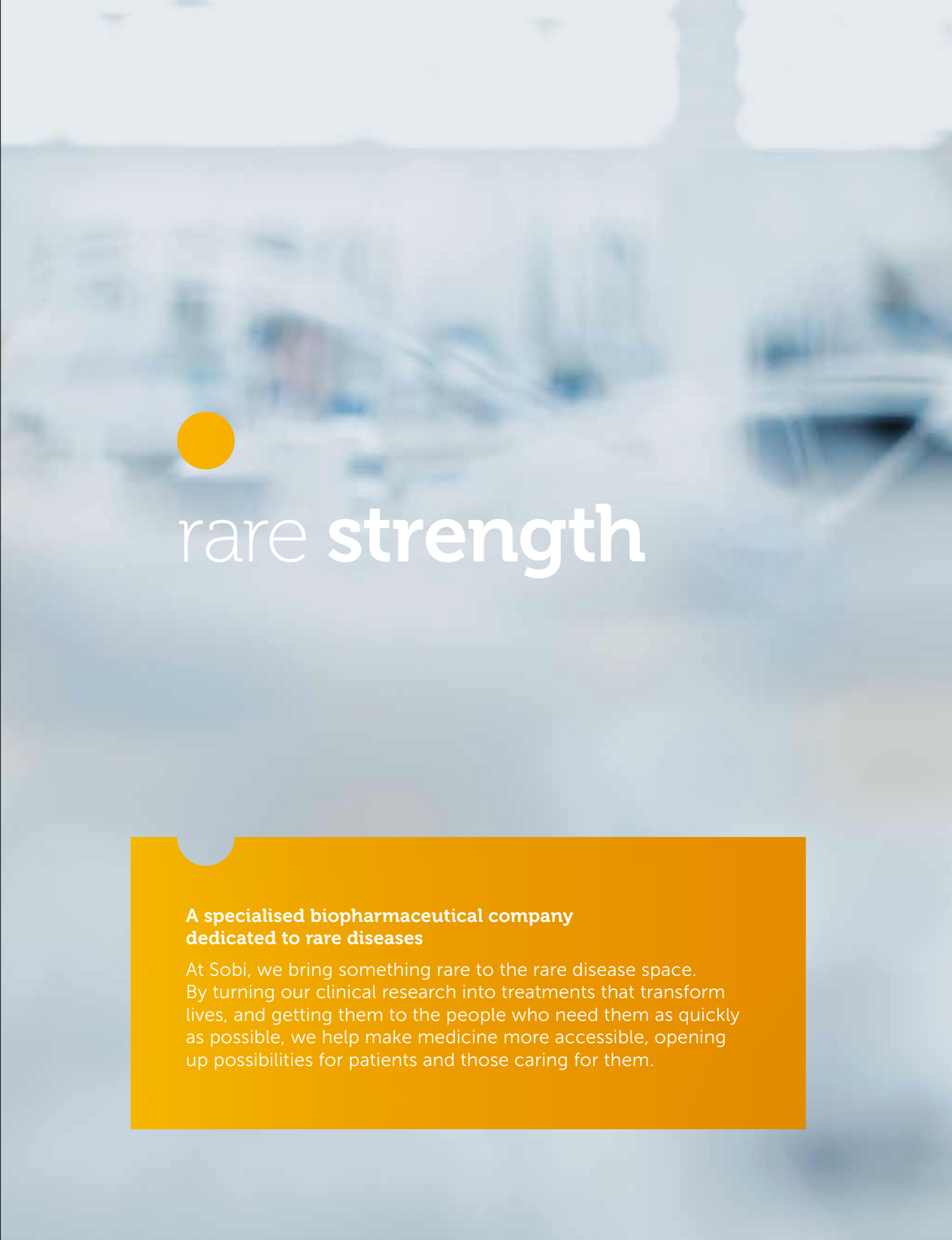
Annual & Sustainability Report

2018

sobi
rare strength

Contents

This is Sobi's Annual and Sustainability Report 2018. The audited Annual Report includes pages 50–106. The Sustainability Report is found on pages 12–13, 15–17, 30–31, 34–41, 58–63 and 123–133 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**

A specialised biopharmaceutical company dedicated to rare diseases

At Sobi, we bring something rare to the rare disease space. By turning our clinical research into treatments that transform lives, and getting them to the people who need them as quickly as possible, we help make medicine more accessible, opening up possibilities for patients and those caring for them.

This is Sobi

Sobi is an international biopharmaceutical company dedicated to rare diseases. As an integrated company, we have extensive capabilities across the value chain, from the discovery, development and manufacture of medicines to patient access and support. Our plan is to continue diversifying to create a broader yet focused R&D and product portfolio.

Haemophilia, Immunology and Specialty Care
Our therapies are concentrated within the areas of Haemophilia, Immunology and Specialty Care. Uptake of our extended half-life recombinant treatments for haemophilia A and haemophilia B, developed in conjunction with Sanofi (formerly Bioverativ), is growing rapidly as they become increasingly accepted as the standard of care in several countries. During 2018, we created a strong Immunology portfolio, and have important specialty treatments in the area of genetics and metabolism.

Patients in over 70 countries
With our global head office in Stockholm, Sweden, our organisation spans 19 countries, delivering treatments to patients in over 70 countries around the globe. Europe and the Middle East – which together with Russia and North Africa comprise our EMENAR region – are the core markets for our Haemophilia franchise, while acquisitions during 2018 greatly strengthened our business and footprint in North America, balancing our success in Europe.

Integrated biopharmaceutical company
We cover the entire value chain, from ideation and research, through preclinical and clinical development, biologics manufacturing, regulatory affairs to patient access and distribution. Our commercial success allows us to reinvest in the research and development of new therapies that transform the lives of people with rare diseases.

By promptly turning our clinical research into groundbreaking treatments, we help make medicine more accessible more quickly, opening up new possibilities for patients and more opportunities for those caring for them.

Our focus and capabilities, track record of bringing rare-disease products to market, and ability to find creative business development and licensing solutions make us an ideal partner for biotech companies with promising drug candidates which could have a high impact in small populations.

Patients' needs first
In all our partnerships, we put the needs of patients first, in the knowledge that good medicine is good business. Working strategically with multiple stakeholders, we create value for all parties – patients and their families, healthcare systems, payers, our employees, investors and the pharmaceutical industry – to deliver new treatments to the people who need them.

Responsible pricing
A vital factor in access to treatment is responsible pricing. That means balancing the role of a sustainable company with being a sustainable part of the healthcare system. Our continual dialogue with rare-disease communities, regulators and budget holders allows us to create powerful value propositions and product validations enabling us to get therapies to patients efficiently and responsibly.

Together with our partners and stakeholders, we ensure that we create solutions that serve the needs of those affected by rare diseases while also facilitating sustainable growth.

We bring something rare to rare diseases – a belief in the strength of being focused, the power of agility and the potential of the people our business is designed to serve.

70
We serve patients in over 70 countries

935
Employees

9,139
SEK M in revenue

Focus is strength

As a specialised biopharmaceutical company, we are dedicated to rare diseases. We see this focus as a strength. With over 80 years of experience, Sobi has a lot to offer in product development and commercialisation.

Research
R&D enables us to generate innovative treatments, as well as evaluate projects and products from outside and further develop them in-house.

Development
We cover the entire development process, from pre-clinical and clinical development, to post-approval clinical studies in a real-world setting.

Manufacturing
In addition to in-house biological manufacturing, Sobi works with 15 contract manufacturing organisations (CMOs) in Europe and the US.

Regulatory and safety
Patient safety is of utmost importance, and is the guiding principle for our work in the regulatory area, including distribution. Stringent pharmacovigilance and drug safety systems help protect patient safety.

Commercialisation and patient access, worldwide
The footprint of our commercial organisation continues to grow and covers issues including access to treatment, responsible pricing and education of healthcare professionals.

+40%

Revenue growth 2018

Share of total revenue, by business area

- 66% Haemophilia
  - of which manufacturing revenue accounts for 5%
- 34% Specialty Care

The year in figures

2018 was a year of impressive growth. Revenue was up 40 per cent year on year, with EBITA rising 74 per cent. Product sales in Haemophilia more than doubled, and we achieved double-digit growth in Specialty Care.

Key figures

SEK M	2014	2015	2016	2017	2018
Total revenue	2,607	3,228	5,204	6,511	9,139
Gross profit	1,548	2,007	3,651	4,657	6,723
Gross margin, %	59	62	70	72	74
Operating expenses	1,873	1,861	2,518	3,057	3,601
EBITA	–44	433	1,543	2,053	3,571
EBIT	–325	146	1,133	1,600	3,122
Profit/loss for the year	–270	83	802	1,149	2,418
Earnings per share, SEK	–1.01	0.31	2.99	4.27	8.97
Cash flow from operations	234	507	343	1,333	2,090
Equity per share, SEK	16.6	17.3	19.8	24.6	33.1
Equity assets ratio, %	71	56	54	61	53
Dividend	0	0	0	0	0
No. of employees (full-time equivalent)	589	702	760	800	902

40%

Revenue growth

74%

EBITA growth

Overview of most important products by revenue

Haemophilia

SEK M	2018	2017	Change, %
Elocta®	3,261	1,557	109
Alprolix®	974	363	168
Manufacturing	436	559	–22
Royalty[1]	1,341	1,203	12
Total	**6,012**	**3,682**	**63**

1. See page 82 for details.

Haemophilia

Product sales more than doubled. The main countries contributing to this growth were France, Germany, Italy and the UK.

Specialty Care

SEK M	2018	2017	Change, %
Kineret®	1,320	1,142	16
Orfadin®	899	862	4
Other	908	825	10
Total	**3,127**	**2,829**	**11**

Specialty Care

There was a strong performance across the Specialty Care portfolio. Solid growth for Kineret continued across all regions for the full year.

The year in brief

Acquisitions helped take Sobi to a new level in 2018. Synagis® will strengthen our footprint in the North American market, where business will almost triple compared with 2018. The acquisitions of rights to emapalumab and Synagis create a strong second leg in Immunology to better balance our success in Haemophilia.

Haemophilia

Q1

Ireland becomes the first country in Europe where every person with haemophilia has access to extended half-life (EHL) therapies after new supply contracts are signed with Sobi.

Sobi becomes the first company in France to make EHL treatments available for both haemophilia A and B.

Q2

Data released at the World Federation of Hemophilia (WFH) World Congress in Glasgow show quality-of-life improvements for patients treated prophylactically with Elocta and Alprolix EHL haemophilia therapies.

Q4

At the American Society of Hematology (ASH) conference, data is presented showing that EHL therapies Elocta and Alprolix demonstrate proven efficacy and well-characterised safety over four years.

Total sales: SEK 4,235M

Sales growth: 145%

Number of new markets: 10

Elocta and Alprolix – market leaders in France.

Specialty Care

Q1

Sobi launches Ravicti® in Europe and advances the care of patients with urea-cycle disorders.

Q2

Kineret approved in the European Union for the treatment of Still's disease.

Q3

Sobi strengthens the Immunology franchise by acquiring the global rights for emapalumab from Novimmune.

Q4

Sobi acquires US rights to Synagis from AstraZeneca, creating a platform for global growth. The acquisition was finalised in January 2019.

The Food & Drug Administration (FDA) approves Gamifant® (emapalumab) in the US, the first approved treatment for primary haemophagocytic lymphohistiocytosis (HLH).

Total sales: SEK 3,127M

Sales growth: 11%

Research & Development

Q1

FDA accepts investigational new drug application and grants Fast Track Designation for SOBI003 for the treatment of mucopolysaccharidosis (MPS) type IIIA.

Q2

Preliminary phase 1/2a data on BIVV001 (rFVIIIFc-VWF-XTEN)[1], presented at the WFH World Congress.

Q3

First patient dosed in phase 1/2 trial evaluating SOBI003 for treatment of MPS IIIA.

Results presented from the anaGO study, a phase 2 trial with anakinra in patients with acute gout.

Q4

BIVV001[1] phase 1/2a data presented at ASH underscores potential for once-weekly dosing with sustained high factor levels in haemophilia A.

Data presented at ASH supports emapalumab as an innovative, targeted therapeutic option for primary HLH.

Total products in pre-clinical stage: 3

Total products in clinical stages: 14

Organisation

Q1

Torbjörn Hallberg joins Sobi as General Counsel and Head of Legal Affairs.

On Rare Disease Day, Sobi launches an enhanced corporate sustainability programme with a strong connection to the company's strategy of providing sustainable access to treatments for rare diseases.

Q2

Sobi appoints Henrik Stenqvist as Chief Financial Officer and Fredrik Wetterlundh as Head of Human Resources.

Q3

Anne Marie de Jonge Schuermans joins Sobi as Head of Technical Operations.

Number of employees[2]:

935

1. A Sanofi development programme. Sobi has elected to add BIVV001 to its collaboration agreement with Sanofi but has not yet opted in.
2. Number of employees at end of year.

Growing globally

2018 was a year of transformation for Sobi. Our progress in Haemophilia, acquisitions in Immunology and sales growth in Specialty Care mean that the company is essentially, on a pro-forma basis, two-and-a-half times the size it was at the end of 2016. But it is important to understand that we see this as an important stepping stone.

Our achievements demonstrate that we are delivering on every aspect of our strategy. By continuing with substantial growth in Haemophilia, enlarging our Specialty Care portfolio and building a new Immunology franchise, through expansion in North America and continued growth in EMENAR, and by strengthening our innovation pipeline, we are ensuring the company can continue to grow. This is essential for achieving our vision of being recognised as a global leader in providing innovative treatments that transform life for people with rare diseases.

The most prescribed EHL treatments

We have positioned Sobi as a leading player in haemophilia in many markets. Elocta (sold by Sanofi as Eloctate® in Sanofi territories) and Alprolix are now the most prescribed extended half-life treatments in the world[1]. We have made a significant leap in terms of market share to become one of the top three companies in Europe, in both haemophilia A and B, on a consolidated basis.

We – along with patients, carers, treaters and payers – have seen how our products help people with haemophilia to liberate their lives and expect more from their treatment. And we are seeing positive results from the phase 1/2a data for BIVV001. I expect the strong growth of our Haemophilia franchise to continue as more people gain and seek access to our treatments.

We have been able to accelerate Kineret significantly, and full-year growth of 16 per cent for 2018 is a testament to this. The approval of Kineret as a treatment for Still's disease in Europe helped in this regard. We expect more growth in the near future from our investment in Kineret in the US.

On the other side, with regard to Orfadin, we have maintained market share in the face of emerging competition.

A strong emphasis on immunology

Our acquisitions in 2018 were a huge step forward for the company. They help articulate what we mean by specialty care, and give us a strong emphasis on immunology. On a pro-forma basis, the acquisitions of rights to Synagis and emapalumab mean that more than 70 per cent of the Specialty Care business will be driven by Immunology. This gives the Group a strong second leg to balance our success in Haemophilia.

The acquisition of global rights to emapalumab last summer represented the first major step in our transformation. The therapy was approved as Gamifant in the US late last year, as the first approved treatment for primary haemophagocytic lymphohistiocytosis (HLH). We have seen good results in the clinical data. It is very encouraging to have such a life-changing product with the financial potential to further transform the Group.

Emapalumab creates a significant growth opportunity for the Group, but also requires further investment. Launch costs for the US were seen in Q4, while future investment will focus on commercialisation, seeking approval in primary HLH in the EU, and advancing the development of emapalumab. Clinical development activities to expand indications, such as into secondary HLH, are under preparation.

Tripled size in north America

With the Synagis rights acquisition signed in November 2018, and finalised in January 2019, we now have a very strong field force in the US, more than 270 people in total. This positions Sobi on a completely different scale in the North American market, where business will essentially triple what we recorded in 2018. Under a committed leadership, we have a skilled team with a strong paediatric focus that will serve us well in the years to come. I was particularly pleased that all 133 people from AstraZeneca who we invited to join in conjunction with the acquisition accepted our offer. This confirms to me that Sobi is an attractive company to join.

In both deals, we were able to demonstrate that not only are we an attractive partner, but that we can also provide creative solutions that address our business partners' needs and create value for both parties.

The combined effect of our commercial success ensures that we have significant

1. Data on file.

»We have laid the foundations and now we have to build. With our capabilities, commitment, strategy and financial strength, I am confident we will succeed.«

earning capacity to support research and development, and particularly strong late-stage development.

In R&D, it was gratifying to see that SOBI003 has now advanced into the clinical phase 1/2 study, and that we are recruiting well for the continuing study. The entire organisation has done a fantastic job in achieving this major milestone, and I am proud of the team for showing that we can take a molecule and potential treatment from idea to patient.

As part of our collaboration partnership agreement with Sanofi, we have seen encouraging results in the phase 1/2 trial of the Fc fusion follow-on drug candidate BIVV001[1], showing unprecedented levels of protection in factor VIII therapy. This investigational treatment shows potential to become one of the products of choice in the treatment of haemophilia A. The results confirm our commitment to play a very active role in this partnership with Sanofi.

Stronger organisation

In 2018, we also strengthened our leadership team with Torbjörn Hallberg as General Counsel and Head of Legal Affairs, Henrik Stenqvist as CFO and Fredrik Wetterlundh as Head of Human Resources. In October, Anne Marie De Jonge Schuermans joined Sobi as head of our new Technical Operations unit, which brings together a variety of functions including the development, manufacture and supply of medicines. Anne Marie is building a technical organisation with strong discipline, a focus on costs and the scale required to serve Sobi for the years to come.

Our entire organisation continues to evolve, with a strong emphasis on the development and maintenance of high-performing teams. While maintaining our foundational focus on patients, we as a company are learning to assert ourselves more strongly and compete in the market. This is a trait that we will increasingly need as we see more competitors entering the haemophilia space. The evolved Sobi values introduced in 2017 and implemented in 2018 – Care, Ambition, Urgency, Ownership and Partnership – provide the guiding principles for everything we do every day. I have been pleased to see that people across the organisation have embraced these as part of their work. These are values that guide and empower us all, and are essential for the growth journey we are on.

Growth empowers us to meet our responsibility of providing sustainable access to our treatments for the people who need them. This is the most obvious aspect of our work in sustainability, but we also continue to advance in areas including corporate governance, ethical partnerships and behaviour, and strong corporate citizenship.

I am pleased to confirm that Sobi continues 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.

Building our pipeline

We are staking out Sobi's direction in terms of building our pipeline and looking for further value-creating acquisitions to accelerate growth. Our vision is to be recognised as a global leader in the rare disease space. We have made significant progress, but to achieve our vision, we still have more to do.

We now have an R&D portfolio with a significant collection of late-stage assets, including BIVV001, financial rights to MEDI8897, additional indications for emapalumab and further opportunities in Kineret. We also have high hopes for the future of SOBI003.

As well as the transformational changes on the R&D side, we have Gamifant in launch phase in the US, and substantial potential in both haemophilia and with Kineret. We are also confident that Synagis can grow further under our ownership.

In the months and years ahead, we will continue to search for more late-stage assets that will diversify the company further, particularly in the areas of haematology and immunology.

I am proud to be working with the great people here at Sobi. I would like to thank all my colleagues for their efforts during a demanding and eventful year, and for their continuing dedication and commitment.

And I would also like to thank our shareholders for their support and trust throughout 2018 and beyond.

We have laid the foundations, and now we have to build. It is a big challenge that we are taking on. With our capabilities and commitment, strategy and financial strength, I am convinced we will succeed.

In summary, I can say that 2018 was a year of achievements and great strides towards our vision. But this was only the beginning.

Guido Oelkers
Chief Executive Officer

1. A Sanofi development programme. Sobi has elected to add BIVV001 to its collaboration agreement with Sanofi but has not yet opted in.

Rare diseases

There are an estimated 6,000–8,000 rare diseases in the world today affecting more than 300 million people[1]. Because only around 500 of these diseases have approved treatments, this is a hugely under-served area with great unmet medical needs. At Sobi, we specialise in rare diseases because it is where we can make the greatest difference to people's lives.

The rare disease space is unlike any other in medicine. 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. Because physicians may never have seen the condition before, many cases can go undiagnosed for years.

Around 75 per cent[2] of identified rare diseases affect children, and many have a devastating effect on life expectancy and quality of life. An estimated 35 per cent of children with a rare disease will not live to see their fifth birthday, and rare diseases are thought to be responsible for around 35 per cent of deaths during the first year of life.

Around 80 per cent of rare diseases are inherited rather than acquired: they involve a defect in the genes that tell our bodies how to work. As a result, the body may fail to produce an essential enzyme or protein, for example, or its own immune defences may attack its own systems.

Because they are most commonly genetic disorders, rare diseases tend to be lifelong. Treatment is often focused on resolving the problem caused by the defective gene, alleviating the symptoms and allowing the person to live a more normal life.

The price of orphan drugs is relatively high compared with other treatments targeting larger patient populations. However, the total cost for the healthcare system is not as great as perceived, particularly considering the transformative value that orphan drugs bring to patients.

Rare challenges

The rare disease landscape also presents specific challenges – scientific, medical and commercial. They range from understanding the biology of a disease, identifying molecules that can become successful treatments, developing the complex biopharmaceutical processes to manufacture a drug, designing and running clinical trials in extremely small patient populations, obtaining regulatory approvals, negotiating pricing and reimbursement, through to working with healthcare professionals and patients to ensure access for the people who need the treatment. At each step, we draw on our expertise and experience, working across functions and with external stakeholders to achieve the best possible outcome.

An example is the way we work with regulatory authorities to get treatments to patients as quickly as possible. In small trials, the process can be accelerated if a candidate treatment demonstrates transformative results for trial patients. Both the FDA and European Medicine Agency (EMA) can allow such breakthrough therapies to be fast-tracked through the approval process, providing priority review procedures. SOBI003, for example, has been granted Fast Track Designation by the FDA.

The growth we have experienced in recent years demonstrates that doing good for patients can also be good business. We focus on small patient populations and are sized accordingly. We know rare diseases, and that is where we concentrate our efforts. When assessing a potential treatment, we look at where our know-how and capabilities can play a significant role, and where we can stand out from the crowd.

Being the first to bring a new orphan therapy to patients also brings advantages. In such a case, regulatory authorities can

1. Global Genes, www.globalgenes.org
2. EURORDIS, www.eurordis.org

grant market exclusivity for a specific time, allowing the company to recoup its investment in the discovery, development and regulatory review processes. Backed by solid science, and with an understanding of the approval, pricing and reimbursement mechanisms, a new therapy can be launched without delay and reach patients in the shortest possible time.

Our size is a strength

We have the scale to invest in innovation and provide comprehensive support in all our territories, yet still have the flexibility and agility required to act quickly. As an integrated biopharmaceutical company, we work in cross-functional teams, across our disciplines. Having patient access experts involved in the early stages of the development process, regulatory approval and pricing negotiations, for example, allows us to get treatments to patients more quickly. Our commercial, medical and research teams work together with healthcare professionals, external researchers and other stakeholders to improve understanding of evolving patient and treater needs. This also allows us to learn how, for example, new formulations can better meet an emerging patient need. We also reinvest revenues back into developing new treatments.

Our close contact with patient and treater communities allows us to identify other non-drug measures to address unmet needs. These can include educational programmes, disease awareness and bridging finance initiatives.[1]

Treatments reaching more people

Advances in scientific knowledge allow us and other companies in the industry to identify and develop new treatments for more of those 6,000–8,000 rare diseases that have been identified. In the US, the FDA approved 80 new orphan indications in 2017, with 59 approvals within the first eight months of 2018[2], the highest figures since the introduction of the Orphan Drug Act in 1983.

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 reduced quality of life.

1. www.sobi.com
2. www.iqvia.com

Delivering on our strategy for growth

Sobi's strategy is based on our vision of becoming a global leader in getting transformational treatments to people with rare diseases. In 2018, we have seen major progress in all four areas of our strategy.

Our strategy for growth is built on four cornerstones:

- Increasing access to our treatments for haemophilia
- Enlarging our Specialty Care franchise
- Expanding our position in EMENAR, and growing in North America
- Strengthening our R&D pipeline.

The strategy builds on our strong position as an integrated biopharmaceutical company covering the entire value chain of treatment for rare diseases in EMENAR and North America.

We continue to invest in our strongly growing market position in haemophilia. Having seen the transformative benefits of our extended half-life treatments for people with haemophilia A and B, enabling access for more people through their local healthcare systems is a moral imperative. The dramatic commercial growth in this area is also generating significant revenue, allowing us to invest further in the haemophilia space.

