FDA and EMA can allow such breakthrough therapies to be fast-tracked through the approval process, providing priority review procedures.

Being the first to bring a new orphan therapy to patients can also have advantages. With comparatively few companies working in the area, first movers can gain a sustainably high market share in an orphan indication. Regulatory

authorities can also grant a company market exclusivity for a specific time.

The nature of rare diseases, and the complex nature of biopharmaceutical therapies in particular, make the rare disease space less attractive for generic or biosimilar competitors.

The price of orphan drugs is relatively high compared with other treatments targeting larger patient populations, while the total cost to the healthcare system is relatively small, particularly considering the transformative value that orphan drugs bring to patients[4].

Rapidly growing market

In 2018, the size of the orphan drugs market was USD 131 billion and it is projected to reach USD 242 billion by 2024, with a compound annual growth rate (CAGR) of 12.3 per cent[5]. This is double the growth rate estimated for the non-orphan market.

Treatments reaching more people

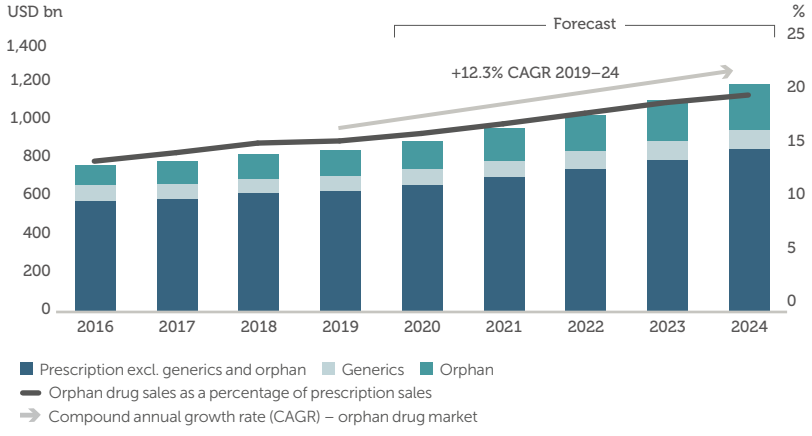
Advances in scientific knowledge are allowing the industry to identify and develop new treatments for more of those 6,000 or so rare diseases that have been identified. In the US, the 21 orphan drugs approved by the FDA[6] in 2019 represented 44 per cent of total novel-drug approvals, while in Europe, orphan drugs accounted for approximately 12 per cent of total positive opinions in 2019[7].

The small size of rare disease populations, and the often high levels of engagement among patients, families and treaters, also stimulate the uptake of new treatments. Such closely connected, well-informed disease communities share information about novel therapies, and better informed patients feel more able to discuss possible new treatments with their physicians. Many people with rare diseases – who historically have been and often still are under-served by their healthcare systems – are increasingly becoming empowered to pursue treatments that can improve their lives.

In many countries with less-developed healthcare systems, improving finances and better infrastructure are also allowing the expansion of screening programmes that can detect rare diseases. In many cases, early diagnosis and treatment can prevent long-term injury and decreased quality of life.

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 sales & share of prescription drug market (2016–2024)



Source: EvaluatePharma Orphan Drug Report 2019.

Worldwide orphan drug market growth

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

Attractive opportunity: Rare disease therapeutics can generally command a higher price due to the transformative value they offer to small patient populations.

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

Limited competition: Few companies are active in orphan indications – translating to sustainably high share for first 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.

1. www.rarediseaseday.org/article/what-is-a-rare-disease
2. Global Genes, www.globalgenes.org
3. EURORDIS, www.eurordis.org
4. www.rarediseases.org/updated-study-analyzes-use-and-cost-of-orphan-drugs/
5. EvaluatePharma® Orphan Drug Report 2019
6. www.fda.gov/media/134493/download
7. www.ema.europa.eu/en/documents/report/human-medicines-highlights-2019_en.pdf

Business model

Sobi's business model spans from late-stage clinical research to 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 and payers in order to transform life for people living with rare diseases.

From late-stage R&D to the patient
Sobi's value chain spans from late-stage clinical research and development to commercialisation and patient access to treatments. Our strengths include evaluating and developing late-stage projects, commercialisation and getting treatments to the patients as quickly as possible.

Partnership and cooperation
By combining our strengths with those of our collaboration partners, we shape unique opportunities to create value within the rare disease landscape. We see partnership as essential in our efforts to provide sustainable access to treatment all around the world. We work with several companies to provide access to innovative treatments to patients.

Commercialisation and patient access
We work in cross-functional teams bringing together our many disciplines. By bringing patient access specialists in as early as possible into development projects, approval applications and pricing negotiations, for example, we can get treatment to patients more quickly.

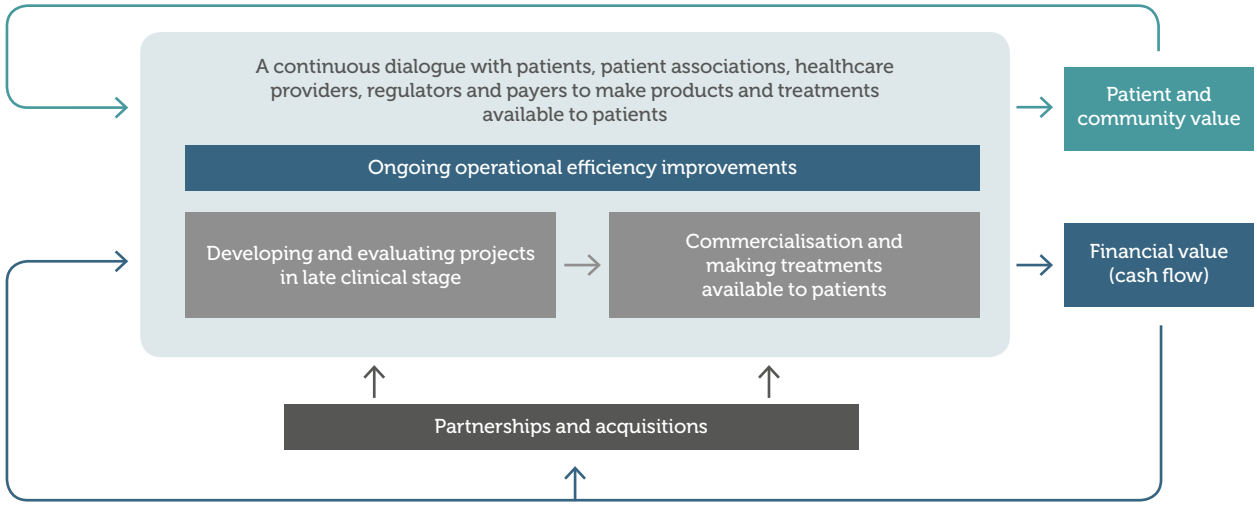
Our commercial and medical teams, as well as those in R&D, work together with healthcare professionals, external researchers and other stakeholders to increase understanding of patients' and healthcare professionals' changing needs. This leads to insights into needs that we continuously feed back into the system to improve our treatments and systems. This also allows us to see, for example, how new formulations or support systems can better meet patient needs.

Ensuring that patients never risk going without their medicine is of the utmost importance. That is why we have built up robust delivery and distribution processes and systems that cover all 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 can ensure that we continue to provide treatments to patients efficiently and responsibly.

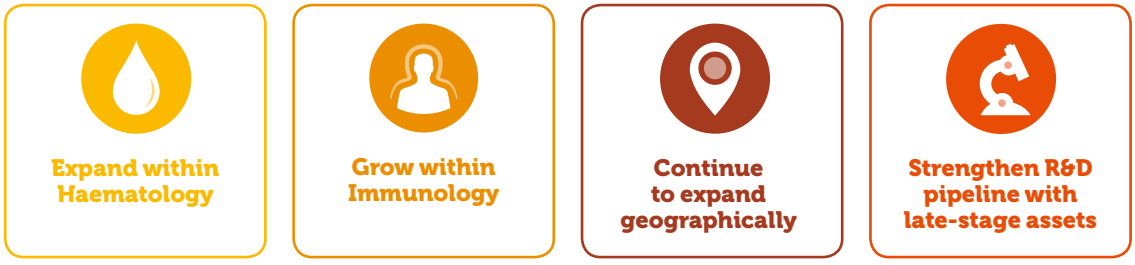
In all pricing negotiations, we take into account the following basic principles: medical need, the benefit the innovation brings to patients, benefits for the healthcare system, and the cost required to continue innovation and meet future medical needs.

Sobi business model



Strategy and objectives

Our strategy established in 2017 remains in place, 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.

Strategy and objectives

We continue to deliver on our strategy which was first put in place in 2017.

We aim to grow within Haematology. Building on our success over the past four years within haemophilia, 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. Within the larger scope of Haematology, we will work to realise the potential of our new product Doptelet, taking it to new markets and new indications. We continue to look for further external growth opportunities.

We have established a strong second leg in Immunology, where we have three growing products with significant potential for further expansion. Work will intensify in order to extract maximum value from these products. And we continue to search for new products for the Immunology portfolio.

We continue to expand geographically. Our North American operations have grown from 54 staff to 420 in just over two years, giving us a significant presence in the world's single largest rare disease market. We continue to build up our operations in Europe, the Middle East, North Africa and Russia, and we have taken a first step into Asia with the establishment of an office in China.

We continue to strengthen our R&D pipeline. During 2019, we took the decision to discontinue early-stage research and focus on late-stage assets that we see address unmet medical needs and have great potential market value. We now have a significant stock of pre-market assets under development, which will provide new therapies for launch in both the short and medium term.

Sustainable growth

Sobi's strategy for sustainable growth is closely linked to our commitment to provide access to treatment for people with rare diseases.

Enabling access to treatments is our key contribution to sustainable development. In order to meet this aim, we will promote a balance between:

- Making a commitment to patients to ensure and expand access
- Providing effective treatments that have favourable safety profiles for both patients and the environment
- Acting responsibly and ethically.

FINANCIAL OUTLOOK 2020

Revenue for 2020 is expected to be in the range of SEK 15,000–16,000 M reflecting double-digit growth in each of the two core businesses, Haematology and Immunology. EBITA is expected to be in the range of SEK 5,500–6,300 M, including the development and launch of Doptelet which will affect EBITA negatively by around SEK 500 M in 2020.

Haematology

Building on our success in haemophilia, we have expanded the therapeutic area to encompass haematology and create a platform for long-term growth.

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. It covers more than 100 benign and malignant disorders of the red and white blood cells, platelets and coagulation system. The science of haematology profoundly affects the understanding of many diseases.

Building a leading position

Our foundation in haemophilia and our track record in getting innovative treatments to the people who need them position us well to take a leading role in haematology.

Continued growth

- Elocta sales up 38 per cent (34 at CER)
- Alprolix sales up 50 per cent (46 at CER)
- Acquired Doptelet

Elocta and Alprolix

Together with Sanofi, we provide Elocta (efmoroctocog alfa) and Alprolix (eftrenonacog alfa), extended half-life (EHL) recombinant clotting factor replacement treatments for haemophilia A and haemophilia B, respectively. We aim to enable access to our treatments for everyone in our territory – Europe, most countries in the Middle East, North Africa and Russia – who has a need.

More people are switching to Elocta and Alprolix. The number of patients using Elocta, for example, has more than doubled since the first quarter of 2017.

Greater expectations

As well as protection from bleeds, EHL treatments are allowing people with haemophilia to expect less pain, better target joint resolution (halting repetitive bleeds into a specific joint and reversing joint damage) and fewer days when they have to worry about their treatment. Results from the pivotal phase 3 A-LONG study and ASPIRE long-term extension study show that weekly prophylactic dosing with Elocta has the potential to provide improved bleed protection over episodic treatment, resolve target joints and reduce the treatment burden associated with more frequent dosing.

Today's available EHL treatments also allow people with haemophilia to personalise their treatment regimes, for example increasing factor levels for greater protection at specific times. The opportunities available have raised expectations. For many years, the main goal of treatment has been protection from bleeds. This remains a primary consideration, but replacement treatment has now progressed beyond bleed prevention. People with haemophilia have the right to treatment that suits their lives and their own ambitions, rather than letting their treatment and condition limit their dreams.

By personalising treatment, a person with haemophilia can be certain they have the right level of protection to suit their lifestyle.

BIVV001: breaking barriers for factor treatment

In September 2019, we announced an expanded agreement with Sanofi to exercise an early opt-in for the development and commercialisation of BIVV001, an investigational long-acting VIII therapy with the potential to provide greater protection from bleeds with once-weekly dosing for people with haemophilia A. BIVV001 shows the potential to deliver a new standard of care by providing near-normal factor levels for much of the week.

In connection with the expansion of the collaboration agreement, a new supply contract with Sanofi until 2027 for Elocta and Alprolix has been agreed, with the potential for expansion to include BIVV001.

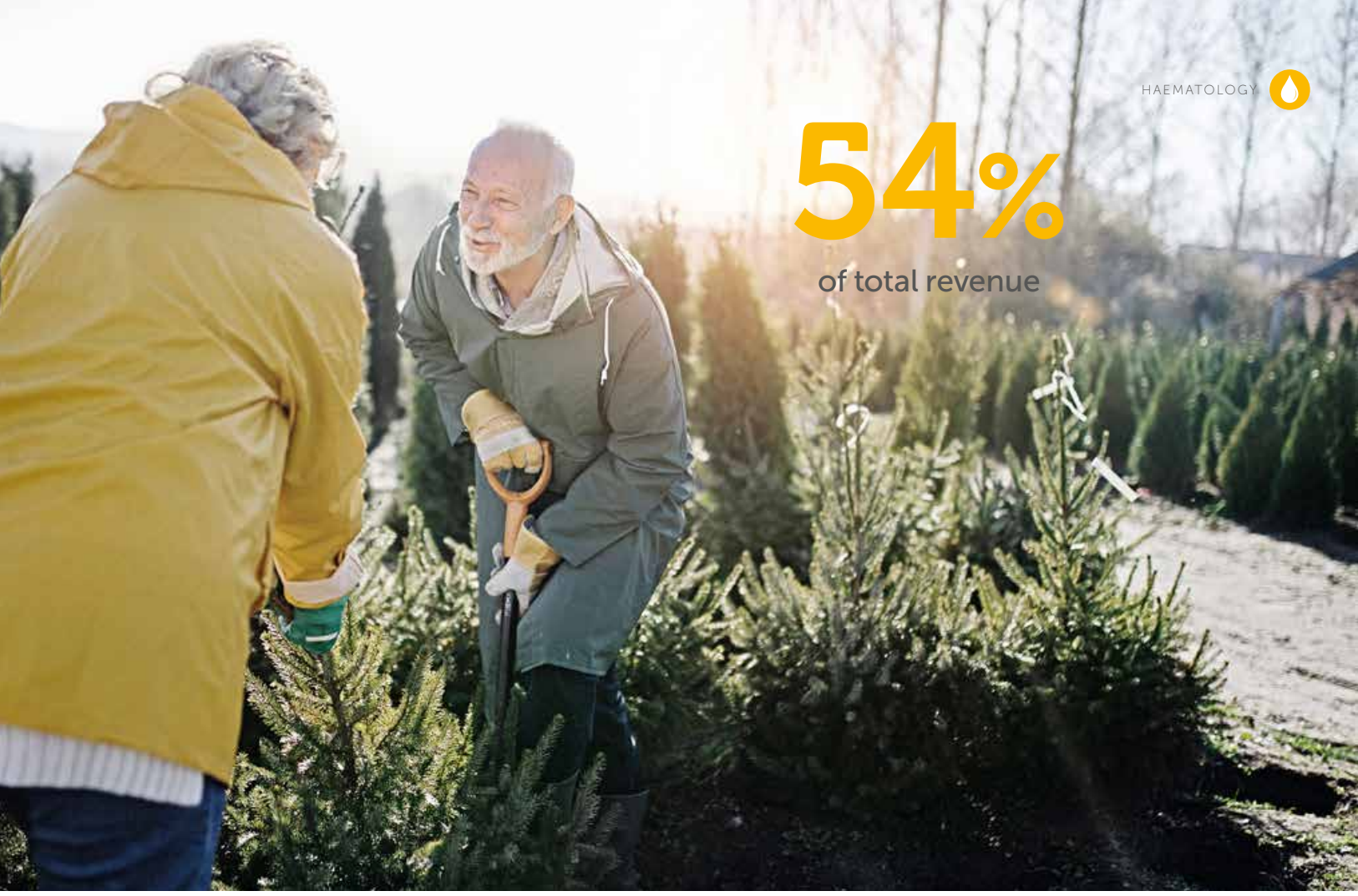
Doptelet strengthens portfolio

The acquisition of Dova Pharmaceuticals, which was finalised in November 2019, has added Doptelet to our Haematology portfolio, in both on-market and pre-market indications in the area of thrombocytopenia. Although Doptelet

Haemophilia

Haemophilia is a type of bleeding disorder in which the blood does not clot properly. The worldwide incidence of haemophilia is estimated at more than 400,000 people, although 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, with the same opportunities as anyone else.

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



54%

of total revenue

is used in another part of the clotting process than the replacement factor therapies used for haemophilia, many healthcare professionals treating people with haemophilia are also active in the general area of haematology.

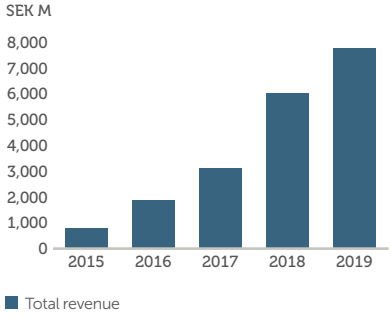
Doptelet was approved by the FDA in May 2018 for the treatment of thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo a procedure, and in June 2019 for chronic immune thrombocytopenia (ITP) in adult patients who have had an insufficient response to a previous treatment. Doptelet was approved in the EU for CLD in June 2019, and we have submitted the marketing authorisation application (MAA) for the treatment of ITP in the EU.

A phase 3 study of Doptelet in chemotherapy-induced thrombocytopenia (CIT), a common side effect of chemotherapy, is currently underway.

The thrombopoietin (TPO) market is estimated at USD 2 billion, growing by 5 per cent, and represents an attractive commercial opportunity.

Doptelet's recent US launch for the treatment of ITP is a first step towards capturing significant mid-term market share. In addition, Doptelet has the potential to become the first-to-market drug to treat CIT.

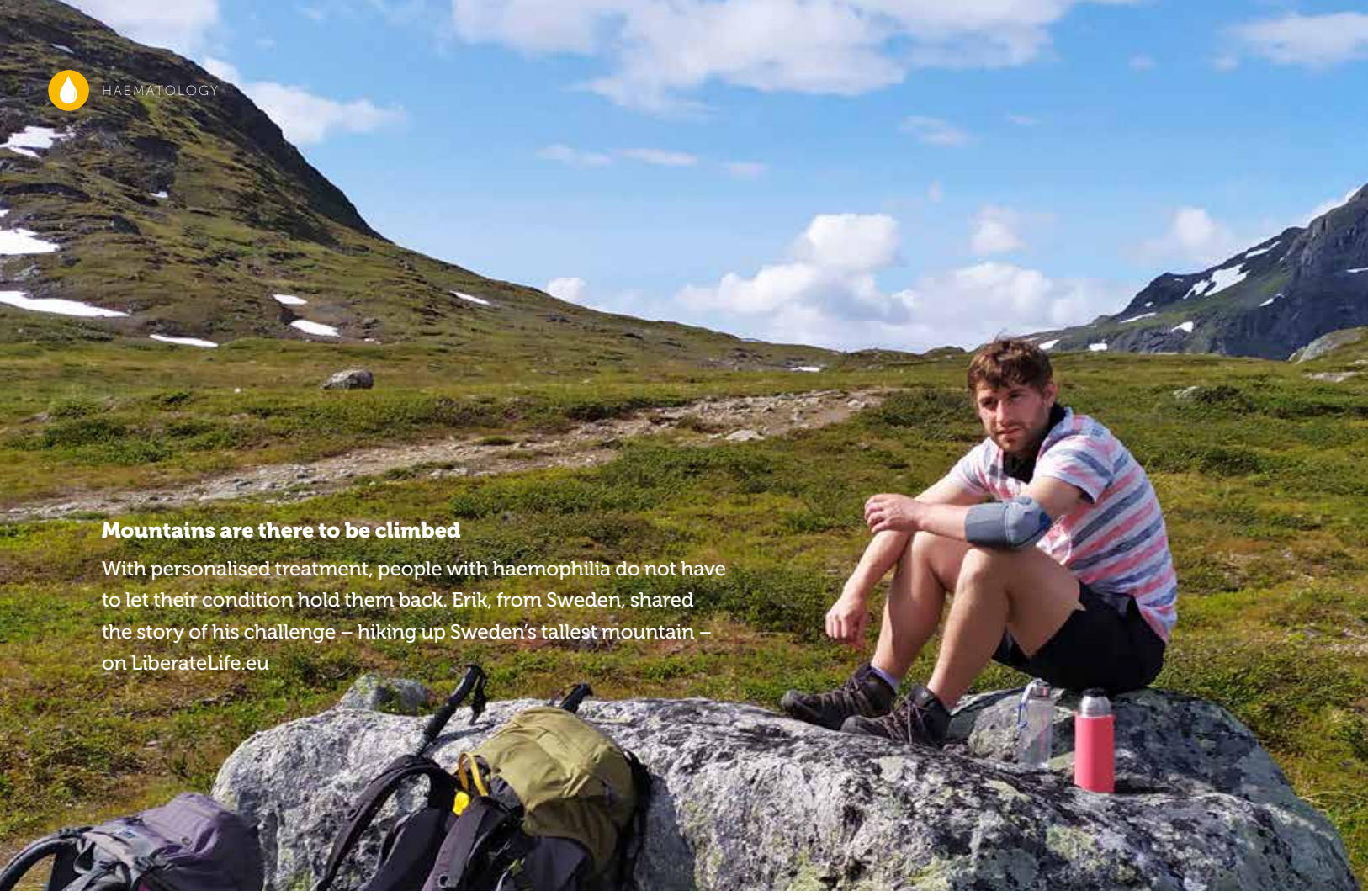
Total revenue, Haematology



Revenue per product, Haematology

SEK M	2019	2018	Change, %
Elocta	4,508	3,261	38%
Alprolix	1,463	974	50%
Doptelet	34	—	N/A
Manufacturing[1]	376	436	–14%
Royalty[2]	1,373	1,341	2%
Total	**7,755**	**6,012**	**29%**

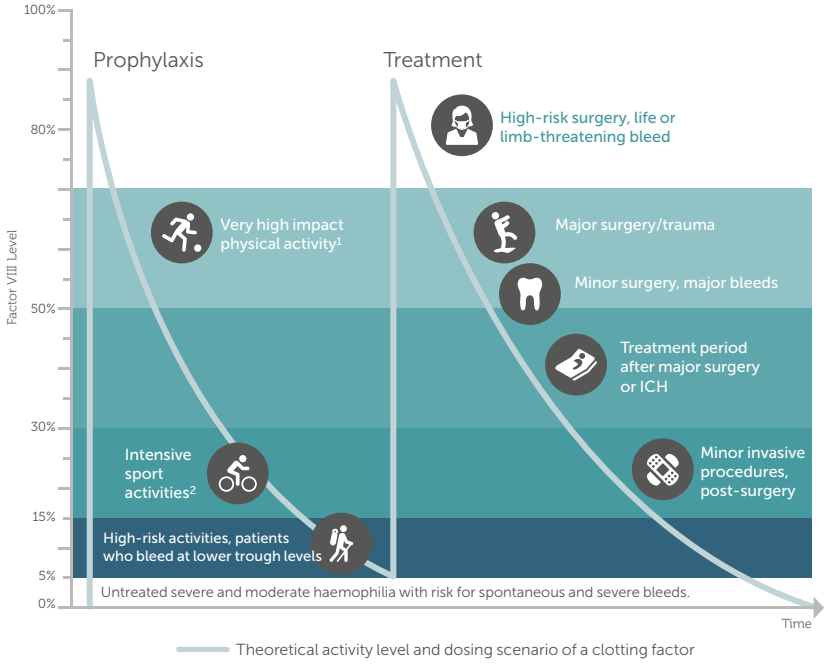
1. Manufacturing of the drug substance for ReFacto AF®/Xyntha® for Pfizer.
2. Sanofi's sales of Eloctate and Alprolix.



Mountains are there to be climbed

With personalised treatment, people with haemophilia do not have to let their condition hold them back. Erik, from Sweden, shared the story of his challenge – hiking up Sweden's tallest mountain – on LiberateLife.eu

Theoretical activity level and dosing scenario of a clotting factor



With factor replacement therapy, different activities and measures require different levels of coagulation factor in the blood. Major surgery and very high-impact physical activity, for example, require factor levels of 50–80 per cent, while minor surgery requires 15–30 per cent. With personalised treatment, a person with haemophilia can adjust their factor levels to ensure they have the right level of protection to suit their activities and lifestyle.

1. Lorio et al. Haemophilia 2017.
2. Srivastava et al. Haemophilia 2013; a,b discussed, but no consensus reached.

Immunology

With three strongly growing products that each address high unmet medical needs, our Immunology portfolio represents a new focus that builds on our heritage in rare diseases.

Our immune system is essential for protecting us from harmful diseases. Yet sometimes the immune system can malfunction, underreacting or overreacting to a real or perceived threat. The field of immunology has long been at the heart of what we do at Sobi, allowing us to gain many years of experience.

During 2019, we established Immunology as its own therapeutic area, providing a strong second leg to balance our success in haemophilia and diversify our revenue base. Immunology makes the most of the strengths we have built up in rare diseases and orphan drugs over the years.

Building on the success of Kineret, we were able to add emapalumab – approved as Gamifant in the US – which we acquired in its entirety in June 2019, and the US rights to Synagis, acquired in 2018 with closing in January 2019.

The three products combined provide strong revenue flows as well as extensive potential for future growth.

Kineret

- Sales up 19 per cent (12 per cent at CER) to SEK 1,571 M.

Sales of Kineret (anakinra) continued to grow strongly in both EMENAR and North America, driven by several factors. One key driver is increasing awareness of IL-1 as a key mediator of inflammation and scientific interest in Kineret as a treatment for systemic autoimmune/autoinflammatory disorders.

Medical need

Kineret has now been launched for Still's disease in all EU markets, and is reimbursed in almost all. Kineret is approved for Still's disease in adults and children from the age of eight months as a first-line treatment before the use of steroids – avoiding the risk of growth retardation, a common side effect of steroids.

The ability to start treatment from as early as eight months is also important considering the risk of organ damage if treatment is delayed.

Expanding patient access

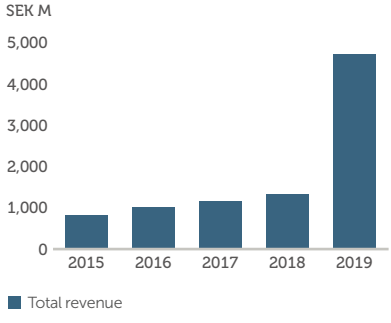
In the US, a new distribution agreement is increasing patient access to Kineret, including co-payment programmes and assistance with reimbursement, improving adherence and helping people stay on their treatment longer. Other programmes include injection education through in-home nurse visits, and increased support for the auto-inflammatory community.

Furthermore, in line with our geographical expansion strategy, we are investigating taking Kineret into new countries where there is an unmet medical need.

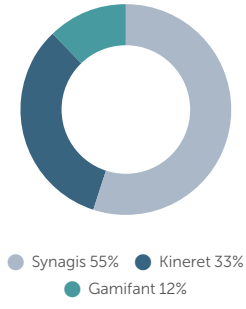
Steady scientific interest

Researchers and healthcare professionals continue to show significant interest in interleukin-1's role in autoimmune/autoinflammatory disease, and the effects of anakinra as an IL-1 receptor antagonist in blocking the inflammation. This interest has been strengthened most recently by EU approval in 2018 of Kineret as a treatment for Still's disease

Total revenue, Immunology



Revenue per product, Immunology



33%

of total revenue

in Europe, and building on the understanding of the role of IL-1 blockade in CAPS. It can be seen in the number of publications in the IL-1 area and continuous requests for investigator-sponsored studies (ISS) as well as independent studies.

Gamifant and HLH

- Sales of SEK 542 M

Before 2018, there was no medicine approved for the treatment of primary haemophagocytic lymphohistiocytosis (HLH), a life-threatening syndrome of hyperinflammation. The most common treatment involved a cocktail of immunosuppressant drugs together with steroids and chemotherapy, a combination that can have significant side effects, ahead of a stem cell transplant. A study showed a 50–60 per cent survival rate among patients with primary HLH, a genetic form of the syndrome which predominantly affects children, receiving the traditional therapy.

In November 2018, the FDA approved emapalumab as Gamifant for second-line treatment of primary HLH in children and adults, and was subsequently launched in the US. A study published in February 2019 showed 90 per cent survival after stem cell transplant for HLH patients treated with emapalumab.[1]

Supporting diagnosis

Launch activities have included negotiations on pricing and reimbursement, and ensuring supply and distribution. There was also a strong focus on education, disease awareness and helping healthcare professionals identify HLH, which is often misdiagnosed.

Gamifant sales reached SEK 542 M for the year. The product is still in launch phase, and sales of products for ultra-rare diseases are often initially volatile due to the limited number of patients and difficulties in obtaining a correct diagnosis.

Material growth driver

We see extensive promise for emapalumab beyond the current indication and market, and believe it has strong potential to be a material growth driver. Investigations are beginning in areas including secondary HLH and haemopoietic stem cell transplant (HSCT). Patient recruitment is going well in the study in secondary HLH in children, and we have started a study in adults. The pilot phase of the study in acute graft failure (HSCT) is scheduled to start towards the end of 2020.

Emapalumab is currently approved only in the US, for the treatment of primary HLH, and is under review by the EMA and in other markets. Some patients in Europe and the Middle East have already received treatment under early access programmes.

Some patients in Canada have also been treated under an early access programme, and filing is expected during 2020.

In line with our strategy of geographical expansion, we are beginning work on the regulatory pathway for emapalumab in China. There is a high unmet medical need in China, which has an accelerated approval path for rare diseases. We are also investigating other Asian markets.

Synagis and RSV

- Sales of SEK 2,594 M

RSV, or respiratory syncytial virus, is a common and highly contagious seasonal virus that is contracted by nearly all babies by the age of two. In most babies, RSV causes only a mild respiratory infection; however, for some – especially babies who are considered high risk – RSV can develop into a much more serious infection.

RSV is the leading cause of hospital admission in infants aged less than one year in the United States[2]. 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. The seasonal nature of RSV has a major effect on sales of Synagis, with the vast majority of sales taking place during RSV season which covers the fourth and first quarters of each year.

Strong growth

Sobi acquired the US rights to Synagis from AstraZeneca in 2018, integrating the Synagis team into our US operations during 2019. We have subsequently seen growth above that achieved in prior seasons. We are seeing a high level of referrals and good momentum working with institutions as we continue to identify high-risk infants who are eligible for Synagis.

Additional opportunities

Our investments in expanding the field force and market access continue to deliver additional opportunities for this important brand, including identifying and gaining label coverage for even more high-risk infants who would benefit from Synagis.

An extensive campaign for RSV Awareness Month in October 2019 helped raise awareness of RSV ahead of the approaching virus season.

1. www.sobi.com/en/press-releases/new-emapalumab-data-presented-transplantation-and-cellular-therapy-tct-meeting
2. www.ncbi.nlm.nih.gov/pmc/articles/PMC5090170/

13%

of total revenue

Specialty Care portfolio

We remain committed to Orfadin® and have also streamlined our Specialty Care portfolio in line with our sharpened strategic focus.

We remain committed to Orfadin, which is approved in the US, the EU and several other markets for the treatment of hereditary tyrosinaemia type 1 (HT-1), in combination with dietary restriction of tyrosine and phenylalanine. HT-1 is a rare genetic disorder that can cause liver, renal and neurological complications.

When Orfadin was first launched in 2002, few patients living with HT-1 would celebrate their second birthday[1]. Today, thanks to improved newborn screening, effective treatment and dietary management, we are seeing the first generation of patients with HT-1 reach an age where they are starting their own families.

Over years of working closely with the HT-1 community, we have continued to develop Orfadin to meet the various challenges facing people with HT-1 during different stages of life.

With an increase in newborn screening in several countries, more patients are being diagnosed earlier. The Sobi-patented oral suspension makes treatment simpler for younger infants. At the other end of the scale, the larger 20 mg capsule – which is the only one on the market – allows older patients to reduce the number of capsules they have to take every day.

Generic competition has entered some markets for other formulations, and sales of Orfadin declined in 2019.

We remain strongly committed to the HT-1 community and providing life-long treatment with Orfadin and associated patient support services.

Streamlining the portfolio

Rather than marketing partner products, where we control a relatively small part of the value chain, we will look for opportunities to acquire or wholly license products focused on rare diseases or niche indications. This will provide long-term strategic ownership while supporting our strengthened focus and increased investments in the areas of Haematology and Immunology.

In conjunction with this adjustment, several contracts in the Specialty Care portfolio were terminated during 2019, including Xiapex® and Ravicti®.

1. von Spronsen et al. Hepatology. 1994; 20(5):1187-1191

Global expansion powers growth

Geographical expansion is taking our treatments to more people and creating new growth opportunities.

We see geographical expansion as an important aspect of our strategy, and are pursuing it through acquisitions, greater market penetration and by establishing operations in new markets.

Expansion in North America, and in the US in particular, is a strategic objective. The US represents half of the global rare disease market, and a significant presence there is a prerequisite for a global leadership position.

Strengthened US presence

US growth has been significant, coming from acquisitions and organic growth. North America's share of revenue has risen from 14 per cent in early 2018 to 32 per cent at the end of 2019. From 55 employees there at the start of 2018, we had a total of 420 by the end of 2019.

The acquisition of the US rights for Synagis in 2018 accelerated the expansion of our workforce there, with all 133 people from the Synagis team joining Sobi when the acquisition was finalised late that year. The workforce continued to grow throughout 2019 with the launch of Gamifant as well as reinforcement of the Synagis and Kineret teams.

Dova bolsters Haematology

The acquisition of Dova Pharmaceuticals, finalised in November 2019, continued the expansion of our operations in the US.

Based in Durham, North Carolina, Dova brought 125 employees to the team, including specialists in haematology, strengthening our infrastructure in Haematology and broadening our competence base in the US.

Growing in Europe and around the world

Europe, the Middle East, North Africa and Russia have traditionally been Sobi's home markets. Even with our growth in North America, these markets continue to play a vital role for both our Haematology and Immunology franchises.

In Haematology, we continue to increase market penetration with our extended half-life factor replacement treatments for haemophilia A and B. Market share in existing markets continues to grow: both Elocta and Alprolix are the market-leading factor therapies in Scandinavia, and in 2019, people with haemophilia in almost 30 countries – including the recent additions of Romania and Hungary – had access to our EHL treatments.

New products for European market

Doptelet, which became a Sobi asset with the acquisition of Dova, was approved in the EU for chronic liver disease (CLD) in June 2019, and a launch is planned in certain European markets during 2020. A European filing for the chronic immune thrombocytopenia (ITP) indication has been submitted.

In Immunology, we have filed for European approval of emapalumab as a therapy for primary HLH.

Following EMA approval of Kineret as a treatment for Still's disease in Europe in 2018, we launched Kineret in this indication in 17 countries in 2019. Several people with Still's disease have commenced treatment.

Launching operations in China

High unmet medical need has been seen in China in HLH and thrombocytopenia. To address this unmet need, we established operations in China in January 2020. China has accelerated paths to approval for orphan drugs.

With the addition of China, we are now represented in more than 30 markets across North America, Europe, the Middle East, North Africa, Russia and Asia, providing treatment for patients in more than 70 countries.

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. This would allow us to maximise the growth potential of our pre-market and on-market portfolio.

Global supply chain

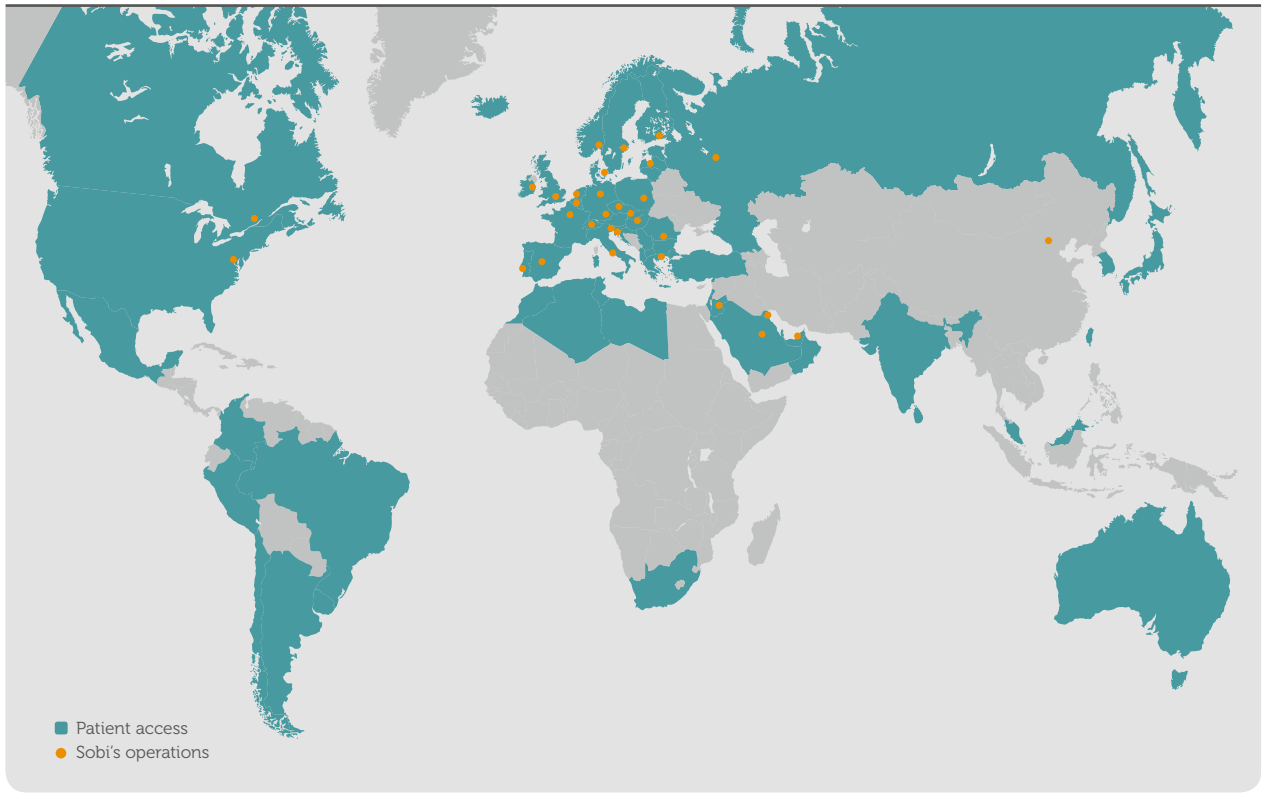
We market and sell a wide range of products in more than 70 countries. It is our key responsibility to ensure that patients never risk being without their medication.