Enlarging our Specialty Care portfolio allows us to create a better balance for our overall business operations, while ensuring sustainable growth in both the short and long term. Acquisitions in 2018 have allowed us to create a strong Immunology franchise; these therapies, together with our other products in the Specialty Care area, will benefit from our extensive commercialisation platform in Europe and emerging strength in North America. The addition of new treatments to our Immunology and Specialty Care portfolios allows us to bring further transformative therapies to patients.

Major expansion in North America, combined with continued growth in our EMENAR-region, allows our business to better match the overall geographic balance of the global rare-disease domain. The growth in both regions strengthens our commercial platform and adds to our financial capacity.

We continue to advance and expand our research & development pipeline. With our ongoing investment in R&D, we are developing new therapies in-house and bringing in external late-stage candidate drugs that address significant unmet medical needs, create synergies in our portfolio, expand our global platform and show potential for future growth.

The combination of our strength with that of our partners creates unique opportunities to create added value in the rare-disease field.

Delivering on our strategy

Outcome

Increasing access to our treatments for haemophilia

- 109 per cent increase in sales for Elocta.
- 168 per cent increase in sales for Alprolix.
- 10 new markets reached agreement on pricing and reimbursement.

Enlarging our Specialty Care franchise

- Synagis rights acquisition provides further diversification into immunology.
- Acquisition of the global rights to emapalumab.
- Emapalumab was approved as Gamifant in the US.
- 16 per cent increase in sales of Kineret across NA and EMENAR.
- Kineret for Still's disease approved and launched in EU.

Expanding our position in EMENAR, and growing in North America

- Acquisition of global rights to emapalumab strengthens geographic footprint, particularly in the US.
- Acquisition of US rights to Synagis nearly triples commercial footprint in the US and allows us to expand our presence beyond Synagis.

Strengthening our R&D pipeline

- Encouraging data from the phase 1/2 study of BIVV001 presented.
- Acquired rights to 50 per cent of future earnings from the MEDI8897 drug candidate in the US.
- First patient enrolled in SOBI003 phase 1/2 trial in August 2018.
- Key results for the phase 2 anaGO trial with anakinra published.

FINANCIAL OUTLOOK 2018	FINANCIAL OUTCOME 2018	FINANCIAL OUTLOOK 2019
Revenues: SEK 7,500–7,700 M	Revenues: SEK 9,139 M	Revenues: SEK 12,500–13,000 M
EBITA: SEK 2,500–2,700 M	EBITA: SEK 3,571 M	EBITA: SEK 5,000–5,300 M
Gross margin of at least 70 per cent	Gross margin 74 per cent	

Sobi's value creation

Our vision and mission ▶

Vision
Our vision is to be recognised as a global leader in providing access to innovative treatments that transform the lives of individuals with rare diseases.

Mission
Our mission is to develop and deliver innovative therapies and services to improve the lives of patients.

For whom ▶

We provide treatments that transform life for people with rare diseases. These people, their families, the healthcare community and society at large benefit from sustainable access to treatment.

Through good business practice, we also provide solid returns on investment and reinvestment in further R&D and business development.

Input ▶

- Rare disease space – high unmet medical need, favourable regulatory environment and growing market
- Patient involvement and patient journey insights
- Skilled workforce specialising in rare diseases and biopharmaceuticals
- Manufacturing facilities
- Intellectual property and innovation capital
- Reputational capital – partnerships and networks
- Proprietary and licensed products
- Strong earnings platform and financial resources
- Geographical footprint in EMENAR and North America

Stakeholders ▶

- Patients, families, carers and patient organisations
- Regulatory authorities and healthcare systems
- Payers and insurance companies
- Pharmaceutical companies
- Healthcare professionals and experts
- Capital markets
- Shareholders

Business model ▶

AN INTEGRATED PROCESS

→ We use an integrated process, from in-house research in protein characterisation, and the development and industrial manufacturing of biologics, to providing sustainable access to treatments for rare diseases.

← Insights about the patient journey and the needs of patient representatives and healthcare systems are continuously fed back into the process to enhance our offering of treatments.

1. Research
2. Development
3. Manufacturing
4. Regulatory and safety
5. Commercialisation and patient access

Value for stakeholders ▶

- Access to treatments that transform life for people with rare diseases.
- Evidence-based generation of treatments and increased knowledge-sharing with rare-disease and patient communities.
- Reduced inequalities and transformative circumstances for people with rare diseases.
- Good business practice helps combat corruption.
- Strategic partnerships and integrated, efficient and innovative processes that create value for shareholders.
- Financial strength enabling investment into research & development.
- Sustainable organisational growth, short and long term.
- Engaged and skilled people. Creating jobs and a skilled workforce.

SEK 507M

Total corporate income tax for 2017, to be paid in 2018

12%

Percentage of revenue reinvested in R&D to deliver potential future treatments for rare diseases

>70

Number of countries with access Sobi's treatments

935

Number of people employed by Sobi at year-end 2018

88%

Increase of patients on our haemophilia treatments

8.97

Earnings per share (SEK)

72%

Share price increase

SUSTAINABLE DEVELOPMENT GOALS

The United Nations describes its 17 Sustainable Development Goals as "a universal call to action to end poverty, protect the planet and ensure that all people enjoy peace and prosperity". Business can and must play an important role in the achievement of these goals. While our operations support several of the goals, based on our growth strategy and materiality analysis, we have focused our efforts on three goals in 2018:

Improving global health by making treatments for rare diseases more accessible is what we do every day. We contribute to the pursuit of universal health coverage, including financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

Transparency regarding business ethics and corruption form the foundation of strong collaborations for qualitative research, development and manufacturing. We work actively to combat corruption in all of its forms, and to ensure compliance with our ethical standards in all our dealings.

By working strategically with multiple partners, we create value for a variety of stakeholders including patients and their families, healthcare systems, payers, our employees, investors and the pharmaceutical industry. We see partnership – with healthcare authorities, patient organisations and other stakeholders – as essential for providing sustainable access to treatment.

Business fundamentals

Key considerations when developing new treatments for rare diseases

Demand/need ▶

Incidence and prevalence
Is there a high unmet medical need? Is the condition life-threatening or debilitating? How many people does it affect? How can patients be identified? Is the biology understood? Does the condition represent one disease or a syndrome of related disorders? How does the disorder develop and progress? What is the prognosis for patients? In what way would the new treatment be transformative?

Current standard of care
Are there treatments in use today? If so, what are the safety and efficacy profiles? Are there significant side-effects? Are current treatments transformative, or do they alleviate symptoms? Would a new treatment be a complement to existing treatments or a replacement?

Horizon scanning
Are there any other prospective treatments currently under development? Can our potential treatment be developed further? Would it be possible to extend the label to other indications or patient groups?

Feasibility ▶

R&D capabilities
Does the new treatment fit with the profile of our R&D expertise? Is this something we could research and develop in-house? Could we conduct the required R&D in partnership?

Clinical and regulatory planning
Are there any clinical obstacles to conducting trials? What are the validated end-points for measuring clinical benefit? Is historical clinical data available, from within Sobi or externally? What new data is required? Is this treatment likely to be approved by regulatory bodies? What clinical end-points would they require? Will the trials be blinded or not? What are the safety requirements? How long will the trials take?

Sourcing capabilities
Do we have the in-house manufacturing capacity for this therapy? Is it something we can manufacture together with a partner? Can we guarantee supply in both the short and long term?

Market potential and commercialisation (viability) ▶

Potential
How many patients will benefit from this therapy? How many are eligible for treatment? How long will they require treatment?

Position
What is the treatment paradigm? What is the competitive landscape like? Will this product be first to market? How is the competitive landscape likely to develop?

Sustainable access to treatment
How can we engage with patient communities, regulators and payers to ensure patients get sustainable access to the treatment? How can our pricing and reimbursement submissions help more people get access to treatment? Is the revenue stream sustainable in the long term?

Taking the treatment to the patient

Our patients cannot wait. The nature of many rare diseases makes it imperative to bring treatments to patients, to save and transform lives. Our experience in rare diseases has helped us refine our processes and systems to bring medicines as promptly as possible to the people who need them, while always having patient safety as the top priority.

At Sobi, we are committed to supporting the rare disease community and partnering with healthcare systems to ensure that our medicines are accessible to the vulnerable patient population for which they are intended.

Insight and understanding

The special circumstances of the rare disease landscape create specific challenges in taking treatment to patients. Bringing innovative therapies that address unmet medical needs to market requires insight and understanding, a commitment to partnership, and determination.

For us, the process is built on understanding the needs of people with rare diseases. From early research through to pricing and reimbursement negotiations, we work in close consultation with stakeholders who are united in their determination to improve the lives of patients and their families.

In clinical research, for example, we work closely with patient advocacy groups and healthcare professionals right from the beginning. This includes discussing the true burden of the disease, for patients and caregivers, to shine a light on what is important for them.

By having these insights early on, we can ensure that the clinical endpoints for trials are the correct ones, to make sure that any eventual therapy truly addresses the unmet medical need.

In parallel, we work with healthcare and regulatory authorities, to provide an all-round understanding of what is relevant for patients, physicians and payers. Our Regulatory Affairs team – with a combined 400 years of experience from the pharmaceutical industry, regulatory consultancy services and regulatory bodies – contributes with its knowledge to the development, approval and maintenance of our products. Early dialogue with bodies such as the EU Network for Health Technology Assessment (EUnetHTA) helps ensure quality data that allows rapid advancement through regulatory approval and pricing/reimbursement processes.

This means that the entire process is aligned, avoiding the need for delays to find additional information later on. A smoother process means earlier access to life-saving treatment.

Responsible pricing

We conduct extensive stakeholder research to ensure that that the price of our medicines is aligned with the benefit they provide to patients, healthcare systems and payers. Such analysis includes discussions of the indicated usage and evidence package with clinical experts and payers/HTA (health technology assessment) bodies, as well as an evaluation of analogues for other ultra-rare, life-threatening disease medicines.

Combined with understanding of patient needs, insight into the requirements of and demands on healthcare systems are also vital in ensuring that pricing levels are negotiated to provide truly sustainable access to treatment.

All our pricing decisions balance three basic principles:

- The benefit that the innovation provides to patients
- The impact on healthcare systems
- The costs required to sustain innovation and continue to meet medical needs in the future.

Our haemophilia therapies are a perfect example. To make the benefits of our extended half-life treatments available to as many people as possible, we have worked together with healthcare systems to apply a pricing strategy based on annual parity with conventional treatments available on the market. This means that our products can reach everyone with haemophilia without any significant extra cost and no additional barriers.

Enabling global access

By working closely with patient organisations, healthcare authorities and payers, we have gained a deeper understanding of the specific challenges facing rare-disease communities in countries and regions around the world.

With offices in 19 countries, serving more than 70 national markets, we have patient access experts on the ground who know what problems can arise and are working to ensure that patients get the medicines they need.

In rare diseases, the patient populations are by definition small. In some cases, there is no regional patient organisation, only national ones; in such a situation, insight into local challenges is vital.

Our agile organisation and depth of understanding allows us to support patients across the broad scope of rare diseases – from ultra-rare conditions such as MPS IIIA to the comparatively large group of people living with haemophilia. Whether the therapy we provide is the first approved, such as emapalumab, or an innovative alternative to existing treatments, our commitment to people with rare diseases drives us to find the best way of bringing the treatment to the patient.

Partnership and collaboration

We see partnership as essential to our efforts to provide sustainable access to treatment around the world. Our collaboration with Novimmune brought emapalumab to the market quickly, being approved and launched in the US late in 2018 as Gamifant, the world's first approved treatment for primary HLH. We partner with several other pharmaceutical companies to bring their treatments to patients across our territories.

As well as a range of healthcare authorities, payers, researchers and other bodies, we also work with patient organisations to support their initiatives to provide access in under-developed countries and regions.

Our largest such commitment is our donation, together with Sanofi Genzyme, the specialty care business of Sanofi, of 1 billion international units (IU) of extended

Fc fusion

Elocta is an extended half-life recombinant clotting factor VIII replacement therapy for treatment of haemophilia A. Seen here in orange, Elocta is an FVIII molecule fused to the Fc domain of immunoglobulin-gamma (in blue). Elocta binds to FcRn receptors (in grey) on the surface of endothelial cells, initiating the recycling pathway which drives the Fc-driven prolongation of its half-life.

half-life clotting replacement factor for use in developing countries: 500 million IUs have been committed to the World Federation of Haemophilia's Humanitarian Donation Program over a five-year period starting in 2015. We were also a founding sponsor of the European Haemophilia Consortium's PARTNERS programme, to increase access to haemophilia treatment in countries in Europe that currently provide little or no such treatment.

Our patient-centric approach, partnership capabilities and in-house expertise and capacity give us the power to deliver on our promise of providing sustainable access to life-changing treatments for people with rare diseases.

Patient safety and product quality

Patient safety throughout the product life cycle is one of our most important tasks. With a robust pharmacovigilance system in place, we continuously oversee the benefit/risk profiles of our products. The pharmacovigilance system complies with all global, national and local regulations. The main purpose of the system is to guarantee patient safety in regards to our products.

Annual training is provided for all employees to ensure that all safety information in relation to our products is reported. By collecting and analysing safety data from all sources, we aim to provide accurate and up-to-date information to regulators, healthcare professionals and patients.

Our aim in each country is the same: to provide timely and sustainable access to transformative treatment for every person with haemophilia.

The most common rare disease in the world

With nearly 200,000 people diagnosed across the globe, haemophilia is the most common rare disease in the world. It is a 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 more rarely in females. Haemophilia B occurs in about one in 28,000 male births annually, and more rarely in females. The World Federation of Haemophilia estimates that approximately 196,700 people are currently diagnosed with haemophilia A and B worldwide.[1]

People with haemophilia A or B experience bleeding episodes that can cause pain, irreversible joint damage and lifse-threatening haemorrhages. Prophylactic injections of factor VIII or IX can temporarily replace the clotting factors that are needed to control bleeding and prevent new bleeding episodes. The World Federation of Haemophilia recommends prophylaxis as the optimal therapy as it can prevent bleedings and joint destruction.

1. World Federation of Haemophilia. Report on the Annual Global Survey 2017. Available at: www.wfh.org

Haemophilia

More and more people living with haemophilia A and B, and their treaters, are seeing the improvements in quality of life that treatment with Elocta and Alprolix brings. This was the key driver of continued strong growth for our Haemophilia franchise throughout 2018.

The ambition within Haemophilia continues: we will do our best to enable access to our treatments for everyone in our territories who has a need. More people are getting access to Elocta (efmoroctocog alfa) and Alprolix (eftrenonacog alfa), and more are choosing to switch to them. Sales of both products showed strong and consistent quarter-on-quarter growth throughout 2018.

The platform that we and Sanofi have developed with Elocta and Alprolix has reshaped the expectations that people with haemophilia A and B can have for their lives.

Liberate life

For many people with haemophilia, the main goal of treatment over the years has been safe protection from bleeds. This is obviously a primary consideration, but replacement treatment has now progressed beyond bleed prevention. As well as protection from bleeds, extended half-life 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. The main benefit of extended half-life treatments is no longer seen simply as convenience but rather the way these treatments let people with haemophilia live well and feel confident.

In 2018, we undertook an extensive ethnographic study of people living with haemophilia. Despite advances in recent years, many people in the study told how they have to live with compromises and limitations. Younger people told of restricting their activities on non-treatment days, of missing out on opportunities to spend time with friends. Adults spoke of having to cope with everyday pain, of living with stiff joints, having to live with constraints.

This study showed us that people with haemophilia can liberate their lives when treatment delivers in four fundamental areas. Treatment needs to:

- Allow you to feel safe
- Provide protection from all types of bleeds
- Preserve long-term joint health and reduce pain; and
- Remove the mental burden of haemophilia.

We believe that every person with haemophilia has the right to live well, to live a life free from constraints and compromises. That is why we have a vision of liberating people's lives.

In recent years, increasing levels of understanding and experience with Elocta and Aprolix, among thousands of people of all ages, have spread throughout the haemophilia community. Patients, carers and treaters talk to each other about lower levels of pain and higher quality of life. This has created a momentum for change, and as a result, we have seen higher numbers of people switching to our treatments.

Proven safety and efficacy

The latest research[1], released at the American Society of Hematology (ASH) annual meeting in December, confirms the efficacy and safety profiles of Elocta and Alprolix.

The results from the ASPIRE and B-YOND studies demonstrate that long-term prophylactic treatment with Elocta and

SEK 6,012 M

Total revenue, Haemophilia

+88%

Increased number of patients on Elocta and Alprolix

Share of total revenue, by business area

66% Haemophilia

1. Sobi press release: At ASH, extended half-life therapies Elocta® and Alprolix® demonstrate proven efficacy and well-characterised safety over four years, 12 January 2018 www.sobi.com

Alprolix consistently improved annualised bleed rates, including joint bleeds, across all patient populations studied and at extended dosing intervals. No inhibitors were observed in subjects enrolled in either of the two extension studies and the overall safety profile was consistent with the pivotal phase 3 trials.

Debilitating joint disease, which is caused by repeated bleeds into joints over time, is one of the most common complications for people with haemophilia. In ASPIRE and B-YOND, subjects on prophylactic treatment experienced low joint and spontaneous joint annualised bleed rates (ABRs) across all dosing regimens. These results support the conclusion that prophylactic dosing with Elocta and Alprolix can effectively manage and control all types of joint bleeds.

In addition to providing the clinical evidence to support the long-term use of our therapies, we continue to explore the impact of Fc fusion on joint health. An interim, post-hoc analysis of ASPIRE[1] published in Haemophilia found that a prophylactic regimen of efmoroctocog alfa can lead to continuous improvement in joint health, regardless of prior treatment regimen, severity of joint damage, or target joints.

EHL factor replacement a mainstay of treatment

We remain convinced that the well-established safety and efficacy profile of both Elocta and Alprolix, confirmed by several years of real-world data from thousands of patients, and their suitability for all patient groups and ages, position them and Sobi well to withstand competition from treatments now entering the market (see box).

We see replacement factor as fundamental to the wellbeing of people with haemophilia, and expect it to be the mainstay of treatment for the foreseeable future. We see significant opportunities for growth in the treatment of haemophilia A and B in our territories, notwithstanding the eventual uptake of alternative treatments.

We estimate the market value of haemophilia A treatments to be around USD 3.5 billion and USD 500 million for haemophilia B. Sobi's market share is estimated at 15 to 20 per cent.

2018 access achievements

Elocta is now available and reimbursed in 26 countries, and Alprolix in 19 countries. Both received new reimbursement in five countries respectively during 2018, Elocta in Slovakia, Poland, Portugal, Croatia and the Czech Republic; Alprolix in Austria, France, Sweden, Slovakia and Hungary. A filing for approval for Elocta in Russia was filed in July following successful GMP inspections.

Committed to treatment for all

Every person with haemophilia should have an equal right to treatment that can liberate their lives and lead to a better tomorrow. But people in different countries face different challenges. So we are working actively to find ways to provide sustainable treatment for as many people with haemophilia as possible. Our aim is the same in each country: to provide timely and sustainable access to transformative treatment for every person with haemophilia.

Yet only 30 per cent of people diagnosed worldwide are currently receiving access to clotting factor replacement treatment. To overcome this fact, we work with stakeholders to improve access to sustainable treatment. Two key initiatives in this commitment are the World Federation of Haemophilia's Humanitarian Donation Program and the European Haemophilia Consortium's PARTNERS programme.

1. Sobi press release: At ASH, extended half-life therapies Elocta® and Alprolix® demonstrate proven efficacy and well-characterised safety over four years, 12 January 2018 www.sobi.com

About the Sobi-Sanofi collaboration

We work together with Sanofi on the development and commercialisation of Elocta/Eloctate and Alprolix. We have final development and commercialisation rights in our territory – essentially Europe, most Middle Eastern markets, North Africa and Russia.

Sanofi has manufacturing responsibility for the products as well as final development and commercialisation rights in North America and all other regions of the world excluding the Sobi territory.

Our development and commercialisation agreement also includes BIVV001[1] (added 2014), an engineered factor VIII molecule that uses Fc fusion and XTEN, a half-life extension technology, and BIVV002 (added 2017), a novel factor IX fusion protein, that also uses Fc fusion and XTEN.

BIVV001 is a Sanofi development programme. Sobi has elected to add BIVV001 to its collaboration agreement with Sanofi but has not yet opted in.

1. The financial terms of the agreement between the companies are described in more detail in Note 17.

Manufacturing of clotting factors

As part of our commitment to providing treatment for haemophilia, we continue to manufacture the drug substance for Pfizer's haemophilia product ReFacto AF, which is produced according to Good Manufacturing Practice (GMP) in our biologics facility in Stockholm, Sweden.

We have more than 35 years' experience in developing therapies for haemophilia. Together with Biogen/Bioverativ (now Sanofi), we developed the process for large-scale manufacturing of Alprolix, based on our experience from manufacturing the drug substance for ReFacto AF.

As the global supplier, we receive manufacturing revenues on Pfizer's sales of ReFacto AF. Manufacturing capacity was decreased during 2018, in line with Pfizer's requirements.

Read more on page 51.

As visionary contributors to the WFH donation programme, Sobi and Sanofi Genzyme, Sanofi's specialty care business, have committed to donate 1 billion international units of our EHL factor treatments to the haemophilia community, of which 500 million IUs has been committed to the WFH Humanitarian Donation Program over a five-year period which started in 2015. As well as treatment and the necessary transportation, we are supporting the programme's efforts to build up infrastructure and expertise in the recipient countries. This will enable them to provide ongoing, sustainable treatment for people with haemophilia.

The impact of the donation programme so far has been extensive and rewarding[1]:

- More than 16,800 people reported treated in 45 countries
- Nearly 2,000 surgeries including operations that have saved people's lives and limbs
- More than 117,000 acute bleeds treated.

More than 370 million IUs of factor have already been donated to the WFH.

The EHC PARTNERS programme is designed to improve access to treatment in countries in Central and Eastern Europe that currently have insufficient budgets to provide sustainable access to the level recommended by the European Directorate for the Quality of Medicines and Healthcare (EDQM)[2].

Sobi was one of the two founding corporate partners in the programme, which aims to provide subsidised treatment to countries that commit to increasing their investment in haemophilia to ensure sustainable access to treatment. We are pleased to see other companies now agreeing to support the PARTNERS programme.

In developed countries in our territory, we work together with healthcare systems to apply a pricing strategy based on annual parity with conventional treatments available on the market. This means that our products can reach everyone with haemophilia without any significant extra cost and no additional barriers.

We work closely with the community – patients, caregivers, treaters and payers – in areas such as education and support services. This is part of our commitment to enabling people living with haemophilia to liberate their lives.

»More and more patients in France are converting to our therapies for haemophilia.«

Sofiane Fahmy,
Head of Southern and Western Europe and North Africa

1. www.wfh.org
2. www.edqm.eu

Brief facts about Sobi's Haemophilia portfolio:

ELOCTA®

Elocta (efmoroctocog alfa) is a recombinant clotting factor VIII therapy developed for haemophilia A with prolonged circulation in the body using Fc fusion technology. Elocta is approved for the treatment of haemophilia A in adults and children of all ages and marketed by Sobi in the EU, Iceland, Liechtenstein, Norway, Switzerland, Kuwait and Saudi Arabia. It is approved under the name Eloctate, for the US, Canada, Japan, Australia, New Zealand, Brazil and other countries, where it is marketed by Sanofi.

For full prescribing information, please see the EMA's website.

Total sales: SEK 3,261M
Sales growth: 109%
Number of new markets: 5

ALPROLIX®

Alprolix (eftrenonacog alfa) is a recombinant clotting factor therapy developed for haemophilia B using Fc fusion technology to prolong circulation in the body. Alprolix is approved for the treatment of haemophilia B in adults and children of all ages in the EU, Iceland, Liechtenstein, Norway, Switzerland, Kuwait and Saudi Arabia, where it is marketed by Sobi. Alprolix is approved for the treatment of haemophilia B in the US, Canada, Japan, Australia, New Zealand, Brazil and other countries, where it is marketed by Sanofi.

For full prescribing information, please see the EMA's website.

Total sales: SEK 974M
Sales growth: 168%
Number of new markets: 5

Therapeutic options for haemophilia A and B

Haemophilia therapy has undergone a major evolution over the past decade. Because haemophilia A and B are caused by deficiencies in factor VIII (FVIII) and factor IX (FIX) respectively, replacement of the missing factor has been and remains the standard of care for both the prevention of bleeding episodes (prophylaxis) and the treatment of breakthrough bleeds (on-demand therapy).

Factor concentrates were initially produced from plasma, but large-scale production first became possible with the development of recombinant technology, which also avoids the inherent risks of using pooled human plasma in the manufacturing process.

A more recent evolution in factor replacement therapy is the use of technologies to extend the relatively short half-life of clotting factor, which allows improved protection without increasing treatment burden. Half-life extension can be accomplished by fusion of factor to the Fc part of antibodies (IgG) or albumin, or the addition of synthetic polyethylene glycol (PEG). In contrast to FIX, the extension of the half-life of FVIII has so far been limited by the binding of FVIII to von Willebrand Factor (VWF), a problem which is circumvented by the development of the VWF-independent product candidate rFVIIIFc-VWF-XTEN (BIVV001)[1]. The long-term safety and efficacy of factor replacement therapies using Fc fusion to extend half-life have been demonstrated in trials including ASPIRE and B-YOND.

When haemophilia patients develop neutralising/inhibitory antibodies to infused factor, eradication of those inhibitors through Immune Tolerance Induction (ITI) therapy is considered a first-choice treatment. To prevent or treat breakthrough bleeds, bypassing agents such as FVIII inhibitor bypass agent and recombinant FVIIa can be used. Recently, a bispecific antibody mimicking FVIIIa has been approved for the prevention of bleeding in haemophilia A patients with or without inhibitors. These patients would however still need alternative/bypass therapy for the treatment of breakthrough bleeds.

Other non-factor replacement therapies are under development. Gene therapy has been under investigation for quite some time now for haemophilia A and B, but remains in clinical development and the long-term efficacy and safety of this potentially curative approach have yet to be established.

1. A Sanofi development programme. Sobi has elected to add BIVV001 to its collaboration agreement with Sanofi but has not yet opted in.
Reference: Peters R, Harris T. Advances and innovations in haemophilia treatment. Nat Rev Drug Discov. 2018 Jul;17(7):493-508.

»Believe in yourself. You can achieve anything.«

Alexis Perdikis has a message for people with haemophilia: "Believe in yourself. You can achieve anything. This is what I feel, it comes right from my heart."

Alexis, 33, is a sports journalist in Athens, the capital of Greece.

He also has severe haemophilia A.

Today, he lives a life full of opportunity and possibility. "I can go to work without having to worry about getting a bleed. I can go swimming, which is very important for my quality of life."

But life hasn't always been so free of limitations. As a boy, Alexis experienced the restrictions familiar to many who grow up with haemophilia.

"Growing up with severe haemophilia is difficult, a bit tough. It is very strange for a parent to have to explain to a little child, you cannot play, you cannot play football with your friends, you cannot run, you cannot ride your bicycle. It's like there is a big DON'T above your head all the time. Don't do this, don't do that.

"That is one part. The second part is your psychology. Haemophilia hits your self-confidence and self-esteem. You grow up and you don't believe in yourself. You think,

Alexis Perdikis is a sports journalist in Athens.

'I won't be able to do this or that'. This is probably the biggest limitation."

Alexis was receiving on-demand treatment until the age of 27. For five years he has been on prophylaxis, the past two years with Elocta.

"There have been many differences. The most important at first was zero bleeds – less pain in my joints and muscles, in my body in general."

"Secondly, it's about your mental health. It's a sense of freedom. You feel freer. You feel that you can do things you couldn't do before."

He emphasises the importance of self-confidence and self-esteem for people living with haemophilia. "It's all about believing in yourself. To realise, I can have a normal job like anyone else, a girlfriend or a family. This is so, so important."

For the past five years, Alexis has served as secretary general of the Greek Haemophilia Society. He sees national member organisations as playing an essential role in the haemophilia community: "They are a link in the chain between the patients and all the other stakeholders: government, ministry of health, hospitals, administration, the companies. Patient organisations must help bring those different parts together."

Asked what someone with haemophilia should expect from their treatment, Alexis says people can set their own ambitions: "Be strong. Use your inner power to achieve whatever you want. Of course, good treatment is important. But in the end everything has to do with you, and with what you want to achieve."

»Sobi is seen today as a major player, making a real difference to the lives of people with rare diseases.«

Armin Reininger

Our Head of Global Medical and Scientific Affairs reflects on highlights from 2018, and emerging trends for the years ahead.

Background
When Armin joined Sobi in January 2017, it was the latest step in a distinguished career in medicine and research. With extensive experience in both blood research and transfusion medicine, Armin has published more than 70 scientific articles. He has also held senior positions at Harvard Medical School, Scripps Research Institute, and at Ludwig-Maximilians-Universität in Munich where he continues as a professor of anatomy. He has served on the boards and committees of several international organisations in the areas of thrombosis and haemostasis. When Armin joined Sobi, he came from a position as Head of Medical Affairs EMEA at Shire/Baxalta.

What have been the highlights for you in Haemophilia in 2018?
The most important is that more people are benefiting from our treatments. As word spreads through the patient and treater communities about the difference our treatments can bring, people are re-examining their initial hesitation about switching from conventional therapies. Key opinion leaders tell us they see significant benefits for patients on EHL treatments.

Real-world experience is showing that patients can expect more from life, and truly live well with haemophilia. Just a few decades ago, we told people with haemophilia not to move – stay at home, don't do anything, in order to avoid bleeds. That has changed dramatically. Now we offer them EHL products that can liberate their lives.

Looking forward, we can see from the preliminary data released last year (see Haemophilia section) that BIVV001 has potential to build on where we have already taken treatment for haemophilia A. We continue to strengthen our relationship with Sanofi, and I see a very bright future here.

How do you see the haemophilia landscape developing?
There is a lot of hype about new treatments being approved. I believe strongly, and I hear constantly from the treater community, that replacing the missing clotting factor is fundamental to the wellbeing of people with haemophilia. The safety and efficacy profiles of Elocta and Alprolix have been confirmed by several years of real-world experience from thousands of patients. They have been shown conclusively to be suitable for all patient groups and ages, and provide the flexibility to truly match treatment to expected outcomes.

I hear clear feedback from physicians that they and their patients appreciate the very physiological approach of replacing the missing clotting factor: you can measure the factor level, you can increase the dose to the level needed. I remain convinced that proven and effective factor replacement that can be matched to an individual's treatment goals in all situations will continue to be the mainstay of treatment for the future.

What do you see as some other major highlights from 2018?
One was definitely emapalumab. This is a huge step forward for Sobi, because it confirms our commitment to the immunology space and demonstrates how our success in haemophilia lets us invest in helping more children with a severe unmet medical need. Our most recent addition, Synagis, fulfils the same fundamental ambition. It helps as a prophylactic treatment so that premature babies survive better, and require fewer hospitalisations and intensive care unit admissions when exposed to RSV (respiratory syncytial virus), which causes respiratory tract infections.

Another highlight for me is the way everyone within Sobi – from the Executive Committee to the many teams throughout the organisation – works together to find innovative treatments and get them to the people who need them. This is a long-standing strength at Sobi. Our position today, as a leading player in rare diseases, is built on a lot of partnership over the years, internally and externally, as well as on our core values, which have been evolved to address the challenges we encounter on a daily basis.

We have a clear strategy on which we are delivering, and a clear path ahead of us. We really have made a mark, in haemophilia in particular, and are no longer the new kid on the block. Sobi is seen today as a major player, making a real difference to the lives of people with rare diseases. And as a physician that is my main motivation for trying to do better every day.

Better meeting patient needs

We are working actively to find better ways to meet patient needs. This can entail product development and innovation driven by medical needs. New medical needs may arise when people with certain rare diseases grow up, reaching adolescence and adulthood for the first time thanks to the treatments we provide.

Specialty Care

More patients than ever before are being helped by our treatments. Sales for Specialty Care surpassed SEK 3 billion for the first time in 2018, with a solid performance across the portfolio. Two major acquisitions in 2018 have given Specialty Care a clear focus on Immunology, creating a strong second leg to our business.

Specialty Care concentrates on rare diseases and niche indications, with treatments that aim to transform life for patients.

The two key acquisitions during 2018 – for the global licence to emapalumab and the US rights for Synagis (palivizumab) – have shifted the weight of the Specialty Care portfolio significantly. The resulting strong Immunology franchise – comprising emapalumab, Synagis and Kineret (anakinra) – will comprise the majority of sales in Specialty Care, and we see immunology as a promising area of development in which we will invest further.

Synagis is the only approved medicine for the prevention of serious lower respiratory tract infections (LRTI) caused by respiratory syncytial virus in high-risk infants. As an important treatment for vulnerable children, Synagis matches our expertise in paediatrics and we are convinced we can get more value from the product. Synagis will constitute the majority share of total Specialty Care sales.

Emapalumab, approved in November in the US as Gamifant for the treatment of primary HLH, is also a perfect fit with our expertise, strategy and infrastructure. As the first approved treatment, it demonstrates our ability to bring innovative solutions to address highly unmet medical needs, and as a therapeutic concept shows potential for expansion into other indications.

It will also provide growth in North America in line with our strategy.

The acquisitions are transformative for the company in several ways, and are an excellent fit with our strategy:

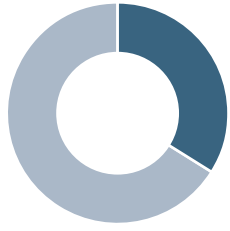
- **New Immunology franchise** – By creating a strong second leg to our portfolio, the acquisitions enable the company to diversify our revenue base and balance our strong growth in Haemophilia.
- **Accelerates US commercial platform** – Both acquisitions strengthen our commercial platform in North America, providing critical scale to drive sustainable growth in the US. We see this as imperative for the company to be recognised as a preferred partner in future global deals. The Synagis acquisition includes the transfer of AstraZeneca employees from a highly qualified sales & marketing team. Synagis is thereby expected to nearly triple both the revenue and size of our US organisation. We have also been expanding our North American organisation to address the expected demand for emapalumab.
- **Enhances financial strength** – Synagis will provide substantial recurring revenue, and we believe that our specialist competence in this area will allow us to extract more value from the product. In the coming year, we expect revenues from Synagis and emapalumab to help us advance our geographical expansion, enable future strategic acquisitions over the mid-term and allow us to continue to invest in our own research and development.

As well as its primary focus on Immunology, our portfolio also includes products in the areas of genetics & metabolism. Specialty Care has a distribution network across EMENAR used to sell both proprietary and partner products, while in North America we currently sell Sobi's own products exclusively. In 2018, total sales amounted to SEK 3,127 M. Specialty Care's largest products in 2018 were Kineret and Orfadin, representing 42 and 29 per cent of sales respectively. The portfolio currently consists of 39 products. From 2019, Synagis will be the largest single product in Specialty Care.

SEK 3,127 M

Total revenue, Specialty Care

Share of total revenue, by business area



34% Specialty Care

We have offices in 19 countries, managing products in over 70 countries. Rising standards of living and improving healthcare systems are allowing more people with unmet medical needs to receive treatment. We continue to adapt and develop our organisation to match this growing demand, particularly in more populous countries.

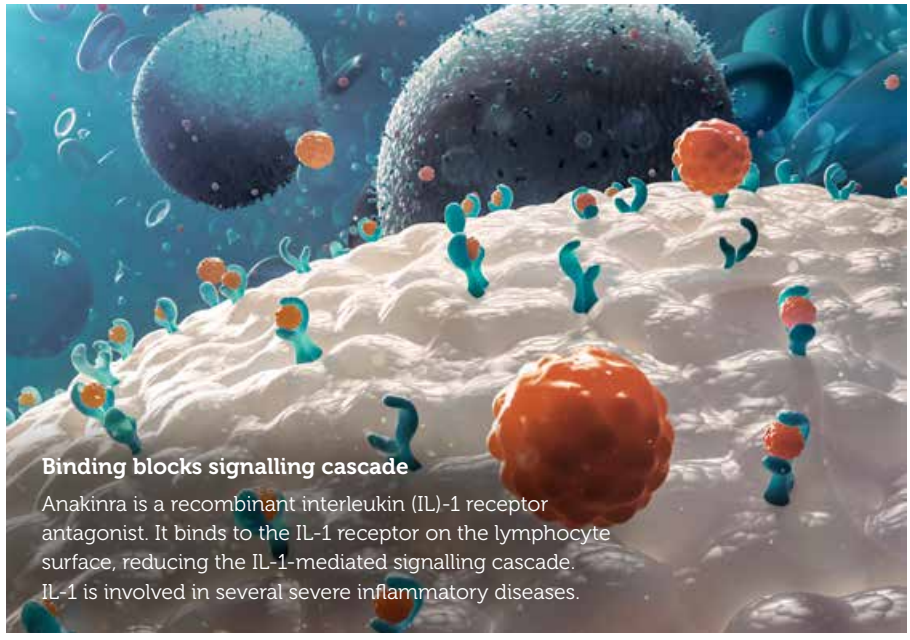
Throughout 2018, the Specialty Care franchise demonstrated our ability to manage products at different stages of the life cycle in diverse regions, and contrasting competitive and payment environments.

As well as double-digit growth for Kineret and a maintained market position for Orfadin despite emerging competition, newly launched Ravicti is now improving quality of life for an increasing number of people with urea cycle disorders (UCD).

We continue to seek further new products to improve our ability to meet the evolving needs of patients. To make better use of our capabilities, we are also seeking to attain more extensive product rights through external opportunities.

Better ways to meet patient needs

We work actively to find better ways to meet patient needs. This can entail product development and innovation driven by medical needs. New medical needs may arise when people with certain rare diseases reach adolescence and adulthood for the first time thanks to the treatments we provide.



Binding blocks signalling cascade

Anakinra is a recombinant interleukin (IL)-1 receptor antagonist. It binds to the IL-1 receptor on the lymphocyte surface, reducing the IL-1-mediated signalling cascade. IL-1 is involved in several severe inflammatory diseases.

We also support rare-disease communities in various ways, including through ambassador programmes, financial support to bridge reimbursement, and teaching tools for healthcare providers, patients and carers.

The continuing growth of our business, the overall development of our products and the successful acquisitions in 2018 all underline our capabilities in the area of rare diseases and specialty care.

We hope to offer these capabilities to future partnering companies to do their therapeutic solutions justice and bring them successfully to patients in North America and EMENAR.

Building up capacity in North America

Our operations in North America expanded dramatically during 2018. From 55 employees at the start of 2018, we grew to 270 colleagues in the US and Canada in early 2019.

More than 130 people are joining Sobi from AstraZeneca as part of the Synagis deal.

Revenue from North America is expected to account for around one-third of global total revenue, up from around 14 per cent.

The additional staff greatly reinforce our medical, commercial and market access capabilities, and will work both with our new products Synagis and Gamifant, and the existing portfolio.

Expanding our footprint in the US and Canada is an important part of our strategy – the North American market represents around 50 per cent of the worldwide market for rare disease treatments. Having a stronger footprint there opens up the possibility of even greater growth opportunities.

One effect of the expansion has been continued double-digit growth for Kineret, approved in the US for rheumatoid arthritis and neonatal-onset multisystem inflammatory disease (NOMID).

Additional staff are reaching out to 1,000 new physicians, who have now started to prescribe Kineret and already represent a double-digit share of prescriptions. As a result, 180 new patients are now benefiting from treatment with Kineret.

The additional capacity is also helping to maintain sales momentum for Orfadin, which is starting to face generic competition.

Brief facts about Sobi's Immunology portfolio:

EMAPALUMAB AND HLH

We acquired the global rights to emapalumab from Novimmune SA in August 2018. In November, it was approved by the US Food and Drug Administration and launched under the name Gamifant in the US in December as world's first approved drug therapy for primary haemophagocytic lymphohistiocytosis (HLH), a rare and life-threatening syndrome of extreme immune activation. An application for market authorisation in the EU was submitted in mid-2018.

The primary form of the disease (inherited) mainly occurs in infants and young children, while the secondary form of the disease is acquired from or associated with infection, autoimmune diseases or malignancy.

Haemophagocytic lymphohistiocytosis is a clinical syndrome of hyper inflammation, driven by high interferon gamma (IFNγ) production, characterised by fever, swelling of the liver and spleen, severe low red and white blood cell counts, bleeding disorders, infections, neurological symptoms, organ dysfunction and organ failure. Primary HLH typically arises in paediatric patients, is fatal if untreated, and has a 40 per cent mortality rate with current best available care.

The patient population in the US, EU and Japan is estimated at around 5,000 people across both primary and secondary HLH.

For full US prescribing information please see gamifant.com

SYNAGIS AND RSV

Synagis is the only approved medicine for the prevention of serious lower respiratory tract infections (LRTI) caused by respiratory syncytial virus (RSV) in high-risk infants. We announced in November that we acquired the US rights to Synagis from AstraZeneca and will also participate in 50 per cent of the future US earnings from the follow-up candidate drug MEDI8897, a monoclonal antibody (mAb) being investigated for the prevention of LRTI caused by RSV in a larger patient population. The completion of the acquisition was announced on 24 January 2019.

Synagis is an attractive product for Sobi due to its orphan-sized paediatric patient population and immunology profile. It remains the only product preventing RSV infection in a young vulnerable patient population with a great medical need. RSV is a virus that can cause severe lung disease in infants who are born either prematurely or during RSV season.

For full US prescribing information please see synagis.com

KINERET

The case of Kineret also illustrates how we work continuously to find new ways to help people with rare diseases. Originally introduced in 2002, Kineret continues to show potential for the treatment of various illnesses involving interleukin-1 (IL-1), a key mediator of inflammation. Increasing interest in and understanding of the IL-1 field is supporting the continued growth of Kineret, which again reached double digits during 2018.

In 2013, when it was approved for CAPS (cryopyrin-associated periodic syndrome) in Europe, we made a fundamental revision of our strategy for Kineret, establishing an organisation focused on patients and treaters to identify and address their needs. As specialists learn more about how Kineret has improved their patients' lives, they share their insights with us and the patient community. Physicians and patients see Sobi as good partner: we take their insights seriously, and try to follow their leads. Then together we examine how we can develop the treatment to benefit patients in other indications.

In 2018 Kineret was approved by the European Medicines Agency (EMA) for use in all 28 European Union (EU) member states for the treatment of Still's disease, including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA), the most severe form of arthritis in children. Still's disease affects approximately 25,000[1] children and adults in the EU. Uptake in the Still's population is expected to accelerate over the coming year. A phase 3 trial (ana-STILLS) is ongoing in the United States, for the use of Kineret in the treatment of Still's disease (SJIA and AOSD).

In August, we published the primary efficacy results from the anaGO phase 2 trial into anakinra (Kineret) as a possible treatment for acute gout.

Kineret is a biologic that reduces the activity of interleukin-1 (IL-1), a key mediator of inflammation in autoinflammatory and autoimmune diseases. Kineret blocks the biological activity of 1α and IL-1β by binding to the interleukin-1 type 1 receptor (IL-1RI), expressed in a variety of tissues and organs, and thereby blocking interleukin-1 (IL-1) signalling. This signal blockade helps manage excess levels of IL-1 in the body, and consequently, inflammation and other symptoms. Kineret has a well-characterised safety profile, a quick onset of action and a short half-life.

Kineret is approved for the treatment of rheumatoid arthritis (RA) in adults, neonatal-onset multisystem inflammatory disease (NOMID) in children and adults (in the US and Canada), and cryopyrin-associated periodic syndrome (CAPS) in adult patients, and in children from eight months and older (in the EU). It is also approved in Australia for the treatment of RA, CAPS and also for the treatment of active SJIA in patients aged two years and above who have failed to respond adequately to non-biological disease modifying anti-rheumatic drugs, and in Israel for RA and CAPS.

For full European prescribing information, please visit the EMA website.

For full US prescribing information please see kineretrx.com.

Total sales: SEK 1,320M

Sales growth: 16%

1. Data on file.

Brief facts about Sobi's Specialty Care portfolio:

ORFADIN

Our patient-centric approach can be seen clearly in the way we have worked with Orfadin. When it was first launched in 2002, few patients living with hereditary tyrosinaemia type 1 (HT-1) would celebrate their second birthday. Today, thanks to improved newborn screening, effective treatment and dietary management, we are seeing the first generation of patients with HT-1 to reach an age where they are starting their own families.

Over the years, we have worked closely with the HT-1 community, and seen that people with HT-1 face different challenges during different stages of life. In 2015 and 2016, an oral suspension for infants and a 20 mg capsule for older patients were approved and introduced for patients in Europe and the US.

With an increase in newborn screening in several countries, more patients are being diagnosed earlier. The oral suspension makes treatment simpler for younger infants. At the other end of the scale, the larger 20 mg capsule allows older patients to reduce the number of times they have to take their treatment every day. Both formulations are exclusive to Sobi.

Generic competition is now entering some markets, although uptake of these generic formulations has been slower than expected. During 2018, Orfadin continued to maintain its market position – we remain strongly committed to the HT-1 community and providing life-long treatment with Orfadin and associated patient support services.

Total sales: SEK 899M

Sales growth: 4%

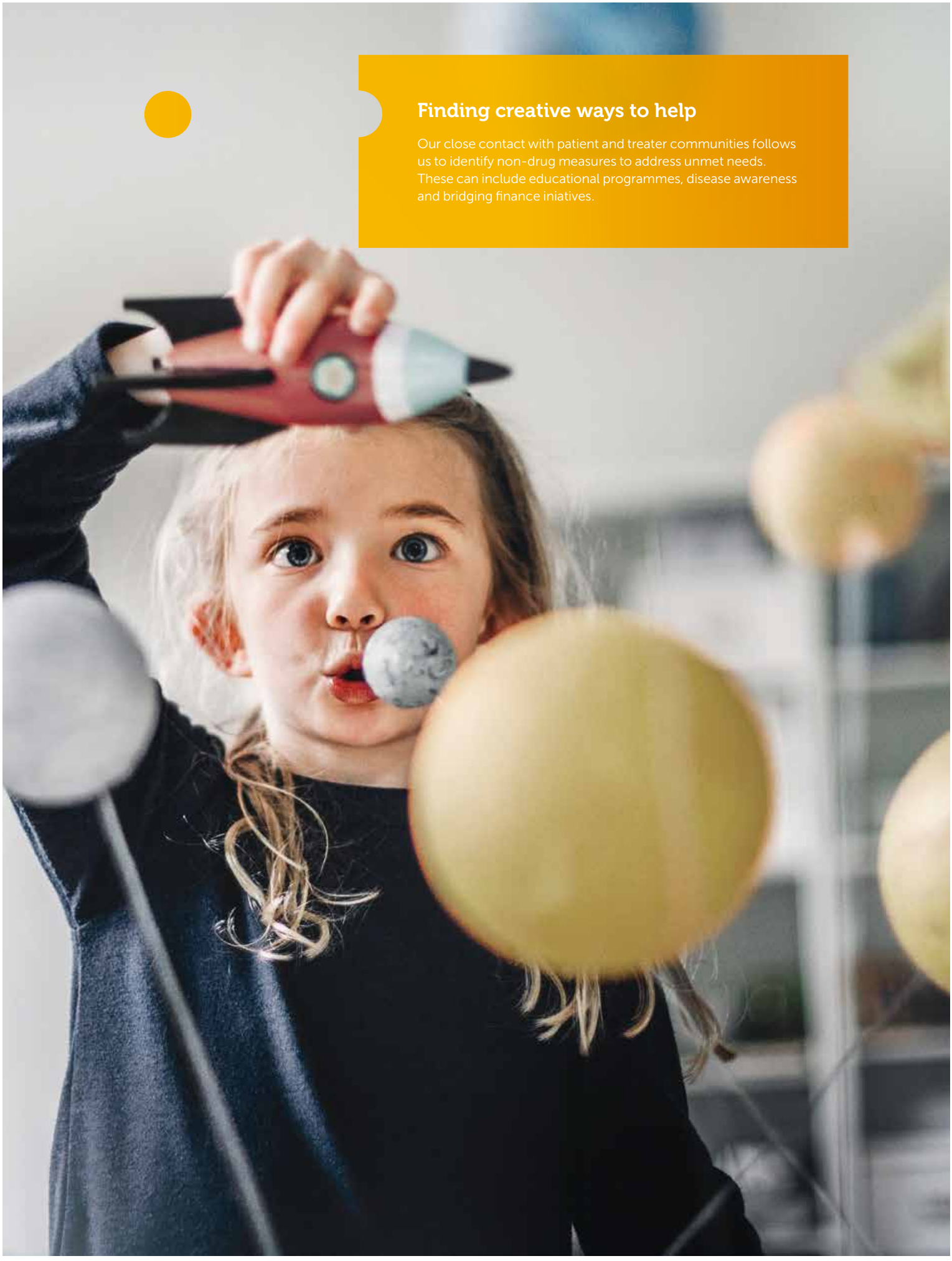
UCD PORTFOLIO

Ravicti® (glycerol phenylbutyrate) was made available across Europe in 2018, as a treatment for all six urea-cycle disorder (UCD) indications. The six, all referred to by the name of the missing enzyme, are: CPS1 (Carbamoyl Phosphate Synthetase); NAGS (N-Acetylglutamate Synthetase); OTC Deficiency (Ornithine Transcarbamylase); AS (Argininosuccinic Acid Synthetase (Citrullinemia)); ASL (Argininosuccinate Lyase (Argininosuccinic Aciduria)); and AG (Arginase). Our other UCD treatment, Ammonaps®, is approved for three indications: CPS1, OTC and ASL.