Our global Technical Operations team ensures the sourcing, manufacturing and distribution of compliant products to patients.

Our supply chain depends on the qualified services of multiple partners engaged in manufacturing, testing, storing and finally distributing our products. Full and often serialised control over the entire chain is vital, as are Good Pharmaceutical Practices to ensure product integrity and quality.

During 2019, we introduced a Responsible Sourcing Programme to verify the sustainability of our supply chain, read more on page 24.

Global presence



Sobi's markets

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

See page 115–116 for full details.

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

»A significant presence in the United States is a prerequisite for a global leadership position.«

Strengthening late-stage pipeline

Innovation has been at the heart of Sobi throughout our history. We combine our expertise with that of our partners to find and develop innovative treatments that address significant unmet medical need among people with rare diseases.

We see innovation as an essential element in achieving our vision of being recognised as global leaders in rare diseases. We take new treatments to patients, expand our existing products into new indications and regions where they address unmet medical need, and gather real-world evidence from available products.

As part of sharpening our strategic focus, our R&D is now concentrated on late-stage research within Haematology and Immunology. With the acquisitions over the past two years, our pre-market portfolio has never been stronger.

Haematology

Within Haematology, we added two major new assets to our pipeline during 2019: BIVV001, an investigational long-acting factor VIII treatment with potential to provide greater protection from bleeds with once-weekly dosing for people with haemophilia A; and Doptelet, a second-generation small-molecule thrombopoietin receptor agonist used in treatment of thrombocytopenia by increasing platelet count.

BIVV001

We see BIVV001 as having the potential to deliver a new standard of care for people with haemophilia A. By adding BIVV001 to our collaboration agreement with Sanofi, we are taking an active role in the development of this potential treatment. The pivotal phase 3 study in adults started in December 2019.

Doptelet

Doptelet is already approved in the US and the EU for the treatment of thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo a procedure, and in the US for chronic immune thrombocytopenia (ITP) in adult patients who have had an insufficient response to a previous treatment.

A phase 3 study of Doptelet in chemotherapy-induced thrombocytopenia (CIT), a common side effect of chemotherapy that results in a low number of platelets, is underway. At present, there are no approved drugs to treat CIT.

Elocta and Alprolix

Several phase 4 studies (some in partnership with Sanofi) of Elocta and Alprolix, our extended half-life factor replacement therapies for haemophilia A and B respectively, are gathering real-world evidence of safety and efficacy.

Immunology

Within Immunology, emapalumab – a monoclonal antibody (mAb) that binds and neutralises interferon gamma – is a key focus. Emapalumab was approved in the US in 2018 for adult and paediatric (newborn and older) patients with primary haemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance for conventional HLH treatment. Currently under evaluation by the EMA for primary HLH, emapalumab is also under investigation for secondary HLH and haemopoietic stem cell transplant failure.

Nirsevimab (MEDI8897)

Nirsevimab, developed by Sanofi and AstraZeneca, has entered phase 3 for the prevention of respiratory syncytial virus (RSV) in high-risk children and in healthy late preterm and term infants. Nirsevimab is a single-dose extended half-life anti-RSV F 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. It has been engineered to have a long half-life so that only one dose will be needed for the entire RSV season. Sobi has the rights to 50 per cent of future US earnings of nirsevimab.

Kineret

We continue to investigate Kineret (anakinra), which still attracts much scientific interest nearly 20 years after it was first described as an interleukin-1 (IL-1) receptor antagonist. IL-1 blockade is one of the oldest biological therapies, yet use continues to rise as the role of IL-1 activation is being recognised

in a wide spectrum of inflammatory disorders, from gout to cancer. As well as investigator-sponsored studies, researchers are also carrying out their own trials without Sobi's involvement.

Approved in several countries for IL-1 related illnesses, Kineret was approved in 2018 for Still's disease in Europe. A study in Still's disease in the US was halted due to recruitment issues, but based on the convincing results we plan to file for FDA approval in Still's disease.

Potential new indications

Anakinra has also been under investigation in other IL-1 related illnesses.

- Deficiency of interleukin-1 receptor antagonist (DIRA), a rare and life-threatening autoinflammatory disease.
- Familial Mediterranean fever (FMF) is an inherited disorder manifested by episodic fevers, often with pain in the abdomen, joints or chest, and rash in the lower extremities.

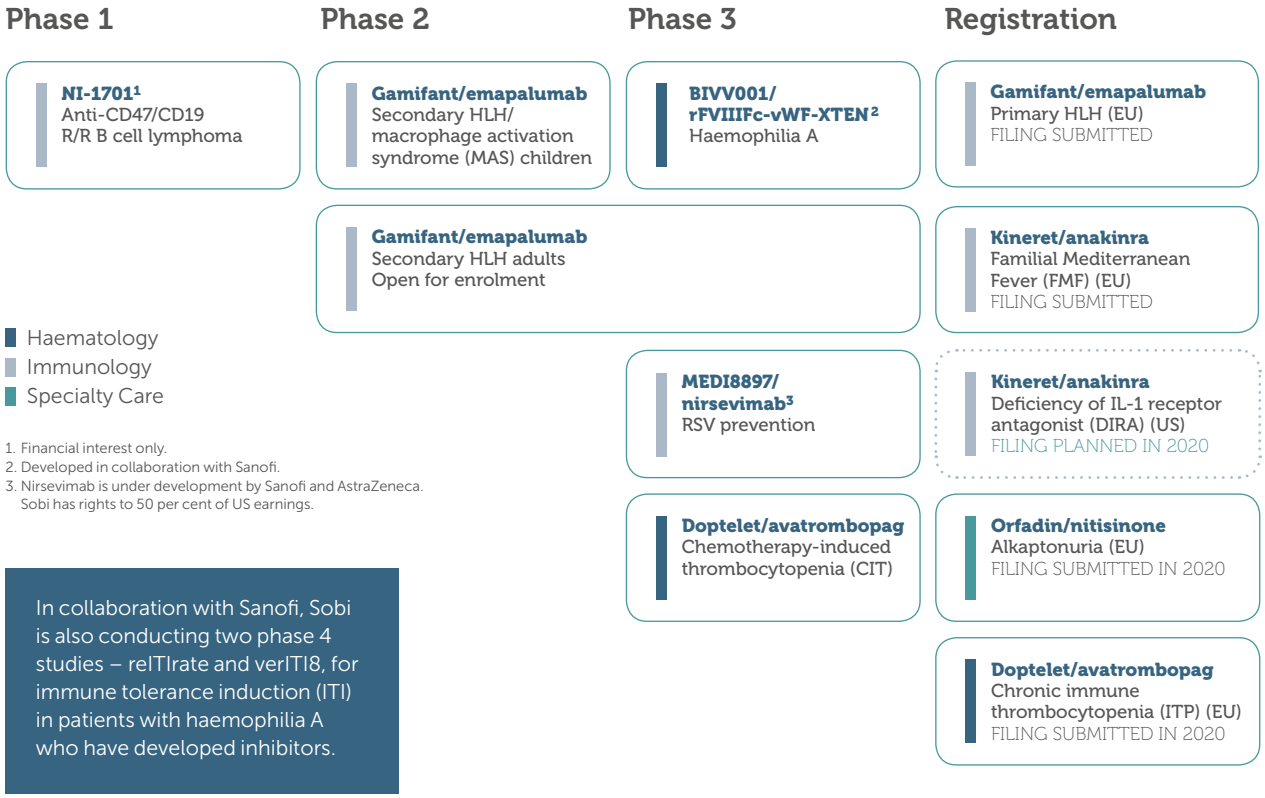
Filing to follow successful trial

Sobi has applied for EMA approval of an extended indication for Orfadin for the treatment of alkaptonuria (AKU) after positive results on efficacy without safety concerns from the phase 3 study SONIA 2.

AKU was the first identified human genetic disease and is said to be the birth of human genetics. It is a serious, autosomal recessive, multisystem disorder affecting around one in every 250,000 to 1 million people, although prevalence is higher in some countries.

For more information, visit DevelopAKUre.eu

Our innovation pipeline as per 25 March 2020



1. Financial interest only.
2. Developed in collaboration with Sanofi.
3. Nirsevimab is under development by Sanofi and AstraZeneca. Sobi has rights to 50 per cent of US earnings.

In collaboration with Sanofi, Sobi is also conducting two phase 4 studies – reITIrate and verITI8, for immune tolerance induction (ITI) in patients with haemophilia A who have developed inhibitors.

Sustainability

Our commitment to provide access to treatment for people with rare diseases is our main contribution to sustainable development.

Access to treatment

Our sustainability strategy consists of three key areas aimed at increasing patient access to treatment:

- Supporting the rare disease community through our commitment to patients and working actively with pricing, reimbursement, knowledge sharing, regulatory approvals and market expansion.
- Providing effective treatments that have a favourable safety profile for both patients and the environment. This is achieved by following high pharmaceutical standards, and undertaking initiatives to promote responsible sourcing and greater environmental responsibility.
- Acting ethically and responsibly in everything we do, through high research standards, business ethics and policies aimed at creating a sustainable organisation purposed to serve the community.

Sobi has been a signatory to the UN Global Compact since 2017[1], and we conduct our business in a manner consistent with the principles of the Global Compact. We report our sustainability performance within the framework of the Global Reporting Initiative (GRI), in accordance with the Core option.

Commitment to patients

Throughout our history, we have worked with the rare disease community to provide access to innovative treatments. We continue this cooperation across a wide range of areas, and see it as vital for the future.

One of the most important ways in which we work with the community is in patient access, ensuring access to treatment for people with rare diseases through the healthcare system. Patient access involves negotiations and discussions with healthcare and regulatory authorities, payers, treaters and patient organisations.

Pricing and reimbursement

Social, economic and healthcare priorities are different in every country, and each assesses medicines in different ways based on its local priorities, context and philosophy. Sobi works with each country on an individual basis to find appropriate solutions to reach patients.

Pricing and reimbursement are two essential areas of enabling patient access. Several factors must be taken into account when pricing a medicine.

At Sobi we follow a value-based pricing approach. The price of our medicines should represent the benefit that the innovation delivers to patients living with rare diseases, to healthcare systems, payers and to societies. A successful pricing strategy supports further investment in innovation so that we can continue to meet the needs of patients in the future.

In some markets, patient access to treatments may be limited by the lack or complexity of reimbursement processes. We have several initiatives in place to support patients and doctors to gain access. One such programme is KINERET ON TRACK[2] in the US.

Knowledge sharing

Each rare disease is so uncommon in its nature that knowledge about the disease is often rare too. It is not uncommon that a rare diagnosis is delayed.

Understanding the patient experience of living with a rare disease can provide

Sustainability strategy

1. www.unglobalcompact.org/what-is-gc/participants/112201-Swedish-Orphan-Biovitrum-AB-publ-
2. www.kineretrx.com/nomid/kineret-on-track

important information and increase knowledge of disease burden and treatment possibilities. In 2018, Sobi commissioned an ethnographic study of over 50 people living with haemophilia in Europe.

By sharing the data from this study with patient organisations, treaters and payers, we hope to increase understanding not only of the challenges facing people living with haemophilia but also of the opportunities. Several organisations have received presentations on the key findings, and a congress poster was presented in October 2019. We intend to publish more detailed manuscripts in 2020.

We support the research community with grants and other forms of assistance. During 2019, we launched the Sobi Scientific Innovation Awards, recognising innovation and scientific excellence by both established and up-and-coming researchers. The inaugural awards focused on haemophilia research, with prizes for clinical and pre-clinical work.

During the year, we have also been a sponsor of FYMCA, a medical education organisation that develops improved rare-disease education and services for the developing world.[1]

Innovative access strategies

In terms of access outside our key markets, our largest single contribution, together with our partner Sanofi, is the 2015 pledge to donate up to 1 billion international units (IUs) of extended half-life coagulation factor replacement for use in developing countries over ten years. During the first five years, 500 million IUs have been earmarked for distribution through the World Federation of Hemophilia (WFH) Humanitarian Aid Program. The donation has so far reached more than 17,200 people in 40 countries, enabling 2,322 surgeries and 160,000 acute bleed treatments, leading to major improvements in quality of life for thousands of people.[2]

Acknowledging that donations do not provide sustainable or long-term access to treatment in recipient countries, we strive to transform donations to access within the regulated healthcare system where possible. One example of this is the achievement of sustainable access to treatment for hereditary tyrosinaemia (HT-1) treatment in Palestine. Sobi has been donating Orfadin for the treatment of HT-1 in Palestine for more than 20 years. During 2019, after constructive discussions between Sobi, the Palestinian Ministry of Health and the treating physician in Palestine, the Ministry of Health was able to take over responsibility and funding for existing and future HT-1 patients, ensuring true sustainable access.

Another example of innovative strategies to increase access to treatments is the European Haemophilia Consortium's (EHC) Procurement of Affordable Replacement Therapies Network of European Relevant Stakeholders – the PARTNERS programme, which Sobi supports. The PARTNERS programme aims to increase access to replacement therapies in countries that provide little or no such treatment to their haemophilia patients. The EHC estimates that more than 5,000 people with haemophilia could benefit from the programme.[3]

Contributing to UN's Sustainable Development Goals

Sobi is a signatory to the UN Global Compact and is committed to supporting the principles it outlines. We have identified the SDGs that we can help to achieve.

Goal 3: Good Health and Wellbeing
Through our day-to-day operations we provide treatments to patients with rare diseases and work to expand access in our markets and beyond.

Goal 12: Responsible Consumption and Production
We continuously monitor and improve the environmental performance of our operations and we work with our supply chain to promote a common Code of Conduct, implement screening processes to promote good practices and improve our sustainability reporting.

Goal 17: Partnerships for the Goals
We believe in working in partnerships – with patient organisations, through industry initiatives, research consortia and healthcare authorities – to create a greater impact in the rare disease space.

Follow our progress towards each of these SDGs in the Sustainability Notes on pages 110–114.

1. www.fymcamedical.com
2. www.wfh.org/en/wfh-humanitarian-aid-program
3. www.ehc.eu/partners/

Safety for patients and the environment

Sobi follows pharmaceutical regulations and standards governing the safe production and monitoring of treatments. We set high standards in regards to the safety of our treatments for patients.

To ensure treatments also are safe for the environment and responsibly produced, we took several initiatives in 2019.

Responsible sourcing

With a largely outsourced supply chain, we rely on sustainable and robust suppliers to produce, package and distribute our products.

In 2019, we introduced a Responsible Sourcing Programme, including the introduction of a Partner Code of Conduct and screening of sustainability aspects, starting January 2020. The screening involves ensuring compliance with standards in the areas of management, labour and human rights, and environmental responsibility. In 2020, our aim is to include the Partner Code of Conduct in all new agreements, to introduce our top 100 partners to the Code and to initiate screening of their operations.

Sobi also became a member of the Pharmaceutical Supply Chain Initiative (PSCI) in 2019.

Environmental responsibility

Sobi's environmental impact is attributed to direct and indirect activities, through our own operations and through sourced activities. Due to our business model, an extensive proportion of our impact arises from the activities we source from our contract manufacturers.

Environmental impacts from production, either in-house or outsourced, are mainly derived from the use of energy, water, chemicals, generated waste and discharge of sewage. We work actively to phase out chemicals that may be harmful to the environment or human health. Chemicals legislation is extensive and continuously expanding; all handling of chemicals in our laboratories and manufacturing processes therefore follows strict instructions.

Our greenhouse gas emissions arise from areas such as energy consumption, business travel, logistics within the supply chain and distribution of our products.

We continuously monitor and evaluate the energy and water consumption of our production facility. The electricity consumed at the Stockholm plant is entirely a mix of certified renewable energy sources. The impact of our manufacturing plant in Stockholm, Sweden, is described in detail on pages 110–112.

Business travel is an area where we are working to find ways to reduce our greenhouse gas emissions. We believe that less travel will benefit not only the planet but also our employees. During the year, we expanded the ability for staff to use video-conferencing facilities in order to reduce travel between offices.

Ethical and responsible behaviour

We aim to always act ethically and require the highest ethical standards of our employees. In line with the growth Sobi is undergoing, we continuously review and adopt our policies and systems to ensure that we continue to maintain our high standards. Our employees receive regular training on appropriate conduct. In 2019, 95 per cent of our employees completed the mandatory anti-corruption, drug safety and Code of Conduct training.

To support the specific area of compliance in healthcare interactions, a Healthcare Interactions Portal was made available in 2019, providing guidance and assistance for all staff.

Ethical behaviour is promoted through our company values and our Code of Conduct. Sobi's five core values are aimed at ensuring that more patients benefit from our therapies, both now and in the future. See the illustration below.

Sobi's core values

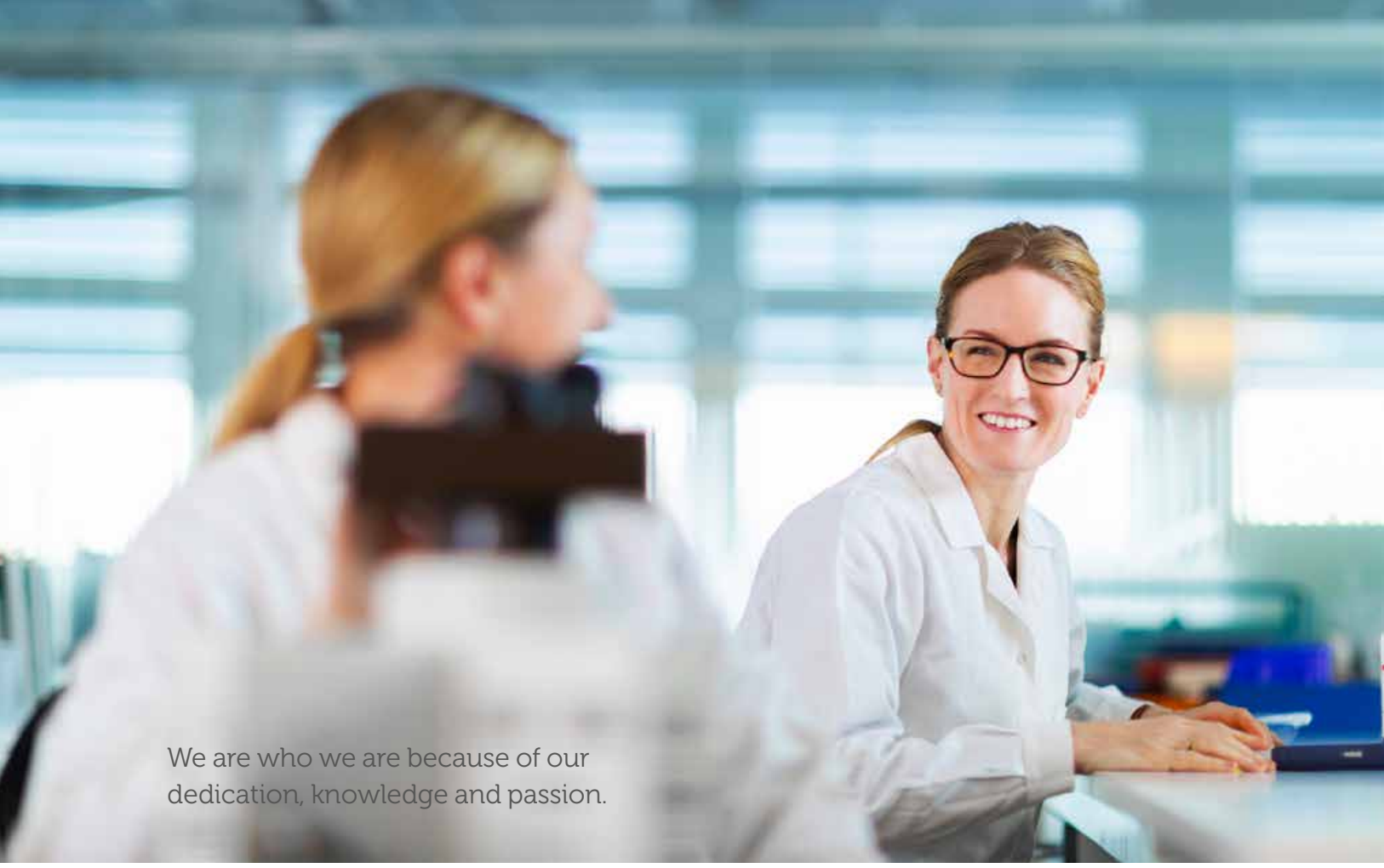
Care
We are who we are because of our dedication, knowledge and passion. Care is the foundation upon which our strategy, our business and our culture are built.

Ownership
It is our duty to act. We therefore encourage intrapreneurship and learn from our experiences.

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

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

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



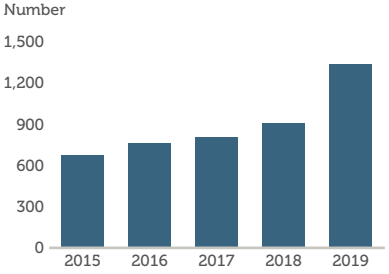
Responsible employer
Our workforce is essential for our ability to deliver on our strategy. At the end of 2019, we had 1,335 highly skilled employees[1] in more than 30 countries around the world. Positive relationships with our employees support their development, wellbeing and job satisfaction, and we are proud to offer a safe, healthy and inclusive workplace with equal development opportunities for all.

In 2019, activities were focused on supporting Sobi's strategic shift and integration of the employees joining Sobi from the companies acquired in 2018 and 2019. We have seen a high level of retention during these integrations, and continue to develop the process of introducing new employees to Sobi's culture and values. Our corporate values are actively promoted within our organisation and lived by our employees. Our Code of Conduct is publicly available on the Sobi.com website.

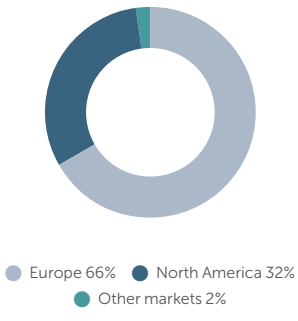
1. FTE, full-time equivalents.

Our employees

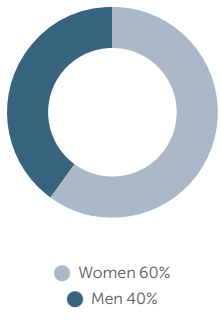
Number of employees



Geographical distribution



Gender distribution

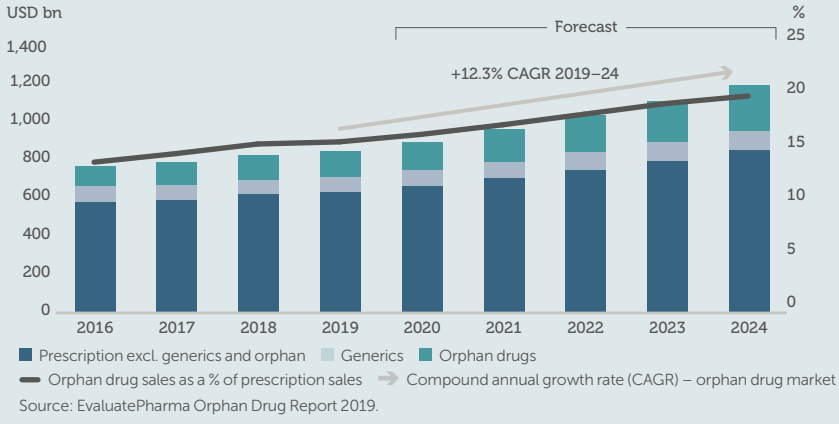


Sobi investment case

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 (2016–2024)



Source: EvaluatePharma Orphan Drug Report 2019.

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.

Significant pre-market pipeline

Sobi has built a significant pre-market pipeline through the continued development of core assets 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	Avatrombopag[1] – CIT, ITP (EU) BIVV001[2] – haemophilia A BIVV002[3] – haemophilia B	Emapalumab[4] – secondary HLH Emapalumab[4] – new indications Anakinra[5] – indication expansion Nirsevimab[6] (MEDI8897) – RSV

1. Avatrombopag – approved as Doptelet for thrombocytopenia in chronic liver disease (CLD) and chronic immune thrompocytopenia (ITP) in the US. Under development for chemotherapy-induced thrombocytopenia (CIT).
2. Developed in collaboration with Sanofi.
3. Sobi has elected to add the BIVV002 programme to the collaboration agreement with Sanofi but has not yet opted in.
4. Emapalumab – approved as Gamifant in the US for primary haemaphagocytic lymphohystiocytosis (HLH).
5. Anakinra – approved as Kineret in the US and in the EU for several autoinflammatory diseases.
6. Nirsevimab (MEDI8897), a follow-on compound to Synagis for respiratory syncytial virus (RSV).

Geographical expansion

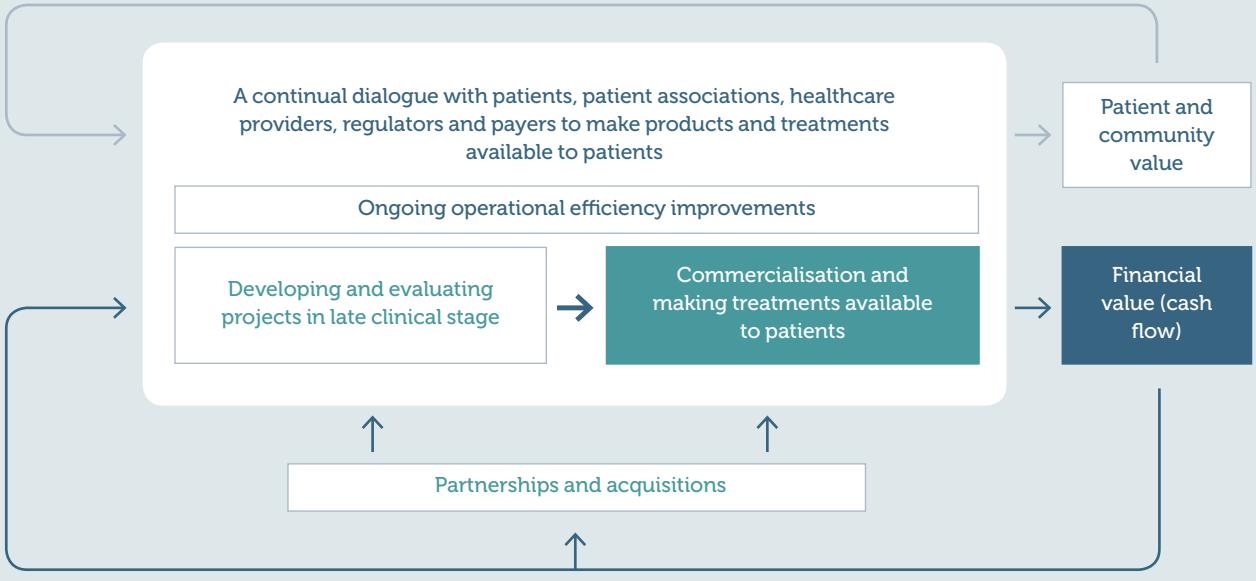
Sobi is represented in more than 30 markets across Europe, North America, the Middle East, Russia, North Africa and Asia. There is significant potential to expand our global position, with focus on the 15 largest markets representing a majority of the global market for rare diseases. With more late-stage 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. Over the 2015–2019 period, the share price has increased by more than 94 per cent.

In 2019 the highest price paid was SEK 234.3 on 8 April, and the lowest was SEK 144.7 on 4 October. Sobi's market capitalisation at year-end 2019 was SEK 46.3 billion. Over 2019, the share price fell 19.9 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 2019, trading on Nasdaq Stockholm accounted for 60 per cent of the total turnover.

Average daily total turnover in Sobi shares was 1,579,560 in official trading. A daily average of 778,920 shares were traded on Nasdaq Stockholm. In 2019, a total of 572.4 million shares were traded, corresponding to a value of approximately SEK 104.1 billion.

Share capital

At year-end, the total number of shares outstanding in Sobi was 299,977,839. All issued shares are ordinary shares and carry one vote per share.

At year-end, the share capital was SEK 164,599,935, distributed between 299,977,839 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 2,052,187 shares, or 0.7 per cent of the total number of shares in the company. For more information, see note 11.

Shareholders

At year-end, the number of shareholders was 25,226 (23,435). The largest shareholder, Investor AB, held 35.9 per cent (39.4) of the shares. Swedish legal entities, including institutions and funds, held 59.3 per cent (61.0) of the shares. Shares held by Swedish Orphan Biovitrum AB (publ) at year-end totalled 5,678,099 common shares.

During the year 208,257 shares were used for allotment under two performance-based long-term share programmes, see Note 11 for further information.

Dividend

The Board proposes that no dividend be paid for 2019. For more information about Sobi's dividend policy, please refer to the Corporate Governance Report.

Largest shareholders at 31 December 2019[1]

SHAREHOLDERS	Number of A shares	Share capital, %	Share votes, %
Investor AB	107,594,165	35.9	35.9
BNY Mellon NA (former Mellon), W9	29,266,145	9.8	9.8
Morgan Stanley Smith Barney LLC, W9	24,193,592	8.1	8.1
Swedbank Robur fonder	14,074,880	4.7	4.7
State Street Bank and Trust Co, W9	13,369,722	4.5	4.5
Fjärde AP fonden	9,512,951	3.2	3.2
AMF – Försäkring och Fonder	7,973,313	2.7	2.7
Swedish Orphan Biovitrum AB (publ.)	5,678,099	1.9	1.9
Handelsbanken fonder	5,564,682	1.9	1.9
Euroclear Bank SA/NV, W8-IMY	4,895,403	1.6	1.6
Cbny-Norges Bank	4,133,805	1.4	1.4
JPM Chase NA	3,236,147	1.1	1.1
Andra AP-fonden	2,842,349	1.0	1.0
SIX SIS AG, W8IMY	2,697,456	0.9	0.9
Gladiator	2,605,000	0.9	0.9
Total 15 largest shareholders	**237,637,709**	**79.6**	**79.6**
Other	62,340,130	20.4	20.4
Total	**299,977,839**	**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. In addition to Investor AB, EdgePoint Investment Group Inc. has flagged for owning more than 10 per cent of the voting rights.

Source: Euroclear

Average value of daily trading volume for the Sobi share

VOLUME '000	2015	2016	2017	2018	2019
A shares	1,391.5	2,263.6	1,502.3	2,272.0	2,289.6

In 2019, the average daily trading volume for the Sobi share on Nasdaq Stockholm was 778,920 shares.

Source: Fidessa.

Shareholder categories

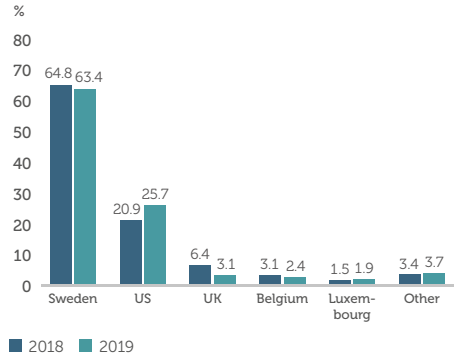
31 DECEMBER 2019	% of capital
Foreign shareholders	36.7
Swedish shareholders	63.4
whereof	
Institutions	59.4
Private persons	4.0

Source: Euroclear.

Key data per share

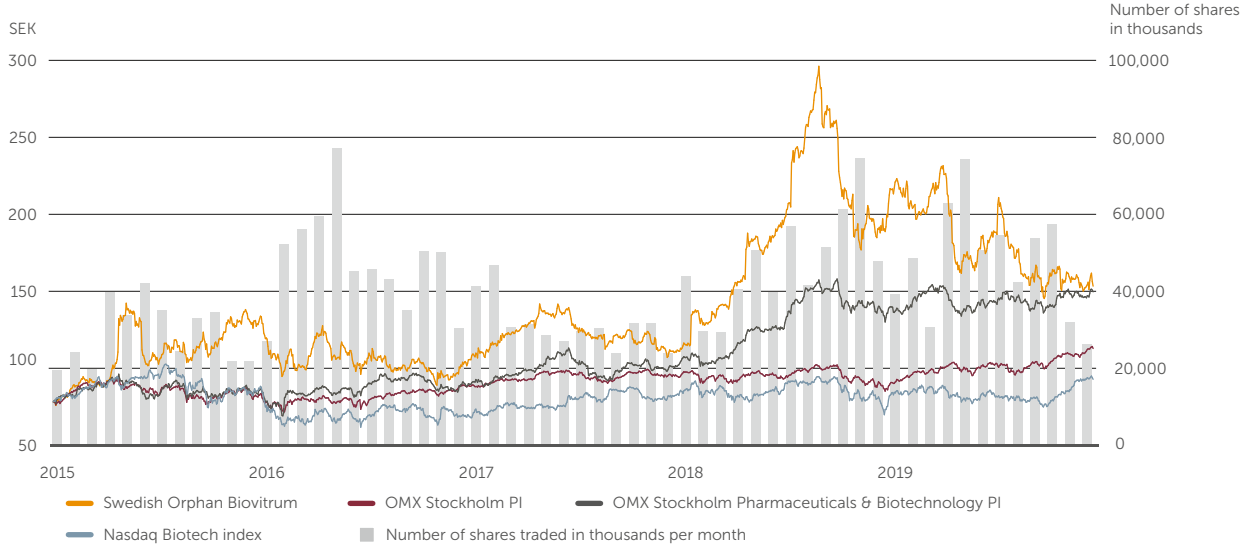
SEK	2015	2016	2017	2018	2019
Earnings/loss per share	0.31	2.99	4.27	8.97	11.29
Equity per share	17.3	19.8	24.6	33.1	56.4
Market price, Series A-share, 31 Dec., last paid price	134.6	106.7	112.3	193.0	154.5
P/E ratio	434.2	35.7	26.3	21.5	13.7
Number of shares at 31 Dec.	271,822,806	272,010,948	272,507,708	273,322,117	299,977,839

Shareholders by country



Source: Euroclear.

Sobi share price and trading volume 2015–2019



Five-year summary – Group development

	2015	2016	2017	2018	2019
Income statement, SEK M					
Operating revenue	3,228	5,204	6,511	9,139	14,248
Gross profit	2,007	3,651	4,657	6,723	10,913
EBITDA[1]	465	1,574	2,086	3,607	6,121
EBITA[1]	433	1,543	2,053	3,571	5,933
EBIT (operating profit)	146	1,133	1,600	3,122	4,533
Profit/loss for the year	83	802	1,149	2,418	3,304
Capital, SEK M					
Total assets	8,315	9,974	10,903	17,183	45,658
Capital employed[1]	5,508	5,880	6,716	9,048	33,560
Equity	4,678	5,365	6,701	9,040	16,930
Cash and cash equivalents	904	786	1,478	2,999	737
Net debt (+)/net cash (–)[1]	–89	–289	–1,478	–2,999	15,404
Cash flow, SEK M					
Cash flow from operating activities before changes in working capital	411	642	1,431	2,341	5,300
Cash flow from operating activities	507	343	1,333	2,090	3,634
Cash flow from investing activities	–143	–158	–139	–575	–21,686
Cash flow from financing activities	22	–308	–500	–1	15,780
Change in cash and cash equivalents	386	–123	694	1,514	–2,271
Key figures, %					
Gross margin[1]	62	70	72	74	77
Return on capital employed[1]	2.6	19.3	23.8	34.5	13.5
Return on equity[1]	1.8	16.0	19.0	30.7	25.4
Equity ratio[1]	56	54	61	53	37
Debt/equity ratio[1]	77	86	63	90	170
Share ratio, SEK					
Earnings/loss per share	0.31	2.99	4.27	8.97	11.29
Equity per share[1]	17.3	19.8	24.6	33.1	56.4
Dividend	—	—	—	—	0
Cash flow per share[1]	1.4	–0.5	2.6	5.6	–7.8
Cash flow from operating activities per share[1]	1.9	1.3	5.0	7.8	12.4

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.

Reporting

Contents

Directors' Report

Highlights 2019

Financial highlights

- Total revenue of SEK 14,248 M (9,139), an increase of 56 per cent.
- The gross margin was 77 per cent (74).
- EBITA was SEK 5,933 M (3,571).
- Adjusted EBITA was SEK 6,145 M (3,571).
- Profit for the year totalled SEK 3,304 M (2,418), representing earnings per share of SEK 11.29 (8.97). Adjusted earnings per share amounted to SEK 11.89 (8.97).
- Cash flow from operating activities was SEK 3,634 M (2,090).

Business highlights

- The acquisition of Synagis® was completed, expanding US operations.
- Sobi completed the business acquisition of emapalumab.
- Sobi discontinued its early-phase R&D operations in order to focus on late-stage R&D projects within the core areas of haematology and immunology.
- Sobi acquired Dova Pharmaceuticals and created a global haematology platform. The acquisition gave Sobi access to Doptelet®, a product used for the treatment of thrombocytopenia.
- Sobi concluded an expanded agreement with Sanofi regarding the early exercise of an opt-in right and acquired the development and commercial rights to BIVV001 in Sobi's territories. BIVV001 is an extended half-life factor VIII product for haemophilia A in clinical development.
- The first patient was dosed in the phase 3 study of BIVV001.
- The FDA granted orphan drug designation to avatrombopag (Doptelet) for the potential treatment of chemotherapy-induced thrombocytopenia (CIT).
- Sobi established operations in China.

Sobi's operations

At Sobi, we are transforming the lives of people affected by rare diseases. As an international biopharmaceutical company, we provide innovative treatments in haematology, immunology and niche indications.