People with a UCD have difficulty removing ammonia – naturally formed as a by-product of metabolising protein – from their bloodstream. Ammonia is toxic, and if it reaches the brain it can cause irreversible brain damage, coma and even death.

Despite the launch of Ravicti in Europe being slightly delayed, there are indications of an accelerated uptake in the second half of 2018. Feedback from physicians indicates that patients appreciate the fact that Ravicti is tasteless and odourless, and is required in smaller volumes than other UCD treatments. A study has also shown fewer treatment-related symptoms, such as body odour, abdominal pain, nausea, burning sensation in mouth, vomiting and heartburn, with Ravicti than with treatment using sodium phenylbutyrate. All these factors are expected to contribute to better adherence and compliance, particularly among children with UCD, leading not only to improved treatment outcomes but greatly improved quality of life.

For full European prescribing information, please see ema.europa.eu.



Finding creative ways to help

Our close contact with patient and treater communities follows us to identify non-drug measures to address unmet needs. These can include educational programmes, disease awareness and bridging finance iniatives.

Innovation

At Sobi, we are driven by science, and drive science in turn. Building on our heritage, we continue to invest in innovation and have made progress on several fronts during 2018. Our most advanced early-stage programme, SOBI003, moved into clinical studies during 2018 with the first patients dosed. And acquisition of the global rights to emapalumab has significantly strengthened our late-stage pipeline.

Strong platform for growth

Innovation is part of our DNA. Throughout the history of Sobi and our predecessors, we have built a legacy of combining our expertise with that of partners to identify and develop innovations that address significant unmet medical needs among people with rare diseases.

From the first B-domain deleted recombinant clotting factor VIII for haemophilia A in the 1980s, through the life-cycle management of Kineret, and the development of Orfadin and the Fc fusion technology that makes our extended half-life treatments Elocta and Alprolix possible for haemophilia A and B, our research and development is built on a record of achievement.

We see innovation as essential to our vision of being a global leader in rare diseases. We need to reinvest in research and development in order to continue to provide innovative treatments.

We made significant strides towards this strategic objective in 2018, not only through progress in our internal pipeline but also by bringing in external innovation.

Our R&D is focused on biological treatments for rare diseases, where we have extensive competence and experience. Our understanding of all the connections – from the molecular format to clinical experience, manufacturing, regulatory, commercialisation and patient access – differentiates us in the pharma space.

In medical terms, we are living in one of the most exciting times in history, on a par with the discovery of antibiotics. Science drives what we are doing, and we are driving science. Our strength in rare diseases puts us at the cutting edge.

As an integrated, patient-centric company, we feed insights from patients, carers and payers back into our research and development organisation, creating a feedback loop. This allows us to concentrate our research efforts on areas in which we can truly make a difference and have the potential to become leaders. These include our ongoing work within haemophilia, and our strong focus in the area of immunology.

Our Immunology franchise emerged largely through anakinra, and our subsequent development of the therapy to include new indications in the IL-1 field. We are now established as a credible partner in the immunology field, as evidenced by the partnership with Novimmune for emapalumab as well as the acquisition from AstraZeneca of the US rights to Synagis.

Our R&D activities span from the discovery phase, through clinical development, to post-approval clinical trials in a real-world setting. We are currently running pre-clinical research programmes, clinical development programmes and studies in a real-world setting.

As well as in-house research, we continue to work extensively with external stakeholders, including patient and healthcare organisations, government-supported initiatives, researchers from the academic community, and with other research partners. We see broad collaboration and partnership as essential to strengthening the knowledge base in rare diseases in order to address unmet medical needs.

In all our research and development work, we constantly strive to maintain the highest ethical, technical and scientific standards.

Emapalumab (in orange) is approved in the US as the world's first approved treatment for primary HLH, a life-threatening disease of the immune system. An anti-IFNγ antibody, emapalumab binds to IFNγ (in blue) and thereby prevents activation of IFNγ receptors (in green) on the monocyte surface. This prevents initiation of the signalling that results in the expression of inflammatory cytokines.

We secure intellectual property rights to safeguard our investments in research and development, enabling a financial performance that allows us to reinvest in the development of new innovative treatments.

Highlights during the year

The commencement of the SOBI003 first-in-human trial, with the first patient dosed in August 2018, was a significant achievement that confirms the strength of our integrated approach to drug development. SOBI003, built on our own research platform, has now been brought all the way to humans. The initial dosing of the first patients has gone well, and ongoing recruitment into the trial is encouraging. (See more in box, on page 33)

With the addition of emapalumab to our portfolio, we have created a bridge between our early and late-stage pipelines. Following emapalumab's approval in the US as Gamifant for treatment of primary HLH, we continue to study its potential in a phase 2 trial in secondary HLH plus a number of potential follow-on indications. Acquisition of the global rights to emapalumab, and resulting partnership with Novimmune, makes the most of our strengths, and benefits both companies.

Considering the competition in the market for assets that address unmet medical needs for patients, we can be justifiably proud of being chosen by Novimmune as partners on this journey.

The approval in April 2018 of Kineret as a treatment for Still's disease in Europe was also a major achievement. It illustrates our commitment to continuous development of our treatments to assist patients through different stages of life, as well as in new indications and new geographical areas.

We completed recruitment for the anaGO phase 2 study with anakinra (Kineret) as a possible treatment for acute gout, and released the top-level outcome on the primary endpoint. Although we did not meet the primary endpoint, we did demonstrate that anakinra does provide pain relief in this disorder. There continues to be an unmet medical need among patients who do not tolerate or respond to conventional treatment, and we will continue discussions with the FDA on how we may potentially proceed with this indication.

In the area of haemophilia, results were presented in several research programmes that confirm the safety and efficacy of Elocta and Alprolix.

The potential of BIVV001, a clinical-stage molecule that uses the Fc fusion technology from Elocta to further extend the half-life of factor VIII, continues to be examined[1]. (Read more, box on Page 33).

Continuous development

Even after a therapy is approved and launched, we continue with research and development as part of a complete life-cycle management approach to provide more value for more patients and explore the full potential of our treatments. Physicians share their insights, experience and results with our researchers, helping us to add new indications, new formulations and real-world data to approved therapies.

As an example, Kineret was originally approved for rheumatoid arthritis. With input from the medical community, we continued to study and develop Kineret in the IL-1 field. It was subsequently approved for CAPS, a group of rare, inherited auto-inflammatory diseases, and NOMID, the most severe form of CAPS – and has led to a transformational improvement in quality of life for people with these disorders. In 2018, Kineret was approved and subsequently marketed in several European countries as a treatment of Still's disease. Similarly, we are deepening our understanding of Elocta and investigating its potential effects in immune tolerance induction for people with haemophilia A who are affected by inhibitors.

Continuous development of our medicines is done both in-house and in partnership with other pharmaceutical companies and with patient organisations and patient-led consortia.

1. A Sanofi development programme. Sobi has elected to add BIVV001 to the collaboration agreement with Sanofi but has not yet opted in.

Our innovation pipeline at 31 December 2018

	Therapeutic area/Indication	Product/Project	Pre-clinical	Phase 1	Phase 2	Phase 3	Phase 4
Haemophilia	Haemophilia A	Elocta/PUP[1,2]				■	
	Haemophilia A	BIVV001[3]/EXTEN-A		■			
	Haemophilia A	Elocta/ASURE					■
	Haemophilia A	Elocta/RelTIrate					■
	Haemophilia A	Elocta/verITI8					■
	Haemophilia A and B	Elocta/Alprolix/PREVENT					■
	Haemophilia B	Alprolix/PUP[1,2]				■	
	Haemophilia B	BIVV002[3]/EXTEN-B	■				
Speciality Care	Primary HLH	Emapalumab				■	
	Secondary HLH	Emapalumab			■		
	RSV prevention	MEDI8897[4]			■		
	Acute gout	Anakinra/anaGO			■		
	Still's disease	Anakinra/anaSTILLs				■	
	Alkaptonuria	Nitisinone/SONIA2				■	
	MPSIIIA	SOBI003		■			
	Anti-C5	SOBI005	■				
	Anti-IL-1	SOBI006	■				

1. Extension trial for an already approved indication.
2. PUP – Previously Untreated Patients.
3. A Sanofi (formerly Bioverativ) development programme. Sobi has elected to add the programme to the collaboration agreement with Sanofi but has not yet opted-in.
4. Sobi has the right to participate in 50 per cent of future earnings in the US.

Brief facts about pipeline innovations:

BIVV001

Our product Elocta is an extended half-life (EHL) version of factor VIII for the treatment of haemophilia A, which is approved in Europe and the Middle East.

BIVV001 is a Sanofi development programme. Sobi has elected to add the programme to the collaboration agreement with Sanofi but has not yet opted in.

BIVV001 (rFVIIIFc-VWF-XTEN) is a novel and investigational recombinant factor VIII therapy that is designed to extend protection from bleeds with once-weekly prophylaxis dosing. BIVV001 builds on the Fc fusion technology used in Elocta by adding a region of von Willebrand factor and XTEN polypeptides to potentially extend the factor VIII molecule's time in circulation.

BIVV001 is the only factor therapy that has been shown to break through the von Willebrand factor ceiling, which is understood to impose a half-life limitation on current factor VIII therapies. BIVV001 was granted orphan drug designation by the Food and Drug Administration in August 2017.

MEDI8897

The agreement with AstraZeneca for the US rights to Synagis also includes our participation in 50 per cent of future earnings for the candidate drug MEDI8897 in the US.

MEDI8897, a follow-on candidate to Synagis, is a monoclonal antibody (mAb) being investigated for the prevention of lower respiratory tract infections caused by RSV in a larger patient population.

MEDI8897 is a single dose extended half-life anti-RSV F mAb being developed for the passive immunisation of a broad infant population. It has been engineered to have a long half-life so that only one dose will be needed for the entire RSV season. Primary analysis from the pivotal, phase 2b study to evaluate the safety and efficacy of MEDI8897 showed that the study met its primary endpoint. The current development plan includes a proposed phase 3 study in late preterm and healthy full-term infants. Based on the results from the phase 2b study, the FDA has granted Breakthrough Therapy Designation (BTD) for MEDI8897, which will help bring MEDI8897 as quickly as possible to all infants at risk for RSV.

In March 2017, AstraZeneca and Sanofi Pasteur announced an agreement to jointly develop and commercialise MEDI8897. Under the agreement, AstraZeneca is responsible for all development activity through initial approvals, as well as manufacturing of MEDI8897, while Sanofi Pasteur leads commercialisation activities. The two companies share all costs and profits equally.

SOBI003

SOBI003 is a clinical-stage molecule being tested for the treatment of patients with mucopolysaccharidosis type IIIA (MPS IIIA), also called Sanfilippo A syndrome.

MPS IIIA is a genetic disease that arises as a result of mutations to the gene that encodes an enzyme called sulfamidase. The disease is a rare inherited disorder that is progressive with significant morbidity and mortality. Patients present with the disease in early childhood and, after significant loss of developmental skills, many die of their disease before the age of 20.

MPS IIIA arises due to a lack of sulfamidase activity, leading to the inability of the body to break down long chains of sugar molecules and resulting in the accumulation of heparan sulphate inside lysosomes in cells. This in turn also affects the cells in the central nervous system and causes severe progressive degeneration.

SOBI003 is a recombinant version of the wild-type form of sulfamidase which has been designed to cross the blood-brain barrier (BBB) and enter the brain. The BBB is the capillary bed of the brain which shows low permeability for blood-borne proteins. Using our proprietary Modifa™ technology to modify the glycan sugar molecules decorating sulfamidase, the resultant SOBI003 molecule has been shown to enter the brains of several animal species and to treat MPS IIIA very effectively in a mouse model of the disease, by reducing the accumulation of heparan sulphate in the brain parenchyma. This is achieved by prolonging the enzyme's presence in the bloodstream and enhancing the passive adsorption of SOBI003 at the BBB with subsequent increased transcytosis into the brain.

SOBI003 has been granted orphan status in both the EU and the US and also has Fast-Track Designation in the US.

Our ability to take a molecule from idea to approved treatment enables us to provide groundbreaking therapies that transform lives.

Manufacture and supply of biologics

We continue to advance our expertise and capacity in the development, planning, sourcing, manufacture and delivery of innovative biologic therapies. The integrated nature of Sobi allows us to bring treatments to patients faster. And our global network of manufacturing and supply partners ensures the reliable provision of medicines to patients around the world.

As an integrated company, we can advance medicines seamlessly from development to commercial scale, reducing the time it takes for innovative therapies to reach patients without compromising safety.

Our Technical Operations organisation, which came into effect in October, brings together our Quality Assurance, CMC (Chemistry, Manufacturing and Control) Development, Biologics Process Development, Procurement, Supply Chain and Internal and External Manufacturing, as well as Environment & Safety functions under a single umbrella.

The new organisation will allow greater synergies between the various functions, allowing cross-functional initiatives to have the greatest possible effect. The introduction of Technical Operations also creates improved career opportunities and development for colleagues across the various functions, ensuring a smooth transition from process development into manufacturing.

We developed and scaled up the SOBI003 drug substance manufacturing process in-house to support the programme with active substance for preclinical and early clinical studies during 2016–2018.

Due diligence

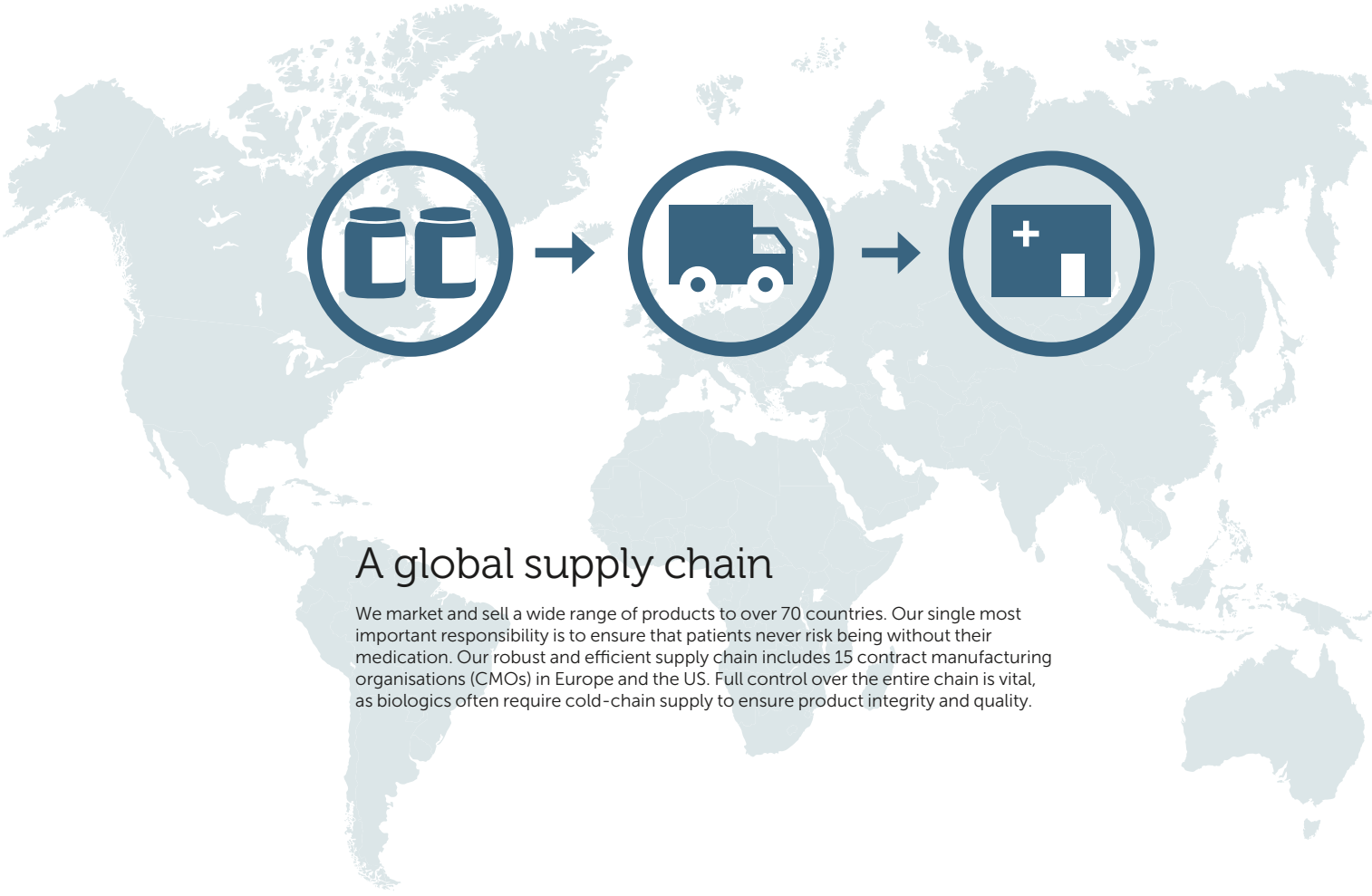
The expertise and experience within Technical Operations was an important component in the due diligence for the announced deals with Novimmune and AstraZeneca. The teams collated and assessed data for information around the manufacturing processes, analytical methods, manufacturing sites, cost structure, operational risks and compliance of the products, processes and facilities in the supply chains of Synagis and emapalumab. The team has been instrumental in securing the manufacturing supply and quality assurance agreements with the new partners.

Ensuring global access to treatment

Patient safety is our most important responsibility; ensuring that patients never risk being without their medication is paramount. That is why we have built up robust and reliable supply and distribution processes covering all our markets; these ensure that the right products arrive in the appropriate quantities for distribution, ensuring quick and efficient delivery to patients. We currently provide access to treatment in more than 70 countries, typically in small volumes for a small number of patients, providing logistical scale for us and our partners across the EMENAR region and North America.

We work with a global network of contract manufacturing organisations to ensure the reliable supply of medicine for patients. All manufacturers of products for which Sobi is Market Authorisation Holder are required to meet our Code of Conduct and Ethics. For products sold on a partner basis, we strive to ensure that all providers comply with the code.

As a measure to combat counterfeit medicines, we use serialisation to ensure the traceability of all our products. A unique serial number on every product provides information on where a product was produced and packaged. All our products have been serialised from February 2019 following a successful implementation project. In May



A global supply chain

We market and sell a wide range of products to over 70 countries. Our single most important responsibility is to ensure that patients never risk being without their medication. Our robust and efficient supply chain includes 15 contract manufacturing organisations (CMOs) in Europe and the US. Full control over the entire chain is vital, as biologics often require cold-chain supply to ensure product integrity and quality.

2018, we became one of the first companies to connect to the EU Hub, a central component of the EU serialisation initiative. We are unaware of any case of Sobi products being subject to falsification.

Due to the sensitive nature of biologic medicines, they often require cold-chain supply to safeguard product integrity and quality. Having full control of the entire supply and distribution chain – from manufacturing to patient – is vital. Our Logistics Development and Supply unit ensures uninterrupted, reliable and sustainable transportation of products sourced from our global CMO network.

Our Trade Compliance unit ensures that trade laws and regulations are followed.

The transfer of the production of the biologic drug substance for Kineret was completed on time and budget during 2018. This resulting increase in capacity allows us to meet the growing demand for Kineret, in existing and new indications.

In 2018, we continued our involvement in three projects funded by Vinnova, the Swedish Innovation Agency, and are collaborating with Lund University in a further Vinnova-funded project.

As well as strengthening connections with a network of students and graduates, these initiative explore new technologies that are expected to have positive effects on development and manufacturing lead times. Such projects reflect our investment in the future of Sweden as a leading country in the development and manufacturing of innovation biologics.

We make it happen

Sobi is a value-driven company with a scientific and patient-centric organisation. As employees, we are the enablers that make it possible to reach our vision of transforming the lives of people with rare diseases and delivering on a strategy for increasing growth. It is our everyday behaviour and achievements that matter the most in shaping the future of our company.

Gender distribution of employees

Focus on growth and leadership

Sobi is an evolving company on a strong growth path. This requires that our organisation remains innovative and high-performing in a time of change – as well as fostering a culture where continuous learning is key. We are one of only a few biotech companies to successfully transition into a commercial biopharmaceutical company. As a result, we need to manage products at very different stages of the life cycle, simultaneously in diverse regions and contrasting competitive and payment environments. To be successful in doing so, we need an organisation that is both stable and agile at the same time.

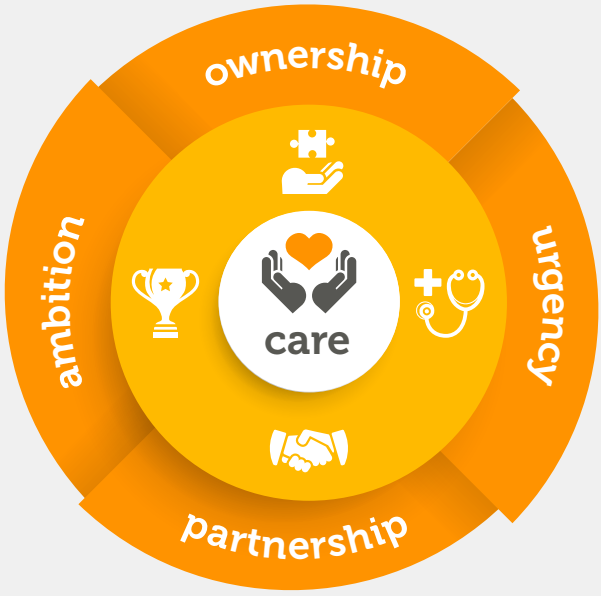
Everything we do at Sobi supports our long-term vision and strategy. As the results of 2018 have shown, we have been successful in delivering on our strategy. As we continue to deliver, we are now promoting and developing high-performing teams throughout the organisation. This involves developing our methods to help managers, leaders and colleagues facilitate continuous growth. We see strong leadership based on cross-functional capabilities as crucial. This focus is part of building an organisation that has a clear direction but is prepared for the unknown, while embracing change as opportunity.

Culture-supported performance

For those of us working at Sobi, our "WHY" – addressing patient needs – is what motivates and drives our high-performance culture. Every day, we work actively to find better ways to understand and meet patient needs. Urgency has always been an important value to us, and in line with Sobi's strategy to extend the reach of our offerings to more patients, it is becoming even more important in our operations.

Our conviction is that because we care, we need to act. To ensure that more patients benefit from our advanced therapies now and in the future, and to align with the company's ambitions for growth, we have identified five values: Care, Ambition, Urgency, Ownership and Partnership. These values help us develop the spirit of leadership and entrepreneurship that we need to be recognised as a leader in rare diseases.

In 2018, we worked together within the organisation to define and implement these values across the company through a series of workshops. We subsequently identified areas and processes that can be improved to better correspond to our values. An internal campaign was launched to support the implementation. We have always included the values as important components when assessing employee performance.



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.

Gender equality analysis
Every employee is offered equal opportunities regardless of ethnicity, age, gender, religion, sexual orientation or physical ability. Our guidelines clearly prohibit any sexual harassment. The Me Too movement at the end of 2017 initiated increased internal discussion at management level on potential challenges in the organisation as well as a raised general awareness of these matters.

In Sweden, our annual salary surveys allow us to carry out a gender equality analysis, designed to prevent discrimination and promote equal rights and opportunities. We carefully evaluate the results in partnership 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.

Of the total number of people in 2018 (2017), 41 per cent (41) were men and 59 per cent (59) women. The corresponding figures for the Executive Committee and Board of Directors (excluding employee representatives) were 74 per cent (73) were men and 26 per cent (27) were women.

Competence leads innovation
Along with good values, competence is one of the essentials that drive our business forward. The combination of rare-disease competencies and specific therapeutic knowledge has guided our professional development and recruitment processes.

Professional development for all employees is essential for both development of our product portfolio and the organisation as a whole. We strive to promote a performance culture based on individual accountability, mandate and ownership. A critical factor is to set, and continuously support, individual goals linked to strategic business objectives as well as in line with the corporate values. 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.

In 2018, all employees underwent a regular performance and career development review. Training in standard operating procedures (SOPs) and on-the-job training is a priority for Sobi, and an essential part of the development of every employee.

This type of training accounts for the largest proportion of Sobi employees' training. It provides an opportunity for our employees to learn new skills and ensure compliance

19
We have offices in 19 countries

935
people employed worldwide on 31 December 2018

with established procedures and practice. During 2018, our employees also spent eight hours on e-learning on issues including compliance and data protection. To support cross-functional approaches and learning, we implemented a system of job rotation in 2018. This has been applied across the organisation at both global head office and affiliate level as an opportunity to develop people and teams while facilitating parental and vacational leave.

An agile approach is essential in responding successfully to our evolving requirements and to stimulate innovation. Building high-performing teams has been identified as a key success factor to meet our ambitious strategic objectives. Across the company, we are working with a focused approach to high-performing teams and organisational efficiency to strengthen our ability to adapt and grow.

Leadership development has focused on supporting high-performing teams as well as fostering mature and enabled leaders. Managers and employees at Sobi need to be courageous and prepared for change. The growth strategy deployed offers numerous opportunities for our employees to develop and grow with the company in new roles and expanding areas of responsibility.

A safe and healthy workplace

We are committed to providing a safe and healthy workplace for our 935 people around the world. Activities to protect labour rights are based on our responsibilities as an employer, and we also encourage suppliers and partners to adopt socially responsible labour practices. We respect the international labour standards set forth by the International Labour Organization (ILO) and comply with national labour laws.

Our policy and guidelines aim to promote a working culture where every employee engages in the creation of a safe and healthy workplace through preventive measures and regular training. Managers are responsible for working systematically with Environmental Health and Safety (EHS) in their operations. One important area is investigating and identifying the cause(s) of an accident, dangerous situation or near miss as this makes it possible to take action to prevent a similar occurrence in the future. All employees are required to report Environmental Health and Safety (EHS)-related incidents to their employer. In 2018, 28 accidents were reported, of which one led to sick leave. This incident was investigated and reported to the Swedish Work Environment Authority.

»Job rotation really is a fantastic opportunity for those of us who are interested in trying a new role and developing our skills in new areas. It also creates a valuable exchange of skills between departments and an understanding for each other's work.«

Susanne, who is working in Global Distribution for one year, rotated from a role in Accounting.

Compliance Hotline
Our Compliance Hotline is a third-party whistle-blower service available to all Sobi employees, enabling anonymous reports of any possible violation of Sobi's Code of Conduct & Ethics, any law, or any company policy. It is Sobi's policy to prohibit any retaliatory action against any employee for making a report in good faith of a suspected violation even if a subsequent investigation proves the report to be unfounded.

Sourcing future talent
To further improve the support we provide for patients, treaters and payers in our territories, we continued to expand our organisation throughout 2018. As we become increasingly recognised as a leading player in the rare-disease landscape, we have been able to attract key talents to join our organisation at both local and global levels. These hires further strengthen a team that is already considered one of the market's best. Competitive terms of employment are also 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.

As we grow, we need to secure competence not only for today, but also for tomorrow. Sobi's business is dependent on specialist skills that are sometimes rare, such as pharmaceutical technicians with both development and industrialisation experience. In collaboration with other pharmaceutical companies, we support educational programmes for pharmaceutical technicians.

To meet our recruitment needs, we recruit and offer vocational in-house training to chemists who have recently completed their graduate education or who come from outside Sweden. This has the added benefit of providing us with valuable perspectives on our activities from colleagues who join the business with new eyes.

Sobi also participates in several collaborative projects within the framework of the Swedish Government's life-science venture on the development of biological drugs. This collaboration has given us the opportunity to contribute to the development of emerging skills within the industry and to broaden our contact network with potential future employees. To recruit young talents, we also participate in business fairs.

Build long-term trust

To achieve our vision of being recognised as a global leader in providing access to innovative treatments, we need to build long-term trust and act responsibly across all parts of our business. Collaboration with different stakeholders within the rare-disease community and in a variety of national and legal contexts requires us always to be trustworthy and transparent.

We see several areas as forming the ethical and legal basis on which we run our business. These have been identified as a part of our materiality analysis (read more on pages 123–125) and are what we call Our Responsibility.

In general terms, we see responsibility as referring to the need to be in control of our processes, setting and meeting high ethical and environmental standards, both for ourselves and our partners. Because our business is strictly regulated under both national and international laws, we always need to be one step ahead in terms of compliance to be seen as a trustworthy partner in the pharmaceuticals market.

The safety and integrity of our patients, customers and employees are of vital importance for the company. The quality of our products is of the highest priority, and to ensure the delivery of safe and effective treatments we follow the good practice (GxP) guidelines that guide all pharmaceutical companies.

Our responsibility issues are described one by one.

Regulatory and legal environment
The highly regulated environment in which we operate is constantly changing, and demands for transparency are increasing. There are also general trends towards greater awareness of liability issues and legal risk. All of our operations, from research and production to marketing, are affected by these expectations. This requires us to ensure the quality of both our research and production, as well as always observing all relevant precautionary principles and being transparent in our marketing and interactions with healthcare stakeholders.

Our internal processes and control measures involve scientific, regulatory and compliance training. In 2018, no incidents of non-compliance concerning marketing communications were identified or reported.

Ethical practices and partnerships
Partnerships and cooperation with stakeholders are essential for us to share knowledge and experiences within the rare-disease community. The stakeholders with whom we work span the entire value chain, from research and clinical programmes to patient access and pricing. All engagements are governed by our Code of Conduct and Ethics, while a majority are also covered by our more specific Healthcare Compliance guidelines. We also enforce ethical standards by supporting a corporate culture that promotes open discussions of ethics both in our operations and among key stakeholders.

It is of the utmost importance that all research involving humans, such as clinical studies, are built on rigorous, scientifically based evaluations by clinical experts in cooperation with regulatory authorities, independent ethics committees and stakeholders. We apply the Declaration of Helsinki's principles for medical research. For more information about the policies and directives we apply, refer to our risk management section on pages 58–63.

Patient and customer privacy
It is important that our customers, clinical trial subjects, employees and others we interact with can rely on Sobi managing and processing personal data in a responsible and secure manner. EU legislation, primarily the General Data Protection Regulation (GDPR) which became fully enforceable in 2018, imposes additional requirements on how businesses process personal data. To comply with these new requirements, we have adopted a governance model that supports full compliance with GDPR and provides relevant training for the organisation.

In 2018, four personal data breach incidents were reported and managed. For more information about the policies and directives we apply based on a legal assessment of our framework, refer to our risk management section on pages 58–63.

Anti-corruption and anti-competitive practices

Transparency and open dialogue about ethical issues form the foundation of strong collaborations for qualitative research, development and manufacturing.

We procure materials, goods and services from more than 1,000 suppliers. Our authorisation and signoff procedures help ensure that we enter agreements and perform procurements in a transparent and responsible manner. We require all suppliers to meet standards aligned with our Code of Conduct and Ethics. We also work with due diligence, based on a risk assessment, to ensure that service providers comply with our anti-corruption standards. The screening process is currently conducted on a manual basis. We are investigating automated systems that would allow us to compile data showing the percentage of suppliers who have undergone screening. Procedures are in place to ensure that trade compliance checks are performed. We plan to create a Supplier Code of Conduct.

We work actively to prevent any form of corruption. The most apparent risk lies within our interactions with healthcare stakeholders. We have an established Healthcare Compliance (HCC) organisation and company-wide programme to minimise the risk of corruption; this function provides policies, training of our own employees in business ethics, as well as reporting and controls. Our zero-tolerance approach to bribery is formulated in our Code of Conduct and Ethics as well as our Policy on Anti-Corruption, which was expanded in 2018 to include a global scope and third-party due diligence.

All employees are required to undergo annual training in our Code of Conduct and Ethics. Topics covered in the Code of Conduct include product safety and quality, competition law, intellectual property, environmental responsibility and employment principles, with additional opportunities to focus on specific areas. In 2018, data protection training was prioritised. This training is an eligibility requirement for incentive payments. In 2018, 90 per cent of our employees participated in the training.

In 2018 we rolled out our adapted Healthcare Compliance Interaction Policy. It contains key principles and global minimum requirements, enabling a common global standard. The Policy is currently being implemented in Sobi's affiliates, where it is supplemented to meet local requirements. As a next step, approval and training will be initiated, including corporate e-training with a focus on anti-corruption for the affiliates.

No cases of corruption and no cases of non-compliance with laws and regulations within the economic and social area were reported during the year. For more information about the policies and directives we apply, refer to our risk management section on pages 58–63.

Responsible tax

Sobi acts responsibly with regard to taxes. This means paying taxes where profits are earned in accordance with international transfer pricing rules. It also means having a balanced tax risk profile, not engaging in tax evasion and maintaining stable and predictable tax levels, insofar as prevailing business conditions permit.

Environmental impact

Our carbon footprint is limited and mainly due to the use of chemical substances in R&D and manufacturing, and to business travel emissions.

Business travel is the main source of greenhouse gas emissions, and is regulated by our travel policy. We continuously evaluate and implement measures to reduce the energy and water consumption of our production facility, which is closely monitored.

We work actively to phase out chemicals that might have adverse effects on the environment and human health. Chemicals legislation is extensive and continuously expanding; all handling of chemicals in our R&D and manufacturing processes therefore follows strict instructions. We perform annual risk assessments and internal audits.

Environmental considerations are integrated into all activities, operational controls and functions across the organisation. All employees are required to undergo annual environmental training, covering risk assessment, greenhouse gas emissions, and chemicals and waste management. We strive to comply with all environmental laws and regulations. We assess and evaluate our environmental risks continuously. Read more about our risk management, sustainability risks and precautionary measures on pages 58–63.

Long history of innovation

1930s
Kabi founded as a subsidiary of Kärnbolaget Aktiebolag Biokemisk Industri. Name of company changed in 1951 to Kabi.

1970s
Kabi and Vitrum merge to become KabiVitrum.

1980s
Trials begin 1981 for recombinant human growth hormone, developed by Sobi-predecessor KabiVitrum and partner Genentech, using new recombinant DNA technology. Work begins in 1983 on developing recombinant factor under the auspices of Sobi predecessor KabiVitrum. The project aims to clone the gene for human coagulation factor VIII (FVIII). Genentech clones the gene (cDNA) for human FVIII in 1984. The expression of human recombinant FVIII in mammal cells is built up on a small scale 1986–87. KabiVitrum is granted a patent for the B-domain delete forms of FVIII.

1990
Kabi Pharmacia was formed following the acquisition of a stake in Pharmacia.

2001
Biovitrum is formed through the merger of several units of the Swedish pharmaceutical company Pharmacia and spun off to a consortium of investors led by Nordic Capital and MPM Capital Funds.

2004
Biovitrum starts to manufacture the active protein component for Wyeth's (now Pfizer's) ReFacto and ReFacto AF/Xynta® drugs for the treatment of haemophilia A.

Marketing of specialty pharmaceuticals (ReFacto, Mimpara and Kineret) is initiated in the Nordic region.

2005
The research and development portfolio is expanded through the acquisition of Arexis, a Swedish biotech company, which includes the Kiobrina project.

2006
An agreement is signed with Syntonix (subsequently Bioverativ, now Sanofi) covering the development and manufacture of an extended half-life recombinant factor IX Fc-concentrate, rFIXFc. This substance was later to become the product Alprolix. Any possible development within haemophilia A is also included in the agreement.

Biovitrum is listed on Nasdaq Stockholm.

2007
Collaboration starts with Syntonix/Biogen Idec on the development of an extended half-life factor VIII Fc for the treatment of haemophilia A, later to become Elocta. Sobi also manufactures the material for the first in-human phase 1/2a rFIXFc trials for the treatment of haemophilia B.

2008
An agreement is signed with Amgen regarding the acquisition of the product Kepivance and the global license for Kineret.

2009
A decision is taken to initiate final registration trials for rFIXFc after safety and efficacy in previously treated (PTPs) haemophilia B subjects is established in phase 1/2a clinical trials.

Investor AB acquires 21 per cent of the shares in Biovitrum.

2010
Swedish Orphan International, a pioneer in orphan drugs, is acquired and a new company, Swedish Orphan Biovitrum AB (publ.), Sobi, is created. With the acquisition comes Orfadin which later becomes an important drug for Sobi, as well as a portfolio of drugs under distribution agreements.

A decision is taken to advance both haemophilia candidates into pivotal phase 3 trials, A-LONG and B-LONG.

2011
Data from the rFVIIIFc haemophilia phase 1/2 trial shows an approximately 1.7-fold increase in half-life compared with a conventional factor treatment.

2012
The supply agreement with Pfizer for ReFacto AF/Xyntha is extended until 2020 and Nordic commercial rights are sold to Pfizer.

Global paediatric clinical trials of rFIXFc and rFVIIIFc candidates are initiated.

A collaboration is formed with the Swedish biotech company Affibody AB within the interleukin-1 (IL-1) field.

Sobi establishes operations in the Middle East and the US.

2013
Sobi acquires full rights for Kineret and receives approval for the CAPS indication in the EU.

Data from the rFIXFc haemophilia phase 3 trial shows an approximately 4.8-fold increase in half-life compared with a conventional replacement factor.

Sobi moves to the Large Cap segment on Nasdaq Stockholm, becoming the first pharmaceutical company to do so in Sweden in eight years.

2014
Biogen launches Eloctate and Alprolix in the US market, marking the start of real-world data collection for extended half-life treatments for haemophilia A and B.

Open-label trials to determine the safety and efficacy of Elocta and Alprolix in previously untreated males with severe haemophilia A and B commence (PUPs A-LONG/PUPs B-LONG).

Sobi exercises an opt-in right to take over final development and commercialisation of Elocta in Sobi territories. Sobi also adds a potentially longer-acting haemophilia A candidate, rFVIIIFc-VWF-XTEN to the agreement with Biogen.

The Kiobrina project is terminated.

2015
Elocta is approved by the EMA for the treatment of haemophilia A and is subsequently launched in Europe in January 2016.

Sobi exercises an opt-in right to take over final development and commercialisation of Alprolix in Sobi territories.

Kineret is approved for the treatment of systemic juvenile idiopathic arthritis (SJIA) in Australia.

2016
Alprolix is approved by the EMA for the treatment of haemophilia B and is subsequently launched in Europe.

The EMA grants Sobi's development product candidate SOBI003 orphan drug designation for the treatment of the rare disease MPS IIIA or Sanfilippo A syndrome.

A licensing agreement is reached with Affibody AB for the development of novel treatments for inflammatory diseases where IL-1 is involved.

The supply agreement with Pfizer for ReFacto AF is extended until 2023.

Orfadin is developed to further meet patient needs with 20 mg capsules and an oral suspension.

The development pipeline is strengthened with two proprietary and in-house developed candidate drugs in early-stage development, SOBI005 and SOBI006, as well as new planned clinical programmes.

Elocta is approved in Kuwait.

2017
Sobi expands its development portfolio by adding a potentially longer-acting haemophilia B treatment candidate, rFIXFc-XTEN, to its collaboration agreement with Sanofi.

The first patients are recruited to the anaGO and anaSTILLs clinical trials with Kineret in acute gout and Still's disease, and A-SURE and ReITIrate with Elocta in haemophilia A.

The US Food and Drug Administration (FDA) grants SOBI003, which at this stage is being prepared for clinical trials, orphan designation.

Alprolix is approved in Kuwait and the Kingdom of Saudi Arabia. Elocta is approved in the Kingdom of Saudi Arabia.

2018
FDA accepts investigational new drug application and grants Fast Track status for SOBI003 for the treatment of MPS IIIA.

Kineret (anakinra) receives a positive opinion from CHMP for the treatment of Still's disease.

Kineret (anakinra) approved in the EU for the treatment of Still's disease.

Sobi launches Ravicti in Europe and advances the care of patients with urea cycle disorders.

Sobi strengthens immunology franchise by acquiring global rights to emapalumab from Novimmune.

First patient dosed in phase 1/2 trial evaluating SOBI003 for the treatment of MPS IIIA.

Results from the anaGO trial – a phase 2 trial with anakinra (Kineret) in patients with acute gout.

Sobi acquires Synagis US rights from AstraZeneca, creating a platform for global growth (agreement finalised in January 2019).

FDA approves Gamifant (emapalumab), the first and only treatment for primary haemophagocytic lymphohistiocytosis (HLH).

Data presented at ASH support emapalumab as an innovative, targeted therapeutic option for primary HLH.

At ASH, extended half-life therapies Elocta and Alprolix demonstrate proven efficacy and well-characterised safety over four years.

The share as an investment

The share (STO:SOBI) is listed on Nasdaq Stockholm, under the company name of Swedish Orphan Biovitrum. Over the past five years, the share price has increased by more than 180 per cent.

In 2018 the highest price paid was SEK 299.6 on 3 September, and the lowest was SEK 110.6 on 2 January. Sobi's market capitalisation at year-end 2018 was SEK 52.8 billion. Over the past five years, the share price has risen 182 per cent.

Turnover and trading locations

The Sobi share is traded on several exchanges and trading platforms. In 2018, official trading accounted for 82 per cent of turnover in the share, of which the Nasdaq Stockholm accounted for 39.6 per cent. Off-book represented 14.6 per cent and dark pools 3.2 per cent of total trading in the share. The largest number of trades were on Cboe BXE.

Average daily total turnover in Sobi shares was 2,271,960 in official trading, with an average 900,760 traded on Nasdaq Stockholm. In 2018, a total of 567.9 million shares were traded, corresponding to a value of approximately SEK 110.9 billion.

Share capital

At year-end, the total number of shares outstanding in Sobi was 273,322,117. All issued shares are ordinary shares and carry one vote per share.

At year-end, the share capital was SEK 149,973,582, distributed between 273,322,117 shares with a par value of approximately SEK 0.55.

Largest shareholders at 31 December 2018[1]

SHAREHOLDERS	Number of A shares	Share capital, %	Share votes, %
Investor AB	107,594,165	39.37	39.37
BNY Mellon NA (former Mellon), W9	14,609,514	5.35	5.35
State Street Bank and Trust Co, W9	12,914,653	4.73	4.73
Swedbank Robur fonder	12,826,879	4.69	4.69
AMF – Försäkring och Fonder	7,052,649	2.58	2.58
BNY Mellon SA/NV (former BNY), W8IMY	7,017,360	2.57	2.57
BNY Mellon NA (former Mellon), W9	6,248,651	2.29	2.29
Cbny-Norges Bank	5,840,290	2.14	2.14
JPM Chase NA	5,826,092	2.13	2.13
Fjärde AP fonden	5,611,902	2.05	2.05
SEB Investment Management	3,720,912	1.36	1.36
Swedish Orphan Biovitrum AB (publ.)	3,423,726	1.25	1.25
Morgan Stanley and Co LLC, W9	3,328,172	1.22	1.22
Handelsbanken fonder	3,096,750	1.13	1.13
State Street Bank & Trust Com., Boston	2,560,704	0.94	0.94
Total 15 largest shareholders	**201,672,419**	**73.80**	**73.80**
Other	71,649,698	26.20	26.20
Total	**273,322,117**	**100.00**	**100.00**

1. The shareholders are presented as they appear in the shareholder register held by Euroclear Sweden AB. The list may therefore not show shareholders whose shares have been registered in the name of a nominee, through the trust department of a bank or similar institution.
Source: Euroclear

Incentive programmes

Sobi has launched several share-based incentive programmes for senior executives and employees. Currently, there are five active share programmes, all vesting within three years. The programmes represent a total maximum of 1,883,574 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 23,435 (22,938). The largest shareholder, Investor AB, held 39.4 per cent (39.5) of the shares. Swedish legal entities, including institutions and funds, held 61.0 per cent (75.9) of the shares.

Shares held by Swedish Orphan Biovitrum AB (publ) at year-end totalled 3,423,726 common shares.

During the year, 640,553 shares were used for allotment under two performance-based long-term share programmes.

Dividend

The Board proposes that no dividend be paid for 2018. For more information about Sobi's dividend policy, please refer to the Corporate Governance Report.

LONG-TERM VALUE CREATION

The long-term price trend for Sobi's share depends on how successful we are in our efforts to create value, by:

- Improving cash flow and profitability in our diversified commercial portfolio,
- Launching new and innovative medications for rare disease patients, and
- Focusing on our business model, with partnership in all areas, from early-stage biopharmaceutical research and development to the commercialisation of niche medicines in Europe.

Average value of daily trading volume for the Sobi share

VOLUME '000	2014	2015	2016	2017	2018
A shares	869.0	1,391.5	2,263.6	1,502.3	2,272.0

In 2018, the average daily trading volume in number of shares for the Sobi share on Nasdaq Stockholm was 900,760 shares.

Source: Fidessa.

Shareholder categories

31 DECEMBER 2018	% of capital
Foreign shareholders	35.2
Swedish shareholders	64.8
Institutions	96.2
Private persons	3.8

Source: Euroclear.

Key data per share

SEK	2014	2015	2016	2017	2018
Earnings/loss per share	–1.01	0.31	2.99	4.27	8.97
Equity per share	16.6	17.3	19.8	24.6	33.1
Market price, Series A-share, 31 Dec., last paid price	79.4	134.6	106.7	112.3	193.0
P/E ratio	–78.6	434.2	35.7	26.3	21.5
Number of shares at 31 Dec.	270,785,950	271,822,806	272,010,948	272,507,708	273,322,117

Analyst coverage during 2018

The following research analysts followed Swedish Orphan Biovitrum (Sobi) during 2018. For a current list, visit sobi.com

ABG Sundal Collier	Christopher W. Uhde
Carnegie	Erik Hultgård
Deutsche Bank	Richard Parkes
DNB	Jon Berggren, Patrik Ling
Handelsbanken	Peter Sehestedt
Jefferies	Eun K. Yang
Nordea	Hans Mähler
Pareto Securities	Peter Östling

Recommendations from analysts, %

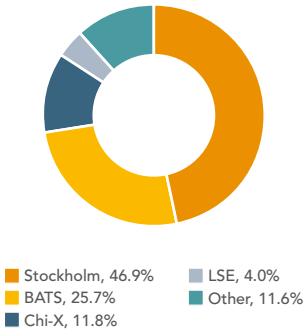
	2016	2017	2018
Buy	73	56	50
Hold	9	33	25
Sell	18	11	25

Source: Based on analyst reports.

Brief facts, the Sobi share

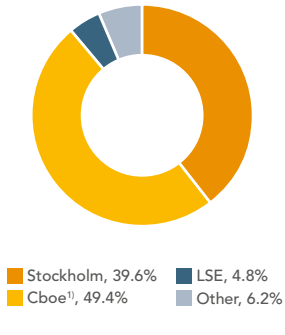
LISTING	Nasdaq Stockholm
Number of shares (A shares)	273,322,117
Market capitalisation, at year end	SEK 52.8 billion
Ticker	SOBI
ISIN	SE0000872095
CUSIP	870321106

Trading places 2017



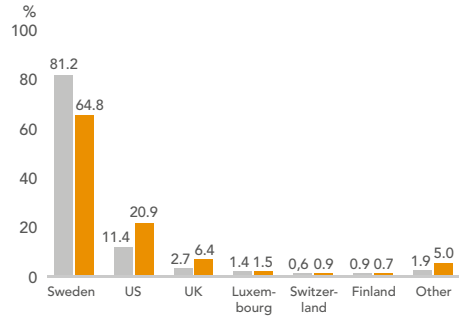
Source: Fidessa.