In 2019, revenue was generated by:

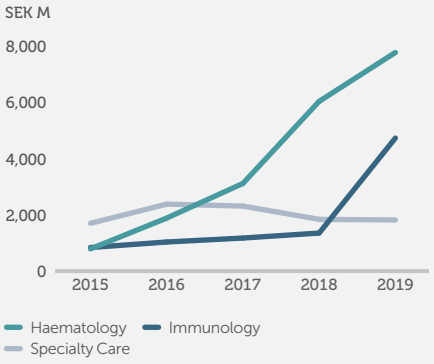
- Sales in Europe and rest of the world of the proprietary products Elocta® and Alprolix®, and royalty revenue from Sanofi's sales of Eloctate® and Alprolix. Global sales of the proprietary products Kineret® and Orfadin®.
- Sales in the US of the proprietary products Gamifant®, Synagis and Doptelet.
- 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	2019	2018
Operating revenue	14,248	9,139
Gross profit	10,913	6,723
Gross margin, %[1]	77	74
EBITA[1]	5,933	3,571
EBITA adjusted[1]	6,145	3,571
EBITA-margin,[1] %	42	39
EBITA-margin, % adjusted[1]	43	39
EBIT (operating profit)	4,533	3,122
Profit for the year	3,304	2,418
Earnings per share, SEK [1]	11.29	8.97
Earnings per share, SEK, adjusted	11.89	8.97

1. Alternative Performance Measures, see Definitions page 122.
See page 30 for a five-year summary of revenue, expenses and earnings.

Five-year revenue trend



Operating revenue
In 2019, revenue amounted to SEK 14,248 M (9,139), an increase of 56 per cent (48 per cent at CER).

Revenue by business area
Haematology
Total Haematology revenue amounted to SEK 7,755 M (6,012), an increase of 29 per cent (24 per cent at CER). Elocta accounted for SEK 4,508 M (3,261) an increase of 38 per cent (34 per cent at CER). France, Germany, Italy and the Middle East accounted for more than half of this growth. Sales of Alprolix amounted to SEK 1,463 M (974) and most of this growth was attributable to more patients using the product in France, Italy, the Netherlands, the UK and Sweden. Sales of Doptelet, which was acquired during the year, amounted to SEK 34 M for the 12 November–31 December period.

Royalty revenue amounted to SEK 1,373 M (1,341), derived from Sanofi's sales of Eloctate and Alprolix.

At year-end, drug reimbursement had been granted for Elocta in 27 European countries, and for Alprolix in 26 countries.

ReFacto manufacturing revenue totalled SEK 376 M (436), down 14 per cent.

The current manufacturing agreement for ReFacto AF/Xyntha is valid until 31 December, 2023, with an option to extend. Sobi's royalty agreements for ReFacto ended in January 2018.

Immunology
Total Immunology revenue amounted to SEK 4,706 M (1,320). Sales of Gamifant amounted to SEK 542 M. During the year, Gamifant showed a volatile sales pattern from quarter to quarter, which is normal for a product for an ultra-rare disease in launch phase.

Sales of Synagis amounted to SEK 2,594 M. The final quarter made a significant contribution to sales for the year as a result of improved commercial effectiveness and wholesaler stocking in the fourth quarter. In addition a positive Gross-to-Net impact and a more severe respiratory syncytial virus (RSV) season than normal influenced the result positively.

Sales of Kineret amounted to SEK 1,571 M (1,320), an increase of 19 per cent (12 per cent at CER). Kineret continued to show a positive trend with double-digit growth. Growth was mainly driven by higher underlying demand in all regions and the ongoing European launch of Kineret for Still's disease.

Specialty Care
Total Specialty Care revenue amounted to SEK 1,787 M (1,807), a decline of 1 per cent (–6 per cent at CER).

Annual sales of Orfadin totalled SEK 827 M (899), a decrease of 8 per cent (–13 per cent at CER).

Revenues for other Specialty Care products amounted to SEK 959 M (908), an increase of 6 per cent (2 per cent at CER).

Gross profit
Gross profit was SEK 10,913 M (6,723), representing a gross margin of 77 per cent (74). The higher gross margin was mainly driven by the addition of high-margin products, such as Synagis and Gamifant.

Expenses
In 2019, operating expenses increased to SEK 6,430 M (3,601).

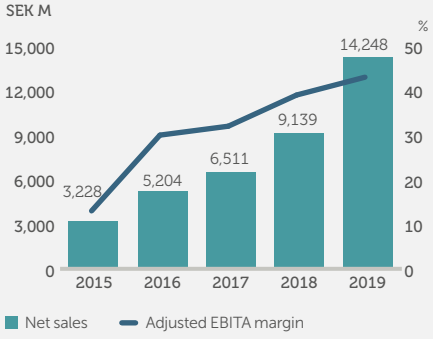
Sales and administrative expenses before amortisation/depreciation and write-downs amounted to SEK 3,535 M (2,062).

The increase was driven by Synagis and the Gamifant operations in North America, continued investments in haemophilia operations and the integration of Dova's operations from 12 November 2019. The full-year was impacted by a non-recurring item – transaction costs of SEK 92 M related to the acquisition of Dova.

Research and development costs amounted to SEK 1,495 M (1,090). Expenses for the year reflect increased concentration in emapalumab and an effect of the acquisition of Dova Pharmaceuticals. Expenses were also affected by restructuring costs of SEK 157 M.

Operating expenses also included costs of SEK 81 M (113) for the long-term incentive programmes. Cash flow will not be affected by the share-based programmes until they expire, and then in the form of social security contributions.

Net sales and adjusted EBITA margin



Revenue by business area

SEK M	2019	2018
Haematology	7,755	6,012
Immunology	4,706	1,320
Specialty Care	1,787	1,807
Total revenue	**14,248**	**9,139**

Other operating income and expenses amounted to SEK 50 M (0). Operating revenue for the year was mainly derived from exchange-rate effects.

Operating profit

Earnings before interest, taxes and amortisation (EBITA) amounted to SEK 5,933 M (3,571), corresponding to a margin of 42 per cent (39). Adjusted EBITA[1] was SEK 6,145 M (3,571), corresponding to a margin of 43 per cent.

Amortisation and write-downs of intangible assets amounted to SEK 1,401 M (449). The increase was mainly attributable to amortisation of product and marketing rights related to Synagis, emapalumab and Doptelet. Operating profit (EBIT) amounted to SEK 4,533 M (3,122), an increase of 45 per cent.

Net financial items

Net financial expenses were SEK −286 M (−40), including exchange-rate losses of SEK −31 M (17). The difference was mainly attributable to increased financing costs related to the acquisition of the rights to Synagis in the US, the acquisition of emapalumab with related assets, and the acquisition of Dova Pharmaceuticals.

Taxes

Total tax for the Group was SEK −942 M (−664), of which SEK −449 M (−767) pertained to current tax and SEK −494 M (103) to deferred tax. The Group's effective tax rate was therefore 22.2 per cent (21.5). See also Notes 16 and 21.

Other comprehensive income

Other comprehensive income amounted (net) to a loss of SEK −57 M (−124), and comprised cash-flow hedges mainly attributable to future inflows in foreign currency, current tax on these, exchange-rate differences, and remeasurment of pension commitments and deferred tax on these.

Cash flow and investments

Cash flow from operations before change in working capital was SEK 5,300 M (2,341). Working capital had a negative impact of SEK −1,666 M (−250) on cash flow for the full-year. The increase in working capital was mainly attribtable to inventory build-up and increased receivables as a result of sales growth.

Cash flow from investing activities was SEK −21,686 M (−575). Sobi completed the acquisition of Dova in the fourth quarter, which had a negative impact of SEK 7,969 M on cash flow, and made the payment of SEK 490 M for the acquisition of BIVV001. The largest investment in intangible assets during the year was SEK 13,869 M for Synagis, which had a negative impact of SEK 9,051 M on cash flow.

Cash flow from financing activities amounted to SEK 15,780 M (−1). The increased borrowing in 2019 was mainly related to acquisitions carried out during the year.

Five-year summary

SEK M	2019	2018	2017	2016	2015
Operating revenue	14,248	9,139	6,511	5,204	3,228
Cost of goods sold	−3,335	−2,415	−1,854	−1,554	−1,221
Research and development costs	−1,495	−1,090	−908	−778	−513
Operating profit (EBIT)	4,533	3,122	1,600	1,133	146
Net financial items	−286	−40	−68	−85	−61
Profit for the year	3,304	2,418	1,149	802	83
Earnings per share, SEK	11.29	8.97	4.27	2.99	0.31
Diluted earnings per share, SEK	11.22	8.93	4.25	2.98	0.31
Number of shares, thousands	299,978	273,322	272,508	270,390	270,390
Equity ratio[1], %	37	53	61	54	56

1. Alternative Performance Measures, see Definitions page 122.

Revenue by business area

SEK M	2019	2018	Change
Elocta	4,508	3,261	38%
Alprolix	1,463	974	50%
Royalty	1,373	1,341	2%
Doptelet	34	—	NA
Manufacturing revenue	376	436	−14%
Haematology	**7,755**	**6,012**	**29%**
Kineret	1,571	1,320	19%
Synagis	2,594	—	NA
Gamifant	542	—	NA
Immunology	**4,706**	**1,320**	**257%**
Speciality Care	**1,787**	**1,807**	**−1%**
Total revenue	**14,248**	**9,139**	**56%**

Sales by region

SEK M	2019	2018	Change
Europe	9,059	7,367	23%
North America	4,587	1,309	250%
Rest of the world	602	463	30%
Total	14,248	9,139	56%

Source of revenue by business area

Haematology	Immunology	Specialty Care
Elocta	Kineret	Akynzeo®
Alprolix	Synagis	Ammonaps®
Doptelet	Gamifant	Ammonul®
Royalty		Deflux®
Manufacturing		Kepivance®
		Orfadin
		Ravicti®
		Relistor®
		Ruconest®
		Xiapex®
		Other

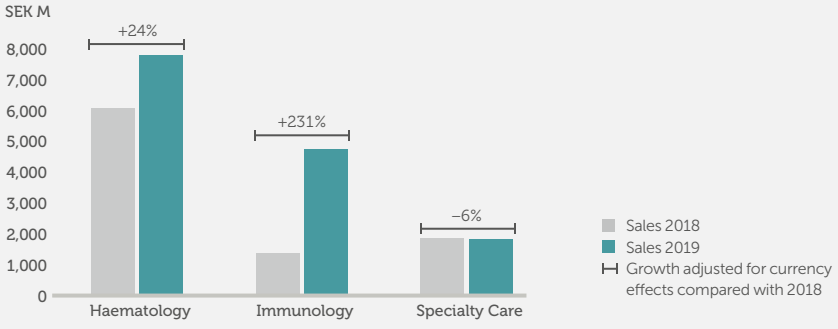
Financial position
At 31 December 2019, cash and cash equivalents and current investments amounted to SEK 737 M (2,999).

The Group's credit facilities (whereof SEK 16,243 M has been drawn) amounts to SEK 20,203 M and consist of credit facilities of EUR 1,540 M and SEK 4,135 M, of which EUR 670 M and SEK 3,000 M were raised in 2019 to finance the acquisitions of emapalumab and Dova Pharmaceuticals. See Note 3 for more information. At 31 December 2019, net debt was SEK 15,404 M (2,999). The Group also has other non-interest bearing financing liabilites that are recognised at discounted value and therefore carries an interest expense. These liabilities are not included in net debt/net cash. For contractual commitments regarding the above-mentioned liabilities, see Note 17.

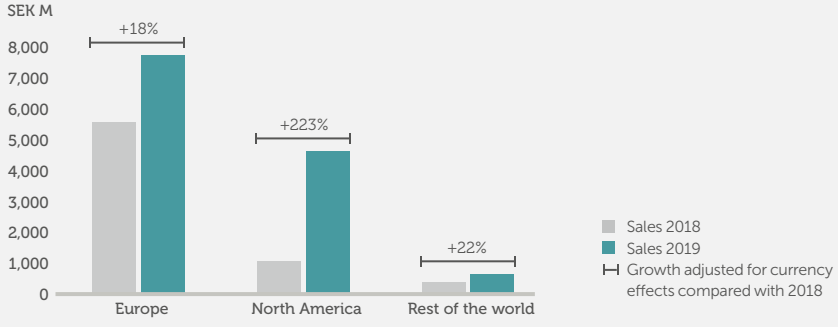
Equity
At 31 December 2019, consolidated equity amounted to SEK 16,930 M (9,040). An issue of shares related to the Synagis acquisition increased equity by SEK 4,513 M. Other changes in addition to profit for the year consist of share-programme costs, hedge accounting and translation differences.

Parent Company
The Parent Company's business model is to develop, register, distribute and market drugs for rare diseases. In 2019, Parent Company revenue amounted to SEK 12,991 M (8,221). Operating profit totalled SEK 4,536 M (3,492). Profit for the year totalled SEK 1,118 M (2,382), including excess depreciation of SEK 400 M and Group contributions of SEK 2,766 M. At 31 December 2019, cash and cash equivalents amounted to SEK 431 M (2,762). At 31 December 2019, equity amounted to SEK 13,534 M (7,731). The change was attributable to an issue of shares, profit for the year, costs related to the company's share programmes, and hedge accounting.

Revenues 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.

In Haematology, R&D consists of among others expanded clinical activities to strengthen the already extensive scientific evidence related to Sobi's approved haemophilia products. In collaboration with our development partner, we are conducting the BIVV001 project, for a novel factor VIII therapy in clinical development that is designed to extend protection from bleeds with once-weekly prophylaxis dosing for people with haemophilia A. BIVV001 entered phase 3 during the year.

In addiation, avatrombopag, which came with the acquisition of Dova Pharmaceuticals, is being studied in a phase 3 study for the treatment of chemotherapy-induced thrombocytopenia (CIT), a common side effect of chemotherapy.

Clinical programmes are ongoing in the area of immunology, with the aim of studying new applications for Kineret and emapalumab, which Sobi acquired in 2019.

The SOBI005 product candidate was divested during the year. Due to Sobi's strengthened focus on immunology and haematology and late-stage product development, a decision was made to discontinue the early-phase research operations. As a

result, Sobi explored during the year the possibilities to divest two projects: The SOBI006 programme in pre-clinical phase and the SOBI003 programme for potential treatment of MPSIIIA.

Development events during the year
Data for the long-term safety and efficacy of prophylactic therapy with Elocta and Alprolix in adults, teenagers and children with haemophilia A and B was presented at EAHAD
Analysis of the data from the A-LONG/Kids A-LONG/ASPIRE and B-LONG/Kids B-LONG/B-YOND studies confirm the long-term safety and efficacy of Elocta (rFVIIIFc) and Alprolix (rFVIXFc) prophylaxis for all types of bleeds in people of all ages with severe haemophilia A each B.

Interim data from the PUPs A-LONG study was presented at EAHAD
Data on the incidence of inhibitors in previously untreated patients (PUPs) with severe haemophilia A shows that Elocta (rFVIIIFc) was well-tolerated and resulted in low bleeding rates in the PUP population. This interim analysis is the first data presented for PUPs for a product with extended half-life. The study is still ongoing and the final results will be presented at a future conference.

New data for emapalumab showing treatment results after transplantation in patients with primary HLH were presented at the Transplantation & Cellular Therapy Meetings (TCT)
In the phase 2/3 study, most of the patients treated with emapalumab proceeded to haematopoietic stem cell transplantation (HSCT): 64.7 per cent of all patients treated, and 70.4 per cent of those patients who did not respond to previous conventional HLH treatment. The mean time to transplantation was 100 days for the entire patient cohort, and 83 days for the cohort that had not responded to previous conventional HLH treatment. Of the total patient cohort, 90.9 per cent survived the stem cell transplantation (post-HSCT). Of the cohort that did not respond to previous conventional HLH treatment, the survival rate after transplantation was 89.5 per cent.

AnaSTILLs study terminated
The AnaSTILLs trial was initiated to meet the regulatory requirements for an approval of Kineret for Still's disease in the US. Only 12 of 81 patients had been recruited after 1.5 years. A decision was therefore made to discontinue the recruitment and terminate the study. The study will be completed for the recruited patients.

New study data with emapalumab was presented at the 2019 Annual Scientific Congress of European League Against Rheumatism (EULAR)/Paediatric Rheumatology European Society (PReS) in Madrid
The interim analysis comprised data for the first six recruited patients with macrophage activation syndrome (MAS), or secondary HLH. MAS is one of the complications of systemic onset juvenile idiopathic arthritis (sJIA). The results showed that treatment with emapalumab led to rapid interferon-gamma (IFN-γ) neutralisation and all six patients who have participated in the study to date achieved a complete response. Emapalumab also demonstrated a good safety profile.

Data from the phase 3 study of Orfadin (nitisinone) for the treatment of alkaptonuria
Based on promising data from the phase 3 study of Orfadin (nitisinone) for the treatment of alkaptonuria, Sobi decided to submit a marketing authorisation application to the EMA for this potential indication in the first half of 2020.

The results from several ongoing studies were presented at the 27th ISTH Congress organised by the International Society on Thrombosis and Haemostasis in Melbourne, Australia:
Data from clinical studies in patients with haemophilia A and B who switched from on-demand treatment to prophylaxis with extended half-life (EHL) factor concentrates showed a positive effect in clinical outcome measures, such as improved quality of life (QoL), lower annual bleeding rates (ABR) and improved joint health.

Positive interim results from verITI-8 – an ongoing prospective phase 4 study to investigare the efficacy of Elocta for first-time Immune Tolerance Induction (ITI) in people with severe haemophilia A who have developed inhibitors – were also presented.

New study data of BIVV001 and results from a patient survey of Doptelet were presented at the 61st Annual Meeting of the American Society of Hematology (ASH) in Orlando:
Final data from the phase 1/2 study of BIVV001 to evaluate the safety and pharmacokinetics of repeat doses in people with severe haemophilia A confirmed BIVV001's potential to further improve treatment for haemophilia A patients.

The results from a study evaluating the relative cost efficiency of avatrombopag compared with thrombocyte transfusion or treatment with lusutrombopag showed that the use of avatrombopag is a more effective strategy than both thrombocyte transfusion and lusutrombopag treatment, because it reduces both costs and the need for prophylactic thrombocyte transfusions.

First patient dosed in the phase 3 study of BIVV001
The first patient in the phase 3, open-label, interventional study of BIVV001 was dosed. The study is designed to investigare the efficacy, safety and tolerability of prophylactic once-weekly dosing.

The FDA granted orphan drug designation to avatrombopag
The U.S Food and Drug Administration (FDA) granted orphan drug designation to avatrombopag for the treatment of chemotherapy-induced thrombocytopenia (CIT). Avatrombopag is currently being studied for the treatment of CIT in a phase 3 study and the results are expected in the second half of 2020.

Other information

Changes in Management
Paula Treutiger, Head of Communication & Investor Relations, and Sofiane Fahmy, Head of Southern and Western Europe & North Africa, joined management on 1 January 2019. In addition, Amy Pott was appointed Head of North America in 2019. Torbjörn Hallberg also assumed responsibility for HR and Philip Wood assumed responsilibity for Northern Eastern Europe, Middle East and Russia during the year.

At 31 December 2019, the Executive Committee consisted of:

CEO: Guido Oelkers

CFO: Henrik Stenqvist

General Counsel and Head of Legal Affairs, Head of HR: Torbjörn Hallberg

Head of Haematology and Head of Northern Eastern Europe, Middle East and Russia: Philip Wood

Head of Immunology: Norbert Oppitz

Head of Southern and Western Europe & North Africa: Sofiane Fahmy

Head of North America: Amy Pott

Head of Medical and Scientific Affairs: Armin Reininger

Head of Research & Development, Chief Medical Officer: Milan Zdravkovic

Head of Technical Operations: Anne Marie De Jonge Schuermans

Head of Communication & Investor Relations: Paula Treutiger

Christian Dreger, Hege Hellström, Rami Levin and Fredrik Wetterlundh stepped down from the Executive Committee in 2019.

Risks and uncertainties
For a description of Sobi's operational risks, see the section under Sustainability Report 2019 and for financial risks see Note 3.

Due to the COVID-19 pandemic, Sobi has been and will continue to focus on disease the patients we serve, our customers and our employees. As the future spread of the disease is so uncertain, there is the potential for this to impact our underlying business. Sobi is evaluating and seeks to mitigate multiple operational risks, including but not limited to: workforce, product supply, research and development, marketing activities and product demand. Our workforce includes not only our internal employees, but our external manufacturing supply network partners across the globe, primarily in Europe. Interruptions in our product supply network have not yet materialized, but could impact any point in the supply chain and distribution.

Sustainability Report
The statutory Sustainability Report is found on pages 22–25, 40–45 and 110–119 of this Annual and Sustainability Report, and has been prepared using the Global Reporting Initiative's (GRI) Sustainability Reporting Guidelines.

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 decided to prepare a Corporate Governance Report that is separate from the Annual Report, refer to pages 94–100.

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. In 2019, 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 2019, Sobi's share capital amounted to SEK 164,599,935, distributed between 299,977,839 shares, with a par value per share of about SEK 0.55. At 31 December 2019, the total number of ordinary shares outstanding, excluding shares in treasury, comprised 294,299,740, each carrying one vote. At 31 December 2019, Investor AB was Sobi's largest single shareholder with a total of 107,594,165 shares, representing 35.9 per cent of the votes and 35.9 per cent of the capital.

Share conversions
The Annual General Meeting (AGM) on 9 May 2019 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 2019, Sobi held 5,678,099 ordinary shares in treasury. All Class C shares issued in 2019 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 28.

The Board of Directors' proposal for Guidelines for Executive

Remuneration
The members of the Executive Committee of Swedish Orphan Biovitrum AB (publ) fall within the provisions of these guidelines. The guidelines also cover any remuneration to members of the Board of Directors, except fees resolved by the general meeting[1]. The guidelines are forward-looking, i.e. they are applicable to remuneration agreed, and amendments to remuneration already agreed, after adoption of the guidelines by the Annual General Meeting 2020. These guidelines do not apply to any remuneration decided or approved by the general meeting.

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.

1. Any remuneration to members of the Board of Directors, except fees resolved by the general meeting, may only consist of consultancy fees.

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

We 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 regarding the Company's business strategy, please see pages 10–11.

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

Types of remuneration
The remuneration shall be on market terms and may consist of the following components: fixed base pay, variable pay, pension benefits and other benefits. Additionally, the General Meeting may – irrespective of these guidelines – resolve on, among other things, share-related or share price-related remuneration. The components are presented below.

Fixed base pay
The fixed base pay of the Executive Committee shall be based on competence, responsibility and performance. The Company uses an international evaluation system to evaluate the scope and responsibility of the position.

Variable pay
The annual Short-Term Incentive plan shall be based on the achievement of predetermined and measurable annual financial (75 per cent) and non-financial objectives (25 per cent). The annual financial objectives shall be related to targets promoting growth and profitability (annual revenues and EBITA[1]). The annual financial objectives are recommended by the Compensation and Benefits Committee and approved by the Board of Directors. 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 of Directors 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 of Directors based on a proposal from the Compensation and Benefit Committee.

Long-term Incentives
Long-term share-related incentive plans have been implemented in the Company. Such plans are proposed by the Board of Directors and presented to the Annual General Meeting 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 on which the outcome depends, please see https://www.sobi.com/en/annual-general-meetings and note 11.

Pension and benefits
The preferred pension plan design 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, 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.

1. Earnings before interest, tax and amortisation.
2. A defined contribution pension plan defines a percentage level of the employee's annual gross fixed base pay as contribution that will be paid into the pension plan for each employee.

Termination of employment
The notice period may not exceed twelve (12) months. Fixed 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 pay for two (2) years.

Consultancy fees to the members of the Board of Directors
The members of the Board of Directors 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 of Directors 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 of Directors.

Salary and employment conditions for employees
In the preparation of the Board of Directors' 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 and Benefits Committee's and the Board of Directors' basis of decision when evaluating whether the guidelines and the limitations set out herein are reasonable.

The decision-making process to determine, review and implement the guidelines
The Board of Directors has established a Compensation and Benefits Committee. The committee's tasks include preparing the Board of Directors' decision to propose guidelines for remuneration to the Executive Committee. The Board of Directors shall prepare a proposal for new guidelines at least every fourth year and present it to the Annual General Meeting. The guidelines shall be in force until new guidelines are adopted by the general meeting. The Compensation and 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 and 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.

Derogation from the guidelines
The Board of Directors 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 and Benefits Committee's tasks include preparing the Board of Directors' resolutions in remuneration-related matters. This includes any resolutions to derogate from these guidelines.

Proposed appropriation of profit

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

SEK 000	
Share premium reserve	8,904,692
Retained earnings	2,546,893
Profit for the year	1,117,739
Total	**12,569,324**

The Board of Directors proposes that no dividend be distributed for the 2019 financial year.

The Board proposes that the share premium reserve and retained earnings at their disposal, SEK 12,569,324 K be carried forward.

Events after the balance-sheet date

Sobi communicated the intention to initiate a clinical study to evaluate whether anakinra and emapalumab may relieve complications associated with severe COVID-19 disease
Sobi will begin a short-term clinical study to evaluate the efficacy and safety of anakinra and emapalumab in the treatment of hyper-inflammatory syndrome, one of the most serious complications associated with severe COVID-19 disease. This is in response to a request from the National Institute for Infectious Diseases, the organisation which is acting as the coordinating site for the SARS-CoV-2 epidemic in Italy.

Possible impact of Covid-19 disease
The COVID-19 "coronavirus", a virus causing potentially deadly respiratory tract infections, was identified as a pandemic in March 2020. The full impact of this virus is still unknown, but it has already had a global socio-economic impact. The coronavirus did not impact Sobi's 2019 financial reporting and is expected to have a limited impact on the financial performance in the first quarter of 2020. Sobi has strong liquidity reserves. At this time, the company cannot quantify the magnitude or duration of the business risk given the uncertainty in the current spread of the virus. A global management response team has been set-up and the Sobi management team and the board of directors are continuously monitoring the situation. More information will be provided with the first quarter, 2020 results. See further info in the key risk area section on page 44.

Financial outlook 2020[1]

Revenue for the full-year 2020 is expected to be in the range of SEK 15,000–16,000 M reflecting double-digit growth in each of the two core business, Haematology and Immunology.

EBITA is expected to be in the range of SEK 5,000–6,300 M including the development and launch of Doptelet which will affect EBITA negatively by around SEK 500 M in 2020.

For information about Forward looking statements, see the inside back cover.

1. At current exchange rates.
The outlook was published on 13 February 2020.

Sustainability Report 2019

At Sobi our key contribution to sustainable development is closely aligned with our mission and our operations – to provide access to treatment for people with rare diseases.

Sustainability strategy

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, immunology and specialty care. Sobi's business model (read more on page 10) spans from late-stage clinical research to international commercialisation.

Our business model supports our key sustainability objectives – through expansion we can increase reach and improve access to treatments for patients worldwide. If we are successful in our operations, we will positively impact the community we serve. This success must be reached in a responsible way in order to safeguard the safety of patients, our environment and the company's reputation.

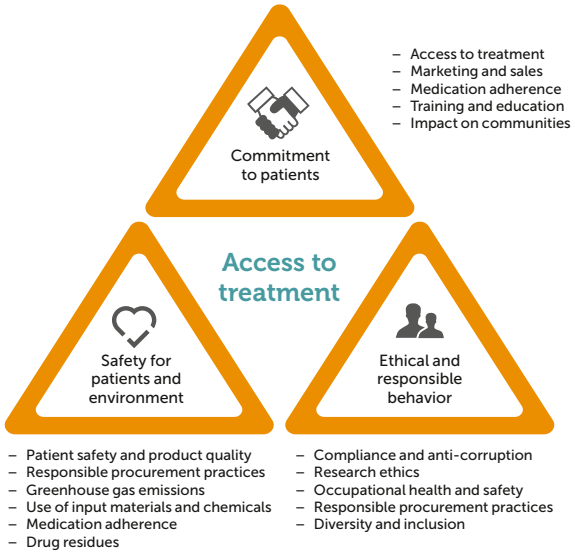
Material sustainability topics
Material sustainability topics are areas that reflect Sobi's most significant impact on economic, environmental and social areas.

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. The purpose was to identify and prioritise our most important sustainability topics.

The key elements of the findings have reiterated access to treatment as the key long-term sustainability goal, in line with the assessment performed in 2016. 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. In the illustration below, the material sustainability topics as defined through stakeholder dialogues are connected to the key areas of our sustainability strategy. These are:

- Commitment to patients
- Safety for patients and the environment
- Ethical and responsible behaviour

Sobi sustainability strategy with material sustainability topics



Commitment to patients
For Sobi, meaningful engagement and cooperation with the rare disease community is key.

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.

To support Sobi's growth strategy and market expansion, and thereby reach more patients with our treatments, regulatory approvals are necessary for commercialisation in new markets. 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.

In 2019, Sobi received regulatory approval in countries such as United Arab Emirates, Tunisia and Chile, an example of how we aim to broaden access to treatments outside our key markets. For a total review of current approval and reimbursement status, see the table on pages 115–116.

Safety for patients and the environment
The safety profile and monitoring of our products is another significant sustainability area in our business. By following pharmaceutical standards we strive to provide products that meet the high quality and regulatory expectations of the pharmaceutical field.

With a robust pharmacovigilance system in place, we continuously monitor the benefit/risk profiles of our products and

ensure our alignment with the precautionary principle. The pharmacovigilance system complies with all global, national and local regulations. To support the increasing number of proprietary products for which Sobi is Market Authorisation Holder, our pharmacovigilance system was substantially expanded in 2019. 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.

Correct labelling is important to ensure proper use. No incidents of non-compliance in regard to product and service information or labelling were reported in 2019.

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 were serialised, given unique identification codes, in 2019. Sobi's products have not yet been subject to falsification.

To ensure sustainable and responsible sourcing, we have introduced a Responsible Sourcing Programme, including the introduction of a Partner Code of Conduct and sustainability screening, starting in January 2020. Sustainability screening of partners involves ensuring compliance with standards in the areas of governance, labour rights, human rights and environmental responsibility. Our aim is to have all new partners acknowledge and support the Partner Code of Conduct and to systematically introduce our current top 100 partners to the Code and screening over the coming year.

In December 2019, Sobi became a member of the Pharmaceutical Supply Chain Initiative (PSCI).

Ethical and responsible behaviour

Sobi promotes business ethics in all we do through high research standards, business ethics and policies. 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 and among key stakeholders.

Our internal processes and control measures involve scientific, regulatory and compliance training. In 2019, the organisation did not identify any incidents of non-compliance concerning marketing communications that led to a fine, administrative or criminal penalty or warning by regulators.

All employees are required to undergo annual training in our Code of Conduct. Topics covered in the Code of Conduct include product safety and quality, competition law, anti-corruption, data privacy, conflicts of interest, intellectual property, environmental responsibility and employment principles, with additional opportunities to focus on specific areas. In 2019, healthcare compliance was prioritised in the annual anti-corruption training. In 2019, 95 per cent of our employees participated in the training.

Sustainability governance

Management

Sobi's Board of Directors has the overall responsibility for Sobi's sustainability performance, which is 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 programme. The leadership teams in each respective area are responsible for implementation and follow-up of the strategy. Risks are reported to the Executive Committee and are also included in the materiality assessment.

All sustainability activities are guided by the Code of Conduct and other sustainability related policies. The Director of Sustainability is responsible on behalf of the Executive Committee for communication and operationalisation of the programme in close collaboration with the business units.

The Sobi Code of Conduct provides a framework for what Sobi considers to be responsible and appropriate conduct. The Code of Conduct applies to all Sobi employees worldwide as well as temporary personnel. The most important policies guiding Sobi's sustainability processes are listed below.

Area	Environment	Social	Ethics and Anti-corruption
Policies	Code of Conduct Environment Compliance Programme Environmental Health and Safety Policy Travel Policy	Code of Conduct Discrimination Policy Environmental Health and Safety Policy	Code of Conduct Anti-corruption Policy Insider Policy Healthcare Interactions Policy Policy on Processing Personal data Policy on Investigations Policy on Fair Competition
Focus areas	Environmental performance Compliance	Child and forced labour Health and safety Discrimination and harassment Collective bargaining and freedom of association	Conflicts of interest Transparency Anti-corruption and antitrust

Important responsibilities for the governance of Sobi's sustainability strategy are:

- Legal Affairs, responsible for the implementation of anti-corruption and healthcare interaction policies, data privacy and the compliance hotline (whistleblower hotline).
- Technical Operations, responsible for environmental compliance and performance regarding in-house operations. Technical Operations is responsible for monitoring suppliers' and partners' adherence to the Partner Code of Conduct.
- Internal Control evaluates and improves processes for management, internal control and risk management.
- The Sustainability function evaluates materiality, creates guidelines and supports implementation of the programme. It is also responsible for maintaining a relevant Code of Conduct.
- Business units are required to run the business in compliance with the sustainability strategy and the Code of Conduct.

Risk management

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

Sobi applies an integrated business risk-management approach that contributes to our ability to achieve set objectives, and to follow the strategy adopted for the operations. Each business unit 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 strategic risk management process, the company's critical flows are identified and business continuity plans for these are implemented.

Environmental impact

Sobi's environmental impact can be broken down into direct and indirect impacts, through sourced activities and caused by our own operations.

Environmental impacts from production and the laboratories, either in-house or outsourced, are mainly due to the use of energy, water, chemicals, generated waste and discharge of sewage. Our carbon footprint arises from energy consumption, business travel, logistics within the supply chain and the distribution of our products.

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. The impact of our manufacturing plant in Stockholm, Sweden, is described in detail on pages 110–112. 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 2019.

We work actively to phase out chemicals that may be harmful to the environment or human health, in line with the precautionary principle. Chemicals regulations are extensive and continuously expanding; all handling of chemicals in our laboratory and manufacturing processes therefore follows strict instructions. We perform annual risk assessments and internal audits. The newly implemented Responsible Sourcing Programme (see page 24) will be an important tool to influence, manage and follow up our supply chain.

The environmental hazards of a specific drug refer to its inherent properties, for example 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 therfore considered not to have a significant impact on the environment.

Sobi's supply chain sources production from contract manufacturing organisations (CMOs) in Europe and the US, with distribution to over 70 markets worldwide. The environmental impact of the logistics and distribution of Sobi's therapies is determined by the special needs of the products and the special characteristics of rare disease populations, such as the low numbers and dispersed nature of patients and treatment centres. Sobi intends to increase our awareness of the environmental impact by mapping the supply chain and optimising it if possible. The safe and timely delivery of our products will always be the primary consideration for our distribution.

In 2019, Sobi expanded the reporting scope of business travel emissions to cover approximately 80 per cent of global operations. With a comprehensive understanding of the emissions, Sobi will set relevant related goals in 2020.

Social impact

Our social impact is derived from the work we do to provide access to treatment as described in this report, but also through our interactions with our employees and the work opportunities and conditions we provide.

Sobi is a value-driven company with a scientific and patient-centric organisation. As we continue to deliver on our strategic goals, high-performing teams have been identified as a key success factor to meet our ambitious strategic objectives. This involves developing our methods to help managers,

leaders and colleagues facilitate continuous growth. We see strong leadership based on cross-functional capabilities as crucial. Sobi's corporate values can be found on page 24 and are important components when assessing employee performance.

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.

Every employee is offered equal opportunities regardless of ethnicity, age, gender, religion, sexual orientation or physical ability. Our guidelines clearly prohibit any sexual harassment.

All employees take part in relevant professional development that is supported and documented by a training matrix system. This system also meets regulatory requirements in the pharmaceutical field and serves as a comprehensive platform for ensuring individualised and specialised training as well as evidence of learning. All employees are offered regular performance and career development discussions.

Ethics and anti-corruption

Transparency and open dialogue about ethical issues form the foundation of strong collaborations. All engagements are governed by our Code of Conduct, while a majority are also covered by our more specific Policy on Healthcare Interactions. 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. To our knowledge there have been 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 2019.

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. Data Privacy is part of Sobi's Code of Conduct and a prioritised area across Sobi. Sobi has implemented a data privacy programme in order to promote data privacy compliance, including appointing a Data Protection Officer, written policies and procedures, and training and education. As an example, in order to raise awareness and understanding of data privacy in general and procedures within Sobi to protect individuals' integrity, all Sobi employees have received online training on data protection.

In relation to our external collaborations and procured services, we apply the principles of our Policy on Anti-Corruption as well as processes for risk-based third party due diligence. We work regularly with risk identification within the corporate risk management process and in detail within day-to-day compliance.

We work actively to prevent any form of corruption. As a pharmaceutical company, the most apparent risk lies within our interactions with healthcare stakeholders. We have an established Healthcare Compliance (HCC), programme to minimise the risk of corruption; this includes policies, training for our own employees, as well as reporting and controls. Monetary transactions with healthcare providers and patient organisations follow local transparency initiatives and are made public on an annual basis on our website, www.sobi.com.

Our zero-tolerance approach to bribery is described in our Code of Conduct as well as our Policy on Anti-Corruption. All employees are required to undergo annual training in our Code of Conduct. In 2019, 95 per cent of our employees and full-time consultants participated in and completed the training. To our knowledge, no confirmed incidents of corruption were reported in 2019.

Sobi's employees are encouraged to report potential misconduct or unethical behaviour openly or by using the Sobi Compliance Hotline, run by a third party to allow for the possibility of anonymous reporting. All relevant reports are reviewed and investigated in accordance with Sobi's Investigations Policy, and followed up with appropriate remediation measures as needed.

Material topics in the value chain

Assessing Sobi's material sustainability topics from a value chain perspective simplifies the process of identifying risks and setting strategic targets. See pages 44–45.

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.

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 reports its sustainability performance on an annual basis, as part of the Annual and Sustainability Report. This sustainability report has been prepared in accordance with the GRI Standards: Core option, see pages 117–119. It also meets the requirements for sustainability reporting under the Swedish Annual Accounts Act.

Sobi has been a signatory to the UN Global Compact since 2017 and we conduct our business in a manner that is consistent with the Ten Principles of the UN Global Compact. 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.

Material topics in the value chain

Sobi group's risk management aims for a uniform process to identify, analyse, evaluate and address risks and effectively embed risk management in decision making. By assesing Sobi from a value chain perspective, the process of describing risks and setting strategic targets is simplified and the correlation with Sobi's material topics is identified.

Product research & development
Sobi's ambition is to bring new products to market that address high medical needs and have strong commercial potential, and further develop current products. Careful evaluation of candidate drugs allows Sobi to acquire promising pipeline products for further late-stage development. Close collaboration between Sobi and the patient community drives relevant patient-centric development.

Risks:
- An increasing competitive market space for late-stage acquisitions
- Missed opportunity due to delayed product development
- Reputational risk

Management:
- Business intelligence
- Maintain strong brand profile
- Robust due diligence programme for potential acquisition objects
- Strong relationships with patient and healthcare stakeholders to map medical need

Influence: High

Value driver: By identifying, acquiring and developing products with a high medical need, robust scientific base and strong market potential, we can expand Sobi's portfolio and serve the patient community.

Contract manufacturing
Sobi's supply chain is mainly outsourced, and all contract manufacturing suppliers are currently based in Europe and the US. Focus lies on continuous monitoring of high pharmaceutical standards and estabishment of a network of contractors to serve our needs.

Risks:
- Non-compliance with good practices (GxP) in the pharmaceutical field
- Dependence on third parties for product supply
- Changes in environmental regulations
- Pharmaceutical waste emissions to the environment
- Occupational health and safety of workers

Management:
- GxP audits of contract manufacturers to ensure strict adherence to standards
- Quality management system monitors all issues relating to GxP deviations, corrective and preventive measures
- Implementation of Responsible Sourcing Programme including screening of suppliers

Influence: Medium

Value driver: Strong collaborations with specialised contractors ensures high level of product quality and reliable supply.

Sobi's operations
Sobi has 1,377 number of employees in more than 30 countries. Approximately 150 people work in our production and laboratory facilities in Stockholm and Geneva. Prioritised areas include high ethics and good working conditions.

Risks:
- Batch loss due to equipment malfunction or process deviations
- Changes in environmental regulations
- Pharmaceutical waste emissions to water
- Occupational health and safety of workers
- Difficulties to recruit and retain competent personnel

Management:
- Standard operating procedures and quality assurance
- Training and leadership support to raise adherence to policies
- Promote good working conditions, leadership and competitive compensation

Influence: Medium

Value driver: Sobi creates value for local communities by creating jobs, transferring knowledge and through economic possibilities. Positive relationships with our employees support development, wellbeing and job satisfaction which in turn creates pride among employees and strengthens the Sobi brand.

Market access
The approval and reimbursement of medical treatments is fully dependant on external evaluation and can thus influence the ability to access markets.

Risks:
- Obtaining authorisation of new products or on new markets
- Obtaining pricing and reimbursement in each market in line with national guidelines
- Managing policy changes
- Aligning with recommendations and treatment guidelines
- Competition

Management:
- Strong regulatory submissions
- Product value dossiers with clear benefit and medical need
- Country-specific strategies

Influence: Low

Value driver: By making treatments accessible in more markets and at a sustainable cost for society, Sobi can deliver treatments to more patients in more countries.

Distribution & transport
Logistics and distribution of Sobi's therapies is characterised by the specific storage requirements of the products and the unique conditions governing rare diseases, ie few, geographically dispersed patients and treatment centres. The safe and timely delivery of our products will always be the primary consideration for efficient transportation.

Risks:
- CO_2 emissions from transportation
- Non-compliance with GxP in the pharmaceutical field

Management:
- Evaluate effective logistic solutions
- GxP audit to ensure standards are followed
- Implementation of Responsible Sourcing Programme including screening of suppliers

Influence: Medium

Value driver: Expand the reach of our distribution to provide patients with treatments in a timely and safe manner. Sobi intends to include transportation in its carbon emissions reporting.

Use of products
The correct use of Sobi's products is essential for maintaining the risk-benefit balance of the products.

Pharmaceutical products may have environmental impacts, although the bulk of Sobi's products are biological and thus generally biodegradable with a low environmental impact.

Risks:
- Improper use leading to safety issues
- Environmental impact of products
- Falsification of products

Management:
- Regular product safety updates
- Pharmacovigilance monitoring
- Education of healthcare professionals
- Serialisation of products

Influence: Medium

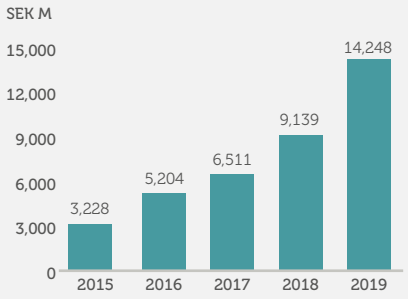
Value driver: Proper and optimal use of Sobi's products increases the likelihood of successful treatment outcomes and increases patient value.

Consolidated statement of comprehensive income

SEK M	Note	2019	2018
	1–4		
Operating revenue	5–6	14,248	9,139
Cost of goods sold		–3,335	–2,415
Gross profit		**10,913**	**6,723**
Selling and administrative expenses		–4,935	–2,511
Research and development costs		–1,495	–1,090
Other operating income	8	68	6
Other operating expenses	9	–18	–6
Operating profit	7, 10, 11, 12, 13, 17, 18, 29	**4,533**	**3,122**
Financial income	14	5	20
Financial expenses	15	–291	–60
Net financial items		**–286**	**–40**
Profit before tax		**4,247**	**3,082**
Tax on profit for the year	16	–942	–664
Profit for the year[1]		**3,304**	**2,418**
Other comprehensive income[2]			
Items that cannot be reclassified into profit or loss			
Actuarial gains/losses on defined-benefit plan		–4	0
Items that can be reclassified into profit or loss			
Translation differences		–97	9
Cash flow hedges		55	–171
Tax effect of cash flow hedges		–12	38
Other comprehensive income		**–57**	**–124**
Comprehensive income for the year[2]		**3,247**	**2,294**
Earnings per share, SEK	34	11.29	8.97
Earnings per share, SEK, adjusted	34	11.89	8.97
Earnings per share after dilution, SEK	34	11.22	8.93
Earnings per share after dilution, SEK, adjusted	34	11.81	8.93
Number of shares (ordinary)		299,977,839	273,322,117
Average number of shares		292,649,020	269,523,784
Number of ordinary shares held in treasury		5,678,099	3,423,726
Number of shares after dilution		301,857,247	274,365,601
Average number of shares after dilution		294,528,428	270,603,665

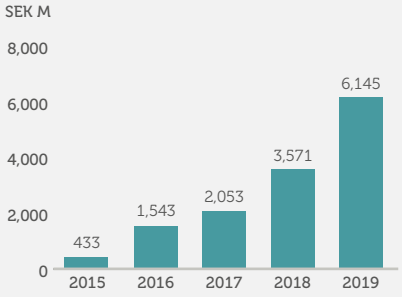
1. Everything attributable to Parent Company shareholders.
2. Under the revised version of IAS 1, all changes in equity not arising from transactions with owners are recognised on the consolidated statement of comprehensive income. Translation differences are wholly related to shares in foreign subsidiaries.

Operating revenue



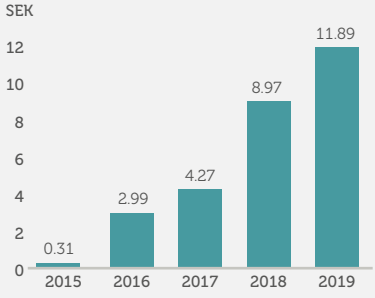
Operating revenue
Revenues for the full-year amounted to SEK 14,248 M (9,139), up 56 per cent.

Adjusted EBITA[1]



Adjusted EBITA for the year rose 72 per cent to SEK 6,145 M compared with 2018.

Adjusted earnings/share[1]



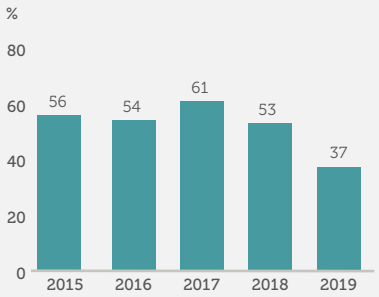
1. Alternative performance measures, see Definitions page 122.

Consolidated balance sheet

SEK M	Note	31 Dec 2019	31 Dec 2018
ASSETS	1–4		
Non-current assets			
Intangible assets	17	37,412	10,159
Tangible assets	18	518	136
Financial assets	20	50	55
Deferred tax assets	21	354	231
Total non-current assets		**38,335**	**10,581**
Current assets			
Inventories	22	1,772	1,284
Account receivables	23	3,736	1,665
Other receivables	23	530	93
Prepaid expenses and accrued income	24	548	561
Cash and cash equivalents	25	737	2,999
Total current assets	26	**7,323**	**6,602**
TOTAL ASSETS		**45,658**	**17,183**
EQUITY AND LIABILITIES			
Equity			
Share capital		165	150
Other contributed capital		9,697	5,069
Other reserves		–202	–144
Retained earnings		3,965	1,547
Profit for the year		3,304	2,418
Equity attributable to Parent Company shareholders		**16,930**	**9,040**
Liabilities			
Non-current liabilities			
Deferred tax liabilities	21	3,726	664
Borrowings	27	16,141	–
Lease liabilities	10	320	3
Provisions	29, 30	179	97
Other liabilities, non interest bearing	28	2,620	428
Total non-current liabilities	26	**22,987**	**1,192**
Current liabilities			
Account payables		681	487
Tax liabilities		281	395
Lease liabilities	10	99	1
Other liabilities	28	1,641	4,458
Accrued expenses and deferred income	31	3,039	1,610
Total current liabilities	26	**5,741**	**6,951**
TOTAL EQUITY AND LIABILITIES		**45,658**	**17,183**

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

Equity/ratio[1]



Net debt (+)/net cash (–)

SEK M	2015	2016	2017	2018	2019
Cash and cash equivalents	904	786	1,478	2,999	737
Borrowings	815	497	–	–	16,141
Net debt (+)/net cash (–)	**–89**	**–289**	**–1,478**	**–2,999**	**15,404**

Net debt increased, due to aqusitions done during the year.

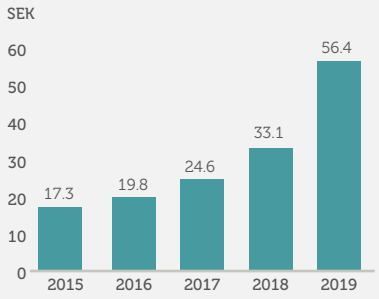
1. Alternative performance measures, see Definitions page 122.

Consolidated statement of changes in equity

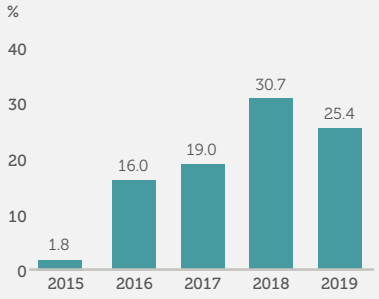
SEK M	Share capital	Other contributed capital	Other reserves[1]	Retained earnings	Total equity
Opening equity, 1 Jan 2018	150	5,024	–20	1,548	6,701
Comprehensive income					
Profit for the year	—	—	—	2,418	2,418
Other comprehensive income					
Cash flow hedges	—	—	–171	—	–171
Tax cash flow hedges	—	—	38	—	38
Actuarial loss/gain	—	—	0	—	0
Exchange differences	—	—	9	—	9
Total comprehensive income	**—**	**—**	**–124**	**2,418**	**2,294**
Shareholder transactions					
Issue/repurchase of shares	0	—	—	0	—
Share programmes	—	46	—	—	46
Total shareholder transactions	**0**	**46**	**—**	**0**	**46**
Closing equity, 31 Dec 2018	**150**	**5,069**	**–144**	**3,965**	**9,040**
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					
Cash flow hedges	—	—	55	—	55
Tax cash flow hedges	—	—	–12	—	–12
Actuarial loss/gain	—	—	–4	—	–4
Exchange differences	—	—	–97	—	–97
Total comprehensive income	**—**	**—**	**–57**	**3,304**	**3,247**
Shareholder transactions					
Issue/repurchase of shares	15	4,498	—	—	4,513
Share programmes	—	80	—	—	80
Tax deductions linked to share programmes[3]	—	50	—	—	50
Total shareholder transactions	**15**	**4,628**	**—**	**—**	**4,642**
Closing equity, 31 Dec 2019	**165**	**9,697**	**–202**	**7,270**	**16,930**

3. The Parent company has during the period been granted additional deductions for tax purposes related to incentive programmes vested in 2013–2018. The additional deductions relate to the difference between the market value of vested shares and recognised IFRS 2 cost.

Equity per share[4]



Return on equity[4]



Return on equity
Return on equity amounted to 25.4 per cent.

4. Alternative performance measures, see Definitions page 122.

[1]Other reserves

SEK M	2019	2018
Exchange differences	–110	–12
Pensions in accordance with IAS 19	–30	–26
Cash flow hedges[2]	–62	–106
Other	0	0
Closing balance, other reserves	**–202**	**–144**

[2]Cash flow hedges

SEK M	2019	2018
Opening balance, cash-flow hedges	–106	28
Change in value for the year, hedging instruments	44	–133
Closing balance, cash-flow hedges	**–62**	**–106**

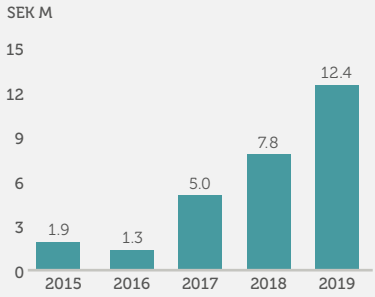
Regarding cash-flow hedges, SEK –106 M (28) was transferred to the income statement. The entry is only reclassified to profit or loss because the hedged item has affected profit or loss. The hedging reserve consists solely of ongoing hedges.

Consolidated cash flow statement

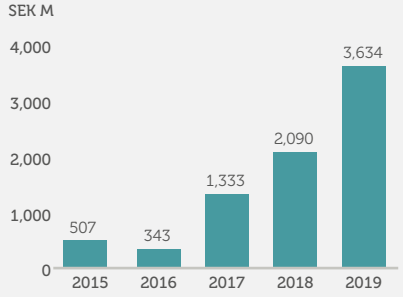
SEK M	Note	2019	2018
Operating activities			
Profit for the year		3,304	2,418
Adjustments for non-cash items		1,995	–77
Cash flow from operating activities before changes in working capital		**5,300**	**2,341**
Cash flow from changes in working capital			
Decrease (+) / Increase (–) in inventories		–459	–231
Decrease (+) / Increase (–) in operating receivables		–2,428	–679
Increase (+) / Decrease (–) in operating liabilities		1,221	659
Cash flow from operating activities		**3,634**	**2,090**
Investing activities			
Acquisition of business[1]	18, 33	–12,880	–
Investment of intangible assets[2]	17	–9,709	–537
Investment of tangible assets	18	–37	–41
Disposal of intangible assets[3]	17	941	–
Disposal of tangible assets	18	–	3
Disposal of financial assets	20	–	0
Cash flow from investing activities		**–21,685**	**–575**
Financing activities			
Borrowings	27	15,875	–
Lease payments		–94	–
Repayment of loans		–	–2
Cash flow from financing activities		**15,780**	**–2**
Change in cash and cash equivalents		**–2,271**	**1,513**
Cash and cash equivalents at beginning of year		**2,999**	**1,478**
Exchange differences in cash flow		**9**	**7**
Cash and cash equivalents at end of year		**737**	**2,999**

1. Relates to business combination acquisitions of (i) Dova and (ii) emapalumab.
2. The largest investments during the year was SEK 13,869 M related to Synagis, with a cash flow impact of SEK –9,051 M and SEK 1,817 M related to the acquisition of the development and commercial rights to BIVV001 in Sobi's territory with a cash flow impact of SEK –490 M.
3. Disposal of intangible assets stemming from the sale of a Priority Review Voucher (PRV), acquired in the business acquisition of emapalumab, and the sale of SOBI005.

Cash flow from operations per share[4]



Cash flow from operations[4]



4. Alternative performance measures, see Definitions page 122.

Consolidated cash flow statement, cont.

Supplemental disclosures to the consolidated cash flow statement

SEK M	Note	2019	2018
Interest paid and received			
Interest received		5	3
Interest paid		−114	−12
Income tax paid		−520	−507
Adjustments for non-cash items			
Depreciation/amortisation and write-downs of intangible assets	7, 17	1,401	449
Depreciation/amortisation and write-downs of tangible assets	7, 18	188	36
Cost of share programmes[1]		80	46
Deferred tax	21	411	−103
Elocta and Alprolix[2]		−454	−485
Translation differences		333	—
Other items		37	−19
Total		**1,995**	**−77**

1. IFRS 2 expense associated with share programmes that is recognised in equity.
2. Pertains to royalty revenue with which the liability to Sanofi was settled, and to interest expense related to the liability to Sanofi.

Parent Company statement of comprehensive income

SEK M	Note	2019	2018
	1–4		
Operating revenue	5–6	12,991	8,221
Cost of goods sold		–3,177	–2,349
Gross profit		**9,814**	**5,872**
Selling and administrative expenses		–4,220	–1,445
Research and development costs		–1,110	–932
Other operating income	8	62	5
Other operating expenses	9	–10	–7
Operating profit	7, 10, 11, 12, 13, 17, 18	**4,536**	**3,492**
Financial income	14	348	35
Financial expenses	15	–287	–69
Net financial items		**61**	**–35**
Profit after financial items		**4,597**	**3,457**
Group contributions		–2,766	63
Excess depreciations		–400	–460
Appropriations		**–3,166**	**–398**
Profit before tax		**1,431**	**3,060**
Tax on profit for the year	16	–313	–678
Profit for the year		**1,118**	**2,382**
Other comprehensive income			
Items that can be reclassified into profit or loss			
Cash flow hedges		55	–171
Tax effect of cash flow hedges		–12	38
Other comprehensive income		**44**	**–133**
Comprehensive income for the year		**1,161**	**2,248**

Parent Company balance sheet

SEK M	Note	31 Dec 2019	31 Dec 2018
ASSETS	1–4		
Non-current assets			
Intangible assets	17	5,572	3,801
Tangible assets	18	65	112
Financial assets			
Participations in Group companies	19	7,676	3,475
Receivables from Group companies[1]		18,389	–
Other financial assets	20	47	52
Deferred tax assets	21	22	11
Total non-current assets		**31,772**	**7,450**
Current assets			
Inventories	22	1,533	1,071
Current receivables			
Account receivables	23	2,402	590
Other receivables	23	449	57
Receivables from Group companies		1,286	1,465
Prepaid expenses and accrued income	24	499	532
Cash and cash equivalents	25	431	2,762
Total current assets		**6,601**	**6,476**
TOTAL ASSETS		**38,373**	**13,926**

1. Receivables from group companies have increased as a result of the acquisitions of Synagis, emapalumab and Dova.

SEK M	Note	31 Dec 2019	31 Dec 2018
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital		165	150
Statutory reserve		800	800
Total restricted equity		**965**	**950**
Unrestricted equity			
Share premium reserve		8,905	4,277
Retained earnings		2,547	122
Profit for the year		1,118	2,382
Total unrestricted equity		**12,569**	**6,780**
Total equity		**13,534**	**7,731**
Untaxed reserves			
Excess depreciations		2,984	2,584
Total untaxed reserves		**2,984**	**2,584**
Liabilities			
Non-current liabilities			
Borrowings	27	16,141	—
Other liabilities, non-interest bearing	28	1,273	428
Provisions	30	84	80
Total non-current liabilities		**17,499**	**508**
Current liabilities			
Account payables		574	376
Liabilities to Group companies		1,358	644
Tax liabilities		230	382
Other liabilities	28	623	731
Accrued expenses and deferred income	31	1,570	969
Total current liabilities		**4,356**	**3,103**
TOTAL EQUITY AND LIABILITIES		**38,373**	**13,926**

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 2018	**150**	**800**	**4,231**	**255**	**5,436**
Cash flow hedges	—	—	—	–171	–171
Tax effect of cash flow hedges	—	—	—	38	38
Issue/repurchase of shares	0	—	—	0	—
Share programmes	—	—	46	—	46
Profit for the year	—	—	—	2,382	2,382
Closing equity, 31 Dec 2018	**150**	**800**	**4,277**	**2,503**	**7,731**
Opening equity, 1 Jan 2019	**150**	**800**	**4,277**	**2,503**	**7,731**
Cash flow hedges	—	—	—	55	55
Tax effect of cash flow hedges	—	—	—	–12	–12
Issue/repurchase of shares	15	—	4,498	—	4,513
Share programmes	—	—	80	—	80
Share-based compensation to employees tax effect[2]	—	—	50	—	50
Profit for the year	—	—	—	1,118	1,118
Total transaction with shareholders	**15**	**—**	**4,628**	**1,161**	**5,804**
Closing equity, 31 Dec 2019	**165**	**800**	**8,905**	**3,665**	**13,534**

2. The Parent company has during the period been granted additional deductions for tax purposes related to incentive programmes vested in 2013–2018. The additional deductions relate to the difference between the market value of vested shares and recognised IFRS 2 cost.

[1] Cash flow hedges

SEK M	2019	2018
Opening balance, cash-flow hedges	–106	28
Change in value for the year, hedging instruments	44	–133
Closing balance, cash-flow hedges	**–62**	**–106**

Regarding cash-flow hedges, SEK –106 M (28) was transferred to the income statement. The entry is only reclassified to profit or loss because the hedged item has affected profit or loss. The hedging reserve consists solely of ongoing hedges.

At year-end, Sobi's share capital amounted to SEK 164,560 K distributed between 299,977,839 ordinary shares with a par value of about SEK 0.55 and one voting right. At the balance-sheet date, the company held 5,678,099 ordinary shares in treasury, corresponding to 1.9 per cent of the total number of shares in the company.

Parent Company cash flow statement

SEK M	Note	2019	2018
Operating activities			
Profit for the year		1,118	2,382
Adjustments for non-cash items		510	301
Cash flow from operating activities before changes in working capital		**1,627**	**2,683**
Cash flow from changes in working capital			
Decrease (+) / Increase (–) in inventories		–462	–177
Decrease (+) / Increase (–) in operating receivables		–15,833	–864
Increase (+) / Decrease (–) in operating liabilities		970	400
Cash flow from operating activities		**–13,698**	**2,042**
Investing activities			
Acqusition of business	33	–4,201	–592
Investment of intangible assets[1]	17	–658	–43
Investment of tangible assets	18	–15	–26
Disposal of tangible assets	17	28	–
Cash flow from investing activities		**–4,846**	**–661**
Financing activities			
Borrowings	27	16,214	–
Cash flow from financing activities		**16,214**	**–**
Change in cash and cash equivalents		**–2,331**	**1,381**
Cash and cash equivalents at beginning of year		**2,762**	**1,381**
Cash and cash equivalents at end of year		**431**	**2,762**

1. Cash flow investments for the year are lower than investments in the balance sheet, the difference is because the entire acquisition of development and commercialisation rights in Sobi's territory linked to BIV001 has not yet been paid.

Supplemental disclosures to cash flow statement – Parent Company

SEK M	Note	2019	2018
Interest paid and received			
Interest received		2	21
Interest paid		–117	–12
Income tax paid		–435	–434
Adjustments for non-cash items			
Depreciation/amortisation and write-downs of assets	7, 17, 18	381	321
Restructuring reserv		88	–
Deferred tax	21	–12	–21
Cost of share programmes[1]		129	46
Excess depreciations		400	460
Elocta and Alprolix[2]		–454	–485
Other items		–22	–19
		510	**301**

1. IFRS 2 expense associated with share programmes that is recognised in equity, and deductions for tax purposes, see Note 2 on previous side.
2. Pertains to royalty revenue with which the liability to Sanofi was settled, and to interest expense related to the liability to Sanofi.

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 the Stockholm Stock Exchange, now Nasdaq Stockholm, since 15 September 2006 and in OMX Stockholm Large Cap segment, since 2 January 2014.

2 Significant accounting policies and basis of preparation for the financial statements of the Parent Company and the Group

Compliance with standards and laws

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 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 income (hedge). The 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 values in parentheses () are comparative figures for the year-earlier period, 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. Since the financial statements and notes in the 2018 Annual Report were presented in SEK K (thousands of Swedish kronor), the tables and notes for the comparative year have been restated in SEK M. All amounts have been rounded to the nearest million.

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.

In 2019, the Parent Company fully adopted IFRS 9 Financial Instruments, which is the same accounting policy that the Group has applied since 2018. For more information about the Parent Company's accounting policies and where these differ from the Group's, see below.

New and amended standards applied by the Group

The new reporting standard IFRS 16 Leases came into effect on 1 January 2019 and superseded IAS 17 Leases. The standard provides new accounting requirements for lessees and stipulates that all leases must be recognised on the lessee's balance sheet as a lease liability and corresponding right-of-use asset. Previous operating lease payments are replaced by depreciation and interest expenses. Lease payments are divided into a lease liability and interest expense. The right-of-use asset is depreciated over the expected lease term using the straight-line method.

Sobi has elected to use the modified retrospective approach, with no impact on consolidated equity at 1 January 2019. Under the modified retrospective approach, right-of-use assets mainly comprising leases for premises and cars, are consistent with the lease liability on the transition date of 1 January 2019, taking prepaid rent into account. When transitioning to IFRS, Sobi has elected to apply the short-term lease and low-value lease exemptions. A short-term lease is defined as a lease that has a lease term of one year or less. A low-value lease essentially relates to computers, printers and copying machines.

The lease liability is measured at the present value of outstanding lease payments. The weighted average discount rate (the lessee's incremental borrowing rate) applied on the date of initial transition is 1.6 per cent, based on an estimate of the borrowing rate Sobi would have received from financial institutions for corresponding maturities. Extension options are taken into account when the Group considers it likely that the option will be exercised.

As an effect of the transition, the Group's total assets rose SEK 397 M on the transition date of 1 January 2019, corresponding to 2 per cent of total assets. The Group's financial liabilities rose SEK 397 M, also corresponding to 2 per cent of total assets.

In 2019, IFRS 16 had an impact of SEK 2 M on operating profit, of which a decline in other operating expenses accounted for SEK 97 M and increased depreciation expense for SEK 95 M. As such, there was no significant effect on operating profit or earnings per share. However, the alternative performance measure EBITDA rose SEK 97 M due to a decrease in other operating expenses under IFRS 16.

Summary of the Group's new accounting policy due to the transition to IFRS 16:

Leased assets (right-of-use assets) are capitalised on the lease commencement date, which means the date on which the underlying asset is available for use. The right-of-use asset comprises the initial lease liability, including any lease payments made on or before the commencement date of the lease. The right-of-use asset is measured at cost less any depreciation, accumulated impairment losses and remeasurement of the lease liability. The right-of-use asset is depreciated over the expected lease term using the straight-line method.

The lease liability is measured at the present value of fixed payments less any lease incentives receivable, and of variable lease payments that depend on an index or rate that have not been paid on the commencement date. Lease payments are discounted using the interest rate implicit in the lease, or the lessee's incremental borrowing rate if the implicit rate cannot be readily determined. The carrying amount of the lease liability is remeasured when there is a change in the assessment of a lease term.

Otherwise, the same accounting policies were applied as in the preceding year. Amendments to IFRS standards effective for reporting periods beginning in or after 2019 had no significant effect on the Group's financial statements.

New and amended standards and interpretations not yet adopted by the Group

Updated standards and interpretations from IASB and IFRIC interpretations that came into effect during the 2019 calendar year have had no material impact on the Group.

CONSOLIDATED FINANCIAL STATEMENTS

The consolidated financial statements are prepared in accordance with the Group's accounting policies and include the financial statements for the Parent Company and all subsidiaries. When preparing Sobi's consolidated financial statements, intra-Group transactions, balance-sheet items and unrealised gains and losses on transactions between Group companies are eliminated.

Subsidiaries

A subsidiary is a company in which the Parent Company has a controlling interest. A controlling influence exists when the company has control over a company, exposure or rights to variable returns from its involvement in the company, and the ability to affect those returns through its controlling influence. Subsidiaries are consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date that control ceases. If a subsidiary uses accounting policies that are not consistent with the Group's, the appropriate adjustments are made to the subsidiary's accounting policies.

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

Note 2, cont.

Transaction costs arising from acquisitions are recognised in the income statement as administrative expenses. Contingent consideration is classified as a liability and measured at fair value on the acquisition date. Conditional consideration is remeasured to fair value at each reporting date, with the change recognised in profit for the year.

The difference between fair value of the purchase price and fair value of the Group's share of the acquired assets, liabilities and contingent liabilities is recognised as goodwill. In step acquisitions, goodwill is determined on 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 for impairment. If the net fair value of the acquiree's identifiable assets, liabilities and contingent liabilities exceeds the cost, the excess (negative goodwill) is recognised directly in profit or loss. Any losses are considered an indication that the transferred asset may be impaired.

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 crowns (SEK), which is the Parent Company's functional currency and the Group's reporting 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. The exception is when the transactions are hedges that meet all hedge accounting criteria. These exchange-rate differences are recognised in other comprehensive income. Operating items are recognised as operating profit, while other items are recognised as financial 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 presentation currency (SEK) using the closing day rate, and all resulting exchange differences are recognised in other comprehensive income and accumulated in a separate line item under equity – foreign currency translation reserve. All items recognised 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 entity are treated as assets and liabilities of the entity and translated at the closing day rate.

SEGMENT REPORTING

Operating segments are presented using the management perspective, which means they are presented in the same manner as the internal reporting. The basis for identifying reportable segments is the internal reporting system, whereby they are reported to, and monitored by, the chief operating decision-maker. The Group has identified its chief operating decision-maker as the CEO. In the internal reporting to the CEO, only one segment is used. For more information, see Note 6.

REVENUES

The Group's revenues are mainly generated by sales of own products, for which Sobi holds the distribution and/or licensing agreements, and receives revenue from manufacturing and royalties.

Revenues include invoiced gross revenue as agreed for goods sold, excluding VAT, discounts, pharmaceutical taxes and returns due to product or quality warranties or transport damage, and after the elimination of intra-Group sales. Revenues are recognised as follows:

Operating revenue

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 end 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 received. 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, are recognised as accounts receivable.

The price of the goods is identified in contract. The consideration is 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.

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 payment terms are 90 days.

Returns from customers do not generally arise within Sobi, since the return of expired goods does not constitute a reason for return. There are product and quality warranties for any defective goods, and a transport warranty if the product is damaged during transport, provided that Sobi has arranged the transport. Should the latter arise, a claim is made against the insurance company.

Royalty revenue is recognised according to agreement. Revenue is recognised over time on a monthly basis, with quarterly reconciliation and invoicing. Sobi is entitled to royalties on pre-sold goods, as per agreement. 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 45 days after the end of the quarter.

Sobi has no customer contracts where the performance obligations extend beyond 12 months after the balance-sheet date.

Revenues may also include revenue from licensing agreements, including out-licensing revenue and milestone payments. Milestone payments refer to partial payments received from partners triggered by the achievement 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 license fee can be recognised in two ways: either directly when the license fee is received, or allocated over its estimated useful life. In 2019 and 2018, Sobi did not recognise any licence fees or milestone payments.

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 on the balance sheet as deferred income and recognised in profit or loss in the period when the cost associated with the grant is recognised.

Sobi mainly receives government grants in the form of reduced employer's contributions for research for commercial purposes, which is fully utilised, and research grants from the EU. A minor share of Sobi projects is funded with government grants, which will cease in 2020.

Other operating income/expenses

Other operating income and expenses are revenues and costs arising from activities outside the normal operations. These items include exchange-rate effects on operating receivables and liabilities. Accumulated gains or losses arising on cash-flow hedges in equity are reclassified to other operating income/expenses in the period in which the hedged item impacts profit or loss. For more information, see Notes 8 and 9.

Note 2, cont.

2

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 between deferred tax liabilities and equity. Deferred tax assets for deductible temporary differences and loss carry-forwards are only recognised to the extent it is probable they will be utilised. Tax is recognised under Tax on profit/loss for the year in the statement of comprehensive income except for those items recognised in other comprehensive income or equity. See Notes 16 and 21.

INTANGIBLE ASSETS

Goodwill

Goodwill arising in a business combination comprises the difference between the cost of the business combination and the fair value of identifiable assets acquired, liabilities assumed and contingent liabilities recognised. Goodwill is measured at cost less any accumulated impairment losses. Goodwill is allocated to the cash-generating units and tested annually for impairment in the fourth quarter, or whenever there is any indication of impairment. Impairment of goodwill is not reclassified. Goodwill arising from the acquisition of associated companies is included in the carrying amount of participations in associated companies.

Product and marketing rights

Product and marketing rights are measured at cost less accumulated amortisation. They have a limited useful life and are amortised to spread the cost over this period (5 to 20 years). Straight-line amortisation is carried out over the asset's useful life, based on the expected earnings of each product and marketing right. Amortisation expenses are considered selling costs. See also Note 4.

Licenses and patents

Licence costs and amortisation expenses are treated in the same way as product and marketing rights above. Cost for patents are expensed directly.

Research and development costs

Costs for development projects are recognised as intangible assets if the company can demonstrate that it is technically possible to complete and profitably commercialise the results, and only if the costs for the project can be measured reliably. In practice, this means that the costs cannot be capitalised until the US Food and Drug Administration (FDA) or the European Commission have granted approval. Acquired development projects are capitalised on the acquisition date. Amortisation is carried out to allocate the cost of development projects over their estimated useful lives, and does not commence until the project begins to generate revenue. Other research and development costs that do not meet the relevant recognition criteria of IAS 38 are recognised when incurred.

Capitalised costs

Software and IT projects in progress

Acquired software licenses 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 are capitalised when the manufacturing of Sobi's products are relocated and are classified as intangible assets. Amortisation commences when the asset is available for use.

Amortisation of intangible assets

Amortisation of product and marketing rights, licenses, patents and acquired R&D is charged to selling and administrative expenses. Amortisation of capitalised costs, etc, is also charged to selling and administrative expenses. For more information, see Note 7.

TANGIBLE ASSETS

Property, plant and equipment are recognised as assets on the balance sheet if it is probable that future economic rewards will accrue to the company and the cost of the asset can be measured reliably.

All tangible assets are recognised 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 is beneficial to the Group and the cost of the asset can be measured reliably. All other forms of repair and maintenance are recognised as costs 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, with consideration for 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 determined by the difference between the selling price and the carrying amount less direct selling costs. The profit/loss item is recognised as other operating income or other operating expenses.

IMPAIRMENT OF TANGIBLE AND INTANGIBLE ASSETS

Goodwill, which has an indeterminable useful life, and intangible assets not yet available for use, are not depreciated but tested annually for impairment or when there is any indication that the value of an asset has declined. Product and marketing rights that are amortised are also tested annually for impairment since the carrying amount is significant for the Group. Other assets that are depreciated/amortised are tested for impairment whenever events or changes in 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 at a rate equivalent to Sobi's weighted average cost of capital (WACC).

When assessing the goodwill impairment, this is grouped at the lowest levels for which there are separately identifiable cash flows. Sobi has made the assessment that the Group's operations as a whole comprise a cash-generating unit. Any impairment of goodwill is not reversed. 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 is described in Note 17.

Note 2, cont.

LEASES
The Group's accounting policies have been changed due to the new financial reporting standard, IFRS 16. The new reporting and disclosure requirements for lessees are described above under New and amended standards applied by the Group and in Note 10 and Note 18. Prior to 2018, leased assets were recognised in the consolidated financial statements as either a finance or operating lease. Leased non-current assets, for which Sobi held the same risks and rewards as owning the asset, were classified as a finance lease. The asset was recognised as a non-current asset on the balance sheet. The corresponding obligation for future lease payments was recognised as a current or non-current liability. The leased assets were depreciated according to plan, while the lease payments were recognised as interest and repayment of debts. Leased assets where the lessor essentially retained ownership of the asset were classified as operating leases and lease payments were expensed on a straight-line basis over the term of the lease.

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
Financial instruments include contract-based rights to receive cash, such as account receivables.
The Group classifies its financial instruments in the following categories:
1. Assets measured at amortised cost
2. Assets measured at fair value through profit or loss
3. Liabilities measured at amortised cost
4. Liabilities measured at fair value
5. Derivatives

The classification depends on the purpose for which the instruments were acquired and the type of financial instrument. Management determines how the instruments will be classified in connection with initial recognition and reviews this decision on each reporting date. Assets expected to mature or be sold within twelve 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 non-current 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 recognised on the balance sheet include such assets as cash and cash equivalents, account receivables and endowment policies. Financial liabilities mainly include borrowings, account payables and other liabilities.

1. Assets measured at amortised cost
Assets are classified in this category if both of the following criteria can be met:

1. The business model objective for the financial asset is to collect its contractual cash flows
2. The terms of the financial asset give rise to fixed or determinable payments and these are solely payments of interest and principal amounts

The Group's assets in this category consist of account receivables, other receivables, cash and cash equivalents. These are measured at amortised cost less any impairment. The maturities of account receivables are mainly short, which is why they are initially measured at nominal value without discounting. Any impairment of account receivables in the Group will use a model based on expected future losses, which have been calculated using historical losses and forward-looking estimates. Any impairment of account receivables based on expected future losses, which are assessed individually like account receivables, is recognised in operating expenses.

2. Assets measured at fair value through profit or loss (excluding derivatives)
Financial assets measured at fair value through profit or loss are financial assets that are not derivatives or that do not meet the requirements for being measured at amortised cost (see above). This category includes the Group's endowment policies.

3. Liabilities measured at amortised cost
This category includes financial liabilities not available for sale including loans, account payables and lease liabilities. Liabilities in this category are measured at amortised cost using the effective interest method. Borrowings are initially measured at fair value, net after transactions 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.

4. Liabilities measured at fair value
This category includes liabilities that are not derivatives and that are not recognised at amortised cost. Liabilities are measured both initially and in subsequent periods at fair value in the balance sheet. This category includes conditional purchase prices related acqusition of business combinations, where changes in fair value are recognised in the income statement. The components of the change in fair value relating to interest and exchange rate effects are recognized in net financial items and other changes in fair value are reported in operating profit or loss.

5. Derivatives
Derivatives are only used for hedging and not for speculative purposes. Sobi differentiates between derivatives included in an effective hedging relationship and other derivatives held for sale. 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 risk in the financial operations are recognised in net financial items, while derivatives held to manage risk in the operational results are recognised in other income/expenses. See below for accounting 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 pertaining 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 hedge 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.

Note 2, cont.

Net investment hedge
Hedging of net investments is done using financial liabilities denominated in foreign currency. The accounting for the liability is analogous with a loan in cash flow hedge.

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. The discount rate corresponds with the market rate before tax, and the risks associated with the liability. Provisions are recognised on the balance sheet under other current and non-current liabilities.