Trading places 2018



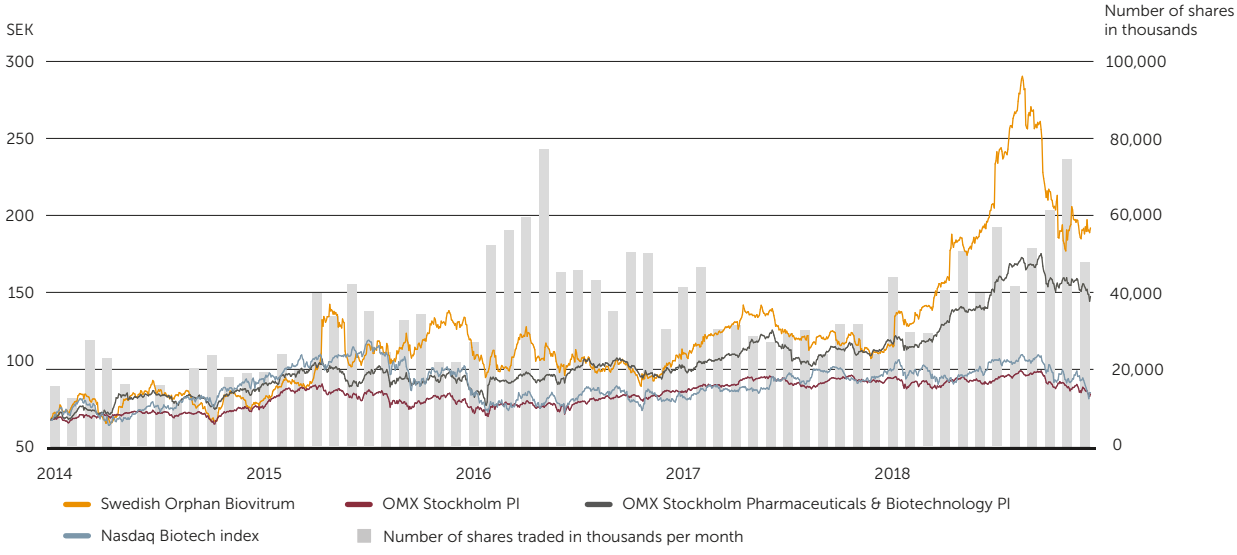
1. Cboe = previously BATS och Chi-x.
Source: Fidessa.

Shareholders by country



Source: Euroclear.

Sobi share price and trading volume 2014–2018



Contact details

For more information about Sobi's American Depositary Receipt (ADR), contact:
US Depositary
BNY Mellon Shareowner services
P.O. Box 30170, College Station, TX 77842-3170, US
Email: shrrelations@cpushareownerservices.com
Toll free in the US: +1 888 269 23 77
International dialling: +1 201 680 6825

Communication with shareholders
For more up-to-date information about the Sobi share, please visit www.sobi.com or call +46 (0)8 697 20 00, to contact Paula Treutiger, Head of Investor Relations and Communications.

Five-year summary – Group development

	2014	2015	2016	2017	2018
Income statement, SEK M					
Operating revenue	2,607	3,228	5,204	6,511	9,139
Gross profit	1,548	2,007	3,651	4,657	6,723
EBITDA[1]	–12	465	1,574	2,086	3,607
EBITA[1]	–44	433	1,543	2,053	3,571
EBIT (operating profit)	–325	146	1,133	1,600	3,122
Profit/loss for the year	–270	83	802	1,149	2,418
Capital, SEK M					
Total assets	6,375	8,315	9,974	10,903	17,183
Capital employed[1]	5,326	5,508	5,880	6,716	9,048
Equity	4,497	4,678	5,365	6,701	9,040
Cash and cash equivalents	519	904	786	1,478	2,999
Net cash (–)/net debt (+)[1]	298	–82	–282	–1,472	–2,995
Cash flow, SEK M					
Cash flow from operating activities before changes in working capital	299	411	642	1,431	2,341
Cash flow from operating activities	234	507	343	1,333	2,090
Cash flow from investing activities	–184	–143	–158	–139	–575
Cash flow from financing activities	20	22	–308	–500	–1
Change in cash and cash equivalents	70	386	–123	694	1,514
Key figures, %					
Gross margin[1]	59	62	70	72	74
Return on capital employed[1]	–6.1	2.6	19.3	23.8	34.5
Return on equity[1]	–5.8	1.8	16.0	19.0	30.7
Equity ratio[1]	71	56	54	61	53
Debt/equity ratio[1]	41	77	86	63	90
Share ratio, SEK					
Earnings/loss per share	–1.01	0.31	2.99	4.27	8.97
Equity per share[1]	16.6	17.3	19.8	24.6	33.1
Dividend	—	—	—	—	—
Cash flow per share[1]	0.3	1.4	–0.5	2.5	5.5
Cash flow from operating activities per share[1]	0.9	1.9	1.3	4.9	7.6

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.


SciLifeLab
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Pioneer in Rare Diseases

Reporting

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Directors' Report

Highlights 2018

Financial highlights

- Total revenues of SEK 9,139 M (6,511), an increase of 40 per cent.
- Product sales amounted to SEK 7,362 M (4,749), up 55 per cent.
- Gross margin was 74 per cent (72).
- EBITA was SEK 3,571 M (2,053).
- Profit for the year was SEK 2,418 M (1,149), representing earnings per share of SEK 8,97 (4,27).
- Cash flow from operating activities was SEK 2,090 M (1,333).

Business highlights

- At year-end, drug reimbursement for Elocta® had been granted in 26 countries and for Alprolix® in 19 countries.
- Sobi appointed Torbjörn Hallberg as General Counsel and Head of Legal Affairs, Henrik Stenqvist as Chief Financial Officer, Fredrik Wetterlundh as Head of Human Resources and Anne Marie de Jonge Schuermans as Head of Technical Operations.
- Kineret® approved in the European Union for the treatment of Still's disease.
- First patient dosed in phase 1/2 trial valuating SOBI003 for treatment of MPS (mucopolysaccharidosis) IIIA.
- Results presented from the anaGO study, a phase 2 study with anakinra in patients with acute gout.
- Sobi strengthens Immunology franchise by acquiring the global rights for emapalumab from Novimmune.
- The Food & Drug Administration (FDA) approves Gamifant® (emapalumab) in the US, the first approved treatment for primary HLH (haemophagocytic lymphohistiocytosis).
- Sobi acquires US rights to Synagis from AstraZeneca, creating a platform for global growth. The acquisition was finalised in January 2019.
- BIVV001 phase 1/2a data presented at ASH, the 60th annual congress of the American Society of Hematology, underscore potential for once-weekly dosing with sustained high factor levels in haemophilia A.
- Data presented at ASH support emapalumab as an innovative, targeted therapeutic option for primary HLH.
- Elocta and Alprolix data presented at ASH demonstrated proven efficacy and well-characterised safety over four years.

1. Middle East, North Africa and Russia.

Sobi's operations

At Sobi, we are transforming the lives of people affected by rare diseases. Sobi is an integrated biopharmaceutical company with in-house capabilities that encompass the entire value chain, from research, to preclinical and clinical development, biologics manufacturing, to distribution and patient access. This integrated approach is a prerequisite for providing proprietary drugs, and an enabler for partnerships, especially at early stages of drug development.

In 2018, revenues were generated by:

- Global sales of the proprietary products Kineret, Orfadin® and Kepivance®. Sales in Europe and MENAR[1] of the proprietary products Elocta and Alprolix and royalty revenue from Bioverativ's sales of Eloctate® and Alprolix.
- Sales in Europe and MENAR of products for which Sobi holds distribution and/or licensing agreements.
- Sales of the drug substance for ReFacto AF®/Xyntha® to Pfizer.

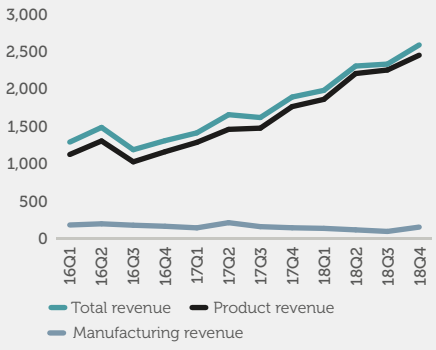
Key figures

SEK M	2018	2017
Operating revenue	9,139	6,511
Gross profit	6,723	4,657
Gross margin, %[1]	74	72
EBITA[1]	3,571	2,053
EBIT (operating profit)	3,122	1,600
Profit for the year	2,418	1,149
Earnings per share, SEK	8.97	4.27

1. Alternative performance Measures, see Definitions page 135.

See page 49 for a five-year summary of revenues, expenses and earnings.

Three-year revenue trend, SEK M



Revenue by business area

SEK M	2018	2017
Haemophilia	6,012	3,682
Specialty Care	3,127	2,829
Total revenues	**9,139**	**6,511**

Operating revenue
In 2018 revenues amounted to SEK 9,139 M (6,511), an increase of 40 per cent.

Revenues by business area
Haemophilia
Total Haemophilia revenues amounted to SEK 6,012 M (3,682), an increase of 63 per cent (57 per cent at CER). Full-year revenues for Elocta were positively affected by SEK 52 M, in Q3 2018, related to adjusted pharmaceutical taxes in France from 2017.

Product sales amounted to SEK 4,235 M (1,920) of which Elocta accounted for SEK 3,261 M (1,557) and Alprolix for SEK 974 M (363).

Royalty revenues amounted to SEK 1,341 M (1,203), of which SEK 1,340 M (1,168) was royalty revenues related to Sanofi's sales of Eloctate and Alprolix.

At year-end, drug reimbursement for Elocta had been granted in 26 European countries, and in 19 countries for Alprolix.

ReFacto manufacturing revenues totalled SEK 436 M (559), down 22 per cent due to the lower year-on-year order pattern.

The current manufacturing agreement for ReFacto AF / Xyntha is valid until December 31, 2023, with the possibility of further extension. Sobi's royalty agreement for ReFacto ended after January 2018.

Specialty Care
Total revenues amounted to SEK 3,127 M (2,829), an increase of 11 per cent (7 per cent at CER).

There was a strong performance across the Specialty Care portfolio. Solid growth for Kineret continued across all regions in 2018. The commercial launch of Kineret for Still's disease in the EU is ongoing. The Still's indication has been launched in nine EU countries, and the pricing and reimbursement process throughout Europe is proceeding. For Orfadin, generics have entered certain markets and a first sign of price erosion has been observed. In 2018, however, patient support programmes and new formulations defended our market position, even though we saw some impact affecting mainly price.

Kineret revenues were SEK 1,320 M (1,142), an increase of 16 per cent (12 per cent at CER).

Revenues for Orfadin were SEK 899 M (862), an increase of 4 per cent (1 per cent at CER).

Gross profit
Gross profit was SEK 6,723 M (4,657), representing a gross margin of 74 per cent (72). A favourable product mix, a positive one-time impact of pharmaceutical taxes in France and currency effects were the main contributors.

Expenses
Operating expenses increased to SEK 3,601 M (3,057).

Sales and administrative expenses before amortisation and write-downs of intangible assets amounted to SEK 2,062 M (1,644). The increase reflects activities in the Haemophilia franchise in EMENAR, including marketing and personnel increases as well as investments in the North American region.

Research and development expenses amounted to SEK 1,090 M (908). The increased expenses reflect activities for programmes for Kineret, SOBI003, and Sobi's 50 per cent share of (Sanofi's) ongoing development costs for haemophilia, as well as development costs related to the acquisition of the global rights to emapalumab.

Operating expenses also included costs of SEK 113 M (84) 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.

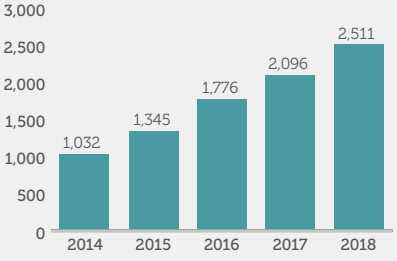
Other operating expenses amounted to SEK 0 M (–52). Operating revenue and expenses for 2018 and 2017 pertained to exchange-rate effects.

Operating profit
Profit before interest, taxes and amortisation (EBITA) amounted to SEK 3,571 M (2,053) corresponding to a margin of 39 (32) per cent.

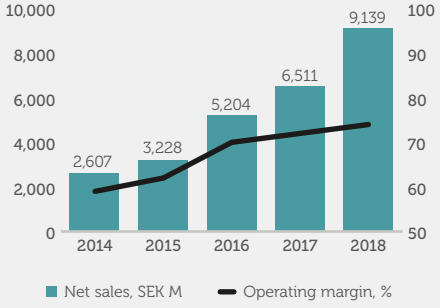
Amortisation and write-downs of intangible assets amounted to SEK 449 M (453). Full-year 2017 included a write-down for one of the early-stage pipeline programmes amounting to SEK 12 M. Operating profit (EBIT) reached SEK 3,122 M (1 600), an increase of SEK 1,522 M.

Net financial items
Net financial items amounted to SEK –40 M (–68) distributed on finance income of SEK 19 M (1) and finance expenses of

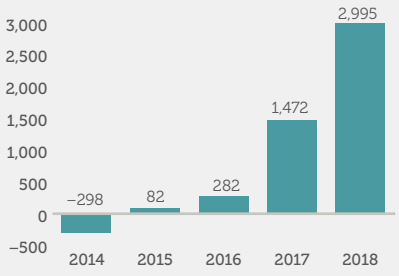
Sales and administrative expenses, SEK M



Net sales (SEK M) and operating margin (%)



Net cash (+)/net debt (–), SEK M[1]



1. Alternative performance measures, see Definitions page 135.

SEK 60 M (69). The difference between the years was mainly attributable to lower interest expenses for the debt to Sanofi and higher exchange-rate gains. Interest expenses comprise of discounted interest on Sanofi liability of SEK –40 M (–50) and interest payments on external loans SEK –16 M (–14). Finance net also includes exchange-rate gains losses of SEK 17 M (–3).

Taxes

Total tax recognised for the Group amounted to SEK –664 M (–384), wherof current tax amounted to SEK –767 M (–209) and deferred tax to SEK 103 M (–175) corresponding to an effective tax rate of 21.5 (25) per cent. On 14 June 2018, the corporate tax rate in Sweden was reduced to 21.4 per cent effective 1 January 2019, and to 20.6 per cent effective 1 January 2021. The Group's deferred tax was revalued in Q2, which resulted in a lower effective tax rate for full-year 2018 compared with full-year 2017. See also Notes 16 and 21.

Other comprehensive income

Other comprehensive income amounted (net) to SEK –124 M (147) and comprised cash-flow hedges attributable to future inflows in USD, current tax on these, exchange differences, and revaluation of pension commitments and deferred tax on these.

Cash flow and investments

Cash flow from operations before change in working capital amounted to SEK 2,341 M (1,431). Working capital had a negative impact of SEK –250 M (–98).

Cash flow from investing activities was SEK –575 M (–139). The largest investment during the year was the acquisition of the global rights to emapalumab, of which cash flow impact amounted to SEK 497 M.

Financial position

At 31 December 2018, cash and cash equivalents and current investments amounted to SEK 2,999 M (1,478).

The long-term funding sources consist of a revolving credit facility of SEK 1,000 M with Handelsbanken and Danske Bank, which matures on 27 June 2020, and a new credit facility of EUR 870 M raised in November with BNP Paribas FORTIS SA/NV, Danske Bank A/S, Skandinaviska Enskilda Banken AB (publ) and Svenska Handelsbanken AB (publ). Both facilities were unutilised at year-end. The new liabilities have been raised to finance the acquisition of Synagis.

At 31 December 2018, net cash amounted to SEK 2,995 M (1,472). The debt to Novimmune is considered current and non-interest-bearing. The liability to Sanofi is also non-interest-bearing, but was raised at discounted value and must therefore be recognised as an interest expense. These liabilities are not included in net debt/net cash. For contractual commitments regarding the above mentioned liabilities see Note 17.

Five-year summary

SEK M	2018	2017	2016	2015	2014
Operating revenue	9,139	6,511	5,204	3,228	2,607
Cost of goods sold	–2,415	–1,854	–1,554	–1,221	–1,059
Research and development costs	–1,090	–908	–778	–513	–501
Operating profit (EBIT)	3,122	1,600	1,133	146	–325
Net financial items	–40	–68	–85	–61	5
Profit for the year	2,418	1,149	802	83	–270
Earnings per share, SEK	8.97	4.27	2.99	0.31	–1.01
Diluted earnings per share (SEK per share)	8.93	4.25	2.98	0.31	–1.01
Number of shares, thousands	273,322	272,508	270,390	270,390	270,390
Equity ratio[1], %	53	61	54	56	71

1. Alternative performance Measures, see Definitions page 135.

Revenue by business area

SEK M	2018	2017
Elocta	3,261	1,557
Alprolix	974	363
Manufacturing	436	559
Royalty	1,341	1,203
Haemophilia	**6,012**	**3,682**
Orfadin	899	862
Kineret	1,320	1,142
Other	908	825
Specialty Care	**3,127**	**2,829**
Total revenues	**9,139**	**6,511**

Sales by region

(Excluding royalty revenue)

SEK M	2018	2017	Change
Europe	6,026	3,784	59%
MENAR[1]	381	272	40%
North America	1,309	1,168	12%
RoW[2]	81	84	–4%
Total	**7,798**	**5,308**	**47%**

1. Middle East, North Africa and Russia.
2. Rest of the world.

Source of revenue by business area

Haemophilia	Specialty Care
Alprolix	Ammonaps®
Elocta	Ferriprox®
Royalty	Kepivance
Manufacturing	Kineret
	Orfadin
	Ravicti®
	Ruconest®
	Valeant portfolio
	Xiapex®
	Yondelis®
	Other

Equity
At 31 December 2018, consolidated equity amounted to SEK 9,040 M (6,701). In addition to profit for the year, the change comprises costs for share programmes, 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 2018, Parent Company revenues amounted to SEK 8,221 M (5,756). Operating profit totalled SEK 3,492 M (1,600). Profit for the year totalled SEK 2,382 M (–508), including excess depreciation of SEK –460 M and Group contributions received of SEK 63 M. At 31 December 2018, cash and cash equivalents amounted to SEK 2,762 M (1,381). At 31 December 2018, equity amounted to SEK 7,731 M (5,436). The change was attributable to profit for the year, costs related to the company's share programmes, and hedge accounting.

Development

Sobi's pipeline projects include development programmes in the areas of haemophilia, immunology, genetic diseases and lysosomal disorders. Sobi is also conducting a number of projects to gather evidence regarding the company's existing products.

In Haemophilia, R&D consists of expanded clinical trial activities to strengthen the already extensive scientific evidence related to Sobi's approved haemophilia products. The ReITIrate trial is studying immune tolerance induction with Elocta. Sobi also conducts pre-clinical and clinical development with Sanofi in regard to the XTEN technology (BIVV001 and BIVV002), with the aim of producing next-generation therapies for haemophilia A and B. The phase 1/2 trial involving BIVV001 continued during 2018 with preliminary data reported.

Clinical programmes in the area of Immunology are ongoing, with the aim of studying new applications for Kineret and emapalumab, for which we acquired the global rights from Novimmune during 2018.

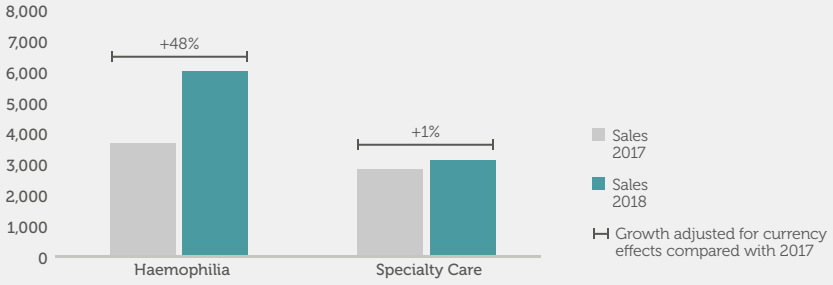
SOBI003 is a product candidate for the treatment of MPS IIIA (mucopolysaccharidosis type IIIA) a lysosomal storage disorder, which entered phase 1/2 during 2018.

A joint trial to study the use of nitisinone in patients with alkaptonuria (AKU) is under way. Surveillance trials to assess the efficacy and safety of long-term treatment with Orfadin in patients with HT-1 are ongoing.

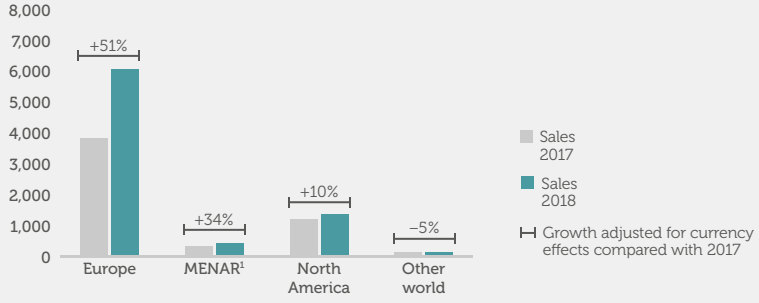
Sobi also has early-stage development programmes for new potential candidates for the treatment of inflammatory conditions in which interleukin-1 (IL-1) is involved. SOBI006 is a product candidate in the immunology area.

SOBI005 is a product candidate in the programme for complement-related disorders.

Revenues by business area, SEK M



Revenue by region (excluding royalty revenue), SEK M



1. Middle East, North Africa and Russia

Regulatory approvals and decisions
- EMA approved Kineret for treatment of Still's disease.
- Orfadin approved in Canada for once-daily dosing.
- Orfadin capsules approved in Argentina and Jordan
- Orfadin oral suspension approved in Tunisia
- FDA granted Fast Track Designation to SOBI003.
- FDA approved emapalumab (Gamifant) for treatment of primary HLH.

FDA accepted investigational new drug application and grants Fast Track Designation for drug candidate SOBI003 for treatment of MPS IIIA
The US Food and Drug Administration (FDA) approved the investigational new drug (IND) application for the drug candidate SOBI003 in the first in-human study. It also granted SOBI003 Fast Track Designation.

Kineret approved in EU for treatment of Still's disease
The European Commission approved an extension of the indication for Kineret (anakinra) to include treatment of Still's disease, including systemic juvenile idiopathic arthritis (SJIA) and adult-onset Still's disease (AOSD), in all 28 member states of the European Union. The approval came after a positive opinion from the Committee for Medicinal Products for Human Use (CHMP).

First patient dosed in phase 1/2 study of SOBI003 for treatment of MPS IIIA
The first patient was dosed in the phase 1/2 study SOBI003-001. This is an open, non-controlled multiple-dose study of nine children aged 1–6 years with MPS IIIA, also called Sanfilippo syndrome A. The aim of the study is to assess the safety, tolerability and efficacy of the drug candidate SOBI003.

Results published from anaGO – a phase 2 study with anakinra in patients with acute gout
The primary endpoint, patient-assessed pain intensity in the most-affected joint, showed a clinically meaningful reduction from baseline both after treatment with anakinra and the comparator triamcinolone. There was a meaningful pain reduction with anakinra of around 50 per cent, in line with expectations of IL-1 blockade in this disease. No statistically significant difference between the two treatments was obtained (primary endpoint). The study confirmed the well-established safety profile of anakinra.

FDA approved Gamifant as the first approved treatment for primary haemophagocytic lymphohistiocytosis (HLH)
The FDA approved Gamifant® (emapalumab-lzsg), an interferon gamma (IFNγ) blocking antibody for the treatment of paediatric (newborn and older) and adult patients with primary haemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance to conventional HLH therapy.

Data supporting emapalumab as an innovative, targeted therapeutic option for primary HLH presented at ASH
Data from the pivotal phase 2/3 study with emapalumab for the treatment of primary HLH showed that treatment with emapalumab induced rapid and sustained responses, helping fragile and often very young patients control HLH activity and reach stem cell transplant.

Data demonstrating the well-established safety and efficacy of Elocta and Alprolix, extended half-life therapies for haemophilia A and B, at ASH
The ASPIRE and B-YOND extension studies show no inhibitor development and consistently low annualised bleeding rates in study participants over four years with Elocta and Alprolix respectively.

New data from the phase 1/2a study of BIVV001 presented at ASH
New data from the EXTEN-A phase 1/2a trial of BIVV001 (rFVIIIFc-VWF-XTEN) showed that a single 65 IU/kg dose of BIVV001 extended the half-life of factor VIII to 44 hours with high factor activity levels and was generally well tolerated. Seven days post-infusion, the factor activity level was 18.5 per cent, which is an unprecedented level of protection in factor VIII therapy.

Other information

Changes in Management
On 20 July 2018, Henrik Stenqvist was appointed as CFO. The following joined the Executive Committee during 2018: Torbjörn Hallberg as General Counsel and Head of Legal Affairs, Anne Marie De Jong Schuermans as Head of Technical Operations and Fredrik Wetterlundh as Head of HR.