Provisions for restructuring 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 benefits at termination, which can be either voluntary or involuntary. Termination benefits are recognised as described above, except in those cases in which a requirement for service is linked 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. Cash-based programmes for employees are treated as a provision until the programme expires, refer to the section on direct pensions under Remuneration of employees.

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.

EMPLOYEE BENEFITS
Pensions
Sobi has both defined-contribution and defined-benefit pension plans, and the vast majority of employees are covered by and recognised in the defined-contribution pension plans. At 31 December 2019, employees in the Norwegian subsidiary, in the Swedish Parent Company, and all employees in the company in Switzerland that was acquired during the year were covered by defined-benefit plans. All other employees were covered by defined-contribution pension plans. See Note 29 for more information.

Recognition of defined-contribution pension plans and management by Alecta
The CEO and management are mainly covered by defined-contribution plans. A defined-contribution pension plan provides a contribution to a pension plan, determined as a percentage of the pensionable salary. The level of pension benefits at retirement is determined by premiums paid and the return on investments, less management costs.

Pension expenses for the defined-contribution plans are reported in the income statement as earned. The obligations are calculated without discounting, since the payments for these plans fall due within 12 months.

Obligations for retirement pensions and family pensions for white-collar employees in Sweden are insured through Alecta. According to the Financial Reporting Board's statement UFR 10 Accounting for ITP 2 plans financed by insurance in Alecta, this is a defined-benefit plan covering multiple employers. For the financial years of 2005–2019, the company did not have access to the information required to recognise this plan as a defined-benefit plan, which is why the ITP pension plan insured through Alecta is recognised as a defined-contribution plan.

A special employer's contribution is calculated on pension premiums.

Recognition of defined-benefit pension plans
In defined-benefit plans, the pension is determined as a percentage of the pensionable final salary, based on the employee's length of service and average final salary. The Group is responsible for ensuring that the established benefits are paid out.

The defined-benefit pension obligations are recognised on the balance sheet as the net total of the estimated present value of the obligations and the fair value of the plan assets, which are recognised as a provision or a non-current financial receivable.

For defined-benefit plans, pension expense and commitments are calculated using the applicable principles of IAS 19. This calculation is performed annually by independent actuaries.

The company's obligations are measured at the present value of expected future payments. When discounting obligations in Sweden, a discount rate equal to the interest on mortgage bonds with a maturity corresponding to the relevant obligations is applied. The most important actuarial assumptions are described in Note 29.

Actuarial gains and losses may arise in connection with the determination of the present value of the obligations and the fair value of plan assets. These arise either because the fair value differs from the previous assumption, or the assumptions change. Actuarial gains and losses are recognised in other comprehensive income in the period in which they arise.

Interest expense, less the estimated return on plan assets, is classified as a financial expense. Other cost items in the pension expense are charged to operating profit.

The accounting principle for defined-benefit pension plans described above applies only to the consolidated financial statements.

Direct pensions
For some senior executives, their pension plan has been supplemented with direct pension obligations. 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
Sobi currently has five active share programmes and one share option programme for senior executives. The fair value of the allotted share programmes is estimated on the issue date using a generally accepted modelling technique, the Monte Carlo simulation model, and taking market conditions into account, and the fair value of the employee option programme is estimated on the issue date using the Black & Scholes model. The 2019 Share Programme, which covers the CEO, senior executives and managers, includes a revenue component

Note 2, cont.

whereby the fair value of the allotted shares may fluctuate, depending on the assumptions of target achievement. The total amount to be expensed is based on the fair value of the shares allotted.

The total amount 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 when vested under the framework of the programmes.

The Group also has three long-term cash-based incentive programmes, which are not classified as share-based payment awards, covering 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 income statement.

The social security contributions are remeasured at the end of every quarter until settlement takes place, and allocated using the same principles as the cost for shares.

A more detailed description of the long-term incentive programmes can be found in Note 11.

Compensation for termination

A provision for the termination of employees is only recognised if the company is demonstrably obliged to terminate a position before the normal period of service has ended, or if compensation is offered to encourage voluntary resignation, such as a retirement package. 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.

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.

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 and the Swedish Financial Reporting Board's recommendation RFR 2 Accounting for Legal Entities, and applicable statements for listed companies. 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.

In 2019, the Parent Company changed its accounting policies and transitioned to the full adoption of IFRS 9 Financial Instruments. The Group has applied IFRS 9 since 2018. At 31 December 2019, the transition to IFRS 9 affected a liability to Sanofi which, after the transition, was measured at fair value and due to that decreased in value. It also meant that the ntangible asset is affected to the same extent as the liability. Since both of these transactions arose during the financial year, the accounting policy change in this respect did not have any effect on prior years. Otherwise, the transition to IFRS 9 did not have any significant effect on the amounts recognised in the Parent Company's financial statements compared with prior years.

As in prior years, 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

The Parent Company applies the provisions of the Pension Obligations Vesting Act when calculating defined-benefit pension plans, which is a prerequisite for tax deductibility. The most significant differences compared with the rules for IAS 19 are how the discount rate is determined, that the calculation of the defined-benefit obligation is based on current salary levels without assumptions on 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.

Right-of-use assets

All of the Parent Company's leases are recognised according to the rules for operating leases.

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

Participations in subsidiaries are recognised using the cost method. 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 the acquisition of companies are expensed. Contingent considerations are recognised as part of the cost if it is probable that they will be realised. If the initial assessment needs to be revised in subsequent periods, the cost must be adjusted.

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 also described in a separate section of the Directors' Report.

Financial risk is managed at central level by Sobi's treasury function, which in addition, is 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 treasury-related issues.

The Treasury Policy, which is adopted by the Board, establishes the division of responsibilities and control of treasury matters between the Board, CEO, CFO and the treasury function. The Board has appointed an Audit Committee to monitor the structure of the Treasury Policy and, if necessary, suggest 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.

Financial risk factors

Currency risk – Commercial transaction risk

Transaction risk arises when sales and purchasing transactions are denominated in different currencies, which may affect the company's profitability, cash flow and financial position. This risk is limited in the subsidiaries as their commercial flows are 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 the vast majority of sales is denominated in EUR while purchasing is spread between several currencies. In the event of a depreciation of SEK against other currencies of 1 per cent, sales in 2019 would have increased by SEK 135 M (85) and EBITA by SEK 85 M (56).

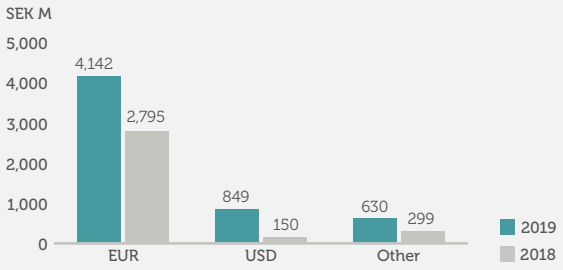
Financial instruments, such as currency forwards, are used to manage the transaction exposure. Sobi also applies hedge accounting and uses cash flow hedges to reduce some of the transaction risk in EUR and USD. These flows are primarily related to the products Synagis, Elocta and Alprolix. This means that the currency revaluation component from the remeasurement of liabilities are recognised in other comprehensive income, and accumulated gains or losses

Note 3, cont.

from these remeasurements are reclassified to profit or loss when the hedged inflows affect profit or loss. See Notes 17 and 28 for more information about these liabilities.

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

Commercial transaction exposure, yearly volume

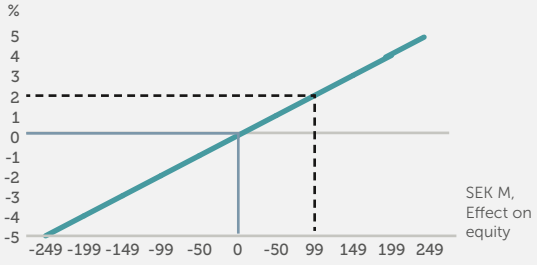


Currency risk – translation exposure

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 2019, translation risk increased for Sobi as a result of the acquisitions that were made. The changes in equity are considered acceptable and not managed by using currency derivatives. The risk is partly managed by limiting the net assets by raising loans in foreign currency. The diagram of translation risk shows the Group's sensitivity to this risk. The diagram shows that the translation effect on the Group's equity would be positive if SEK depreciated, and vice versa. If SEK, for example, were to depricate 2 per cent against all currencies, the translation effect on consolidated equity would be SEK –99 M (18).

Translation risk

Currency change in SEK



Liquidity risk

Liquidity risk is the risk that Sobi cannot 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 poliy, Sobi shall maintain an appropriate liquidity reserve. The liquidity reserve comprises bank balances, current investments and undrawn committed credit facilities. At 31 December 2019, the company's undrawn committed credit facilities totalled SEK 3,959 M (10,075). At 31 December 2019, SEK 16,243 M of the facilities had been drawn. See the distribution in the table in the next column.

Credit facilities, maturity structure

GROUP	2020	2021	2022	2023	2024	Total
Credit facilities, undrawn	1,135	103	2,595	0	126	3,959
Credit facilities; drawn	0	6,053	900	3,495	5,795	16,243
Credit facilities, total	**1,135**	**6,156**	**3,495**	**3,495**	**5,921**	**20,203**

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

Maturity analysis

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	–
Account payables	681	–	–	–
Lease liabilities	99	320	–	–
Other liabilities[2]	1,124	1,218	2,430	–
Total	**1,964**	**8,491**	**11,721**	**–**

AT 31 DECEMBER 2018, GROUP	Less than 1 year	Between 1–2 years	Between 2–5 years	More than 5 years
Derivatives[1]	8	–	–	–
Account payables[1]	487	–	–	–
Other liabilities[2]	3,640	1,130	1	–
Total	**4,136**	**1,130**	**1**	**–**

1. Part of other liabilities in balance sheet.
2. Other liabilities primarily relate to liabilities to Sanofi and AstraZeneca. The liabilities in the table are presented at nominal value according to an assessment of the contracts at 31 December 2019. 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, either in earnings resulting from increased interest costs, or from adverse effects on market value on instruments with fixed interest rates. 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. In the case of interest-bearing borrowings, the Group is exposed to interest rate risk. Borrowings are normally done with fixed interest period of three months. At the end of the year, the average fixed interest period was 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.

There were no outstanding interest rate derivatives on the balance sheet date.

The sensitivity to interest rate changes in earnings is measured by assuming a lasting interest rate change of 1 percentage point. At 31 December 2019, such a change would have had an annual impact of SEK 161 M (0) on net financial items excluding effects from changes in fair value. At 31 December 2019, Sobi's interest-bearing liabilities amounted to SEK 16,141 M (4). The loans raised are managed with 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 arising from account receivables, and financial credit risk.

Sobi's credit risk is mainly related to account receivables. At the balance-sheet date, these amounted to SEK 3,736 M (1,665), of which SEK 685 M (518) were overdue, see Note 23 for information about overdue account receivables. Sobi's customers are mainly large distributours with low 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 2019, these amounted to SEK 69 M (70). Only a small portion of the account receivables are secured with trade finance solutions.

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 credit worthiness. The credit ratings must be obtained from a reputable credit 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 investment of surplus liquidity is done 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 capital costs 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 2019, the equity/assets ratio was as follows:

GROUP	2019	2018
Equity	16,930	9,040
Total assets	45,658	17,183
Equity/assets ratio, %	37.1	52.6

4 Significant accounting judgements, estimates and assumptions

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

ACCOUNTING JUDGEMENTS

Revenues
The Group assesses the likelihood of future economic rewards accruing to the Group 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 is made for an expected credit loss in accordance with the principles described in Note 2.

When revenue is recognised, each agreement is interpreted separately and the company makes an assessment of any obligations. Revenue is recognised when control has been transferred to the buyer, depending on the shipping terms. Revenues are calculated as invoiced gross revenue according to agreement less variable pay corresponding to actual and estimated discounts to public and private customers, pharmaceutical taxes.

Since actual and final conditions for discounts and pharmaceutical taxes on sales in the current period are not always known on the balance-sheet date, some of the deductions from gross revenue are based on estimates. See also Note 2 on revenue recognition of license fees and milestone revenue.

Inventories
Production costs
Costs for production consist of direct production costs, such as raw materials, consumables, media and manpower, as well as indirect costs, such as personnel costs, depreciation and maintenance.

Calculation of indirect production costs is based on a method for calculating standard costs. This method is regularly revised in order to ensure reasonable calculation of the utilisation rate, lead times and other relevant factors. Changes in the method may have an impact on gross margins and the overall valuation of inventories.

Research and development costs
The company conducts research and development as internal projects and with external partners. In cases where the company 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, the company agrees to make milestone payments. These payments are capitalised as research and development, and amortisation does not commence until the project has reached the commercialisation phase and meets the requirements of IAS 38 Intangible Assets. Evaluation of a project's progress and impairment testing are performed regularly, at least annually. During 2019 one of the early-phase clinical programmes were written down with M 18 SEK.

Costs for internal development and payments for projects and substances under agreement with third parties are expensed when incurred if they do not meet the requirements of IAS 38. Rules and uncertainty usually mean that the criteria are not fulfilled. However, in cases where the requirements are met, intangible assets are capitalised and amortised according to plan. Capitalisation commences when the company can demonstrate that it is technically feasible and profitable to commercialise the results. For a sensitivity analysis, see Note 17.

Note 4, cont.

ESTIMATES AND ASSUMPTIONS

Intangible assets

The Group's intangible assets are essentially attributable to goodwill, development projects and licence, product and marketing rights. Goodwill arose from the acquisition of Swedish Orphan, Dova and emapalumab that were acquired during 2019. Annual impairment testing of goodwill, development projects, product and marketing rights is based on their recoverable amounts, including key assumptions such as sales growth, margins and discount rates. See below and Note 17.

Goodwill

The Group conducts regular goodwill impairment testing, in accordance with the policy described in Note 2. The recoverable amount of the cash-generating unit is determined by calculating the value in use. This calculation requires certain estimates to be made, see Note 17. At 31 December 2019, Sobi's goodwill amounted to SEK 6,678 M (1,554). The testing showed no indication of impairment.

Acquired development projects

The Group makes annual impairment assessments of acquired development projects in accordance with the principle described in Note 2. When testing for impairment, a number of assumptions are made. These assumptions are specified in Note 17.

Product and marketing rights

Product and marketing rights have a limited useful life and amortisation is used to spread the cost over this period. The amortisation period ranges from 5 to 20 years, and is adapted to the expected earnings of each product right.

As the carrying amounts of these product and marketing rights are highly significant for the Group, they are tested annually for impairment. The company has determined that most of the amortisation is attributable to selling costs, as the intangible assets classified as product rights are primarily related to marketing rights. The product and licensing rights are not related to any inventory cycle or production, nor is it necessary to otherwise bring the product to its current location and condition. The rights enable Sobi to market and sell certain products. The use of rights is not consumed in a manufacturing process but over a useful life that corresponds to the related product's length of relevance on the market.

The assumption that has the greatest impact on the future value is projected sales growth. It is based on assumptions about underlying growth and future product development, and expanded applications for the drug. If the company's assumptions regarding product development and expanded applications for any drugs prove incorrect, this could indicate that the product right is impaired. The other assumptions made when testing product rights for impairment are presented in Note 17.

Taxes

Deferred tax is estimated and measured according to the principles described in Note 2. Under Swedish tax rules, any future tax losses may be carried forward indefinitely. Deferred tax assets on losses are recognised when it is probable they can be utilised against future taxable profit. Previously recognised deferred tax assets on losses that are not likely to be of benefit to the Group are reduced. Foreign tax rates were used for measurement.

Assumptions for the calculation of pension benefits

The actuarial calculation of pension commitments and pension expenses is based on the actuarial assumptions specified in Notes 2 and 29.

Inventory

Obsolescence

Sobi operates within the pharmaceuticals industry, an industry regulated and controlled by several authorities within Sweden and internationally. The company also cooperates with external parties within Sweden and internationally which monitor and evaluate its operations. All stocks of finished products are evaluated continuously in terms of product shelf life. Inventories consist of raw materials for production, drug substance and finished product for stocks of Alprolix, Ammonaps, Doptelet, Elocta, Gamifant, Kepivance, Kineret, Orfadin, Synagis and other products. No provision is made for obsolescence of these stocks. The shelf life of inventory stocks can vary over time. This can lead to an increased risk of obsolescence: significant changes in demand for a product or changes to shelf life can potentially lead to an impairment. Products that are not approved by Quality Control are written off immediately. The remainder of the inventory is largely comprised of Refacto. Production of Refacto is carried out in two stages: cultivation and purification. If a proportion of the inventory is not approved by either Sobi's or Pfizer's Quality teams, the material is written down immediately. Assessments of obsolescence are adjusted regularly based on historical figures and sales forecasts.

5 Distribution of operating revenue

GROUP	2019	2018
Operating revenue by major revenue type		
Product sales	12,441	7,362
Manufacturing	376	436
Royalties[1]	1,373	1,341
Service fees	58	–
Total	**14,248**	**9,139**

GROUP	2019	2018
Revenues by geographic market[2]		
France	2,004	1,503
Germany	1,254	999
Italy	793	555
Rest of Europe	3,636	2,969
Europe[3]	**7,686**	**6,026**
North America	**4,587**	**1,309**
Rest of the world	**602**	**462**
Royalties[1]	1,373	1,341
Total	**14,248**	**9,139**

PARENT COMPANY	2019	2018
Operating revenue by major revenue type		
Product sales	11,198	6,444
Manufacturing	376	436
Royalties[1]	1,373	1,341
Service fees	45	–
Total	**12,991**	**8,221**

PARENT COMPANY	2019	2018
Revenues by geographic market[2]		
France	1,815	1,354
Germany	1,002	866
Italy	703	438
Rest of Europe	3,377	2,860
Europe[3]	**6,897**	**5,518**
North America	**4,266**	**1,021**
Rest of the world	**455**	**341**
Total	**11,618**	**6,880**
Royalties[1]	1,373	1,341
Total	**12,991**	**8,221**

1. Royalty revenue includes royalties related to our haemophilia products that are not attributable to a specific region according to the distribution above. All royalty refer to Sanofi sale of Eloctate and Alprolix.
2. The geographic distribution is based on where end-customers are located.
3. Sales in Sweden amounted to SEK 240 M (199).

The accounts of the Group and the Parent Company do not include revenues for 2019 or 2018 relating to performance obligations in previous years. Furthermore, there are no customer contracts with performance obligations that are recognised as contract liabilities.

In 2019, revenues for the Parent Company, Swedish Orphan Biovitrum AB (publ), amounted to SEK 12,991 M (8,221) of which SEK 6,154 M (4,554) pertained to sales to Group companies.

Estimated, unbilled accrued royalty revenue is to be classified as a contract asset under IFRS 15. see Note 2 and 24.

GROUP	2019	2018
Operating revenue per Business Area		
Elocta	4,508	3,261
Alprolix	1,463	974
Royalties	1,373	1,341
Doptelet	34	–
Manufacturing	376	436
Haematology	**7,755**	**6,012**
Kineret	1,571	1,320
Synagis	2,594	–
Gamifant	542	–
Immunology	**4,706**	**1,320**
Specialty Care	**1,787**	**1,807**
Total revenues	**14,248**	**9,139**

GROUP	2019	2018
Gross to Net		
Product revenue, gross	17,192	8,933
Mandatory and contractual price reductions	–4,750	–1,571
Product revenue, net	**12,441**	**7,362**
Manufacturing	376	436
Royalty	1,373	1,341
Service fee	58	–
Operating revenue	**14,248**	**9,139**

PARENT COMPANY	2019	2018
Gross to Net		
Product sale, gross	14,050	6,795
Mandatory and contractual price reductions	–2,852	–351
Product sale, net	**11,198**	**6,444**
Manufacturing	376	436
Royalty	1,373	1,341
Service fee	45	–
Operating revenue	**12,991**	**8,221**

6 Segment reporting

The Group reports one operating segment, sales of pharmaceuticals. The basis for identifying reportable segments is the internal reporting system, whereby they are reported to, and monitored by, the chief operating decision-maker. The Group has identified its chief operating decision-maker as the CEO. Sobi reports revenue by geographic area. See Note 5 for more information about the distribution of revenues per revenue type and geographic area.

In 2019, Sobi's largest customers are MedImmune LLC (Synagis), with revenue of SEK 2,843 M (0) and Sanofi (Alprolix/Eloctate), with revenue of SEK 1,049 M (825), corresponding to 20 and 7 per cent, respectively, of the company's total revenues.

Of the fixed assets, 51 per cent (59) are found in Sweden, 31 per cent (0) in the US and 14 per cent (41) in Switzerland.

7 Depreciation/amortisation and write-downs of intangible and tangible assets[1]

GROUP	2019	2018
Depreciation/amortisation according to plan by type of asset		
Licenses and patents	–38	–39
Product and marketing rights	–1,305	–387
Capitalised costs	–39	–23
Plant and machinery	–22	–19
Equipment, tools and fixtures and fittings	–13	–15
Other intangible and tangible assets	–2	–2
Right-of-use-assets	–89	—
Total	**–1,508**	**–485**
Write-downs by type of asset[2]		
Licenses and patents	–18	—
Plant and machinery	–32	—
Right-of-use-assets	–30	—
Total	**–80**	**—**
Total depreciations, amortisations and write-downs by type of asset	**–1,588**	**–485**
Depreciation/amortisation according to plan by type of function		
Cost of goods sold	–34	–13
Selling and administrative expenses	–1,445	–463
Development costs	–28	–9
Total	**–1,508**	**–485**
Write-downs by type of function[2]		
Cost of goods sold	–16	—
Selling and administrative expenses	–18	—
Utvecklingskostnader	–47	—
Total	**–80**	**—**
Total depreciations, amortisations and write-downs by type of function	**–1,588**	**–485**

PARENT COMPANY	2019	2018
Depreciation/amortisation according to plan by type of asset		
Licenses and patents	–3	–6
Product and marketing rights	–262	–262
Capitalised costs	–39	–23
Plant and machinery	–19	–19
Equipment, tools and fixtures and fittings	–7	–10
Other intangible and tangible assets	–1	–1
Total	**–331**	**–321**
Write-downs by type of asset[2]		
Licenses and patents	–18	—
Plant and machinery	–32	—
Total	**–50**	**—**
Total depreciations, amortisations and write-downs by type of assets	**–381**	**–321**
Depreciation/amortisation according to plan by type of function		
Cost of goods sold	–11	–13
Selling and administrative expenses	–312	–299
Development costs	–8	–9
Total	**–331**	**–321**
Write-downs by type of function[2]		
Cost of goods sold	–16	—
Selling and administrative expenses	–18	—
Development costs	–17	—
Total	**–50**	**—**
Total depreciations, amortisations and write-down by type of function	**–381**	**–321**

1. See Note 17 and 18 for further information.
2. Refers to one of the clinical programmes in early stage as well as tangible assets and right-of-use assets for premisis used in early research that were discontinued 2019

8 Other operating income

GROUP	2019	2018
Re-invoiced costs to partners	8	5
Disposal of clinical program in early stage	46	—
Other	14	1
Total	**68**	**6**

PARENT COMPANY	2019	2018
Re-invoiced costs to partners	8	5
Exchange-rate gains[1]	8	—
Disposal of clinical program in early stage	46	—
Other	—	—
Total	**62**	**5**

1. Exchange-rate effects are recognised net and in 2019 constituted a small loss for the group and a gain for the parent company, see Note 9.

9 Other operating expenses

GROUP	2019	2018
Exchange-rate losses on operating receivables/liabilities	—	–2
Exchange-rate losses[1]	–1	—
Scrapping/disposal of non-current assets	–12	–4
Other	–6	0
Total	**–18**	**–6**

PARENT COMPANY	2019	2018
Exchange-rate losses on operating receivables/liabilities	—	–5
Scrapping/disposal of non-current assets	–10	–3
Total	**–10**	**–7**

1. . Exchange-rate effects are recognised net and in 2019 constituted a small loss for the group and a gain for the parent company, see Note 8.

10 Leasing

As of 1 January, 2019, Sobi has applied IFRS 16 leases. For a description of the Group's accounting policy, as applied in 2019, see further in Note 2. The Group reports right-of-use assets, linked to lease agreements, in the balance sheet under the heading tangible assets, see Note 18. The Group recognises lease liabilities in the balance sheet under separate headings. For maturity analysis, see Note 3.

The Group mainly leases offices and cars. The contract length for premises is usually about 2–10 years, for cars 36–48 months. Extension options are in many cases entered into contracts for premises. Every quarter, an assessment is made of whether it is reasonable and likely that the agreements will be extended and whether any index clauses are activated for future rents. Invoiced service is not included in capitalised amounts under IFRS 16.

Reported amounts in the balance sheet related to lease agreement

GROUP	2019
Right-of-use assets	
Premises	364
Vehicles	31
Total Right-of-use assets	**395**
Lease liabilities	
Short term	99
Long term	320
Total lease liabilities	**419**

Reported amounts in the income statement

GROUP	2019
Depreciation and write-down of right-of-use assets	
Premises[1]	–110
Vehicles	–9
Total	**–119**
Interest expenses	–6
Short term leases and assets of low values (in administration)	–7
Total amount recognised in profit for the year	–132
Reported amounts in the cash flow statement	
Lease payments	–94

1. Write-down of SEK 30 M relates to right-of-use premises used for early-phase clinical programmes, terminated during the year.

Previous year lease assets and lease liabilities attributable to financial leases were reported in accordance with IAS 17 Leases. The assets were presented as part of tangible fixed assets and the liabilities as part of the Group's liabilities to credit institutions. For adjustments reported at the transition to IFRS 16 as of 1 January, 2019, see Note 28.

Additional right-of-use assets in 2019 amounted to SEK 102 M, of which SEK 10 M was acquired through acquisitions.

Changes in accounting policies

GROUP	2019
Operating lease commitments disclosed as at 31 December 2018[1]	426
Reassessments	–4
Discounted using the group's incremental borrowing rate of 1.5%	–19
Short-term leases recognised as expense	–6
Lease liability, 1 January 2019	**397**

1. Total leasing fees for operating leases reported in 2018 in table "Lease payment for operating leases".

GROUP	31 Dec 2018	IFRS adjustment	1 Jan 2019
ASSETS			
Non-current assets			
Intangible assets	10,159	–	10,159
Tangible assets	136	412	548
Financial assets	286	–	286
Total non-current assets	**10,581**	**412**	**10,993**
Current assets			
Current assets	6,602	–15	6,587
Total current assets	**6,602**	**–15**	**6,587**
Total assets	**17,183**	**397**	**17,580**
EQUITY AND LIABILITIES			
Equity	**9,040**	–	**9,040**
Non-current liabilities			
Lease liabilities	3	320	323
Non-current liabilities, non-interest bearing	1,189	–2	1,187
Total non-current liabilities	**1,192**	**318**	**1,510**
Current liabilities			
Lease liabilities	1	81	82
Current liabilities, non-interest bearing	6,950	–2	6,948
Total current liabilities	**6,951**	**79**	**7,030**
Total equity and liabilities	**17,183**	**397**	**17,580**

LEASE PAYMENT FOR OPERATING LEASES

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

	Parent Company		Group
	2019	2018	2018
Within one year	60	61	81
Between 1–5 years	226	222	293
Later than 5 years	–	15	24
Total	**286**	**298**	**399**
Rental costs premises for the year	61	58	76

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

	Parent Company		Group
	2019	2018	2018
Within one year	0	0	12
Between 1–5 years	–	0	15
Later than 5 years	–	–	–
Total	**0**	**0**	**27**
Rental costs other for the year	0	0	11

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

No. of employees[1]

GROUP	2019	of whom women, %	of whom men, %	2018	of whom women, %	of whom men, %
Sweden[2]	435	66	34	468	64	36
Denmark	15	67	33	15	60	40
Finland/Baltics	8	50	50	9	56	44
Norway	5	80	20	5	80	20
UK	47	44	56	45	56	44
France	55	64	36	54	61	39
Germany	51	59	41	45	64	36
Italy	46	54	46	44	55	45
Greece	4	75	25	4	75	25
Spain	37	63	37	35	60	40
Belgium	22	45	55	22	45	55
Russia	4	75	25	5	60	40
Switzerland[3]	128	66	34	13	48	52
Austria	6	46	54	6	67	33
Central and Eastern Europe	25	49	51	21	52	48
US[3]	414	58	42	80	54	46
Canada	6	33	67	5	40	60
United Arab Emirates	27	22	78	26	15	85
Total	**1,335**	**60**	**40**	**902**	**59**	**41**

1. At 31 December 2019, the number of full-time employees was 1,335 people, while the number of employees at the same date was 1,377.
2. During the year, the early-phase R&D operations that were based in Sweden were discontinued.
3. Companies were acquired in the US and Switzerland during the year, which is the reason for the increase in staff in these countries. For further information see Note 33.

Gender composition of the Board and management

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

GROUP	2019	2018
Board		
Men	5	5
Women	3	3
Total	**8**	**8**
CEO and senior executives		
Men	8	9
Women	3	2
Total	**11**	**11**

GENDER COMPOSITION EMPLOYEES

60% ♀ ♂ 40%

Salaries, other remuneration and social security costs

GROUP AND PARENT COMPANY	2019 Salaries and remuneration	2019 Social security costs	2018 Salaries and remuneration	2018 Social security costs
Parent Company	577	273	444	281
(of which pension expense)	—	*(103)*	—	*(89)*
Subsidiaries	1,171	202	647	125
(of which pension expense)	—	*(58)*	—	*(30)*
Group, total	1,748	475	1,092	406
(of which pension expense)	—	*(161)*	—	*(119)*

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

	2019 Board and CEO	2019 Other employees	2018 Board and CEO	2018 Other employees
Parent Company				
Salaries and other remuneration	24	553	20	424
(of which bonus)	*(8)*	*(67)*	*(6)*	*(69)*
Subsidiaries				
Salaries and other remuneration	—	1,171	—	647
(of which bonus)	—	*(239)*	—	*(145)*
Group, total	**24**	**1,724**	**20**	**1,071**
(of which bonus)	*(8)*	*(306)*	*(6)*	*(214)*

Guidelines and remuneration 2019

The 2019 Annual General Meeting (AGM) resolved on remuneration guidelines for the company's senior executives as set forth below, that will apply until the 2020 AGM. Senior executives refer to the Chief Executive Officer of Swedish Orphan Biovitrum AB (publ) and the managers who report to the Chief Executive Officer and are members of the Executive Committee.

Objective

The objective of the guidelines is to ensure that the company can attract and retain the best people in order to support the vision and strategy of the company. The remuneration of senior executives is based on a total remuneration approach. The total remuneration should be market based, but not leading in relation to competitors in each local market. The peer comparisons should be made against a group of companies of similar size, that operate in a similar industry, and with similar complexity. The guidelines should enable international hiring and support diversity amongst the senior executives. The remuneration may consist of the following components:

- A, Base salary
- B, Variable pay (short-term incentives)
- C, Long-term incentives
- D, Pensions
- E, Other benefits

To the extent a member of the Board performs assignments on behalf of the company or another Group company, in addition to Board duties, consulting fees and/or other remuneration for such work shall be payable.

Note 11, cont.

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

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[3]	33,412
Other senior executives (10–12 people)[2]	43,840	18,225	5,796	5,701[4]	8,162[3]	81,724
Total	**59,319**	**26,610**	**8,577**	**5,701**	**20,884**	**121,092**

1. Other senior executives refers to Sobi's Executive Committee, consisting of ten individuals in addition to the CEO, at 31 December 2019. Additional people were included in the management team during the year. Their remuneration is included in the table. For information on 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 agreed severance pay of SEK 4,951 K.
3. See also allotment and fulfilment of long-term incentive programmes for the 2016 share programme, the year's cost for Sobi is not to be equated with remuneration to employee.
4. Other benefits includes cost for relocation.

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

2018	Base salary/fees	Bonus	Pension expense	Other benefits	Share programmes	Total
Chair of the Board						
Håkan Björklund	1,388					1,388
Other Board members						
David Allsop[2]	367					367
Annette Clancy	592					592
Matthew Gantz	610					610
Lennart Johansson	577					577
Helena Saxon	567					567
Hans GCP Schikan	627					627
Elisabeth Svanberg[2]	377					377
Executive Committee, 2018						
Guido Oelkers, Chief Executive Officer	9,107	6,278	2,516	0	7,814[3]	25,714
Other senior executives (10 people)[3]	31,603[4]	16,519	3,235	1,701[4]	3,581[3]	56,639
Total	**45,815**	**22,797**	**5,751**	**1,701**	**11,395**	**87,458**

1. Other senior executives refers to Sobi's Executive Committee, consisting of ten individuals in addition to the CEO, at 31 December 2018. The table shows the company's costs (excluding social security contributions). For more information about Board fees, see the Corporate Governance Report.
2. David Allsop and Elisabeth Svanberg were elected new Board members at the AGM on 9 May 2018.
3. See also allotment and fulfilment of long-term incentive programmes for the 2015 share programme.
4. Base salary and other benefits include agreed severance pay of SEK 4,463 K.

Note 11, cont.

Base salary
The base salary of senior executives shall be based on competence, responsibility and performance. The company uses an international evaluation system to assess the scope and responsibilities of the various positions.

Variable pay
The annual short-term incentive programme is based on the fulfilment of annual performance objectives (company-specific and individual). Payment is based on the fulfilment of pre-determined objectives. The annual performance objectives are defined in advance by the Compensation & Benefits Committee and approved by the Board of Directors.

These objectives are determined for the promotion of the company's long-term development, value creation and financial growth and shall be designed in a way that does not encourage an excessive risk-taking. Short-term incentives are limited to 100 per cent of annual gross salary for the CEO, and 60 per cent of fixed annual salary for other senior executives.

Long-term incentives
The company may introduce long-term incentive programmes for all or some of its employees. The aims of such a programme should be to align the employees' interests with those of the shareholders, to create a long-term commitment to the company, to be a tool to retain and attract managers and top talent, to enable the participants to share the company's long-term success and value creation, and to contribute to competitive total remuneration.

Pensions
The preferred pension plan design is defined-contribution. Defined-benefit pension plans may be established if required by law or other regulations. In such cases, the defined-benefit level shall be limited to the mandatory level.

Other benefits
Fixed salary during notice periods and severance pay, including payments for any restrictions on competition, shall in total not exceed an amount equivalent to the base salary for two years. In addition to this restriction, the total severance payment shall be limited to the current monthly salary for the remaining months up to the age of 65.

Other remuneration may also be paid in extraordinary circumstances, provided that such arrangements are one-off and only concluded on a case by case basis for the purpose of recruiting or retaining senior executives, or as compensation for extraordinary efforts in addition to the person's ordinary duties. Such remuneration shall be market-based and may, for example, include a one-time cash payment, a support package including relocation and tax filing support, a retention bonus or severance payment in the event of a change in ownership, or similar. The remuneration shall not exceed an amount corresponding to the base salary for three years and not be paid more than once per year per individual. Decisions on such remuneration shall be made by the Board based on a proposal from the Compensation & Benefits Committee.

Deviations from the guidelines
The Board may decide to deviate from the above guidelines if there are special reasons to justify such a decision in an individual case.

Senior executives' employment terms and remuneration
Sobi aims to offer market-based terms, which enables the company to recruit and retain competent personnel (for a proposal for the complete guidelines for 2020, see the Director's Report).

Remuneration to the Board members elected by the AGM is paid in accordance with a resolution adopted by the 2019 AGM. No pensions are paid to the Board.

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 to 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 to the CEO and other senior executives consists of fixed 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.

Fixed salary
Each senior executive's area of responsibility, experience and performance is taken into account when determining the fixed salary. The fixed salary is reviewed every year.

Short-term variable pay
For the CEO, short-term variable pay in 2019 was capped at 100 per cent of annual gross salary. Variable pay was based on Group targets and individual targets established by the Board. For other senior executives, short-term variable pay was capped at 60 per cent of fixed salary and based on Group and individual 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 2019, Sobi paid out a premium of SEK 2,781 K. 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
At the balance-sheet date, Sobi had five (five) active share programmes. 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 programmes have a four-year vesting period.

Long-term incentive programmes
The 2016–2019 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 2016–2019 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 requires 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 rate over a three-year period, and that actual annual sales during the vesting period must meet or exceed the budget for annual sales.

In 2019, the AGM resolved to introduce a share option programme for senior executives. 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 programmes.

Note 11, cont.

2016 Share Programme (paid in 2019)
The 2016 share programmes expired in 2019. For 2016, the Board resolved that the following performance conditions and other vesting terms were fully met when the 2016 share programme was redeemed on 28 October 2019. In the Management Programme, 153,250 shares with a market value of SEK 23.5 M were allotted. In the All Employee Programme, 55,007 shares with a market value of SEK 8.4 M were allotted. The performance target was a 15–75 per cent increase in the share price from the volume-weighted share price ten days prior to roll-out of the programme. The performance outcome is 0 if the share price is below 15 per cent, with a straight-line allotment for 15–75 per cent.

When Sobi's 2016 share programme was introduced, a number of employees, including former CEOs and other senior executives in the Group, were legally prohibited from participating in the programme as they had access to insider information at that particular time. In view of the legal obstacles and to safeguard Sobi's ability to attract and retain senior executives, the Board decided to establish a long-term cash-based incentive programme instead, effective from 1 January 2017. The programme expired on 31 December 2019 and the targets for 2017, 2018 and 2019 were fully met.

2016 Cash-Based Programme (paid in 2019)
The 2016 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 four-year period. The programme expired in 2019 and the outcome for share price performance was 100 per cent, the outcome for sales was also achieved in full.

2017 Share Programme
The 2017 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 revenues during the vesting period must meet or exceed the budget for annual revenues. The performance target was achieved for 2017, 2018 and 2019. The maximum possible allotment of shares is 740,059. 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 41,668.

2017 Cash-Based Programme
The 2017 AGM adopted a long-term cash-based programme to cover all employees in the US and Canada, of which one senior executive participates in the programme. 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 four-year period.

2017 Share Programme

	Number of performance shares	Number of matching shares	Value in SEK K
CEO and other senior executives in the Group (5)	228,130	–	7,521
Total	**228,130**	**–**	**7,521**

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 revenues during the vesting period must meet or exceed the budget for annual revenues. The performance target was achieved for 2018 and 2019. The maximum possible allotment of shares is 715,346. 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 38,490.

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 for new employees since the roll-out of LTI 2018A. The maximum allotment of shares in LTI 2018B programme is 31,944 for mangement and 3,838 for employees.

2018 Cash-Based Programme
The 2018 AGM adopted a long-term cash-based programme to cover all employees in the US and Canada, of which one senior executive participates in the programme. 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 four-year period.

2018 Share Programme

	Number of performance shares	Number of matching shares	Value in SEK K
CEO and other senior executives in the Group (9)	238,523	–	11,317
Total	**238,523**	**–**	**11,314**

Note 11, cont.

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.

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 revenues during the vesting period must meet or exceed the budget for annual revenues. 100 per cent of the performance target for 2019 was achieved. The maximum possible allotment of shares is 807,824. 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 41,726.

2019 Employee 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 1,420,154. 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 adopted a long-term cash-based programme to cover all employees in the US and Canada, of which one senior executive participates in the programme. 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 four-year period.

2019 Share Programme

	Number of performance shares	Number of matching shares	Value in SEK K
CEO and other senior executives in the Group (10)	210,891	–	8,573
Total	210,891	–	8,573

Expensing of the 2017–2019 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 [1]	Fair value of performance share[2]	Expected employee turnover, %	Max. allotment of shares	Forfeited shares 2019
2017 Share Programme:[1] All Employee	9 May 2017	9 May 2020	41,668	n/a	36	136.85	n/a	n/a	5	41,668	2,598
2017 Share Programme:[2] Management	19 May 2017	19 May 2020	n/a	740,059	36	n/a	54.95	136.85	6	740,059	26,470
2018 Share Programme:[1] All Employee	11 May 2018	11 May 2021	38,490	n/a	36	184.32	n/a	n/a	7	38,490	2,460
2018 Share Programme:[2] Management	11 May 2018	11 May 2021	n/a	715,346	36	n/a	79.75	184.32	7	715,346	26,686
2018B Share Programme: All Employee	1 Nov. 2018	1 Nov. 2021	3,838	n/a	36	185.6	n/a	n/a	7	3,838	152
2018B Share Programme: Management	1 Nov. 2018	1 Nov. 2021	n/a	31,944	36	n/a	66.92	185.6	7	31,944	1,817
2019 Share Programme:[1] All Employee	28 May 2019	28 May 2022	41,726	n/a	36	179.26	n/a	n/a	7	41,726	560
2019 Share Programme:[2] Management	28 May 2019	28 May 2022	n/a	807,824	36	n/a	67.75	173.5	7	807,824	18,963

1. Fair value of performance shares linked to share price development, see 2017, 2018 and 2019 Share Programmes above.
2. Fair value of performance shares linked to revenues, see 2017, 2018 and 2019 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.

12 Remuneration of auditors

GROUP	2019	2018
EY		
Auditing assignments[1]	–9	–5
Audit activities in addition to the auditing assignment	–1	–1
Tax consultancy	0	0
Other services	0	0
Total EY	**–10**	**–6**

PARENT COMPANY	2019	2018
EY		
Auditing assignments[1]	–4	–2
Audit activities in addition to the auditing assignment	–1	–1
Tax consultancy	0	0
Other services	0	–1
Total EY	**–5**	**–4**

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

13 Costs according to type of cost

GROUP	2019	2018
Raw materials and consumables	–2,962	–2,056
Other external costs	–2,763	–1,860
Costs for remuneration of employees	–2,452	–1,616
Depreciation/amortisation and impairment[1]	–1,588	–485
Other operating expenses	–18	–6
Total	**–9,783**	**–6,023**

PARENT COMPANY	2019	2018
Raw materials and consumables	–2,831	–1,995
Other external costs	–4,404	–1,646
Costs for remuneration of employees	–891	–765
Depreciation/amortisation and impairment[1]	–381	–321
Other operating expenses	–10	–7
Total	**–8,517**	**–4,734**

1. Increase in depreciation during the year is explained by acquired assets.

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

14 Financial income

GROUP	2019	2018
Interest income[1]	5	3
Exchange-rate gains[2]	–	17
Total	**5**	**20**

PARENT COMPANY	2019	2018
Interest income, Group companies	346	20
Interest income, other	2	1
Exchange-rate gains[2]	–	13
Total	**348**	**35**

1. According to effective interest method.
2. Exchange-rate effects are recognised net and amounted to a loss in 2019, and a gain in 2018. See Note 15. For 2019, SEK 0 M (–48) is attributable to derivatives measured at fair value through profit or loss. Other items are measured at amortised cost using the effective interest method.

15 Financial expenses

GROUP	2019	2018
Interest expense, borrowings[1]	–182	–16
Interest expense, other[2]	–59	–40
Exchange-rate losses[3]	–31	–
Management costs[1]	–18	–2
Other	–1	–1
Total	**–291**	**–60**

PARENT COMPANY	2019	2018
Interest expense, Group companies	–11	–11
Interest expense, borrowings[1]	–184	–16
Interest expense, other[2]	–30	–40
Exchange-rate losses[3]	–42	–
Management costs[1]	–18	–2
Other	–1	–1
Total	**–287**	**–69**

1. According to effective interest method.
2. Refers to interest expense on loans from Sanofi and AstraZeneca.
3. Includes realised and unrealised exchange-rate effects of SEK –42 M (0) from derivatives in 2019.

16 Income tax

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

GROUP	2019	2018
Current tax		
Current tax on profit for the year[1]	–449	–765
Adjustment of tax prior years[1]	1	–1
Total current tax reported for the Group	**–449**	**–767**
Deferred tax		
Excess depreciation[2]	–805	–65
Inventories	137	65
Sale of PRV (priority review voucher)[3]	125	–
Acquired product rights	81	–10
Other intangible assets	–8	–8
Tax loss carry-forwards	–43	84
Pharmaceutical tax	11	3
Change in depreciation method	–	20
Other	7	13
Total deferred tax reported for the Group	**–494**	**103**
Total tax reported for the Group	**–942**	**–664**

PARENT COMPANY	2019	2018
Current tax		
Current tax on profit for the year[1]	–318	–698
Adjustment of tax prior years[1]	2	–1
Total current tax reported for the Parent Company	**–316**	**–700**
Deferred tax		
Change in depreciation method	–	20
Other	4	2
Total deferred tax reported for the Parent Company	**4**	**22**
Total tax reported for the Parent Company	**–313**	**–678**

Reconciliation of effective tax

GROUP	2019	2018
Profit before tax	**4,247**	**3,082**
Tax at applicable tax rate for the Parent Company[4]	–909	–678
Tax effect from non-deductable/non-taxable items		
Utilisation of non-capitalised tax losses carry forward	49	–
Non-capitalised tax losses carry forward	–73	–
Changed tax rate in Sweden[4]	31	41
Difference foreign tax rates	0	–11
Non-deductible expenses	–49	–24
Adjustment of tax prior years	1	–1
Other	8	10
Total recognised effective tax for the Group	**–942**	**–664**

PARENT COMPANY	2019	2018
Profit before tax	**1,431**	**3,060**
Tax at applicable tax rate for the Parent Company[4]	–306	–673
Tax effect from non-deductable/non-taxable items		
Changed tax rate in Sweden[4]	0	–1
Controlled Foreign Company taxation	–2	–2
Non-deductible expenses	–7	–5
Adjustment of tax prior years	2	–1
Other	1	4
Total recognised effective tax for the Parent Company	**–313**	**–678**

1. In addition to current tax recognised in earnings, current tax of SEK –12 M (38) has been recognised in other comprehensive income, related to exchange rate effects on the Parent Company's liabilities/derivates in other comprehensive income. Additionally, current tax of SEK 42 M (–) has been recognised directly in equity, related to the Parent Company's long-term incentive programme (deferred tax of SEK 8 M has also been recognised directly in equity, see note 21 for other deferred tax items).
2. The increase in excess depreciation compared to 2018 relates to products aquired during the year.
3. See also note 33.
4. The current tax rate for the Swedish Parent Company amounts to 21.4 per cent (22), but is reduced to 20.6 per cent from 2021. Deferred tax has been valued using the applicable tax rate for the period that reversal/resolution is expected to occur.

Non capitalised tax loss carry-forwards

GROUP	2019	2018
Tax loss carry-forwards for which no deferred tax asset has been recognised	2,212	–
Potential tax benefit	480	–

Of non-capitalised tax loss carry-forwards, SEK 1,246 M are due within the next seven years and the other tax loss carry-forwards have an unlimited life. A deferred tax asset has not been recognised as it is considered uncertain if the tax loss carry-forwards, attributable to subsidaries and previous years, have a tax value to the Group.

17 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 2018						
Opening accumulated cost	1,554	561	6,797	139	51	9,102
Investments[1]	—	—	4,186	16	27	4,229
Disposals[2]	—	–11	—	—	—	–11
Reclassification	—	—	–75	72	–2	–5
Exchange differences	—	0	–59	0	—	–59
Closing cost	**1,554**	**550**	**10,850**	**227**	**76**	**13,256**
Opening accumulated amortisation and write-downs	—	–388	–2,172	–97	—	–2,657
Amortisation	—	–39	–387	–23	—	–449
Disposals[2]	—	8	—	—	—	8
Exchange differences	—	0	—	0	—	0
Closing accumulated amortisation and write-downs	**—**	**–418**	**–2,559**	**–120**	**—**	**–3,097**
Closing carrying amount	**1,554**	**132**	**8,291**	**106**	**76**	**10,159**
1 January–31 December 2019						
Opening accumulated cost	1,554	550	10,850	227	76	13,256
Investments[1]	—	3	15,686	74	260	16,023
Acquisition of business[3]	5,293	35	7,555	11	—	12,895
Disposals[2]	—	–16	—	–58	—	–74
Reclassification	—	—	—	3	0	3
Exchange differences	–169	0	–88	0	—	–257
Closing cost	**6,678**	**572**	**34,003**	**258**	**336**	**41,846**
Opening accumulated amortisation and write-downs	—	–418	–2,559	–120	—	–3,097
Amortisation	—	–38	–1,305	–39	—	–1,382
Write-downs[4]	—	–18	—	—	—	–18
Disposals[2]	—	7	—	57	—	65
Exchange differences	—	0	0	0	—	0
Closing accumulated amortisation and write-downs	**—**	**–467**	**–3,864**	**–102**	**—**	**–4,434**
Closing carrying amount	**6,678**	**104**	**30,139**	**155**	**336**	**37,412**

1. Investments 2019 refer to the acqusition of Synagis SEK 13,689 M, BIVV001 rights of SEK 1,817 M and capitalised IT costs. Investments 2018 were mainly related to investments in emapalumab.
2. Disposals 2019 refer to licences and various IT projects. Disposals 2018 referred to terminated contracts.
3. Acquisition of business 2019 refers to goodwill, SEK 4,391 M related to the acquisition of Dova and SEK 902 M related to the acquisition of emapalumab. (Priority Review Voucher (PRV) was not classified as intangible asset). Acquired product and marketing rights refers to Doptelet, SEK 7,555 M, see Note 33.
4. Refers to write-down of one of the early-phase clinical programmes.
5. Capitalised costs comprises IT projects and costs to relocate manufacturing of active substance. Items under capitalised costs are amortised according to plan.

Note 17, cont.

PARENT COMPANY	Licenses and patents	Product and marketing rights	Capitalised costs[1]	Ongoing capitalised costs[1]	Total
1 January–31 December 2018					
Opening accumulated cost	65	4,851	132	50	5,099
Investments[2]	—	—	16	27	43
Disposals[3]	–11	—	—	—	–11
Reclassification	—	–75	72	–2	–5
Closing cost	**54**	**4,776**	**220**	**75**	**5,125**
Opening accumulated amortisation and write-downs	–25	–923	–93	—	–1,041
Amortisation	–6	–262	–23	—	–292
Disposals	8	—	—	—	8
Closing accumulated amortisation and write-downs	**–23**	**–1,185**	**–116**	**—**	**–1,325**
Closing carrying amount	**30**	**3,591**	**104**	**75**	**3,801**
1 January–31 December 2019					
Opening accumulated cost	54	4,776	220	75	5,125
Investments[2]	3	1,817	74	207	2,101
Disposals[3]	–16	—	–58	—	–74
Reclassification	—	—	3	0	3
Closing cost	**40**	**6,593**	**240**	**282**	**7,155**
Opening accumulated amortisation and write-downs	–23	–1,185	–116	—	–1,325
Amortisation	–3	–262	–39	—	–304
Write-downs[4]	–18	—	—	—	–18
Disposals[3]	7	—	57	—	65
Closing accumulated amortisation and write-downs	**–37**	**–1,447**	**–98**	**—**	**–1,583**
Closing carrying amount	**3**	**5,146**	**141**	**282**	**5,572**

1. Capitalised costs comprises IT projects and costs to relocate manufacturing of active substance. Items under capitalised costs are amortised according to plan.
2. Investments 2019 mainly refer to the acqusition of product and marketing rights, BIVV001 of SEK 1,817 M and capitalised IT costs. Investments 2018 were mainly IT related.
3. Disposals 2019 refer to licences and various IT projects. Disposals 2018 referred to terminated contracts.
4. Refers to write-downs of one of the early-phase clinical programmes.

17

IMPAIRMENT TESTING OF INTANGIBLE ASSETS

Goodwill

The assessment of the value of the Group's goodwill is based on value in use for the smallest cash-generating unit, which for Sobi is deemed to be the Group (excluding ReFacto).

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 includes 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. At 31 December 2019, Sobi's goodwill amounted to SEK 6,678 M (1,554). 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, %	2019	2018
Growth rate beyond the initial five-year period	2	2
Discount rate before tax	10.2	11.5
Discount rate after tax	8.0	9.0

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: 6.6 per cent (6.3).
- Beta coefficient: Sobi's beta coefficient is 1.26 (1.31).
- Interest expense: according to Sobi's borrowing cost.
- Tax rate: according to the tax rate in Sweden, except where revenues are taxed in another country.

Sobi has conducted a sensitivity analysis for the following variables in the impairment testing of goodwill: the discount rate, margin, sales volume and eternal growth rate. The sensitivity analysis indicates that there are good margins in the calculation.

Product and marketing rights

Significant product and marketing rights and their related development projects are tested annually for impairment. Products were reviewed for impairment individually. 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. The review of product and marketing rights showed no indication of impairment.

When testing development projects for impairment in relation to product or marketing rights, the key parameters are future cash flows from the individual asset, the likelihood of achieving positive outcomes in clinical trials and assumptions of 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 likelihood that the project will be commercialised. The earlier

Note 17, cont.

in the chain of development the project is, the higher the risk. As it passes through the defined phases of development, the likelihood of reaching the market increases. The 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. A best-case assumption is made on the basis of the parameters with the greatest effect on whether the project will develop into a drug with the highest possible 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.

Write-downs in 2019
In 2019, write-down of SEK 18 M was recognised for one of the early-phase clinical programmes. The write-down had a negative impact on intangible assets. There were no write-downs in 2018.

CONTRACTUAL COMMITMENTS RELATED TO INTANGIBLE ASSETS
Sobi has undertaken to make additional payments under certain acquisition and licensing agreements (often referred to as milestone payments) linked to the achievement of certain defined targets. The most significant agreements are listed below.

AGREEMENT WITH SANOFI, FORMERLY BIOVERATIV
Under the agreement between Sobi and Sanofi regarding the development and commercialisation of Elocta and Alprolix, Sanofi took full responsibility for development and production, plus associated costs, until Sobi exercised its opt-in right to the programmes. There are similar arrangements in place with Sanofi for programmes BIVV001 and BIVV002. Sobi exercised its opt-in rights to BIVV001 in 2019.

Under Sobi's opt-in rights to the development and commercialisation of the programmes, Sobi obtained the commercial rights for Europe, North Africa, Russia and certain countries in the Middle East (Sobi's territory). Sanofi has 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). Sobi and Sanofi receive a royalty on each other's sales of Elocta/Eloctate and Alprolix in the respective company's territory according to the royalty rates set out in the table below.

Sobi elected to assume responsibility for the final regulatory process and other commercialisation activities in Sobi's territory by paying a deposit of USD 10 M per programme – for Elocta in 2014, and Alprolix in 2015.

Liability arising from development programmes
On taking over commercialisation and the regulatory process, Sobi became liable to reimburse Sanofi for 50 per cent of the development and production costs arising for each programme from 1 October 2009.

Sobi reimbursed 100 per cent of the development activities that only benefited Sobi's territory.

Debt settlement
Sobi's reimbursement to Sanofi for each development programme takes the following three forms:

- When regulatory approval was granted in the EU, a deposit of USD 10 M per product was transferred to Sanofi and offset against Sobi's liability.
- With the first commercial sales of each of its products, Sobi was able to credit retroactive royalty revenue corresponding to the difference between the base rate and the 2 per cent Sobi had already received on Sanofi's sales. This amount was offset against the liability and generated non-recurring revenue that did not affect cash flow.
- From Sobi's first commercial sales, the royalty rates between the companies are adjusted until the liability has been repaid in full (see the table).
- If full payment has not been made within six years of Sanofi's first commercial sales for each programme, Sanofi is entitled to request that Sobi pay the remaining amount within 90 days of the sixth anniversary of the date of Sanofi's first commercial sales.

Elocta
On 24 November 2015, Sobi and Sanofi announced that the European Commission approved Elocta for the treatment of haemophilia A in all 28 EU member states as well as Iceland, Liechtenstein and Norway. The liability for the development and commercialisation of Elocta was repaid in full in the third quarter of 2019.

Alprolix
The total liability for the development and commercialisation of Alprolix is USD 185 M. On 13 May 2016, Sobi and Sanofi announced that the European Commission approved Alprolix for the treatment of haemophilia B in all 28 EU member states, plus Iceland, Liechtenstein and Norway. In connection with the approval, the deposit was transferred to Sanofi and offset against the liability. In connection with its first commercial sales in June 2016, Sobi credited a retroactive royalty revenue of SEK 386 M against the liability. At 31 December 2019, the remaining liability was SEK 475 M (USD 51 M), corresponding to the discounted value of the nominal liability, which amounted to USD 52 M.

Percentage rates for royalties and reimbursement between the companies

		Percentage rates after initial commercial sales in Sobi's territory if Sobi exercises its opt-in right[1]		
	Method	Base rate[1], %	Adjusted royalty rate during repayment period[1]	Net royalty payment during the repayment period[2], %
From Sobi to Sanofi based on net sales in Sobi's territory	Royalty on sales	12	Base rate plus 5%	17
Sanofi to Sobi based on net sales in North America	Royalty on sales	12	Base rate minus 5%	7
Sanofi to Sobi based on net sales in Sanofi's territories outside North America	Royalty on sales	17	Base rate minus 5%	12
Sanofi to Sobi based on net profit[3] from Sanofi's distribution territory[4]	Royalty on net profit	50	Base rate minus 15%	35

1. Base rate impacts earnings. Repayment of the liability comprises the difference between the base rate and the adjusted royalty.
2. Actual payments that impact cash flow.
3. Net profit relates to Sanofi's revenue before tax from distributors (third parties), less costs incurred by Sanofi for supporting this sale.
4. Sanofi's distribution territory pertains to the territory in which sales are conducted through a third party.

Note 17, cont.

BIVV001 (rFVIIIFc-VWF-XTEN)
In September 2014, Sobi decided to include the preclinical development programme for the potentially long-acting haemophilia A treatment BIVV001 (rFVII-IFc-VWF-XTEN) in the agreement with Sanofi. Under the agreement between Sobi and Sanofi, Sobi has 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.

This right was exercised in autumn 2019 through a contract with Sanofi for BIVV001 where Sobi, conditional upon marketing authorisation from the European Commission, will pay a milestone payment corresponding to 50 per cent of the total development costs, estimated to be USD 280–290 M less USD 50 M that has already been paid. For 2019, Sobi recognised SEK 1,817 M as an intangible asset and corresponding liability, less SEK 490 M (USD 50 M) that was paid in 2019. Fair value of the liability amounted to SEK 1,273 M at 31 December 2019.

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

OTHER AGREEMENTS

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

- Under a contract with Eisai, Sobi will pay up to USD 135 M (approximately SEK 1.3 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 license agreement with Astellas, Sobi will make additional milestone payments of up to USD 3 M (approximately SEK 28 M) to Astellas if certain regulatory milestones are achieved. In addition, Sobi will pay royalties to Astellas based on net sales of Doptelet in the corresponding mid-to-high single-digit percentage range.
- 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 123 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 candidate drug MEDI8897 (Nirsevimab) in the US market. The upfront consideration was approximately USD 1,500 M (SEK 13.5 billion). In addition, Sobi will pay USD 20 M (approx. SEK 186 M) in cash per year for 2020 and 2021 at the end of each year. These obligations are recognised as financial liabilities on the balance sheet.

Provided that some terms related to sales of Synagis are met, sales-related milestones of up to USD 470 M (approximately SEK 4.4 billion) may be paid as of 2026. Sobi may also pay USD 175 M (approximately SEK 1.6 billion) when a Biologics License Application (BLA) for MEDI8897 is submitted to the FDA. The agreement also includes possible net payments of about USD 110 M (approx. SEK 1.0 billion) on achievement of other MEDI8897 profit and development-related milestones. If payable, these are expected from 2023 onwards.

Emapalumab
On 18 July 2019, Sobi completed the acquisition of a newly established company that owned emapalumab and related assets. Due to the acquisition, the previously announced license agreement with Novimmune was replaced by this agreement. At 31 December 2019, there were no other obligations remaining from previous agreements.

18 Tangible assets

GROUP	Plant and machinery	Equipment, tools, fixtures and fittings	Other non-current assets	Construction in progress	Right-of-use assets	Total
1 January–31 December 2018						
Opening accumulated cost	463	234	15	21	—	733
Investments	2	10	2	26	—	41
Reclassification	33	6	—	–39	—	1
Disposals	–33	–6	–6	—	—	–45
Exchange differences	0	1	—	—	—	1
Closing cost	**466**	**245**	**12**	**9**	**—**	**731**
Opening accumulated depreciation and write-downs	–392	–202	–5	—	—	–599
Depreciation	–19	–15	–2	—	—	–36
Reclassification	—	–1	—	—	—	–1
Disposals	33	6	3	—	—	42
Exchange differences	0	–1	—	—	—	–1
Closing accumulated depreciation and write-downs	**–377**	**–212**	**–5**	**—**	**—**	**–594**
Closing carrying amount	**88**	**33**	**7**	**9**	**—**	**136**
1 January–31 December 2019						
Opening accumulated cost	466	245	12	9	—	731
Changed accounting principle	—	—	—	—	412	412
Investments	18	16	—	3	92	129
Acquisition of business	19	3	3	—	10	35
Disposals	–19	–85	–2	—	–2	–108
Reclassification	–1	–2	4	–3	—	–2
Exchange differences	0	1	—	—	2	3
Closing cost	**483**	**178**	**16**	**8**	**515**	**1,200**
Opening accumulated depreciation and write-downs	–378	–212	–5	—	—	–594
Depreciation	–22	–13	–2	—	–90	–128
Write-downs[1]	–32	—	—	—	–30	–62
Acquisition of business	—	0	–1	—	0	–1
Disposals	18	84	1	—	0	104
Reclassification	—	1	–1	—	—	—
Exchange differences	–5	5	0	—	0	0
Closing accumulated depreciation and write-downs	**–418**	**–135**	**–8**	**—**	**–120**	**–682**
Closing carrying amount	**65**	**43**	**8**	**8**	**395**	**518**

1. Write-downs 2019 refer to write-down of plant and machinery and right-of-use assets related to premises used for early-phase clinical programmes terminated during the year.

As defined in the table above, property, plant and equipment also includes right-of-use assets, i.e. leased assets prior to the adoption of IFRS 16, which came into effect on 1 January 2019. Associated lease liabilities are presented in Note 28 and additional information regarding leases in Note 10.

Note 18, cont.

PARENT COMPANY	Plant and machinery	Equipment, tools, fixtures and fittings	Other non-current assets	Construction in progress	Total
1 January–31 December 2018					
Opening accumulated cost	458	202	5	21	686
Investments	—	—	—	26	26
Disposals	–33	–6	—	—	–39
Reclassification	33	6	—	–39	—
Closing cost	**458**	**202**	**5**	**9**	**674**
Opening accumulated depreciation and write-downs	–385	–185	–2	—	–572
Depreciation	–19	–10	–1	—	–29
Disposals	33	6	—	—	39
Closing accumulated depreciation and write-downs	**–371**	**–189**	**–3**	**—**	**–562**
Closing carrying amount	**87**	**14**	**3**	**9**	**112**
1 January–31 December 2019					
Opening accumulated cost	458	202	5	9	674
Investments	11	1	—	3	15
Reclassification	–18	–83	—	—	–101
Disposals	—	0	—	–3	–3
Closing cost	**451**	**121**	**5**	**8**	**585**
Opening accumulated depreciation and write-downs	–371	–189	–3	—	–562
Depreciation	–19	–7	–1	—	–27
Write-downs[1]	–32	—	—	—	–32
Disposals	18	83	—	—	101
Closing accumulated depreciation and write-downs	**–404**	**–113**	**–3**	**—**	**–520**
Closing carrying amount	**47**	**8**	**2**	**8**	**65**

1. Write-downs 2019 refer to write-down of plant and machinery used for early-phase clinical programmes terminated during the year.

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19 Participations in Group companies

PARENT COMPANY	2019	2018
Accumulated cost		
At beginning of year	4,652	4,060
Investment[1]	4,201	592
Total	**8,853**	**4,652**
Closing book value		
Accumulated impairment		
At beginning of year	–1,177	–1,177
Total	**–1,177**	**–1,177**
Carrying amount at end of period	**7,676**	**3,475**

1. Investment for the year, SEK 4,201 M, relates to the acquisition of Dova and the investment in Sobi US Holding Corp. made up of three legal entities shown in the following specification. In the sub-group, the parent company Swedish Orphan Biovitrum International AB has created two new subsidiaries, Sobi Pharma (Guangzhou) Company Limited, in China, and Swedish Orphan Biovitrum Unipessoal Lda, in Portugal. Last years investment of SEK 592 M referred to the acqusition of the rights to emapalumab, made through the swiss subsidiary. Through an internal restructuring in 2019, this subsidiary is now a subsidiary company to Swedish Orphan Biovitrum AB.

Note 19, cont.

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

SUBSIDIARY/CORP. REG. NO./REGISTERED OFFICE	Number 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			
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, US	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. Book value i SEK K.

20 Financial assets

GROUP	2019	2018
Accumulated cost		
At beginning of year	55	35
Endowment insurance[1]	0	14
Financial receivables	2	2
Returned deposit	–3	–1
Fair value hedges	–5	5
Accumulated cost	**50**	**55**
Carrying amount at end of period	**50**	**55**

PARENT COMPANY	2019	2018
Accumulated cost		
At beginning of year	52	32
Endowment insurance[1]	0	14
Fair value hedges	–5	5
Accumulated cost	**47**	**52**
Carrying amount at end of period	**47**	**52**

1. Endowment insurance amounts to SEK 47 M as per dec 2019, for corresponding debt see Note 30.

21 Deferred tax assets and deferred tax liabilities

Deferred tax assets and liabilities

GROUP 2019	Deferred tax assets	Deferred tax liabilities	Net
Excess depreciation	—	–1,338	–1,338
Inventories	318	—	318
Acquired product- and market-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**

GROUP 2018	Deferred tax assets	Deferred tax liabilities	Net
Excess depreciation	—	–532	–532
Inventories	181	—	181
Acquired product rights	—	–263	–263
Other intangible assets	61	—	61
Tax loss carry-forwards	86	—	86
Pharmaceutical tax	6	—	6
Other	28	—	28
Total	**362**	**–795**	**–433**
Offsetting	–131	131	—
Tax assets/liabilities, net	**231**	**–664**	**–433**

The Parent Company's total deferred tax asset amounted to SEK 22 M (11), mainly comprising a deferred tax asset of SEK 13 M (12) related to pension provisions and a deferred tax asset of SEK 8 M (–) related to long-term incentive programmes. Deferred tax has been valued at enacted future tax rate in Sweden, see Notes 2 and 16.

Change in deferred tax

GROUP 2019	Amount at beginning of year	Recognised in profit or loss	Recognised in other comprehensive income	Recognised directly through equity	Increase through acquisition of business	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 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 rights compared to 2018 refer to product rights acquired during the year.
2. This year's deferred tax on loss carry-forwards relates to foreign losses accumulated during the year expected to be utilised as well as resolution of last year's deferred tax on loss carry-forwards, that has either been utilised or deemed to no longer have any value, see also Note 4.

GROUP 2018	Amount at beginning of year	Recognised in profit or loss	Recognised in other comprehensive income	Recognised directly through equity	Increase through acquisition of business	Amount at end of year
Excess depreciation	–467	–65	—	—	—	–532
Inventories	116	65	—	—	—	181
Acquired product rights	–252	–10	–1	—	—	–263
Other intangible assets	69	–8	—	—	—	61
Tax loss carry-forwards	—	84	2	—	—	86
Pharmaceutical tax	3	3	0	—	—	6
Change in depreciation method	–20	20	—	—	—	—
Other	15	13	0	—	—	28
Total	**–536**	**103**	**1**	**—**	**—**	**–433**

22 Inventories

GROUP	2019	2018
Raw materials and consumables	13	17
Work in progress	775	581
Finished goods and goods for resale	985	686
Total	**1,772**	**1,284**

The cost of inventories recognised as an expense is included in cost of goods sold and amounted to SEK 2,962 M (2,056).

PARENT COMPANY	2019	2018
Raw materials and consumables	13	17
Work in progress	775	581
Finished goods and goods for resale	745	472
Total	**1,533**	**1,071**

The cost of inventories recognised as an expense is included in cost of goods sold and amounted to SEK 2,831 M (1,995).

23 Account and other receivables

GROUP	2019	2018
Account receivables	3,804	1,735
Minus: Provision for expected credit losses	–69	–70
Account receivables, net	**3,736**	**1,665**
Tax assets	35	15
Other receivables	495	78
Total other receivables	**530**	**93**
Total account and other receivables	**4,266**	**1,758**

PARENT COMPANY	2019	2018
Account receivables	2,410	598
Minus: Provision for expected credit losses	–8	–8
Account receivables, net	**2,402**	**590**
Tax assets	27	1
Other receivables	422	56
Total other receivables	**449**	**57**
Total account and other receivables	**2,851**	**647**

Sobi's single largest customers are MedImmune LLC and Sanofi, in addition to these, Sobi 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. The Group's exposure to future credit losses is continuously monitored by country and by 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 includes information about customers' payment terms.

At 31 December 2019, overdue customer receivables for the Group amounted to SEK 685 M (518), on which SEK 69 M (70) are included in the provision for future credit losses. Actual credit losses of SEK 751 K were charged to profit for the year, of which SEK 275 K was attributable to the Parent Company.

Changes in the provisions for expected credit losses are as follows:

Expected credit losses

GROUP	2019	2018
At beginning of year	–70	–35
Provision for expected credit losses	–24	–41
Reversed provisions	25	6
At end of year	**–69**	**–70**

PARENT COMPANY	2019	2018
At beginning of year	–8	–8
Provisions for expected credit losses	–22	–2
Reversed provisions	22	2
At end of year	**–8**	**–8**

Maturity analysis

GROUP	2019	2018
Not past due	3,051	1,147
Past due 1–30 days	459	371
Past due 31–90 days	130	80
Past due 91–120 days	53	10
Past due > 121 days	43	56
Total	**3,736**	**1,665**

PARENT COMPANY	2019	2018
Not past due	2,246	439
Past due 1–30 days	141	142
Past due 31–90 days	13	6
Past due 91–120 days	2	2
Past due > 121 days	0	1
Total	**2,402**	**590**

Note 23, cont.

Recognised amount per currency for account receivables and other receivables

GROUP	2019	2018
CHF	136	44
CZK	9	2
DKK	10	34
EUR	1,003	1,134
GBP	117	122
NOK	36	38
RON	7	10
SEK	807	191
USD	2,138	162
Other currencies	2	20
Total	**4,266**	**1,758**

PARENT COMPANY	2019	2018
CHF	85	38
CZK	9	1
DKK	10	34
EUR	238	294
GBP	0	–
NOK	36	38
RON	7	10
SEK	807	192
USD	1,662	26
Other currencies	–1	14
Total	**2,851**	**647**

24 Prepaid expenses and accrued income

GROUP	2019	2018
Accrued royalty revenue[1]	358	364
Prepaid rents	15	22
Prepaid insurance expenses	22	1
Accrued interest income	1	43
Prepaid IT licenses	25	18
Prepaid fees, regulatory authorities	–	19
Other prepaid expenses	127	94
Total	**548**	**561**

PARENT COMPANY	2019	2018
Accrued royalty revenue[1]	358	364
Prepaid rents	20	16
Prepaid insurance expenses	10	–
Accrued interest income	–	43
Prepaid IT licenses	25	18
Prepaid fees, regulatory authorities	–	19
Other prepaid expenses	86	71
Total	**499**	**532**

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

25 Cash and cash equivalents

	2019		2018	
GROUP	Fair value	Carrying amount	Fair value	Carrying amount
Cash and cash equivalents	737	737	2,999	2,999
Total	**737**	**737**	**2,999**	**2,999**

	2019		2018	
PARENT COMPANY	Fair value	Carrying amount	Fair value	Carrying amount
Cash and cash equivalents	431	431	2,762	2,762
Total	**431**	**431**	**2,762**	**2,762**

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

26 Financial assets and liabilities per category

	Assets measured at amortised cost	Assets measured at fair value through profit or loss	Derivatives	Total
31 December 2019				
Assets on the balance sheet				
Account receivables	3,736	–	–	3,736
Endowment insurance	–	47	–	47
Derivatives[1]	–	–	57	57
Cash and cash equivalents	737	–	–	737
Total	**4,473**	**47**	**57**	**4,577**
31 December 2018				
Assets on the balance sheet				
Account receivables	1,665	–	–	1,665
Endowment insurance	–	47	–	47
Derivatives[1]	–	–	15	15
Fair value hedges	–	5	–	5
Cash and cash equivalents	2,999	–	–	2,999
Total	**4,664**	**52**	**15**	**4,731**

	Liabilities at amortised cost	Liabilities measured at fair value	Derivatives	Total
31 December 2019				
Liabilities on the balance sheet				
Borrowings	16,141	–	–	16,141
Lease liabilities	419	–	–	419
Derivatives[2]	–	–	60	60
Account payables	681	–	–	681
Liability Sanofi	–	1,273	–	1,273
Contingent consideration	–	388	–	388
Milestone obligation	1,177	–	–	1,177
Other liabilities	1,363	–	–	1,363
Total	**19,782**	**1,661**	**60**	**21,503**
31 December 2018				
Liabilities on the balance sheet				
Lease liabilities	4	–	–	4
Derivatives[2]	–	–	8	8
Account payables	487	–	–	487
Other liabilities	4,887	–	–	4,887
Total	**5,378**	**–**	**8**	**5,386**

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

1. Of the 2019 derivatives, SEK 57 M (8) is measured at fair value through profit or loss, and SEK 0 M (7) is included in cash-flow hedges. Classified as other liabilities in the balance sheet.
2. Of the derivative liabilities 2019, SEK 60 M (5) is a fair value hedge and SEK 0 M (3) is included in cash-flow hedges. Classified as other liabilities in the balance sheet.

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 using significant, non-observable data (level 3)
The table below shows the significant, non-observable data used for determining fair value in level 3 instruments.

	Fair value				Effect on fair value if	
	2019	2018	Espected cash flow	Discount rate	Discount rate +1%	Notional cash flow +10%
Contingent consideration	388	0	417	5%	–5	39
Liability to Sanofi	1,273	0	1,473	4%	–51	127

AT 31 DECEMBER 2019	Level 1	Level 2	Level 3	Total
Financial assets measured at fair value through profit or loss				
Derivatives held for sale	—	–4	—	–4
Endowment insurances	—	—	47	—
Liabilities	—	—	–1,661	—
Total assets	—	–4	–1,614	–4

AT 31 DECEMBER 2018	Level 2	Level 3	Total
Financial assets measured at fair value through profit or loss			
Derivatives held for sale	2	—	2
Derivative instruments used for hedging purposes	4	—	4
Total assets	7	—	7

All derivatives are measured at fair value based on market data in accordance with IFRS. At 31 December 2019, the carrying net amount of derivatives on the balance sheet was SEK –4 M (7).

27 Borrowings

During 2019, Sobi raised new credit facilities to finance the company's acquisitions of emapalumab and Dova. The loan agreement of EUR 390 M raised in July matures in 2021. In November, loans of additional EUR 280 M and SEK 3,000 M with a term of five years were raised. The company has since earlier one loan agreement of EUR 870 M from 2018, as well as SEK 1,000 M that was originally raised in 2016. For time of expiry, see further under Note 3. The acquisition of Synagis in January 2019 was partly financed through the loan agreement of EUR 870 M from 2018. Sobi also has an overdraft facility of SEK 135 M with a term of up to three months.

GROUP	2019	2018
Debt to banks and credit institution	16,141	—
Total	16,141	—

PARENT COMPANY	2019	2018
Debt to banks and credit institution	16,141	—
Total	16,141	—

Specification per currency, converted to SEK M

GROUP	2019	2018
Currency		
EUR	7,669	—
SEK	5,398	—
USD	3,074	—
Total	16,141	—

PARENT COMPANY	2019	2018
Currency		
EUR	7,669	—
SEK	5,398	—
USD	3,074	—
Total	16,141	—

28 Other liabilities, current and non-current

GROUP	2019	2018
Non-current		
Liability to Sanofi	1,273	428
Liability to AstraZeneca	170	—
Milestone obligation[1]	1,177	—
Total	**2,620**	**428**
Current		
Liability to Sanofi	475	677
Liability to AstraZeneca	178	—
Liability to Novimmune	—	3,640
Unbilled goods received	77	29
Contingent consideration Dova[2]	388	—
Other	523	114
Total	**1,641**	**4,459**

PARENT COMPANY	2019	2018
Non-current		
Liability to Sanofi	1,273	428
Total	**1,273**	**428**
Current		
Liability to Sanofi	475	677
Unbilled goods received	77	29
Other	72	26
Total	**623**	**731**

1. Under a contract with Eisai, Sobi will pay up to USD 135 M (approximately SEK 1.3 billion) based on annual net sales of Doptelet, calculated per calendar year. This obligation is reported as a financial liability of SEK 1,177 million in the balance sheet.
2. Contigent Value Right (CVR), see Note 33 for more information.

The acquisition of the rights to Synagis included a contract for Sobi to pay USD 20 M to AstraZeneca at the end of 2020 and 2021. These liabilities are measured at amortised cost on the balance sheet.