As of 31 December 2018, the Executive Committee comprised:

CEO: Guido Oelkers

CFO: Henrik Stenqvist

General Counsel and Head of Legal Affairs: Torbjörn Hallberg
Head of Haemophilia: Philip Wood

Head of Specialty Care: Norbert Oppitz

Head of EMENAR: Hege Hellström

Head of North America: Rami Levin

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 HR: Fredrik Wetterlundh

From the previous Executive Committee, Mats-Olof Wallin, formerly CFO, left the company during 2018. Hege Hellström left Sobi on 1 January 2019.

Sustainability Report
The statutory Sustainability Report can be found on pages 12–13, 15–17, 30–31, 34–41, 58–63 and 123–133 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. It can be found on pages 108–113.

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 water emissions and include a requirement to adjust the pH of the process water. In 2018, 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

Sobi's share capital at 31 December amounted to SEK 149,973,582, distributed between 273,322,117 shares, with a par value per share of about SEK 0.55. At 31 December 2018, the total number of shares outstanding comprised 269,898,391 ordinary shares, each carrying one vote. At 31 December 2018, Investor AB was Sobi's largest single shareholder with a total of 107,594,165 shares, representing 39.37 per cent of the votes and 39.37 per cent of the capital.

Share conversions

The Annual General Meeting (AGM) on 9 May 2018 authorised Sobi's Board to resolve on an issue of C shares and to repurchase all C shares issued in order to hedge the long-term incentive programme. The AGM also resolved to approve the Board's proposed transfer of shares.

At 31 December 2018, Sobi held 3,423,726 ordinary shares in treasury. All C shares issued in 2018 have been 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 'Shares' on page 44.

Proposal regarding guidelines for remuneration for the Management

The Board of Directors proposes that the Annual General Meeting 2019 resolves on guidelines for remuneration for the Management as set forth below which shall apply until the Annual General Meeting 2020.
The Management is defined as the managing director of Swedish Orphan Biovitrum AB (publ) and the executives who report to the managing director and are members of the senior management.

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.

Remuneration for the Management is designed on a total remuneration approach. The position of total remuneration should be competitive without being leading relative to competitors in each local market. Market comparisons should be made against a set of peer group companies with comparable sizes, industries and complexity. The remuneration guidelines should enable international hiring and should support diversity within the Management.
The remuneration may consist of the following components:

- A, Fixed base pay
- B, Variable pay – short-term incentives
- C, Long-term incentives
- D, Pensions
- E, Other benefits

To the extent a member of the Board of Directors carries out work for the company or for another group company, in addition to the board work, consulting fees and/or other remuneration for such work may be payable.

Fixed base pay
The fixed base pay of the Management should be based on competence, responsibility and performance. The company uses an international evaluation system in order to evaluate the scope and responsibility of the position.

Variable pay
The annual short-term incentive plan is based on the achievement of annual performance objectives (corporate and individual). Payment is based on achievement of the 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 excessive risk-taking. The short-term incentives are limited to 100 per cent of the annual gross salary for the Managing director and 60 per cent of the fixed annual salary for the other members of the Management.

Long-term incentives
The company can introduce long-term incentive programmes for all or some of its employees.

The objectives 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 executives and top talent, to allow participants to take part in the company's long-term success and value creation, and to contribute to a competitive total remuneration.

For further information on the company's current incentive programmes, see note 11.

Pensions
The preferred pension plan design is defined-contribution.[1] If the operating environment requires the establishment of a defined-benefit pension plan by law or other regulations, such a plan may be established. The defined-benefit level should in such cases 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 fixed base pay for two years. In addition to this restriction, the total severance payment shall be limited to the existing monthly salary for the remaining months up to the age of 65.

Additional compensation 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, a support package including relocation and tax filing support, retention bonus or severance payment in case of a change of control, or similar. The compensation shall not exceed the amount of the fixed base pay

1. In a defined-contribution plan, the contribution paid into the pension plan for each employee is determined.

Sobi's values

Sobi promotes a good working environment. Sobi strives to comply with all health and safety-related laws and regulations and therefore conducts systematic health and safety efforts integrated with environmental and quality awareness. The company has also worked actively for several years to raise awareness of the company's values among all employees throughout the organisation.

Sobi's values are: Care, Ambition, Urgency, Ownership and Partnership. Compliance with the company's values is evaluated every year in Sobi's performance appraisal process.

Employees
At 31 December 2018 the number of employees (full-time equivalents) was 902 (800), with 468 (451) based in Sweden.

Salaries and other remuneration amounted to SEK 1,092 M (927), of which the Parent Company accounted for SEK 444 M (427).

Of the total number of employees in 2018, 59 per cent were women and 41 per cent Men. All employees are treated equally and offered the same opportunities regardless of age, gender, religion, sexual orientation, functional disability or ethnicity.

Care
We are who we are because of our dedication, our knowledge and our 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 experience.

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

for three years and shall not be paid more than once a year per individual.

Resolutions on such compensation shall be made by the Board of Directors based on a proposal from the Compensation & Benefits Committee.

Deviation from the guidelines
The Board of Directors may resolve to deviate from the guidelines if the Board of Directors, in an individual case, is of the opinion that there are special circumstances justifying that.

Proposed appropriation of profit

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

SEK	
Share premium reserve	4,277,038,162
Retained earnings	121,508,296
Profit for the year	2,381,763,358
Total	**6,780,309,816**

The Board of Directors proposes that no dividend be distributed for the 2018 financial year.

The Board proposes that the share premium reserve and retained earnings at their disposal, SEK 6,780,309,816, be carried forward.

Events after the balance-sheet date, up to 27 March 2019

- Sobi completed the acquisition of the Synagis US rights from AstraZeneca and exercised authorisation to issue shares. The upfront consideration payable at closing of the acquisition, announced on 24 January 2019, corresponds to approximately USD 1.5 B (SEK 13.8 B) consisting of cash and 24,193,092 newly issued Sobi common shares.
- In connection to the acquisition from AstraZeneca of the rights to Synagis in the US, Sobi announced a new number of shares and votes due to the issue of 24,193,092 new common shares. Thereafter, the total number of shares and votes amounts to 297,515,209. At 31 January 2019, the company held 3,423,726 common shares in treasury.
- The US Food and Drug Administration granted Breakthrough Therapy Designation (BTD) för MEDI8897.
- Christian Dreger (Head of Northern Europe, Middle East and Russia), Sofiane Fahmy (Head of Southern & Western Europe and North Africa) and Paula Treutiger (Head of Communications & Investor Relations) were appointed to the Executive Committee in January 2019. Hege Hellström (Head of EMENAR) left the Executive Committee and the company in January 2019.

Outlook for 2019[1]

Sobi expects revenue for the full year to be in the range of SEK 12,500 – to 13,000 M.

Main drivers of revenue growth are: continued market share growth of our haemophilia franchise with Elocta and Alprolix, the acquisition of Synagis and growth of this franchise in the US and the launch of Gamifant in the US.

EBITA for the full year is expected to be in the range of SEK 5,000 – to SEK 5,300 M.

In 2019, we will increase market investments in the haemophilia franchise and in the commercial launch of Gamifant. Furthermore, we will expand clinical activities for emapalumab.

For information about forward-looking statements, refer to the inside cover.

1. At current exchange rates as of 20 February 2019
The outlook was published on 20 February 2019.

Risk Management

The Sobi Group risk management process is documented in Sobi Group Risk Management Policy as well as in Sobi Group Risk Management Instruction.

Sobi applies an integrated business risk-management process that contributes to our ability to achieve set objectives, and to follow the strategy adopted for the operations. Each operational unit works actively to identify and address any uncertainties related to our ability to achieve our set objectives. Identified risks are analysed against 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.

Key risk areas

The discovery and development of novel drugs, and the regulations governing research and development, manufacturing, testing, and the marketing and sales of pharmaceutical products are complex and may change over time. The specialty pharmaceuticals market consists of highly qualified and resource-intensive companies and is characterised by rapid technological development, making competition a key area to monitor. A summary of the main operational risks is presented below. The risks are not ranked in any particular order, but they are categorised and described.

Policies guiding Sobi's sustainability performance

Alcohol and Drug Policy
Annual Limits on Compensation for Healthcare professionals
Anti-Corruption Policy
Charitable Contributions and Sponsorships Policy
Chemical Management
Code of Conduct and Ethics
Communications Policy
Compensation for Healthcare Professionals Policy
Consultants and Speakers Policy
Corporate Car Policy
Discrimination Policy
Educational Grants Policy
Environmental Control Program
Environmental Health and Safety Policy
Fair Competition Policy
Information Security Policy
Insider Policy
Interactions with Patient Organisations Policy
IT Security Policy
Parental Policy
Patient Access Bridging Programmes Policy
Pension Policy
Policies on Health Care Interactions
Processing of Personal Data Policy
Procedure for Conducting Market Research Activities
Procurement Policy
Promotional and Scientific Material Review Policy
Publications Policy
Requirements and Approval Process for Non-Promotional Material
Requirements and Approval Process for Promotional Material
Research Agreements, Grants and Fellowships Policy
Risk Management Policy
Reporting Investigating and Responding to Compliance Issues Policy
Sobi Career with focus on personal and professional development
Sobi Quality Management System
Sobi's Global HR Processes
Tax Policy
Travel Policy
Treasury Policy

Operational risks

Risk	Risk description	Management and comments
Product risks		
Novel drug development	Developing and bringing novel drugs to market is a costly, complex and risky process. The probability of reaching the market increases as the project advances through the development process. However, the risks remain substantial until phase III studies, while costs increase at a faster rate as the project moves through the final clinical phases.	Sobi currently has a number of clinical and preclinical development projects. Sobi's innovation model is used to determine how attractive a project is, and its risk profile.
Obtaining and maintaining authorisation for new products	Failure to demonstrate that drug candidates maintain high quality, or ascertain their expected safety and efficacy, in adequate and well-controlled preclinical and clinical studies, may result in delays or failure to launch. Preclinical and clinical development is a lengthy process that is impacted by a variety of factors, including those beyond the company's control, such as changing regulatory requirements. Before it can be launched, the drug must meet the rigorous quality, safety and efficacy requirements imposed by regulators in the countries or regions in which Sobi plans to market the drug.	In order to make sure that the clinical studies meet the needs of regulators and society for evidence, relevant stakeholders are identified and consulted, which can result in faster development and availability, or the discovery of new opportunities.
Biologics manufacturing and quality	Compliance with current GMP regulations for manufacturing. The manufacture of Sobi's products requires that all manufacturing processes, methods and equipment are compliant with Good Manufacturing Practice (GMP) regulations. GMP regulations control all aspects of pharmaceutical production, including quality control and quality assurance, production processes and documentation. Sobi's production facility may be inspected at any time by the regulators or the company's customers.	Sobi has been working with the Qase system (Quality Case management) since 2017. The system is used to address Non Conformances (NC) with Corrective and Preventive Actions (CAPAs). All GMP, GDP (distribution), GVP (pharmacovigilance) and GCP (clinical)-related cases are registered and handled in the system, which is used for all inspections. Internal audits in respect of GxP (the relevant form of good practice) were carried out as planned for 2018, covering such areas as finished goods supply and production, Quality Assurance, Quality Control and IT systems. All actions resulting from the audit were monitored in the CAPA system.
GMP/GDP compliance for partner facilities	Risk that partners are not GMP/GDP-compliant. In drug manufacturing, Sobi collaborates with other pharmaceutical companies as a customer and is dependent on the partner facilities being maintained and available.	GMP/GDP regulations apply to Sobi and its distributors, contract laboratories and suppliers. Sobi conducts audits of its distributors, contract laboratories and suppliers. In Sobi's external network, a total of 48 GMP/GDP audits were carried out in 2018. All audited parties were approved as a supplier.
Third-party risks		
Collaborations and partnerships	The strategy includes entering into collaboration agreements regarding, for example, joint development and/or authorisation with other pharmaceutical and biotechnology companies for the development and launch of some of Sobi's products. Risk of low influence for Sobi, since these partners hold considerable discretion when it comes to defining the project's processes and resources, depending on the nature of the agreement between the various parties. This could delay the development and launch of new products.	A structured flow of information is essential for a successful partnership. The success of such collaborations will largely depend on the work carried out jointly with Sobi's partners or licensees. Sobi forms a Joint Steering Committee in all partnership agreements to ensure continuous coordination and information sharing.
Expertise, willingness and regulatory guidelines	Collaborations with patient organisations, academic institutions, healthcare professionals and other relevant groups are dependent on the other party's knowledge and willingness, and the regulatory guidelines governing these collaborations. Risk of our partners not abiding by Sobi's internal guidelines and regulatory guidelines, which may have a negative impact on Sobi's reputation.	Sobi strives to uphold and maintain long-term commitment and collaboration. We support and collaborate with a wide range of patient organisations, both national and regional, to attain our joint objective of achieving the best possible outcome for patients with rare diseases. There are Group-wide guidelines to ensure compliance with ethical standards and transparency in all of Sobi's business areas.

Risk	Risk description	Management and comments
Intellectual property protection and patents	Risk of Sobi not being able to obtain/extend intellectual property protection and patents. The ability of the company, or its licensors, to obtain protection in the US, the EU and other countries or regions for the intellectual property rights covering the products that the company develops, manufactures, markets and sells, is of great importance. Sobi's success will largely depend on the protection of intellectual property.	Sobi has a number of patents and patent applications which are managed by experienced and established patent representatives. Sobi has a number of patents which are very important for the business. The patent licence rights are managed through regular meetings with licence issuers. In addition to patented products and technologies, Sobi has its own technology, processes and know-how that are not protected by patents. The company strives to protect such information by entering into, for example, confidentiality agreements with employees, consultants and partners.
Competition and external risks		
Pricing of drugs for rare diseases	The market is increasingly affected by cost-awareness due to the growing cost of healthcare in many countries. Market approval of drugs in the product portfolio does not guarantee that these products will be granted reimbursement and pricing approval by the national or regional healthcare systems. A significant decline in revenues from Sobi's key products could have a material adverse effect on Sobi's operations, earnings and financial position – regardless of whether this is due to reduced demand, increased competition or other reasons, such as policy changes for a national drug reimbursement scheme.	Sobi's way of working with most stakeholders throughout the entire development process is designed to anticipate market needs and the demands that will be imposed on the product by payers in the event of an approval.
Use and recommendation of Sobi's drugs	The use of drugs may be impacted by the treatment guidelines, recommendations and studies published by regulators and other bodies. The products must achieve market acceptance among physicians, patients and procurement organisations. The degree of market acceptance for each of the company's products is therefore dependent on several factors. Many of these are beyond the company's control and dependent on external decision-making procedures and policy-making bodies.	Sobi's way of working with regulators throughout the entire development process is designed to anticipate market needs and the demands that will be imposed on the product by regulators and prescribers in the event of an approval, with the aim of ensuring that patients receive rapid and sustained access to these new and approved therapies, and that they meet the demands that arise over time.
Competition	The market for specialty pharmaceuticals is characterised by intense competition and rapid technological development. Sobi's competitors include international pharmaceutical, biotechnology and specialty pharmaceutical companies. Some competitors have considerable financial, technical and human resources, as well as substantial manufacturing, distribution, sales and marketing capabilities.	To secure a leading position in terms of technological development, Sobi collaborates with a wide range of groups, for example, within the framework of the Swedish strategic cooperation programme in life science to support the future development and production of biologics.
Product counterfeiting	Risk of Sobi's drugs being exposed to competition from illegally produced pharmaceutical products and the availability of pirated products in some distribution channels.	Sobi's products have not yet been exposed to pirating. Sobi participates in global efforts initiated to improve drug traceability. To minimise the risk of counterfeiting, all of Sobi's distribution processes comply with Good Distribution Practice. Sobi has been using the TraceLink system to record the serial numbers of all products that require serialisation since 2017. This system complies with the regulatory requirements of all markets in which we operate. In 2019, all of Sobi's products that are required to have a unique identifier will have one.

Risk	Risk description	Management and comments
Financial risks		
Currency risks	The company's operations are exposed to foreign-exchange risk. Most of the company's expenses are incurred in SEK, while a considerable amount of revenue is generated in other currencies. Due to the company's international expansion, lower exchange rates for the EUR in particular, but also for other currencies in which revenue is generated, could have an adverse effect on Sobi's earnings and financial position.	More information about financial risks can be found in Note 3.
Tax risks	Sobi is a multinational group and thus subject to complex and changing international and local tax laws and guidelines. Sobi is affected by changes in, e.g., corporate tax rates, interest deduction possibilities and transfer pricing principles. The current global focus on transfer pricing, along with international initiatives such as BEPS (base erosion and price shifting), specifically entail an increased risk of transfer pricing exposures.	Sobi is proactively working on managing tax risks by: • having processes for tax compliance in place; • ensuring that the group tax function closely collaborates with both local affiliates, accounting, treasury and legal functions; and • engaging external tax advisors for analysis of complex tax issues.
Environmental risk		
CO_2 emissions	Sobi's business activities involve business trips that give rise to greenhouse gas emissions.	Our Travel Policy emphasises the importance of considering travel carefully, to minimise the need and also improve work-life balance. The policy also emphasises the need to consider virtual meetings and Sobi provides tools to facilitate them.
Energy and water consumption	The consumption of energy, water, products and services have an environmental impact.	Sobi monitors legislation in the environmental field and integrates requirements into controlling procedures for the business activity concerned. A control programme for the manufacturing facility has been coordinated with compliance authorities. We reduce our greenhouse gas emissions by improving the energy efficiency of our facilities and monitor the operational expenses for our facilities. By implementing an energy management plan for the production facility in Stockholm we have reduced energy and water consumption relative to production capacity.
Chemical handling	The handling of chemicals in the manufacturing facility could have an environmental impact.	The handling of chemicals in our R&D and manufacturing processes is covered by annual risk assessments in order to avoid any impact on the future ability to deliver as agreed.
Environmental impact of products	Sobi's products could have an environmental impact in production, distribution and consumption.	Sobi products are mainly biologics and the environmental impact of these are seen as very low because they are biodegradable without permanent environmental impact. According to EU guidelines on the environmental risk assessment of medicinal products, some drugs are not expected to have any environmental impact, for example products composed of carbohydrates, amino acids, peptides and proteins. A high percentage of our products are biopharmaceuticals composed of amino acids, proteins and peptides, and are therefore unlikely to pose any significant risk to the environment.

Risk	Risk description	Management and comments
Social risk		
Attract new employees and develop existing personnel	Sobi operates in a competitive market, where our employees form the basis of the company's ability to develop special drugs to meet patients' needs. If we cannot attract employees with different skills and experience to contribute to this process, we could become less effective and fail to produce the right drugs at the right price.	Sobi is a learning organisation and involves employees in high-performance teams in order to achieve and deliver in a competitive market.
Patient and customer privacy	Risk that personal data processed in the course of Sobi's business is not protected. Sobi is committed to protecting the personal rights of any individual whose personal data it processes – including its employees, customers, suppliers and other contractual partners, stakeholders, subjects and patients in clinical trials.	The pharmaceutical business is highly regulated, meaning that Sobi as a company is very well prepared to adjust to new compliance requirements. Sobi initiated its GDPR compliance work early in 2016, and after two and a half years, we can see good results. The policy on processing of personal data has been updated. Relevant data flows have been analysed in order to close potential gaps under the new legislation. An updated data privacy governance structure to facilitate compliance was introduced during 2018.
Patient safety and ethics	Risk of poor patient safety and ethical values in research. For all research involving humans, such as clinical trials, it is of the utmost importance that these are built on rigorous, scientifically based evaluations by clinical experts in cooperation with regulatory authorities, independent ethics committees and stakeholders.	Sobi applies the Declaration of Helsinki's principles for medical researchers. All Sobi-sponsored clinical trials are conducted and reported in accordance with applicable law and the international Good Clinical Practice (GCP) standard. To a substantial extent we collaborate with contract research organisations (CROs). These collaborations are governed by mutual high standards and procedures. Sobi follows the European Medicines Agency's (EMA) policy on the publication of clinical trial data.

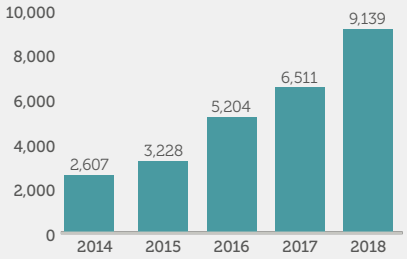
Risk	Risk description	Management and comments
Governance risk		
Legal risks	Risk of not acting in compliance with changes in regulations. Sobi operates in a strictly regulated environment and we must comply with laws and regulations governing not only production, but also research and marketing. Changes in legislation and regulations can have a direct impact on Sobi by limiting access to the market, manufacturing opportunities or development strategies. Therefore it is also highly important for Sobi to be aware of and ahead of upcoming legislation.	Sobi's Risk and Regulatory Compliance Committee continuously monitors the development and implementation of Sobi's regulatory compliance programme, which aims to reduce the company's risk of non-compliance with laws and regulations. The most important elements of the compliance programme include identifying risks, promoting clear messages, establishing clear guidelines and processes, training and continuous monitoring. In cases where legislation concerns requirements for the approval of drugs, we adopt an agile approach to adapt development processes rapidly in order to meet the new requirements and thereby not risk extending the time it takes for the drug to reach the patient.
Anti-corruption, anti-competitive behaviour, ethical approach and collaboration	Collaborations with stakeholders are essential for us to share knowledge and experience within the rare disease community. The risk of corruption is greatest in activities in which Sobi interacts with the healthcare sector.	Sobi has a zero-tolerance policy towards bribery, supported by the Sobi Code of Conduct and Ethics and the Sobi Global Policy on Anti-Corruption. Both have been translated into relevant business processes, such as those governing interactions with healthcare professionals and organisations. To mitigate corruption risks, Sobi has for several years had a Health Care Compliance ("HCC") program in place. Health Care Compliance within Sobi is defined as the ethical business standard for transparent promotional and non-promotional activities and interactions with healthcare professionals, providers, payers and patient organisations. The program includes processes and controls that aim to mitigate the risks of, for example, corruption. Sobi supports transparency initiatives, including the European Federation of Pharmaceutical Industries and Associations (EFPIA), Disclosure Code in Europe and the Physician, Payments Sunshine Act in the US. We have implemented the EFPIA Disclosure Code and made all payments and transfers of value to healthcare professionals and healthcare organisations in Europe publicly available on www.sobi.com, including sponsorships to attend meetings, grants and donations, speaker fees, consultancies and advisory board postings.

Consolidated statement of comprehensive income

SEK 000s	Note	2018	2017
	1–4		
Operating revenue	5–6	9,138,892	6,510,831
Cost of goods sold		–2,415,426	–1,853,998
Gross profit		**6,723,466**	**4,656,833**
Sales and administrative expenses	12	–2,510,740	–2,096,470
Research and development costs		–1,090,416	–907,721
Other operating income	8	6,144	471
Other operating expenses	9	–6,486	–52,748
Operating profit	7, 10, 11, 13, 17, 18, 28	**3,121,968**	**1,600,365**
Financial income	14	19,426	1,219
Financial expenses	15	–59,659	–69,161
Net financial items		**–40,233**	**–67,942**
Profit before tax		**3,081,735**	**1,532,423**
Tax on profit for the year	16	–663,940	–383,811
Profit for the year[1]		**2,417,795**	**1,148,612**
Other comprehensive income[2]			
Items that cannot be reclassified into profit or loss			
Actuarial gains/losses on defined-benefit plan		–85	–1,042
Items that can be reclassified into profit or loss			
Translation differences		9,463	–1,258
Cash flow hedges		–170,920	191,856
Tax effect of cash flow hedges		37,628	–42,208
Other comprehensive income		**–123,914**	**147,348**
Comprehensive income for the year[2]		**2,294,051**	**1,295,960**
Earnings per share, SEK	32	8.97	4.27
Diluted earnings per share (SEK per share)	32	8.93	4.25
Number of shares (ordinary)		273,322,117	272,507,708
Average number of shares		269,523,784	269,020,363
Number of ordinary shares held in treasury		3,423,726	3,249,870
Number of shares after dilution		270,522,788	269,975,826
Average number of shares after dilution		270,603,665	270,003,546

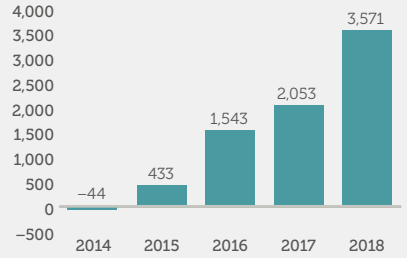
1. Everything attributable to Parent Company shareholders.
2. Under the revised version of IAS 1, all changes in equity not arising from transactions with owners are recognised in the consolidated statement of comprehensive income. Translation differences are wholly related to shares in foreign subsidiaries.