In autumn 2019, Sobi entered into a contract with Sanofi for BIVV001, see further Note 17, where Sobi, conditional upon marketing authorisation from the European Medicines Agency (EMA), will pay a milestone payment corresponding to 50 per cent of the total development costs, estimated to be USD 280–290 M less USD 50 M that has already been paid. For 2019, Sobi recognised SEK 1,817 M as an intangible asset and corresponding liability, less SEK 490 M (USD 50 M) that was paid in 2019. The liability corresponds to expected discounted liability until payment is received, and fair value amounted to SEK 1,273 M at 31 December 2019.

Following EU approval of Elocta and Alprolix, Sobi acquired the rights to market the products in certain markets. The cost of marketing rights corresponds to 50 per cent of Sanofi's development costs for each product. After revision, the original nominal amounts were USD 211 M for Elocta and USD 185 M for Alprolix. As these liabilities will be repaid over a number of years, it is the discounted values after the repayments that are reflected on the balance sheet, USD 0 M for Elocta and USD 51 M for Alprolix. Alprolix is now recognised as a current liability of SEK 475 M, and Elocta was repaid in full in the third quarter of 2019. The right to market the products in certain markets, recorded as intangible assets, is initially recognised at the same value as the liabilities. If full payment has not been made within six years of the first commercial sale of each product, Sanofi is entitled to request that Sobi pay the remaining amount within 90 days of the sixth anniversary of Sanofi's first commercial sale.

29 Post-employment benefits

Group employees have various forms of pension benefits, either defined-contribution or defined-benefit plans. In Sweden, post-employment benefits are mainly funded by defined-contribution plans. At 31 December 2019, five people in the Norwegian subsidiary, two people in the Swedish Parent Company and 114 people in the Swiss company acquired during the year were covered by defined-benefit plans, while all other employees were covered by defined-contribution pension plans.

Defined-contribution plan by 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 2019 financial year, the company did not have access to sufficient information to report its proportionate share of the plan's obligations, plan assets and expenses, which meant that it has not been possible to report the plan as a defined-benefit plan. The ITP 2 pension plan is therefore reported 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 the next reporting period, expected contributions for ITP 2 plans insured through Alecta amount to SEK 24 M (25). The Group's share of the total plan contributions and the Group's share of the total number of active members in the plan are insignificant.

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 2019, Alecta's surplus in the form of the collective funding ratio was 148 per cent (142).

Some current and former executives are not covered by the premium, so a direct pension is used for that part of the premium which is not deductible. A direct pension is secured by the company undertaking an endowment insurance policy which is credited to the executive.

Defined-benefit pension plan

The defined-benefit pension obligations are calculated annually on the balance-sheet date, based on actuarial principles. Sobi has a defined-benefit pension plan for the subsidiaries in Norway, Switzerland and for two persons in the Parent Company in Sweden.

The present value of the obligation includes special payroll tax, in accordance with IAS 19, for the Swedish, Norwegian and Swiss pension plans.

Pension expenses are recognised under the items of selling costs, administrative expenses and research and development costs.

Risks connected to defined-benefit pension plans

Through its defined-benefit pension plans for post-employment benefits, the Group is exposed to a number of risks. The most significant risks are:

Life expectancy assumption: Most of the pension commitments 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. This is particularly significant in the Swedish plan, in which inflation increases result in higher sensitivity to changes in life expectancy assumptions.

Inflation risk: Some of the plan's pension commitments 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.

Note 29, cont.

Discount rate: A decrease in the interest rate on corporate bonds will increase the liabilities of the plan, although this will partially be offset by an increase in the value of the bond holdings.

The Norwegian pension plan is covered by the Norwegian Corporate Pension Act (Foretagspenjonsloven), the Swiss pension plan is covered by The Swiss Federal Act on Occupational Retirement, Survivor's and Disability Pension Plans (BVG), and the Swedish plan is covered by the Pension Obligations Vesting Act and the consortium agreement. Under the consortium agreement, Sobi is required to allocate the funds required to ensure that the pension assets correspond to Sobi's share of the pension liability.

The Swedish, Norwegian and Swiss plans are based on final salary.

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

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
Current service cost	–6	–	–6
Interest expense	–1	–	–1
Remeasurements:			
Return on plan assets, excl. amounts included in interest expense	–	1	1
Changed financial assumptions	–5	–	–5
Experience-based assumptions	–3	2	–2
Contributions:			
Employer	–	6	6
Settlements	–	–	–
Exchange differences	1	–1	–
At end of year	**–227**	**145**	**–83**

1. Related to business acquisition of emapamulab, see Note 33.

1 JANUARY–31 DECEMBER 2018	Present value of obligations	Fair value of plan assets	Total
At beginning of year	**–41**	**33**	**–9**
Current service cost	–2	–	–2
Interest expense	–1	–	–1
Remeasurements:			
Return on plan assets, excl. amounts included in interest expense	–	1	1
Changed financial assumptions	–1	0	–1
Experience-based assumptions	5	–2	4
Contributions:			
Employer	1	0	1
Settlements	–	0	0
Exchange differences	0	0	0
At end of year	**–39**	**32**	**–7**

Net obligation per country

	2019	2018
Sweden	–1	1
Norway	–10	–8
Switzerland	–72	–
Total	**–83**	**–7**

Actuarial assumptions on the balance-sheet date

SWEDISH PENSION PLAN	2019	2018
Discount rate, %	1.2	2.3
Expected annual inflation, %	2.0	2.0
Remaining life expectancy after retirement age, male, years	20.8	20.8
Remaining life expectancy after retirement age, female, years	23.4	23.4

NORWEGIAN PENSION PLAN	2019	2018
Discount rate, %	2.6	2.6
Expected annual inflation, %	1.5	1.5
Remaining life expectancy after retirement age, male, years	21.3	21.3
Remaining life expectancy after retirement age, female, years	24.4	24.4

SWISS PENSION PLAN	2019	2018
Discount rate, %	0.2	–
Expected annual inflation, %	0.7	–
Remaining life expectancy after retirement age, male, years	22.6	–
Remaining life expectancy after retirement age, female, years	24.7	–

Demographic assumptions

Mortality assumptions for the Swedish plans correspond to the Swedish Financial Supervisory Authority's recommendations, which came into force on 31 December 2007 for the Swedish pension plan, while assumptions for the Norwegian plan are based on the K2013 BE mortality table, and the assumptions for the Swiss plan are based on the BVG2015 mortality table. On the balance-sheet date, Norway had five active employees and Sweden had no active employees and two retired employees. The retirement age is set at 65 years.

Distribution by plan assets

	2019	Quoted, %	2018	Quoted, %
Equity funds[1]	19	100	12	100
Interest-bearing securities	64	100	17	100
Properties	19	–	1	–
Other funds	43	–	3	–
Other	–	–	0	–
Total	**145**		**32**	

1. The pension and its assets are managed by Procordias Pensionsstiftelse. Some of their selected equity funds, such as AMF Aktiefond Sverige, have shareholdings in Sobi.

Note 29, cont.

Sensitivity analysis

	2019	2018
Pension commitments under current assumptions	227	39
Discount rate –0.5%	249	43
Discount rate +0.5%	205	36
Inflation +0.5%	235	43
Inflation –0.5%	220	39
Life expectancy after retirement –1 year	221	36
Life expectancy after retirement +1 year	231	41

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 2020 financial year, contributions to plans for post-employment benefits are expected to be SEK 1,641 K (1,439). The weighted average maturity of the obligation is an estimated 33.5 years.

30 Provisions

	Group		Parent Company	
	2019	2018	2019	2018
Provision at beginning of year	97	98	80	82
Endowment insurance[1]	0	14	–	14
Cash-based incentive programme[2]	0	–17	0	–17
Commitments, leases	0	0	0	–
Restoration reserve[3]	–	0	0	0
Changes in pension commitments	79	–2	4	–
Other	2	4	0	–
Provisions at 31 December	**179**	**97**	**84**	**80**

1. On the balance-sheet date in 2019, endowment insurance amounted to SEK 47 M. For corresponding assets, see Note 20.
2. The Long-Term Cash-Based Incentive Programme in 2018 referred to programmes expired in 2019 and was therefore reclassified during 2018. See Note 11 for further information.
3. Sobi will restore the rented property Paradiset 14 to an acceptable condition with consideration for the operations conducted by the company, in accordance with the Rental Agreement (IAS 16). At 31 December 2019, the company recognised a provision of SEK 34 M on the balance sheet.

	Group		Parent Company	
	2019	2018	2019	2018
Non-current portion	177	96	84	80
Current portion	2	2	–	–
Total provisions	**179**	**97**	**84**	**80**

31 Accrued expenses and deferred income

GROUP	2019	2018
Provision for vacation pay and bonuses, incl. social security contributions	426	322
Accrued social security contributions	155	139
Accrued royalty expense	230	184
Accrued manufacturing costs	152	107
Accrued R&D costs	181	129
Accrued interest expense	98	4
Accrued consulting and travel costs	72	59
Accrued discounts	650	260
Pharmaceutical tax	108	140
Accrued costs for audit and Annual Report[1]	24	3
Accrued costs of items sold	36	23
Co-Promotion	277	77
Other accrued expenses	632	163
Total	**3,039**	**1,610**

1. Accrued audit costs for 2019 includes audit costs related to aquisitions during the year.

PARENT COMPANY	2019	2018
Provision for vacation pay and bonuses, incl. social security contributions	171	182
Accrued social security contributions	94	83
Accrued royalty expense	226	184
Accrued manufacturing costs	152	107
Accrued R&D costs	172	99
Accrued interest expense	70	4
Accrued consulting and travel costs	15	29
Accrued discounts	83	66
Pharmaceutical tax	74	53
Accrued costs for audit and Annual Report[1]	5	1
Accrued costs of items sold	5	4
Co-Promotion	277	76
Other accrued expenses	227	81
Total	**1,570**	**969**

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32 Pledged assets and contingent liabilities

GROUP	2019	2018
Pledged assets		
Endowment insurance	47	47
Other pledged assets	1	1
Total	**48**	**48**

PARENT COMPANY	2019	2018
Pledged assets		
Endowment insurance	47	47
Other pledged assets	0	0
Total	**47**	**47**

PARENT COMPANY	2019	2018
Contingent liabilities		
Guarantee commitment	24	96
Total	**24**	**96**

Guarantees for 2019 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 a number of 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). Through the acquisition, Sobi received access to Dova's commercial product Doptelet. Dova became an indirect wholly owned subsidiary of Sobi through the aqusition.

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 92 M were paid and are included under administrative expenses in the income statement, and are part of operating cash flow on the cash flow statement.

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 liabilites and provisions	–1,687
Deferred tax	–1,946
Total liabilities	**–3,633**
Total identifiable net assets at fair value	**4,427**
Goodwill[1]	4,391
Consideration transferred	**8,818**
Analysis of cash flows in asqusition	
Contingent consideration purchase price[2]	–404
Net cash acquired with the business	–444
Acquisition of business, net of cash	**7,969**

1. 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.
2. Contingent Value Right (CVR).

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.

GROUP	Final PPA
Agreed purchase price	4,914
Redemtion 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.

Note 33, cont.

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 18 M 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	4,391	902	5,293
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	**12,451**	**1,938**	**14,389**
Other liabilites and provisions	–2,091	–3,557	–1,466
Deferred tax	–1,946	582	2,528
Total liabilities	**–4,037**	**–2,975**	**1,062**
Total acquired assets and liabilities	**8,414**	**4,913**	**3,327**
Net cash acquired with the business	–444	–3	–447
Acquisition of business net of cash	**7,969**	**4,911**	**12,880**

34 The share

At year-end, Sobi's share capital was SEK 165 M, distributed between 299,977,839 shares with a par value of about SEK 0.55. The issue of 24,193,092 shares related to the Synagis acquisition has increased equity by SEK 4,513 M. All shares issued on the balance-sheet date were ordinary shares. Ordinary shares carry one vote per share. The company held 5,678,099 ordinary shares in treasury on the balance-sheet date. The own shares item corresponds to 1.9 per cent of the total number of shares in the company.

Earnings per share

Earnings per share before dilution is 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.

	2019	2018
Earnings attributable to Parent Company shareholders (in SEK K)	3,304,479	2,417,795
Weighted average number of ordinary shares outstanding (000s)	292,649	269,524
Weighted average numbers of ordinary shares outstanding exclusive the issue regarding the acquisition of Synagis (000s)	269,980	—
Undiluted earnings per share (SEK per share)	11.29	8.97
Undiluted earnings per share, adjusted (SEK per share)	11.89	8.97
Diluted earnings per share (SEK per share)	11.22	8.93
Diluted earnings per share, adjusted (SEK per share)	11.81	8.93

35 Related-party transactions

Apart from what is stated in the Notes on remuneration of senior executives and intra-group transactions, there have been no related party transactions.

See Note 5 for internal transactions between the Group's subsidiaries.

36 Proposed appropriation of profit

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

SEK 000S	
Share premium reserve	8,904,692
Retained earnings	2,546,893
Profit for the year	1,117,739
Total	**12,569,324**

The Board of Directors proposes no dividend for the 2019 financial year.

The Board proposes that the share premium reserve and retained earnings of SEK 12,569,324 K be carried forward.

37 Events after the balance-sheet date

A clinical study to evaluate whether anakinra and emapalumab may relieve complications associated with severe COVID-19 disease was initiated.

See the Directors' report for more information relating to 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 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 13 May 2020 for adoption.

Stockholm, 25 March 2020

Håkan Björklund
Chairman

David Allsop
Board member

Annette Clancy
Board member

Matthew Gantz
Board member

Lennart Johansson
Board member

Helena Saxon
Board member

Hans GCP Schikan
Board member

Elisabeth Svanberg
Board member

Pia Axelson
Employee representative

Kristin Strandberg
Employee representative

Guido Oelkers
Chief Executive Officer

Our auditor's report was submitted on 25 March 2020
Ernst & Young AB

Björn Ohlsson
Authorised Public Accountant

Letter from the Chairman

The transformation of Sobi continued during 2019, preparing the company for long-term growth and value creation. By providing a clear governance structure, the Board supports Sobi on its growth journey.

Sobi is undergoing a transformation, reshaping the company in order to provide long-term growth and value generation. This transformation is an essential step in achieving the vision of being recognised as a global leader in rare diseases.

The Board's role in this transformation includes providing advice so the company can pursue opportunities that move it towards this vision. During 2019, one of the most important steps was the decision to discontinue early-stage research and increase focus on late-stage R&D and commercialisation. That move, together with the acquisition of additional assets that allow the creation of two strong, balanced therapeutic areas, will power future growth.

These acquisitions were largely debt-financed, but the Board is confident that the strong operating cash flow will allow the repayment of debt, strengthening the balance sheet and allowing for further expansion organically and through continued acquisitions.

As Sobi's governance body, the Board also plays an important role in managing risk. A certain level of risk is necessary as a company evolves – for example moving into new markets, taking on debt, and acquiring companies or products – and such risks must be well managed and balanced. We continue to work with the Executive Committee to assess and monitor risk, and find the right balance. The composition of the Board is a major asset in this respect. The majority of Board members have expertise from the medical sector, and this deep and broad knowledge is an advantage both in terms of good corporate governance and for identifying and assessing new avenues for value creation.

Sobi made significant progress during 2019 in the area of Sustainability, a key area of interest for the Board. The implementation of the Responsible Sourcing Programme will allow Sobi to ensure compliance with the highest standards across the value chain, while expanded reporting on key performance indicators in line with Sobi's commitments under the UN Global Compact and the Global Reporting Initiative are improving transparency.

I am confident that Sobi is well placed for continued growth during 2020.

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. In addition to the rules under laws or other regulations, Sobi applies the Swedish Corporate Governance Code (www.bolagsstyrning.se) without any deviations. This report for the 2019 financial year is part of Sobi's Director's Report and has been audited.

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. Sobi has presently 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.

2019 AGM

The AGM was held on 9 May 2019 in Stockholm. The Meeting was attended by 385 shareholders (264), in person or by proxy, representing 64.6 per cent (69.6) of the total number of votes. Lawyer Eva Hägg was elected to chair the meeting.

The full minutes and information from the 2019 AGM are available at www.sobi.com.

2020 AGM

The AGM will be held on Wednesday, 13 May 2020 at Norra Latin, Drottninggatan 71B, Stockholm, Sweden. For more information about the AGM, see page 120.

Shareholders, share capital, the share and voting rights

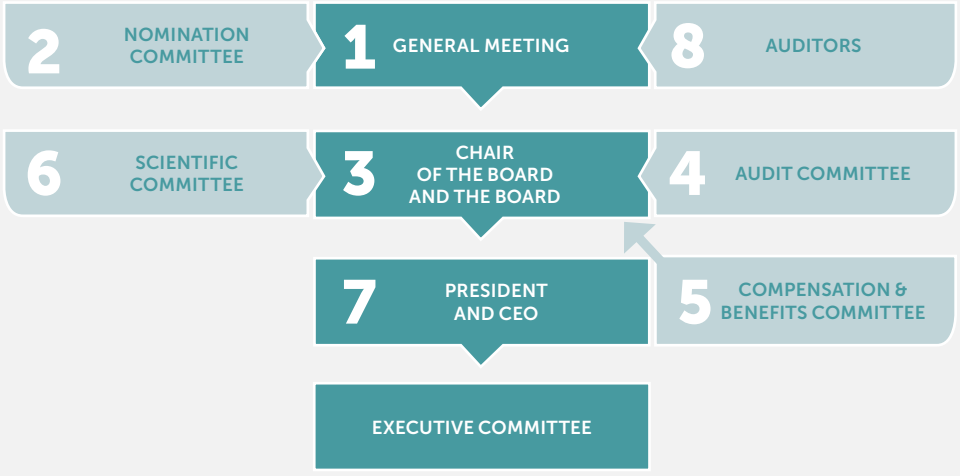
At year-end, Sobi had a total of 25,227 (23,435) shareholders. Investor AB was the largest shareholder, with 35.9 per cent (39.4) of the share capital and 35.9 per cent (39.4) of the votes. The 15 largest shareholders accounted jointly for 78.1 per cent (73.3) of the share capital and 78.1 per cent (73.3) of the votes. No shareholders other than Investor AB and EdgePoint Investment Group Inc. 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 on 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 9 May 2019 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 85,775 of Sobi's own shares in order to cover some expenses, mainly social security contributions, that may arise due to



the 2016 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 2019, Sobi held 5,678,099 ordinary shares in treasury. In 2019, all previously issued C shares were converted into ordinary shares. For more detailed information about the total number of shares in the company, the number of different classes of shares and the votes carried by the company's shares, refer to the section on shares on page 28.

Dividend policy

One of Sobi's most important 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 2019. In the short term, the company intends to use accrued profits to finance the continued development and expansion of its operations.

Important internal regulations

- Articles of Association
- Charter of the Board
- CEO Instructions
- Policy documents, including the Sobi Code of Conduct and Ethics
- Charters of the Board's committees

Important external regulations

- Swedish Companies Act
- Swedish and international accounting law
- Nasdaq Stockholm's Rule Book
- Swedish Corporate Governance Code

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 the shareholder register maintained by Euroclear Sweden AB. 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.

In the period up to the 2020 AGM, the Nomination Committee has had the following composition: Petra Hedengran (Investor AB), Chair of the Nomination Committee, Lennart Francke (Swedbank Robur Fonder AB), Anders Oscarsson (AMF and AMF Funds) and Håkan Björklund, Chair of the Board of Sobi. Prior to the 2020 AGM, the Nomination Committee held three minuted meetings with telephone contact between these 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, an 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 producing pharmaceutical products to treat rare diseases. The product portfolio contains both marketed products as well as products in various development phases. 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 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 twelve 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 diversity policy. The objective of the policy is that the Board shall have an appropriate composition with regard to the company's business, stage of development and situation in general, characterised by versatility and breadth in respect of the competence, experience and background of members elected by the AGM, and that efforts shall be made to achieve an even gender distribution. As set out in the Nomination Committee's motivated opinion to the 2019 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, with the aim of achieving and maintaining an even gender distribution.

Nomination Committee prior to the 2020 AGM

Name/Representing	Votes 31 Dec 2019, %	Votes 31 Aug 2019, %
Petra Hedengran (Chair of the Nomination Committee) Investor AB	35.9	36.2
Lennart Francke Swedbank Robur Fonder AB	4.7	4.8
Anders Oscarsson AMF & AMF Funds	2.7	2.9
Håkan Björklund Chair of Swedish Orphan Biovitrum AB (publ)	0.0	0.0
Total	**43.3**	**43.9**

The current composition of the Board is the result of the Nomination Committee's work prior to the 2019 AGM. The 2019 AGM adopted the Nomination Committee's proposal that, as of the 2019 AGM, the Board would consist of eight AGM-elected members (eight re-elected at the 2019 AGM) and two employee representatives appointed by the trade union organisations (plus two deputies for the employee representatives). Three of the eight AGM-elected members are women.

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

Resolutions 2019 AGM

The following resolutions were adopted by the 2019 AGM:

- Re-election of eight Board members
- Re-election of the Chair
- Re-election of EY as auditor
- Remuneration of the Board and auditors
- Remuneration guidelines for senior executives
- Discharge from liability for the Board and CEO for the 2018 financial year
- Instructions and Charter for the Nomination Committee

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.

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 at least two of them are independent of major shareholders. The table on page 97 shows the independence of Board members on the publication date of this report.

Number of meetings

The Board shall meet at least four to six times per year, generally in connection with the publication of interim, year-end and annual financial statements 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 2020, the Board has planned a total of nine meetings.

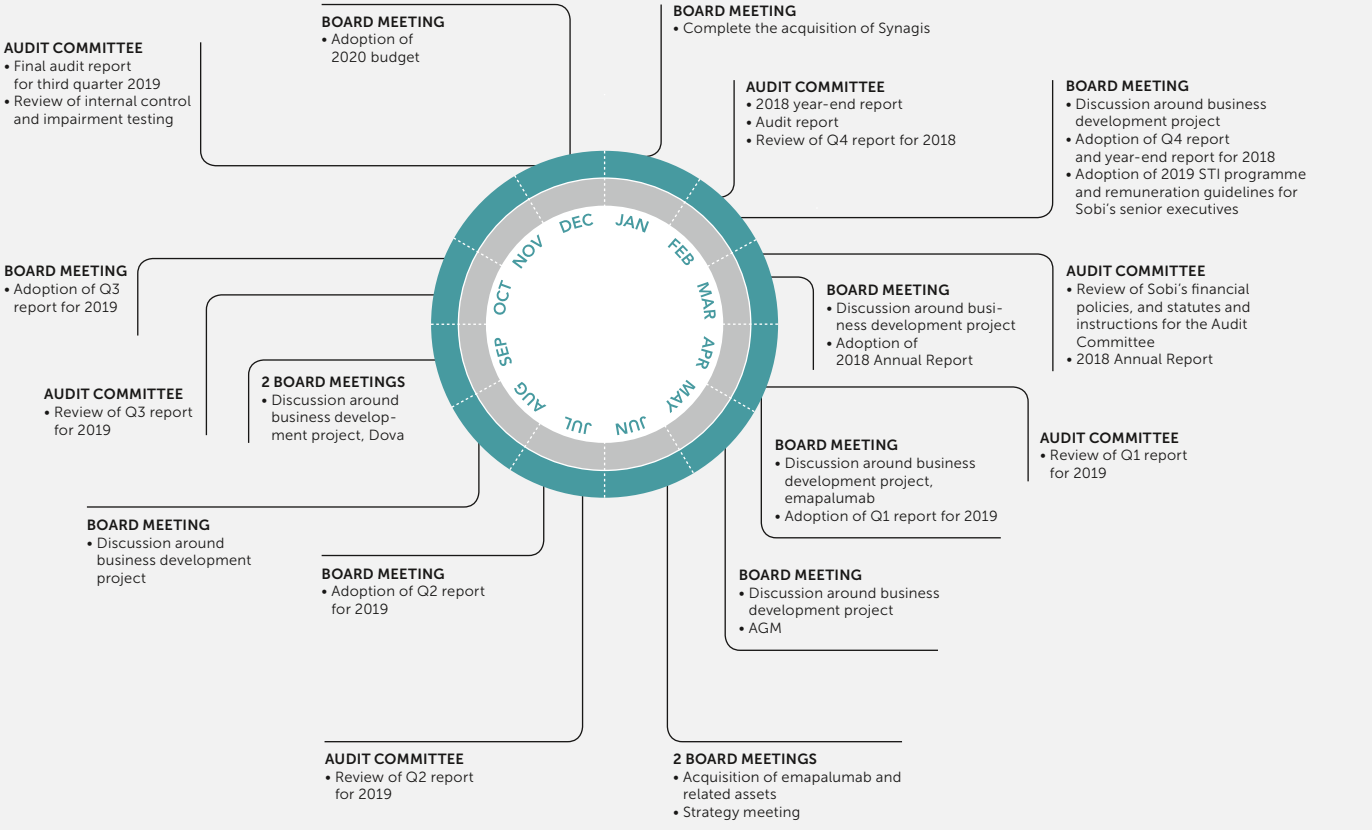
Board work in 2019

In 2019, the Board held a total of 13 meetings, of which nine were scheduled and four extra meetings. Sobi's CEO and President attends Board meetings, as does Sobi's General Counsel, who serves as secretary at the meetings. Other Sobi employees have attended in a reporting capacity. The number of extra Board meetings was motivated by discussions concerning business development projects. The matters addressed are shown in the illustration below.

Board fees

At the AGM on 9 May 2019, 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

Important events in Board work in 2019



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 2019, Board fees of SEK 5,955 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.

For more information about the remuneration of Board members, see Note 11 and 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 2019, 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)
- Hans GCP Schikan
- Helena Saxon

Sobi's CFO serves as secretary of the Committee, but is not a member. Sobi's CEO attended the meetings but is not a formal member. The Committee held six meetings during the year. Sobi's auditor attended five of the meetings. The matters addressed are presented in the illustration on page 96. 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 remuneration of the company's employees. Sobi's Compensation & Benefits Committee consists of four members who are all independent of management:

- Håkan Björklund (Chair)
- Helena Saxon
- David Allsop
- Matthew Gantz

Sobi's Head of HR serves as secretary of the Committee, but is not a member. The Compensation & Benefits Committee met seven 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.

The proposed remuneration guidelines for the CEO and senior executives will be presented at the AGM in May 2020 for approval by the shareholders. The Board members' attendance and remuneration for Committee meetings is presented in the table below. For information about salaries and remuneration of the CEO and senior executives, see Note 11.

		Remuneration, (SEK 000s)						Attendance[1]			
	Independence	Fees	Audit Committee	Compensation & Benefits Committee	Scientific Committee	Other[4]	Total	Board	Audit Committee	Compensation & Benefits Committee	Scientific Committee
David Allsop	x	482	—	53	—	50	585	12/13	—	7/7	—
Håkan Björklund	x	1,442	—	100	—	—	1,542	13/13	—	7/7	—
Annette Clancy	x	482	—	—	100	50	632	11/13	—	—	4/4
Matthew Gantz	x	482	—	53	—	142	677	13/13	—	6/7	—
Lennart Johansson	[2]	482	148	—	—	—	630	13/13	6/6	—	—
Helena Saxon	[2]	482	92	53	—	—	627	12/13	6/6	7/7	—
Hans GCP Schikan	x	482	92	—	53	50	677	12/13	6/6	—	4/4
Elisabeth Svanberg	x	482	—	—	53	50	585	13/13	—	—	4/4
Pia Axelson	[3]	—	—	—	—	—	—	7/13	—	—	—
Emily Chamberlain	[3]	—	—	—	—	—	—	4/13	—	—	—
Kristin Strandberg	[3]	—	—	—	—	—	—	2/13	—	—	—
Bo-Gunnar Rosenbrand	[3]	—	—	—	—	—	—	10/13	—	—	—

1. The figures in the table show the totals for attendance/meetings. In 2019, the Board held a total of 13 meetings, of which nine were scheduled and four extra meetings. In 2019, the Audit Committee held six meetings, the Compensation & Benefits Committee held seven meetings and the Scientific Committee held four meetings.
2. Board member does not qualify as independent in relation to major shareholders.
3. Employee representatives. Emily Chamberlain was appointed ordinary employee representative at the AGM on 9 May 2019. Pia Axelson was appointed deputy employee representative at the same meeting. In October 2019, Pia Axelson and Kristin Strandberg were appointed ordinary members when Emily Chamberlain and Bo-Gunnar Rosenbrand ended their employment.
4. For each physical Board meeting, a fee of SEK 10 K is paid to members who live in Europe but outside the Nordic region, and of USD 3 K to each member who lives outside Europe.

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. The Scientific Committee consists of three members who are all independent of management:

- Annette Clancy (Chair)
- Hans GCP Schikan
- 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 Committee meetings is presented in the table on page 97.

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 and HR. In 2019, the Executive Committee held one meeting every month For more detailed information about the Executive Committee, refer to pages 104–105

Each year, the Board defines 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.

Remuneration of senior executives

To attract and retain talented and motivated employees, Sobi has established long-term incentive programmes. All employees receive fixed and variable pay. The variable component, derived from a system adopted by the Board, is based on both company goals and individual goals. The maximum outcome of the variable component is 100 per cent of gross annual salary for the CEO, and 60 per cent of fixed annual salary for other senior executives. For more information, see Note 11.

8. Auditors

Sobi's auditor is the auditing firm Ernst & Young (EY), with Authorised Public Accountant Björn Ohlsson as chief auditor. EY was elected as Sobi's auditor until the end of the 2020 AGM and has been Sobi's auditor since the 2014 AGM. The external auditors discuss the external audit plan and risk management with the Audit Committee. The auditor conducts a review of the Q3 interim report and an audit of the annual accounts 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 12.

Internal control and risk management in relation to financial reporting

The Board is responsible for internal control in accordance with the Swedish Companies Act and the Swedish Corporate Governance Code. The Board presents the most important elements of Sobi's internal control and risk management systems in relation to the financial reporting process below.

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 annual internal control plan, which is approved and monitored by the CFO.

Björn Ohlsson
Authorised Public Accountant

COSO framework

Sobi's internal control environment follows the established COSO[1] framework, comprising the following five components:

1. Control environment
2. Risk assessment
3. Control activities
4. Information and communication
5. Supervision including monitoring and evaluation

The description below shows how the five components of the COSO model work together to improve the operations' ability to achieve set targets.

1. 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. It is the foundation for all other internal governance and control components, bringing order and structure in the form of manuals, processes and policies.

The basis for internal control over financial reporting consists of a clear organisational structure, decision-making channels, powers and responsibilities that are documented and communicated in governing documents.

The guidelines for Sobi's business activities have been compiled on the company's intranet and include the following:

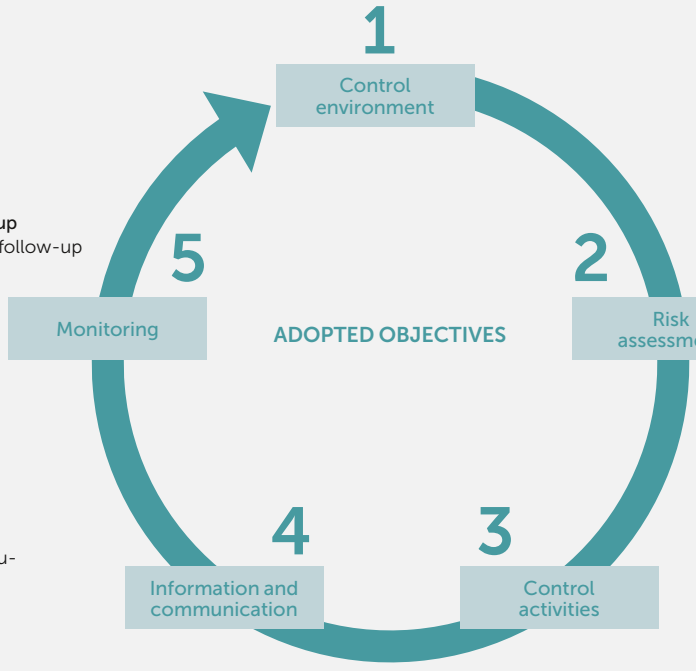
- The Group's mission, vision, strategies, objectives and values
- Sobi's Code of Conduct and Ethics
- Organisational structure and descriptions of positions
- Administrative processes, guidelines and instructions such as authorities, authorisation instructions, risk management policy, purchasing and investment policy, workplace health and safety policy, and accounting and reporting instructions
- Information about the company's ethics and core values, expertise matters and the regulatory environment in which the company operates

2. 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 help the company create profitable business opportunities combined with good control over risk taking, and to secure and strengthen stakeholder confidence in Sobi, thereby supporting the implementation of the business strategy adopted by the company. 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. Material risks identified by Sobi are described on pages 44–45.

As part of risk management, annual risk assessments are carried out to determine measures for ensuring good control of identified risks and, if necessary, to take measures to reduce risk. In regard to financial reporting, the operational units perform risk assessments together with the responsible controllers to identify, analyse and ensure control over risks in the accounting and reporting processes.

Sobi's COSO framework



Corporate culture
Management's behaviour is important

Governing documents
Overall framework and policies are in place and implemented

Evaluation, monitoring and follow-up
1. Implement a process for ongoing follow-up
2. Evaluation and reporting of identified deviations

1. Identify and analyse risks that may impede target achievement
2. Identify the risks with a material effect on operations
3. Decide on measures and the people responsible

Internal
Clearly functioning two-way communication between management and operations

External
Correct information to external stakeholders within the prescribed time

Implement control activities that reduce, eliminate or monitor material risks identified.

1 Committee of Sponsoring Organizations.

3. Control activities

The aim of the control activities is to prevent and detect errors and deviations, and to propose corrective actions for identified control deficiencies. These activities include analytical monitoring and comparison of earnings performance, reconciliation of accounts, monitoring, reconciliation of Board decisions, approval and accounting of business transactions and collaboration agreements, proxy and authorisation instructions, and recognition and measurement principles.

The controls are carried out manually or are incorporated into the systems used (IFS, Cognos, Business Intelligence etc.).

Controllers are responsible for maintaining internal control in each area and ensuring that this is developed as necessary. They follow up activities using a variety of control measures, such as forecasting and monitoring budgets, analysing earnings and balance-sheets, reconciliations, trend analyses and market intelligence. The results of this work are reported back to the management of each business area, and to management and the Board.

4. Information and communication

Sobi has internal information and communication channels aimed at ensuring effective and accurate information disclosure with respect to financial reporting. Effective communication is important for all the company's employees. Guidelines for financial reporting are set out in the communication policy, which are communicated to employees and are available on the company's intranet.

Meetings are held within the company at Executive Committee level, and at the level that each department head considers appropriate. There are also a number of large meetings which all employees attend.

The Board receives regular financial reports on the Group's position and performance.

Procedures for external information disclosure aim to provide the market with relevant, reliable and correct information about Sobi's performance and financial position. Sobi has a communication policy that meets the requirements for a listed company.

Financial information is presented regularly in the form of:

- Year-end and 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 telephone conferences for financial analysts, investors and media representatives on the publication date for year-end and interim reports and in connection with the release of other important information
- Meetings with investors and financial analysts
- All reports, presentations and press releases are simultaneously published on the Group's website www.sobi.com when communicated to the market

5. Supervision, including monitoring and evaluation

Forms of supervision for internal control are determined by the Board and the Audit Committee. Sobi's CFO is responsible for ensuring internal control is conducted in accordance with the Board's decisions. Group-wide monitoring takes place at various levels.

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 information that is published is evaluated on a regular basis. The company's external auditor reports their observations and their assessment of the internal control to the Audit Committee.

Activities in 2019 that strengthened internal control

- Implementation of a new risk-management process for the Group and an update of the Group's risk management policy
- Update of the Group's crisis management process, crisis plan and crisis policy
- Local visits by the internal control function to selected subsidiaries to provide support for the development of their internal control processes
- Development of a process for analysing Sobi's partners from an ethical perspective
- Creation of a Partner Code of Conduct
- Establishment of a process for incorporating the finance functions of acquired operations efficiently
- Mapping of processes for functions outside the finance function

Activities in focus for 2020 to further strengthen 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

Internal audit

Sobi does not have a separate internal audit function, but has chosen to conduct monitoring and the annual evaluation of compliance with the internal control and risk management related to financial reporting through the existing organisation. The Board and the Audit Committee regularly examine the issue of whether an internal audit function should be established.

Breaches

Sobi did not breach any rules or generally accepted market practices of the trading venue on which its shares are traded.

Auditor's report on the corporate governance statement

To the general meeting of the shareholders of Swedish Orphan Biovitrum AB (publ), corporate identity number 556038-9321

Engagement and responsibility
It is the Board of Directors who is responsible for the corporate governance statement for the year 2019 on pages 94–100 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 RevU 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 25 2020
Ernst & Young AB

Björn Ohlsson
Authorised Public Accountant

The Board

Hans GCP Schikan

Born 1958.

Board member since 2011. Member of the Audit Committee and Scientific Committee.

Pharm D, Utrecht University.

Other assignments: Chair of the Board of Directors of InteRNA, The Netherlands, and Complix, Belgium. Member of the Board of Directors of Pharvaris, The Netherlands, Vicore Pharma, Sweden, VectivBio, Switzerland as well as of the Dutch Top Sector Life Sciences & Health, The Netherlands. Chair of the Investor Board of Swanbridge Capital, The Netherlands.

Previous positions: CEO of Prosensa, Director of the Supervisory Board of Prosensa, Member of the Board of Directors of Hansa Medical, Wilson Therapeutics and Asceneuron. Various senior management positions within former Organon and Genzyme.

Shares: 4,000

Kristin Sandberg

Born 1989.

Employee representative

Board member since 2019.

Deputy board member since December 2018.

Deputy representative of the council for negotiation and cooperation.

MSc Biotechnology.

Global regulatory affairs manager.

Shares: 368

Håkan Björklund

Born 1956.

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

Ph.D. from Karolinska Institutet, Stockholm.

Other assignments: Industry Executive at Avista Capital Partners.

Previous positions: CEO of Nycomed. Extensive international background in the life-science industry, from both R&D and sales and marketing. Member of the Board of Directors of several international life-science companies including Alere, Coloplast, Danisco, and Lundbeck. Member of the Board of Directors for Biovitrum 2001–2007.

Shares: 15,800

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 in France since 2016. Member of the Board of Directors of PledPharma AB.

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.

Shares: 1,550

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 Vectura Fastigheter AB, 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.

Shares: 21,200

David Allsop

Born 1963.

Board member since 2018. Member of the Compensation and Benefits Committee.

BSc Hons Chemistry from Coventry University, UK.

Other assignments: Director U-R-NOT Ltd.

Previous positions: Head of International in Amicus Therapeutics Ltd. A number of senior positions in Biogen 1998–2015.

Shares: 1,314

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.

Shares: 7,021

Annette Clancy

Born 1954.

Board member since 2014. Member of the Scientific Committee (Chair).

BSc Hons Pharmacology from Bath University UK.

Other assignments: Non-executive Chair of the Board, Enyo SA. Member of the Board of Directors, 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.

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 OxThera AB. Member of the Board for Pennsylvania Life Sciences Association and Marine Corps Scholarship Foundation.

Previous positions: Executive Vice President of BTG Plc, Founder and previously CEO of Acureon Pharmaceuticals, President and CEO of Hydrabiosciences Inc., VP Europe for Chiron's Biopharmaceutical Division and General Manager for PathoGenesis Europe. Prior to Chiron/PathoGenesis, a variety of US sales and marketing roles at Abbott Laboratories Diagnostic Division.

Shares: 0

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 of Hallvarsson & Halvarsson, Vice President at Investor AB and financial analyst at Goldman Sachs. Board member of Aleris and Mölnlycke Health Care.

Shares: 15,500

Executive committee


SOFIANE FAHMY


ANNE MARIE DE JONGE SCHUERMANS


GUIDO OELKERS


TORBJÖRN HALLBERG


NORBERT OPPITZ

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, Member of the Board of Directors at Sartorius AG.

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

Shares: 49,000

Sofiane Fahmy

Head of Southern and Western Europe & North Africa

Born 1972

Employed since 2013

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

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

Shares: 0

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, Sweden.

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

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 in the Netherlands and in Environmental Management & Technology from the Ecole Polytechnique Féderale Lausanne (EPFL) in Switzerland.

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

Norbert Oppitz

Head of Immunology

Born 1967

Employed since 2017

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

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


AMY POTT


HENRIK STENQVIST


PHILIP WOOD


ARMIN REININGER


PAULA TREUTIGER


MILAN ZDRAVKOVIC

Amy Pott

Head of North America

Born 1976

Employed since 2019

Master of Science, European Policy & Intl Relations, London School of Economics & BA (Hons), History, University of Bristol, UK.

Other assignments: Board Member Wave Life Sciences.

Previous positions: Group Vice President, US Franchise Head Internal Medicine & Oncology as well as Head of Commericial Operations at Shire. Vice President, Global Market Access, & Vice President, Strategy, Planning & Analytics at Baxalta, Several managerial roles at Baxter Healthcare.

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.

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. Professor of Anatomy at the Ludwig Maximilians-University Munich, Germany.

Shares: 0

Henrik Stenqvist

Chief Financial Officer

Born 1967

Employed since 2018

Degree in Finance and Business Administration from the University of Linköping, Sweden.

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

Paula Treutiger

Head of Corporate Communication & Investor Relations

Born 1967

Employed since 2019

Degree in Finance and Business Administration, Stockholm University, Sweden.

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

Philip Wood

Head of Haematology, Head of North Eastern Europe, Middle East and Russia.

Born 1968

Employed since 2012

BSc Joint Honours degree in Geology and Physical Geography, Chartered Institute of Marketing certification, UK.

Previous positions: Head of European Strategic Asset team, Haemophilia, and Business Unit Head Haemophilia, UK, Pfizer.

Shares: 29,014

Milan Zdravkovic

Head of Research & Development, Chief Medical Officer

Born 1970

Employed since 2016

MD, PhD University of Aarhus, Denmark, MSc Pharmaceutical Medicine, University of Surrey, UK.

Other assignments: Board member of Selma Diagnostics Aps and Empros Pharma.

Previous positions: Corporate Vice President, Novo Nordisk. 18 years in R&D organisation, Novo Nordisk, responsible for diabetes, devices, growth hormone deficiency, obesity and immunology.

Shares: 8,820

Auditor's report

TO THE GENERAL MEETING OF THE SHAREHOLDERS OF SWEDISH ORPHAN BIOVITRUM AB, 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 2019. The annual accounts and consolidated accounts of the company are included on pages 32–92 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 2019 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 2019 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 statement of comprehensive income and balance sheet for the parent company and the group.

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

Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Key Audit Matters

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters. For each matter below, our description of how our audit addressed the matter is provided in that context.

We have fulfilled the responsibilities described in the Auditor's responsibilities for the audit of the financial statements section of our report, including in relation to these matters. Accordingly, our audit included the performance of procedures designed to respond to our assessment of the risks of material misstatement of the financial statements. The results of our audit procedures, including the procedures performed to address the matters below, provide the basis for our audit opinion on the accompanying financial statements.

Valuation of product and marketing rights and goodwill

Description	How our audit addressed this key audit matter
Per 31 December 2019 the majority of (80 per cent or SEK 36,511 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 fall below 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 17. 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 – Claw back tax and discount adjustments

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 2019 are based on the Company's best assessment of the expected outcome of future settlement of the commitments at year end. The assessment is complex and often requires access to both internal and external market and sales data that may be limited at the time of assessment. Refer to Note 2, 4 and 31 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.

Business combinations and asset deals

Description	How our audit addressed this key audit matter
The Company and the Group (below referred to as the Company) has during 2019 made two business combinations through acquisition of all shares in Dova Pharmaceuticals Inc. and EmaCo SA. As described in Note 2, the Company's acquisition values are determined through a purchase price allocation in connection with the acquisition. Contingent consideration is included in the acquisitions values and is reported at fair value at the time of acquisition. Subsequent effects of revaluations of contingent consideration are recognised in the statement of comprehensive income. Acquired identifiable assets and liabilities assumed are initially recognised at fair value at the time of acquisition and the difference between the acquisition value and the fair value of identifiable assets and liabilities assumed is recognised as Goodwill. In addition to the business combinations, the Company has made two for the Company large asset deals in the form of the marketing rights and related assets to Synagis in the US and the future marketing rights in Europe for BIVV001. As described in Note 2, asset deals are initially recorded at cost which represents the fair value of the paid purchase price and if applicable contingent considerations. Subsequent effects of revaluations of contingent considerations are recognised against the value of the asset excluding foreign exchange movements and interest expenses. As described in Note 4 and 33, management is required to make assessments and assumptions in order to estimate the fair value of acquired assets and liabilities, especially when identifying and valuing intangible assets and accounting for contingent consideration. In some cases, the contingent consideration is determined on the basis of the financial performance of the acquired business or asset over a predetermined period. The fair value measurement attributable to business combinations and contingent considerations involves, to a large extent management's judgment based on the company's own assumptions and therefore constitutes a key audit matter in our audit. Established fair values for the Company's acquisitions are reported in Note 26, 28 and 33. Important assumptions used in the determination of fair value are described in Note 4, 26, 28 and 33.	Our review has included, among other things, the following audit procedures; • Review of significant acquisition agreements including any contingent considerations. • Evaluation of management's process for preparing purchase price allocations and valuation of acquired assets and liabilities. • Evaluation of management's assessments and valuation of identified assets and liabilities assumed, including contingent considerations. • Reconciliation of purchase price allocation to accounting records. • Evaluating, using valuation experts, used valuation methods and management assessments and assumptions. • 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 2–31, 93 and 102–105 and 121–124. 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, related safeguards.

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 2019 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

Basis for opinions
We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Responsibilities of the Board of Directors and the Managing Director
The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

Auditor's responsibility
Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional skepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

Ernst & Young AB, Box 7850, 103 99 Stockholm with Björn Ohlsson as auditor in charge was appointed auditor of Swedish Orphan Biovitrum AB (publ) by the general meeting of the shareholders on the 9th of May 2019 and has been the company's auditor since the 8th of May 2014.

Stockholm, March 25, 2020
Ernst & Young AB

Björn Ohlsson
Authorized Public Accountant

Sustainability Notes

Sobi performed a materiality assessment of sustainability issues during the autumn of 2019. For a detailed description of stakeholder groups and outcomes of the assessment see page 40. The assessment has defined the scope of Sobi's sustainability reporting.

Economic performance

Total revenue for 2019 was SEK 14,248 M, up 56 per cent year-on-year. The Immunology business was strengthened by the business acquisitions of the US rights for Synagis and of emapalumab. Sobi also expanded into Haematology with the business acquisition of Doptelet. The growth of the portfolio directly contributes to our key sustainability commitment – enabling access to treatments to more patients in more markets.

Direct economic value generated

SEK M	2019	2018
Revenue	14,248	9,139
Operating costs	6,430	3,601
Employee wages & benefits	1,748	1,092
Payments to providers of capital	86	12
Payments to government[1]	520	507
Community investments[2]	23	19

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.

Sobi and Sanofi have pledged to donate up to 1 billion IUs of coagulation factor to humanitarian aid between 2015–2025. Of this, 500 million IUs have been allocated over five years in support of the World Federation of Hemophilia's (WFH) Humanitarian Aid Program.

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	2019	2018	2017
Total MIUs[1] delivered	449	362	262
Total patients treated (cumulative)	17,223	16,885	15,072
Acute bleeds treated	42,881	37,896	40,557
Surgeries	355	461	709
Paediatric patients, %	37	39	39

1. International units

Environmental performance

The scope of Sobi's environmental impact reporting is limited to its biological manufacturing operations and headquarters in Sweden, and business travel. Reporting for 2019 includes more environmental data than has been available in previous reports.

During 2019, Sobi acquired emapalumab and a laboratory operation in Switzerland. In 2020, reporting will include data from all Sobi-owned production and laboratory operations.

Sobi's Responsible Sourcing Programme will report on management of environmental impact in the contract manufacturing supply chain as of 2020.

E1. GHG Emissions

Scope 1 and 2 include data from Sobi's biological manufacturing operations and headquarters in Sweden. Reported Scope 1 emissions have reduced due to fewer cars in the Swedish fleet. Scope 2 emissions have over time reduced due to more effective use of energy at the production site in Stockholm as well as lower production volumes.

The reporting base for Scope 3 was expanded in 2019 to include travel covering approximately 80 per cent of Sobi's operations. Scope 3 has increased in correlation with the increasing size of the organisation as well as a more comprehensive data reporting base. Travel emissions originating from Sweden remain relatively constant compared with previous years (963 tonnes).

Greenhouse gas emissions (CO_2) (tonnes)

	2019	2018	2017	2016	2015
Own activities (direct and indirect)					
Total	4,326	1,323	1,204	1,334	1,097
Scope 1- Direct emissions					
Facilities' energy use	2	–	3	–	–
Fleet vehicles[1]	98	129	156	167	–
Total	**100**	**129**	**159**	**167**	**–**
Scope 2- Indirect emissions					
District heating	155	213	221	222	236
Cooling	0	0	0	0	0
Electricity	0.02	0.02	–	–	–
Total	**155**	**213**	**221**	**222**	**236**
Scope 3- Indirect emissions					
Business travel	4,070[2]	981[3]	830[3]	945[3]	861[3]
Total	**4,070**	**981**	**830**	**945**	**861**

1. Includes fleet vehicles in Sweden.
2. Includes business travel data for flight originating in Germany (DACH), Sweden (incl train and taxi), US, UAE, France, UK, Denmark, Belgium, Russia, Finland, Norway and Poland in falling order of contribution.
3. Includes business travel data for flight and taxi originating in Sweden.

Emission factors used

Aspect	Emission factor	Source
Electricity, Sweden	0.003 g CO_2/kWh	A mix of certified renewable energy sources
Cooling, Sweden	0 g CO_2/kWh	Annual environmental report, District heating supplier
Heating, Sweden	77.3 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

E2. Emissions intensity

Emissions intensity is not considered material to Sobi and is thus not reported on.

E3. Energy usage

Energy consumption refers to operations in Sweden which includes contract manufacturing, in-house manufacturing and office space. The laboratory facility in Switzerland acquired in 2019 has not yet been included.

Energy consumption (facilities' energy use) (MWh)

	2019	2018	2017	2016	2015
Electricity	7,518	7,694	7,852	7,687	7,048
of which renewable	7,518	7,694	7,852	7,687	7,048
District heating	2,550	2,596	2,690	2,713	2,879
of which renewable	2,015	2,051	1,991	2,116	2,130
Fossil fuel (oil)[1]	0.0072				
Cooling	3,059	3,167	2,793	2,745	2,232
Total	**13,127**	**13,457**	**13,335**	**13,145**	**12,159**

1. Direct energy

E3.1 Total amount of energy directly consumed

The direct energy produced on-site and consumed is generated by an emergency generator that is tested each month. 2019 is the first year the generator's fuel consumption at the production facilities is reported upon.

E3.2 Total amount of energy indirectly consumed

Energy consumption is regularly followed up in relation to internal performance indicators.

Energy-saving possibilities are regularly evaluated at the production facilities in Stockholm, Sweden. During 2019, ventilation adjustments were made which led to lower consumption of electricity. Increased use of district cooling is due to warmer weather over the past two years.

E4. Energy intensity

Total direct energy usage for in-house manufacturing per output scaling factor.

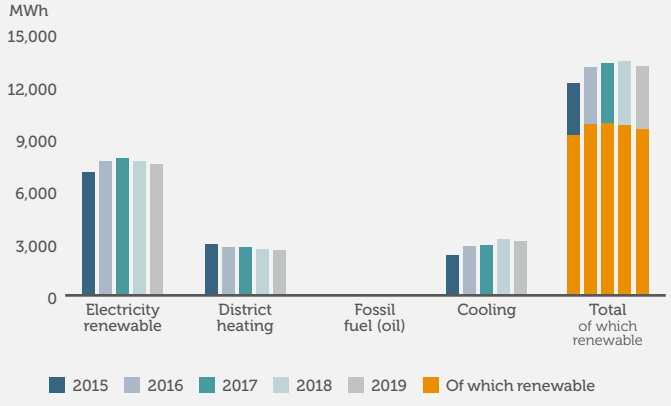
Total direct energy usage (MWh/SEK M)

	2019	2018	2017	2016	2015
Energy (MWh)	5,867	6,313	6,480	6,425	5,135
Revenue manufacturing (SEK M)	376	436	559	569	504
MWh/SEK M	15.6	14.5	11.6	11.3	10.2

E5. Energy mix

Energy consumption by source of origin and the proportion that is renewable are reported in note E3.

Energy consumption



E6. Water usage

Water consumption refers to Sobi's head office, production and research facilities in Solna and Stockholm, Sweden. Water consumption is regularly followed up in relation to internal performance indicators.

Water in the production facilities is not reclaimed but warm water is recycled from the production of steam to extract heating and cooling.

Water consumption increased in 2018 due to a technical issue but has stabilised to a normal level during 2019.

Water consumption

	2019	2018	2017	2016	2015
Purchased water	31,776	57,374	45,913	40,491	34,988
Reclaimed water	—	—	—	—	—
Total	**31,766**	**57,374**	**45,913**	**40,491**	**34,988**

E7. Environmental operations

The EHS policy emphasises the importance of EHS management and states the basic overall principles and guidelines for managing Environment, Health and Safety (EHS) 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 2019.

Management of water and energy consumption, chemicals, waste and emissions has high priority in our production and research facilities. More specific and detailed environmental guidance for the facilities is given in specific standard operating principles and in the environment compliance programme, which aims to support control of the environmental impact of the production.

In an effort to reduce energy and water consumption by half at the Stockholm production site a number of 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 to a great extent despite increased production volumes (see Sobi's Annual Report 2016 and 2017 for details).

E8–9. Climate oversight

Sobi's operations are not substantially impacted by climate-related risks. Related partners in the value chain with high impact are monitored within the risk analysis regarding climate-related risk.

E10. Climate risk mitigation

No investment has been made in climate-related infrastructure, resilience or product development.

E11. Waste

Waste reporting is based on Sobi's head office, production and research facilities in Solna and Stockholm, Sweden. Waste data does not include waste from marketing and sales offices outside Sweden.

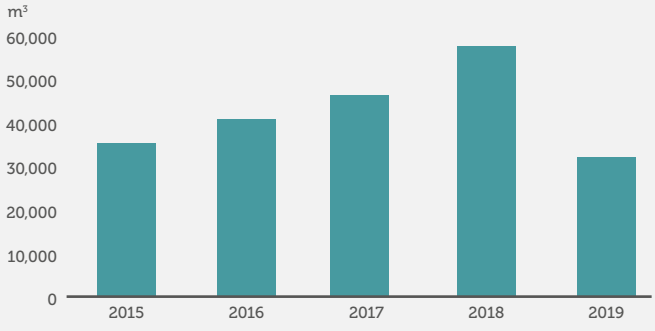
As of 2019, reporting of waste includes a breakdown of different waste types and final treatment. It can be noted that the amount of non-hazardous waste has decreased in recent years as a result of several measures, including digitalisation of deviation management and change of available archive spaces.

Office and production sites waste (tonnes)

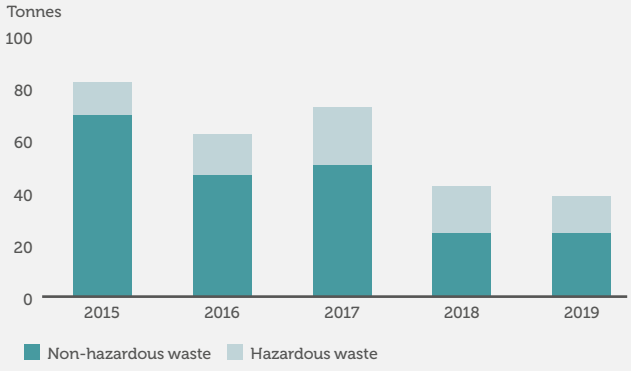
	2019	2018	2017	2016	2015
Total amount of waste	40	42	72	61	82
Non-hazardous waste					
Recycling	6				
Combustion with energy recovery	12.9				
Other treatment	0.6				
Landfill[1]	0.2	0.1	0.1	0.021	1.6
Total	**20**	**24**	**50**	**46**	**69**
Hazardous waste					
Recycling	12				
Combustion with energy recovery	—				
Other treatment	9.1				
Landfill	—				
Total	**21**	**18**	**22**	**16**	**13**

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.

Water consumption



Office and production sites waste



Social performance

During 2019, Sobi's commercial operations were based in Europe, North America, northern Africa and the Middle East with manufacturing and laboratory operations in Sweden and laboratories Switzerland. In terms of number of employees, Sobi has grown organically as well as through acquisitions in 2019. The social data reported below reflects employees with a high level of education, career opportunities and fair and respectful working conditions. In 2020, we will continue to monitor employee satisfaction and support organisational growth and further internationalisation.

S1. CEO Pay Ratio

See note 11 for further details on CEO remuneration.

S2. Gender pay ratio

In Sweden, our annual salary survey allows us to carry out a gender equality analysis, designed to prevent discrimination and promote equal rights and opportunities. We carefully evaluate the results in collaboration with trade unions, and take action when needed. We also map roles and responsibilities proactively to ensure that salaries and development opportunities are provided in an equitable manner.

S3. Employee turnover

In 2019, the business acquisition and integration of emapalumab, the Synagis US franchise, and Dova has added 371 new employees. The expanded franchises and markets have also increased the need for additional personnel. During 2019, early-stage research at the Stockholm office was discontinued to increase focus on and investment in late-stage development.

S4. Gender diversity

Every employee is offered equal opportunities regardless of ethnicity, age, gender, religion, sexual orientation or physical ability.

Gender diversity

	2019		2018		2017	
%	Female	Male	Female	Male	Female	Male
Board	38	62	38	62	38	62
Executive management	27	73	18	82	22	78
All employees	60	40	59	41	59	41

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 2019
Employees	532	803	435	900	1,335
Permanent contract	470	758	418	891	1,309
Fixed-term contract	7	19	17	9	26

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

S6. Non-discrimination

Sobi enforces a open and respectful workplace. Sobi's statement against sexual harassment and non-discrimination is described in the Code of Conduct and outlined in the Discrimination policy and Global EHS Policy.

S7. Injury rate

Total number of accidents includes reports that have not led to a lost workday, but can include accidents that need medical treatment. Statistics include the Swedish operations and some contractors in Sweden.

Investigating and identifying the cause(s) of an accident, dangerous situation or near miss makes it possible to take action to prevent a similar occurrence in the future. All employees are required to report EHS-related incidents to their employer; this is done through an electronic system. Managers are required to report serious incidents and significant EHS risks and ensure that regulatory requirements and internal procedures for reporting of incidents are followed.

Injury rate

Incidents:	2019	2018	2017	2016	2015
No. of accidents	26	28	23	22	15
Lost workday injury (LWI)	0	1	0	0	0
Lost time incident rate (LTIR)	0	0.39	0	0	0

LWI – Accidents that led to sick leave (in addition to the day of the accident)
LTIR – Lost time incident rate per million hours worked

S8. Global Health & Safety

Sobi enforces a global environmental health and safety policy. EHS management is integrated in overall activities and operational control as an ordinary part of daily work. EHS should be regularly addressed at meetings and any EHS aspects regarding activities considered. All employees should be included and participate in day-to-day EHS work. Managers are responsible for addressing any concerns raised.

The joint management-worker health and safety committee operates from the head office and includes representatives from all operations. The committee meets quarterly and reports to the Executive Committee.

S9. Child & Forced Labour

Sobi's statement against child and forced labour is described in the Code of Conduct and, specifically addressing the supply chain, in the Partner Code of Conduct, both of which are publicly available on www.sobi.com.

S10. Human rights

Sobi's human rights statement is described in the Code of Conduct and, specifically addressing the supply chain, in the Partner Code of Conduct, both of which are publicly available on www.sobi.com.

S11. Training and education

All Sobi employees have access to the Sobi Learning Management system and are assigned training based on role. The system also lists available business, management and product training. 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).

A strong connection between Sobi's corporate goals and individual goals is important. All Sobi's employees receive regular performance and career development reviews. Training documentation and performance management is digitalised. 97 per cent completed their performance management process (PMP) in 2019.

Governance performance

In 2020, we will expand the scope of our monitoring to include partners and suppliers within the scope of the Responsible Sourcing Programme.

G1. Board diversity

The Nomination Committee applies Clause 4.1 of the Rules for Corporate Governance in Swedish Corporate Governance Code in regard to diversity of the Board.

Board diversity

	2019	2018	2017
Male	5	5	4
Female	3	3	2
Nationalities	4	4	4
30–50 years	1	1	1
Over 50 years	7	7	5
Committee chairs			
Male	2 (3)	2 (3)	2 (3)
Female	1 (3)	1 (3)	1 (3)

G2. Board Independence

See Corporate Governance Report.
The company fulfils the Swedish Corporate Governance Code's independence requirements in that a majority of the Board members elected at the Annual General Meeting are independent of the company and its management, and at least two of them are independent in relation to the Company's major shareholders.

G3. Incentivised Pay

Executives are formally incentivised to perform on sustainability in accordance to Renumeration guidelines in Note 11.

G4. Collective bargaining

All Sobi employees are free to form, join or refrain from joining organisations which represent their interests as employees. All employees are also allowed to bargain collectively. 48 per cent of Sobi's employees (Sweden, Austria, France, Italy, Spain) are covered by collective agreements.

Employees covered by collective bargaining

Region	2019
Sweden	100 %
Europe[1]	28 %
North America[2]	0
Rest of the world	0
Total	**48 %**

1. Excluding Sweden
2. US and Canada

G5. Suppier Code of Conduct

In 2019, Sobi introduced a Partner Code of Conduct for vendors, suppliers and partners. The Code is made publicly available on www.sobi.com.

The Partner Code of Conduct is being implemented starting January 2020. The percentage of suppliers who have formally certified their compliance with the Code as well as the number of suppliers who have agreed to sustainability screening will be reported from 2020 onwards.

G6. Ethics and Anti-Corruption

Sobi's ethical standards are described in the Code of Conduct and, specifically regarding the supply chain, in the Partner Code of Conduct. Sobi's anti-corruption policy applies to all employees.

95 per cent of Sobi's workforce has formally certified its compliance with the Code of Conduct. Due to recent integration of acquired companies, this number does not take into account those employees.

To our knowledge, no confirmed incidents of corruption were reported in 2019.

G7. Data privacy

Sobi follows a Data Privacy policy made available through training. Data Privacy is also covered in Sobi's Code of Conduct and is a prioritised area across Sobi.

Sobi has implemented a data privacy programme in order to promote data privacy compliance, including appointing a Data Protection Officer, written policies and procedures, and training and education.

In 2019, 15 personal data breach incidents were reported and resolved. The incidents were identified and handled within the scope of internal revisions. No external actions were needed.

G8. ESG Reporting

Sobi publishes an annual sustainability report in accordance with the Annual Accounts Act. The report is available on www.sobi.com.

Sustainability data is included in Sobi's regulatory filings.

G9. Disclosure practices

Sobi provides sustainability data to GRI Standards: Core option and UN Global Compact Communication on Progress. See GRI Index on pages 117–119. Reports and links are available on www.sobi.com.

Sobi focuses on UN Sustainable Development Goals 3: Good health and well-being, 12: Responsible consumption and production and 17: Partnerships for the goals. See page 23.

Sobi has begun to report progress on the UN SDGs, see pages 117–119.

G10. External assurances

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

Regulatory approval and availability of Sobi products

The regulatory approvals and indications for Sobi's products vary depending on geographical region. As well as regulatory approval, local agreement must be reached on pricing and reimbursement. The table below shows in which countries Sobi has marketing authorisation approval (MAA), including for which indication, as well as pricing and/or reimbursement in place (marked with x), thereby showing in which countries Sobi's products are available through the regular healthcare pathways.

Sobi commercialises the following proprietary products: Alprolix, Elocta, Doptelet, Synagis, Gamifant, Kineret and Orfadin. Sobi only has rights to Synagis in the US and it is therefore not included in the table.

See Glossary on page 123 for definitions of listed indications.

	Access to Sobi's products – *new in 2019					
Region	**Alprolix[1]**	**Elocta[1]**	**Doptelet**	**Kineret**	**Gamifant**	**Orfadin**
EU and EFTA states	Haemophilia B	Haemophilia A	CLD*	RA, CAPS, Still's	MAA submitted	HT-1
Austria	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
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
Italy	x	x		x		x
Latvia				x		
Liechtenstein	x	x		x		x
Lithuania				x		
Luxembourg	x	x		x		x
Malta						
Netherlands	x	x		x		x
Norway	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
Sweden	x	x		x		x
UK[2]	x	x		x		x

1. Sobi has final development and commercialisation rights in Europe, most Middle Eastern markets, North Africa and Russia.
2. Sobi has applied for local regulatory approval of products to secure market authorisation approval after formal exit from the EU.

Regulatory approval and availability of Sobi products, cont.

	Access to Sobi's products – *new in 2019					
Region	**Alprolix[1]**	**Elocta[1]**	**Doptelet**	**Kineret**	**Gamifant**	**Orfadin**
Europe – other	Haemophilia B	Haemophilia A		RA, CAPS		HT-1
Russia				x		x
Switzerland	x	x		x		x
Turkey						
Ukraine						x
North America	Not Sobi territory	Not Sobi territory				HT-1
Canada				RA, NOMID x		x
Mexico						x
US			CLD, ITP* x	RA, NOMID x	pHLH x	x
Asia						HT-1
China	Not Sobi territory	Not Sobi territory	Out-licensed			
Kuwait	x	x				
Israel	Not Sobi territory	Not Sobi territory		x		x
Japan	Not Sobi territory	Not Sobi territory				x
Palestine						x*
Saudi Arabia	x	x			x*	x
United Arab Emirates	x*	x*			x* (named-patient use)	
Africa						HT-1
Algeria						x
Jordan						x
Tunisia		x*				x*,[3]
South America	Not Sobi territory	Not Sobi territory				HT-1
Argentina						
Chile						x*,[4]
Australia	Not Sobi territory	Not Sobi territory		RA, CAPS, Still's x		x*,[4]

1. Sobi has final development and commercialisation rights in Europe, most Middle Eastern markets, North Africa and Russia.
2. Sobi has applied for local regulatory approval of products to secure market authorisation approval after formal exit from the EU.
3. Additional approvals of capsule strength 20 mg.
4. Additional approvals of oral formulation and capsule strength 20 mg.

Global Reporting Initiative Index

Sobi's Sustainability Report 2019 is defined in the GRI Index below. Its main components are found in the following sections of the Annual and Sustainability Report 2019:

- Business Model is found on page 10.
- Description of sustainability approach, activities and performance 2019 are found on pages 22–25, 40–43 and 110–114.
- Information on performance is reported in the Sustainability notes section, on pages 110–114.

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 40. All page references below refer to pages in Sobi's 2019 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	56, 94		
	102-2	Activities, brands, products, and services	10, 32–35, 56		
	102-3	Location of headquarters	56, 94		
	102-4	Location of operations	18–19, 81		
	102-5	Ownership and legal form	28–29, 56, 94–95		
	102-6	Markets served	18–19, 32–35, 65		
	102-7	Scale of the organisation, including total number of employees, operations, net sales, and capitalisation	2–3, 5, 30, 32–35		
	102-8	Information on employees and other workers	68		6
	102-9	Supply chain	18, 44–45		
	102-10	Significant changes to the organisation and its supply chain	4, 32		
	102-11	Precautionary Principle or approach	40–43		
	102-12	External initiatives	40–45		
	102-13	Membership of associations	www.sobi.com		
Strategy and analysis					
	102-14	Statement from senior decision-maker	6–7, 93		
Ethics and Integrity					
	102-16	Values, principles, standards, and norms of behaviour	24, 41		10
Governance					
	102-18	Governance structure	41–43, 94–100		
Stakeholder Engagement					
	102-40	List of stakeholder groups	28, 40		
	102-41	Collective bargaining agreements	114		
	102-42	Identifying and selecting stakeholders	40		3
	102-43	Approach to stakeholder engagement	40–41		
	102-44	Key topics and concerns raised	40		
Reporting methodology					
	102-45	Entities included in the consolidated financial statement	56–61		
	102-46	Defining report content and topic boundaries	40, 50–61		
	102-47	List of material topics	40, 117		
	102-48	Restatements of information	42–43, 110–114		
	102-49	Changes in reporting	40		

GRI Standard	Disclosure		Page reference	Comment	UN Global Compact Principle
	102-50	Reporting period	94		
	102-51	Date of most recent report		April 2019	
	102-52	Reporting cycle	94, 114		
	102-53	Contact point for questions regarding the report	43		
	102-54	Claims of reporting in accordance with the GRI Standards	22, 43, 114		
	102-55	GRI content index	117–119		
	102-56	External assurance	120		
GRI 103: MANAGEMENT APPROACH 2016					
	103-1	Explanation of the material topic and its boundary	41–43		1, 2, 6, 7, 8, 9, 10
	103-2	The management approach and its components	41–45		1, 2, 6, 7, 8, 9, 10
	103-3	Evaluation of the management approach	110–114		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	110		
GRI 203: Indirect economic impacts 2016					
	203-2	Significant indirect economic impacts	110		
GRI 205: Anti-corruption 2016					
	205-1	Operations assessed for risks related to corruption	114		10
	205-2	Communication and training about anti-corruption policies and procedures	24, 41, 43, 114		10
	205-3	Confirmed incidents of corruption and actions taken	43, 114		10
GRI 206: Anti-competitive behaviour 2016					
	206-1	Legal actions for anti-competitive behaviour, anti-trust, and monopoly practices	41, 43		
SPECIFIC DISCLOSURES – GRI 300: ENVIRONMENTAL					
GRI 302: Energy 2016					
	302-1	Energy consumption within the organization	110–111		
	302-3	Energy intensity	111		
	302-4	Reduction of energy consumption	112		
GRI 303: Water and effluents 2018					
	303-1	Water withdrawal by source	112		
GRI 305: Emissions 2016					
	305-1	Direct (Scope 1) GHG emissions	110		7, 8
	305-2	Indirect (Scope 2) GHG emissions	110		7, 8
	305-3	Other indirect (Scope 3) GHG emissions	110		
	305-4	GHG emissions intensity	110		
GRI 306: Effluents and waste 2016					
	306-2	Waste by type and disposal method	112		8
GRI 307: Environmental compliance 2016					
	307-1	Non-compliance with environmental laws and regulations	42, 112		
GRI 306: Supplier environmental assessment 2016					
	308-1	New suppliers that were screened using environmental criteria	114		

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	113		6
GRI 403: Occupational Health and Safety 2016					
	403-2	Types of injury and rates of injury, occupational diseases, lost days, and absenteeism, and number of work-related fatalities	113		
GRI 404: Training and Education 2016					
	404-1	Average hours of training per year per employee	113		6
	404-2	Programs for upgrading employee skills and transition assistance programs	113		
	404-3	Percentage of employees receiving regular performance and career development reviews	42–43, 113		6
GRI 405: Diversity and Equal Opportunity 2016					
	405-1	Diversity of governance bodies and employees	113, 114		
GRI 406: Non-discrimination 2016					
	406-1	Incidents of discrimination and corrective actions taken	113		6
GRI 413: Local Communities 2016					
	413-1	Operations with local community engagement, impact assessments, and development programs	110		1
GRI 414: Supplier Social Assessment 2016					
	414-1	New suppliers that were screened using social criteria	114		2
GRI 416: Customer Health and Safety 2016					
	416-1	Assessment of the health and safety impacts of product and service categories	40–41		
GRI 417: Marketing and Labelling					
	417-1	Requirements for product and service information and labelling	40–41		
	417-2	Incidents of non-compliance concerning product and service information and labelling	41		
	417-3	Incidents of non-compliance concerning marketing communications	41		
GRI 418: Customer Privacy 2016					
	418-1	Substantiated complaints concerning breaches of customer privacy and losses of customer data	114		
GRI 419: Socioeconomic Compliance 2016					
	419-1	Non-compliance with laws and regulations in the social and economic area	43		

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 2019 on pages 22–25, 40–45 and 110–119 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 RevU 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, 25 March 2020
Ernst & Young AB

Björn Ohlsson
Authorized Public Accountant

2020 Annual General Meeting

2020 Annual General Meeting
Swedish Orphan Biovitrum AB (publ) will hold its Annual General Meeting on Wednesday, 13 May 2020 at Norra Latin, Drottninggatan 71B, Stockholm, Sweden.

To participate
Shareholders who wish to participate in the Meeting must be recorded in the share register maintained by Euroclear Sweden AB on Thursday, 7 May 2020. Shareholders must notify the company of their intention to participate no later than Thursday, 7 May 2020 in one of the following ways:

- On Sobi's website: www.sobi.com
- By phone: +46 (0)8-697 31 91, Monday to Friday 9:00–16:00
- By mail: Swedish Orphan Biovitrum AB (publ), "Annual General Meeting", SE-112 76 Stockholm, Sweden

The notification should include the shareholder's:

- Name
- Personal/corporate identity
- Address and telephone number (daytime)
- Number of shares held
- Where applicable, information about any representatives/advisors

Nominee shares
Shareholders who have registered their shares with a bank or another nominee must, to be entitled to participate in the Annual General Meeting, register their shares in their own name, so that the person concerned is recorded in the share register maintained by Euroclear Sweden AB on Thursday, 7 May 2020. Shareholders wishing to register their shares in their own name should inform the nominee in good time before this date. Such registration may be temporary.

Proxy
Shareholders who intend to be represented by proxy must issue a written and dated power of attorney for the proxy. If the power of attorney is issued by a legal entity, a certified copy of the registration certificate or equivalent for the legal entity must be attached. The power of attorney is valid for one year from the date of issuance, or until the date of expiry shown on the power of attorney, but not later than five years. The registration certificate shall state the circumstances prevailing at the date of the meeting and should not be older than one year on the date of the meeting. The original power of attorney and any registration certificate should be sent to the company by mail at the address indicated below well in advance of the meeting. A proxy form is available on the company's website, www.sobi.com, and can also be sent to shareholders upon request.

Financial calendar 2020

January–March Interim Report	29 April
Annual General Meeting	13 May
January–June Interim Report	16 July
January–September Interim Report	22 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.

Contact details
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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 report that are not defined according to 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 with a risk premium. The risk-free rate is an average of 10-year Treasury bill over the last five years. Beta is the correlation between Sobis share and 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.

Glossary

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.

BIVV001
A novel, investigational factor VIII therapy designed to extend protection from bleeds with prophylaxis dosing of once weekly or longer for people with haemophilia A. Builds on the 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.

Doptelet
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.

FDA
The US Food and Drug Administration.

Gamifant (emapalumab)
An anti-interferon-gamma (IFN-γ)monoclonal antibody (mAb), approved by the FDA and currently under EMA review for the treatment of primary haemophagocytic lymphohistiocytosis (HLH), a life-threatening syndrome of immune activation.

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.

IL-1
Interleukin-1 (IL-1) is a key mediator of inflammation and driver of autoinflammatory diseases.

ITI – Immune tolerance induction
A therapy used when haemophilia patients develop inhibitors to treatment. Factor concentrate is given regularly and at high doses over a period of time until the body is trained to recognise the treatment product without reacting to it.

Kineret (anakinra)
A recombinant protein drug that blocks the biological activity of interleukin-1 a and b (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.

LRTI
Lower respiratory tract infections.

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.

MEDI8897 (nirsevimab)
A single dose extended half-life anti-RSV F monoclonal antibody (mAb) being developed for the prevention of lower respiratory tract infections (LRTI) caused by RS-virus 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, .

Mucopolysaccharidosis (MPS) type IIIA (Sanfilippo A syndrome)
A progressive, life-threatening and rare inherited metabolic disorder affecting children from a young age. Belongs to a group of diseases called lysosomal storage disorders (LSDs).

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.

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.

RelTIrate
An open-label, multicentre study designed to investigate the immune tolerance induction (ITI) potential of Elocta in patients with haemophilia A who have developed inhibitors which have failed to be resolved with other therapies.

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 fall until late spring and peaks during the winter.

SOBI003
A product candidate and a chemically modified variant of a recombinant human sulfamidase, intended as an enzyme-replacement therapy in the lysosomal storage disease MPS IIIA, aimed at reducing heparan sulfate storage materials in affected cells.

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 RS-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 a RSV F protein inhibitor monoclonal antibody (mAb) that acts as a 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.

XTEN
XTEN is a technique used to extend the half-life of proteins.

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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