Operating revenue, SEK M



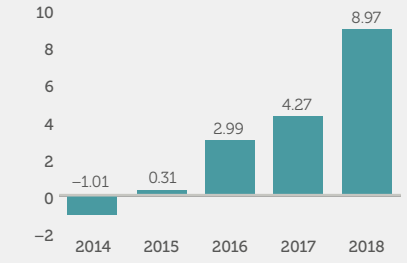
Operating revenue
Revenues for the full-year amounted to SEK 9,139 M (6,511), up 40 per cent.

EBITA[1], SEK M



EBITA
EBITA for the year rose 74 per cent to SEK 3,571 M compared with 2017.

Earnings/share[1], SEK



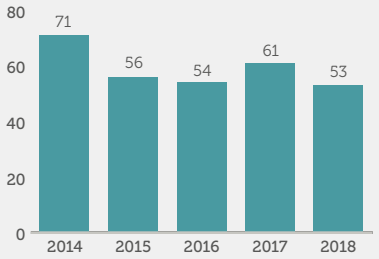
1. Alternative performance measures, see Definitions page 135.

Consolidated balance sheet

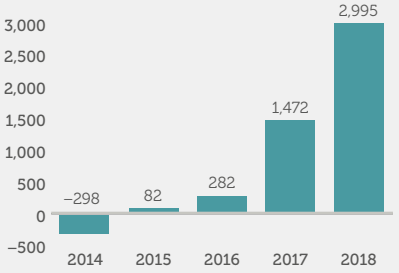
SEK 000s	Note	31 Dec 2018	31 Dec 2017
ASSETS	1–4		
Non-current assets			
Intangible assets	17	10,158,676	6,445,071
Property, plant and equipment	18	136,299	134,182
Financial assets	20	55,440	35,155
Deferred tax assets	21	230,834	131,429
Total non-current assets		**10,581,249**	**6,745,837**
Current assets			
Inventories	22	1,284,112	1,053,268
Trade receivables	23, 26	1,665,208	1,129,016
Other receivables	23	92,736	63,964
Prepaid expenses and accrued income	24	561,110	432,326
Cash and cash equivalents	25, 26	2,998,742	1,478,496
Total current assets		**6,601,908**	**4,157,070**
TOTAL ASSETS		**17,183,157**	**10,902,907**
EQUITY AND LIABILITIES			
Equity			
Share capital		149,974	149,527
Other contributed capital		5,069,248	5,023,557
Other reserves		–144,299	–20,386
Retained earnings		1,547,379	399,214
Profit for the year		2,417,795	1,148,612
Equity attributable to Parent Company shareholders		**9,040,097**	**6,700,524**
Liabilities			
Non-current liabilities			
Deferred tax liabilities	21	663,821	667,733
Liability to Sanofi	27	427,699	1,066,833
Liabilities to credit institutions		2,991	5,044
Provisions	28, 29	97,479	97,955
Total non-current liabilities		**1,191,990**	**1,837,565**
Current liabilities			
Trade payables	26	486,972	358,449
Tax liabilities		394,501	225,579
Liability to Sanofi	27	676,778	579,895
Other liabilities	27	3,782,524	82,217
Accrued expenses and deferred income	30	1,610,295	1,118,678
Total current liabilities		**6,951,070**	**2,364,818**
TOTAL EQUITY AND LIABILITIES		**17,183,157**	**10,902,907**

Related to pledged assets and contingent liabilities, see Note 31.

Equity/ratio[1], %



Net cash[1] (+) / net debt (–), SEK M



Net cash
During the year, net cash increased from SEK 1,472 M to SEK 2,995 M.

Net cash (+)/net debt (–)

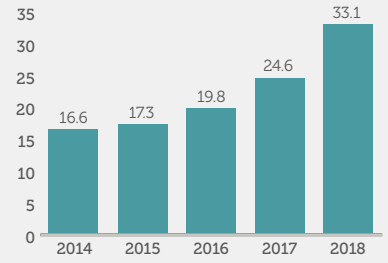
SEK M	2014	2015	2016	2017	2018
Cash and cash equivalents	519	904	786	1,478	2,999
Interest-bearing liabilities	818	822	504	7	4
Net cash (+)/net debt (–)	**–298**	**82**	**282**	**1,472**	**2,995**

1. Alternative performance measures, see Definitions page 135.

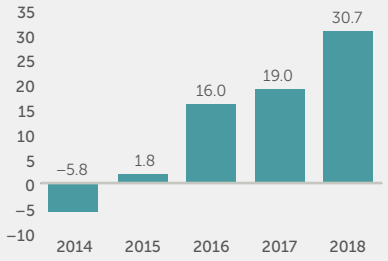
Consolidated statement of changes in equity

SEK 000s	Share capital	Other contributed capital	Other reserves	Retained earnings	Total equity
Opening equity, 1 Jan 2017	149,254	4,983,959	–167,734	399,487	5,364,966
Comprehensive income					
Profit for the year	—	—	—	1,148,612	1,148,612
Other comprehensive income					
Cash flow hedges	—	—	191,856	—	157,417
Tax cash flow hedges	—	—	–42,209	—	–7,769
Actuarial loss/gain	—	—	–1,042	—	–1,042
Exchange differences	—	—	–1,258	—	–1,258
Total comprehensive income	**—**	**—**	**147,348**	**1,148,612**	**1,295,960**
Shareholder transactions					
Issue/repurchase of shares	273	—	—	–273	—
Share programmes	—	39,598	—	—	39,598
Total shareholder transactions	**273**	**39,598**	**—**	**–273**	**39,598**
Closing equity, 31 Dec 2017	**149,527**	**5,023,557**	**–20,386**	**1,547,826**	**6,700,524**
Opening equity, 1 Jan 2018	149,527	5,023,557	–20,386	1,547,826	6,700,524
Comprehensive income					
Profit for the year	—	—	—	2,417,795	2,417,795
Other comprehensive income					
Cash flow hedges	—	—	–170,920	—	–170,920
Tax cash flow hedges	—	—	37,628	—	37,628
Actuarial loss/gain	—	—	–85	—	–85
Exchange differences	—	—	9,463	—	9,463
Total comprehensive income	**—**	**—**	**–123,914**	**2,417,795**	**2,293,881**
Shareholder transactions					
Issue/repurchase of shares	447	—	—	–447	—
Share programmes	—	45,691	—	—	45,691
Total shareholder transactions	**447**	**45,691**	**—**	**–447**	**45,691**
Closing equity, 31 Dec 2018	**149,974**	**5,069,248**	**–144,299[1]**	**3,965,174**	**9,040,097**

Equity per share[1], SEK



Return on equity[1], %



Return on equity
Return on equity increased from 19.0 to 30.7 per cent year-on-year.

1. Alternative performance measures, see Definitions page 135.

[1]Other reserves

SEK 000s	2018	2017
Exchange differences	–11,990	–21,453
Pensions in accordance with IAS 19	–26,358	–26,273
Cash flow hedges	–105,750	27,543
Other	–201	–203
Closing balance, 31 Dec 2018	**–144,299**	**–20,386**

Cash flow hedges

SEK 000s	2018	2017
Opening balance, cash-flow hedges	27,543	–122,105
Change in value for the year, hedging instruments	–133,293	149,648
Closing balance, cash-flow hedges	**–105,750**	**27,543**

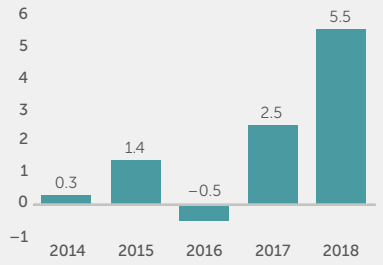
Regarding cash-flow hedges, SEK 27,850 K (12,662) was transferred to profit or loss. The cash flow hedge is included in other income and expenses in profit and loss. The reversal to profit and loss has been made solely because the hedged item has been recognised in profit and loss. The hedging reserve consists solely of ongoing hedges.

Consolidated cash flow statement

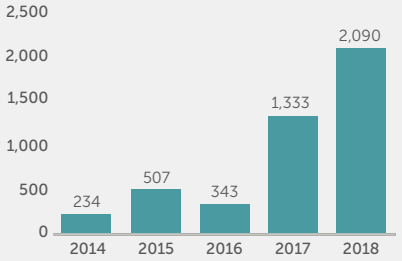
SEK 000s	Note	2018	2017
Operating activities			
Profit for the year		2,417,795	1,148,612
Adjustments for non-cash items		–77,051	282,377
Cash flow from operating activities before changes in working capital		**2,340,744**	**1,430,989**
Cash flow from changes in working capital			
Decrease (+) / Increase (–) in inventories		–230,844	–183,222
Decrease (+) / Increase (–) in operating receivables		–678,931	–369,889
Increase (+) / Decrease (–) in operating liabilities		659,307	455,064
Cash flow from operating activities		**2,090,276**	**1,332,942**
Investing activities			
Acquisition of intangible assets[1]	17	–537,365	–91,922
Acquisition of property, plant and equipment	18	–40,512	–47,523
Acquisition of financial assets	20	–700	–737
Disposal of property, plant and equipment	18	3,220	1,204
Cash flow from investing activities		**–575,537**	**–138,978**
Financing activities			
Repayment of loans[2]		–2,053	–500,000
Cash flow from financing activities		**–2,053**	**–500,000**
Change in cash and cash equivalents		**1,512,866**	**693,964**
Cash and cash equivalents at beginning of year		**1,478,496**	**785,790**
Exchange differences in cash flow		**7,380**	**–1,258**
Cash and cash equivalents at end of year		**2,998,742**	**1,478,496**

1. The largest investments during the year affecting cash flow was to the aqusition of Emapalumab, totalling CHF 50 M, and further aqusition costs of CHF 2.6 M, SEK 497 M and investments within IT, see Note 17.
2. Repayment of loans refers to the settlement of a loan of SEK 500 M from Handelsbanken and Danske Bank.

Cash flow per share[1], SEK M



Cash flow from operations, SEK M



Cash flow for the year
Cash flow for the year totalled SEK 1,513 M.

1. Alternative performance measures, see Definitions page 135.

Consolidated cash flow statement, cont.

Supplemental disclosures to the consolidated cash flow statement

SEK 000s	Note	2018	2017
Interest paid and received			
Interest received		2,742	1,219
Interest paid		–18,259	–13,886
Income tax paid		506,542	28,421
Adjustments for non-cash items			
Depreciation/amortisation and impairment of non-current assets	7, 17, 18	484,575	485,977
Pensions	28	–85	–1,042
Cost of share programmes[1]		45,691	39,598
Deferred tax	21	–103,317	174,683
Elocta and Alprolix[2]		–485,261	–437,660
Other items		–18,654	20,821
Total		**–77,051**	**282,377**

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

Parent Company income statement

SEK 000s	Note	2018	2017
	1–4		
Operating revenue	5–6	8,221,227	5,756,370
Cost of goods sold		–2,349,466	–1,861,398
Gross profit		**5,871,761**	**3,894,972**
Selling and administrative expenses	12	–1,445,001	–1,400,380
Research and development costs		–932,394	–854,862
Other operating income	8	5,181	120
Other operating expenses	9	–7,575	–39,824
Operating profit	7, 10, 11, 13, 17, 18	**3,491,972**	**1,600,026**
Profit/loss from participations in Group companies	19	—	–1,000,000
Financial income	14	34,812	11,656
Financial expenses	15	–69,478	–76,299
Net financial items		**–34,666**	**–1,064,643**
Profit after financial items		**3,457,306**	**535,383**
Group contributions		62,670	58,956
Excess depreciation		–460,000	–970,000
Appropriations		**–397,730**	**–911,044**
Profit/Loss before tax		**3,059,976**	**–375,661**
Tax on profit for the year	16	–678,212	–132,175
Profit/Loss for the year		**2,381,764**	**–507,836**

Parent Company statement of comprehensive income

SEK 000s	2018	2017
Profit/Loss for the year	2,381,764	–507,836
Items that can be reclassified into profit or loss		
Cash flow hedges	–170,920	191,856
Tax effect of cash flow hedges	37,628	–42,208
Other comprehensive income	**–133,292**	**149,648**
Comprehensive income for the year	**2,248,472**	**–358,188**

Parent Company balance sheet

SEK 000s	Note	31 Dec 2018	31 Dec 2017
ASSETS	1–4		
Non-current assets			
Intangible assets	17		
Patents, licenses, trademarks and similar rights		3,800,629	4,057,718
Property, plant and equipment	18		
Plant and machinery		87,099	72,441
Equipment, tools, fixtures and fittings		16,197	20,579
Construction in progress		8,567	21,041
Financial assets			
Participations in Group companies	19	3,474,608	2,882,333
Other financial assets	20	51,979	32,392
Deferred tax asset	21	10,519	—
Total non-current assets		**7,449,598**	**7,086,504**
Current assets			
Inventories	22		
Raw materials and consumables		17,165	20,905
Work in progress		581,185	536,603
Finished goods and goods for resale		472,462	336,166
Current receivables			
Trade receivables	23	589,596	405,702
Other receivables	23	56,989	53,092
Receivables from Group companies		1,465,003	901,936
Prepaid expenses and accrued income	24	531,782	418,194
Cash and cash equivalents	25	2,761,759	1,381,369
Total current assets		**6,475,941**	**4,053,967**
TOTAL ASSETS		**13,925,539**	**11,140,471**

SEK 000s	Note	31 Dec 2018	31 Dec 2017
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital		149,974	149,527
Statutory reserve		800,257	800,257
Total restricted equity		**950,231**	**949,784**
Unrestricted equity			
Share premium reserve		4,277,038	4,231,347
Retained earnings		121,507	763,083
Profit/Loss for the year		2,381,764	–507,836
Total unrestricted equity		**6,780,309**	**4,486,594**
Total equity		**7,730,540**	**5,436,378**
Untaxed reserves			
Excess depreciation		2,584,000	2,124,000
Total untaxed reserves		**2,584,000**	**2,124,000**
Liabilities			
Non-current liabilities			
Deferred tax liabilities	21	—	10,196
Liability to Sanofi	27	427,699	1,066,833
Provisions	29	80,122	82,443
Total non-current liabilities		**507,821**	**1,159,472**
Current liabilities			
Trade payables		376,350	312,771
Liabilities to Group companies		644,458	628,848
Tax liabilities		381,580	189,064
Liability to Sanofi	27	676,778	579,895
Other liabilities	27	54,550	27,213
Accrued expenses and deferred income	30	969,462	682,830
Total current liabilities		**3,103,178**	**2,420,621**
TOTAL EQUITY AND LIABILITIES		**13,925,539**	**11,140,471**

Related to pledged assets and contingent liabilities, see Note 31.

Parent Company statement of changes in equity

	Restricted equity		Unrestricted equity		
SEK 000s	Share capital	Statutory reserve	Share premium reserve	Retained earnings and profit/loss for the year	Total equity
Opening equity, 1 Jan 2017	149,254	800,257	4,191,749	613,708	5,754,968
Cash flow hedges	—	—	—	191,856	191,856
Tax effect of cash flow hedges	—	—	—	–42,208	–42,208
Issue/repurchase of shares	273	—	—	–273	—
Share programmes	—	—	39,598	—	39,598
Profit/loss for the year	—	—	—	–507,836	–507,836
Closing equity, 31 Dec 2017	**149,527**	**800,257**	**4,231,347**	**255,247[1]**	**5,436,378**
Opening equity, 1 Jan 2018	149,527	800,257	4,231,347	255,247	5,436,378
Cash flow hedges	—	—	—	–170,921	–170,921
Tax effect of cash flow hedges	—	—	—	37,628	37,628
Issue/repurchase of shares	447	—	—	–447	—
Share programmes	—	—	45,691	—	45,691
Profit/loss for the year	—	—	—	2,381,764	2,381,764
Closing equity, 31 Dec 2018	**149,974**	**800,257**	**4,277,038**	**2,503,271**	**7,730,540**

[1]Cash flow hedges

SEK 000s	2018	2017
Opening balance, cash-flow hedges	27,543	–122,105
Change in value for the year, hedging instruments	–133,293	149,648
Closing balance, cash-flow hedges	**–105,750**	**27,543**

Regarding cash-flow hedges, SEK 27,850 K (12,662) was transferred to profit or loss. The cash flow hedge is included in other income and expenses in profit and loss. The reversal to profit and loss has been made solely because the hedged item has been recognised in profit and loss. The hedging reserve consists solely of ongoing hedges.

At year-end, Sobi's share capital amounted to SEK 149,973,582 distributed between 273,322,117 ordinary shares with a par value of about SEK 0.55 and one voting right. The company held 3,423,726 ordinary shares in treasury at the balance-sheet date. The Equity item corresponds to 1.3 per cent of the total number of shares in the company.

Parent Company cash flow statement

SEK 000s	Note	2018	2017
Operating activities			
Profit/Loss for the year		2,381,764	–507,836
Adjustments for non-cash items		301,454	1,897,033
Cash flow from operating activities before changes in working capital		**2,683,218**	**1,389,197**
Cash flow from changes in working capital			
Decrease (+) / Increase (–) in inventories		–177,138	–127,290
Decrease (+) / Increase (–) in operating receivables		–864,446	–319,144
Increase (+) / Decrease (–) in operating liabilities		400,152	406,024
Cash flow from operating activities		**2,041,786**	**1,348,787**
Investing activities			
Investment in subsidiaries		–592,274	–195
Acquisition of intangible assets[1]	17	–42,628	–91,922
Acquisition of property, plant and equipment	18	–26,494	–37,411
Cash flow from investing activities		**–661,396**	**–129,528**
Financing activities			
Repayment of loan[2]		—	–500,000
Cash flow from financing activities		**—**	**–500,000**
Change in cash and cash equivalents		**1,380,390**	**719,259**
Cash and cash equivalents at beginning of year		**1,381,369**	**662,110**
Cash and cash equivalents at end of year		**2,761,759**	**1,381,369**

1. The largest investment during the year was primarly investments within IT, see Note 17.
2. Repayment of loans in 2017 refers to the repayment of a loan of SEK 500 M from Handelsbanken and Danske Bank.

Supplemental disclosures to cash flow statement – Parent Company

SEK 000s	Note	2018	2017
Interest paid and received			
Interest received		21,412	11,656
Interest paid		–28,691	–22,831
Income tax paid		433,973	—
Adjustments for non-cash items			
Depreciation/amortisation and impairment of assets	7, 17, 18	320,816	322,750
Impairment of participations in subsidiaries	19	—	1,000,000
Deferred tax	21	–20,715	–14,616
Cost of share programmes[1]		45,691	39,598
Excess depreciation		460,000	970,000
Elocta and Alprolix[2]		–485,261	–437,690
Other items		–19,077	16,991
		301,454	**1,897,033**

1. IFRS 2 expense associated with the share programmes that is recognised in equity.
2. Pertains to royalty revenue with which the liability to Sanofi was settled and 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 as a Large Cap company since 2 January 2014.

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

Summary of significant accounting policies for Groups

The most significant accounting policies for the preparation of these consolidated financial statements are set out below. These policies have been consistently applied to all years presented, unless otherwise stated. The consolidated financial statements have been prepared in accordance with the Annual Accounts Act, the Swedish Financial Reporting Board's recommendation RFR 1, Supplementary Accounting Rules for Groups, International Financial Reporting Standards (IFRS) 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) that are measured at fair value through profit or loss.

For the Parent Company's accounting principles, where these deviate from the Group's, see below.

New and amended standards applied by the Group

The new reporting standards IFRS 9 Financial Instruments and IFRS 15 Revenues from Contracts with Customers have been applied since 1 January 2018.

IFRS 9 Financial Instruments replaces IAS 39 Financial Instruments: Recognition and Measurement and includes requirements for the classification and measurement of financial assets and liabilities, impairment of financial instruments and rules for hedge accounting. One of the changes pertains to liabilities measured at fair value. The part of the fair value change that is due to changes in own credit risk is to be recognised in other comprehensive income rather than profit or loss, unless this causes inconsistencies in the accounts. Sobi has no liabilities measured at fair value and is not therefore affected by the change. Another change relates to hedge accounting, which requires more detailed disclosures on risk management and the effect of hedge accounting. Sobi's hedge accounting will comply with IAS 39 until further notice, with disclosures according to IFRS 7. The new hedge accounting requirements will have no material impact on current hedging activities. Finally, new policies have been introduced for the impairment of financial assets, where the model is based on expected losses. Sobi has applied the full retrospective approach for the transition, which had no material impact on either earnings or financial position. In accordance with IFRS 9, Sobi has chosen not to restate the comparative figures.

IFRS 15 contains a comprehensive revenue model for all contracts with customers and supersedes existing standards for revenue recognition, including IAS 18. Sobi has made a thorough analysis of the effect of IFRS 15 on the Group's financial statements and does not believe that this standard will have any material impact on either earnings or financial position. This conclusion is based on a review of contracts and transactions, and testing them against the standard's five-step model for revenue recognition. Revenue recognition is now fully compliant with IFRS 15 and remains unchanged compared with the current standard. Receivables relating to royalty income, which are classified in the balance sheet as accrued income, are the assets Sobi classifies as contractual assets. Otherwise, Sobi has no commitments that classify as contractual liabilities related to future commitments. Sobi has chosen to apply the retrospective approach for the transition.

Otherwise, the same accounting policies were applied as in the preceding year. IFRS changes applied as of 2018 have had no material impact on the Group's financial statements. For more information about to the Group's accounting policies for revenue, refer to "Revenues" further down in this Note.

New standards, interpretations and amendments not yet adopted by the Group

The new reporting standard IFRS 16 Leasing comes into effect on 1 January 2019 and supersedes IAS 17 Leases. The standard establishes new accounting requirements for lessees and stipulates that all leases are to be recognised in the lessee's balance sheet as a right of use asset and the associated liability. Previous lease payments will be replaced with depreciations and interest expense.

Sobi has chosen to apply the modified retrospective approach, with no effect on equity at 1 January 2019. The modified retrospective approach entails that right of use assets, mainly comprising leases for premises and vehicles, are consistent with the leasing liability on the transition date of 1 January 2019. In connection with the transition, Sobi has chosen to apply the exemption for short-term leases and low-value assets. Short-term leases are defined as leases with a duration of 12 months or less, and mainly relate to leased vehicles. Low-value assets essentially relate to computers, printers and copying machines.

As an effect of the transition, the total value of the Group's assets on the transition date rose by SEK 397 M, corresponding to 2 per cent of the balance sheet. The Group's financial liabilities rose by SEK 397 M, corresponding to 2 per cent of the balance sheet. The effect of the transition on the key figures presented in the Annual Report that contained these parameters is considered insignificant. The main effect arises in the alternative performance measure of EBITDA (earnings before interest, tax, depreciation and amortisation). Refer also to Note 10 for lease payments related to operating leases for the 2018 financial year.

Changes in standards and interpretations from IASB and statements from IFRIC that came into effect during the 2018 calendar year have not had any material impact on the Group.

CONSOLIDATED FINANCIAL STATEMENTS

General information

The consolidated financial statements include the Parent Company and its subsidiaries.

Subsidiaries

The consolidated financial statements have been prepared using the acquisition method. A business combination is therefore considered a transaction in which the Group directly acquires the subsidiary's assets and assumes its liabilities. The consolidated income statement and balance sheet include all companies over which the company directly or indirectly exercise a controlling influence. A controlling influence exists when the company has control over a company, is exposed to, or has the right to a variable returns from its involvement in the company and can influence returns through its controlling influence.

Subsidiaries are consolidated from the date on which the controlling influence is transferred to the Group. They are deconsolidated from the date on which the controlling influence ceases.

All contingent payments are measured at fair value on the acquisition date. Subsequent changes to the fair value of a contingent consideration classified as a provision are recognised in the statement of comprehensive income. All transaction costs attributable to an acquisition are expensed. Identifiable assets acquired, as well as liabilities and contingent liabilities assumed through a business combination, are measured at fair value on the acquisition date.

The difference between the acquisition cost and the 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, measured at fair value, and any gains or losses arising from the revaluation 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.

Intra-group transactions, balance-sheet items and unrealised gains and losses on transactions between Group companies are eliminated. Any losses are considered an indication that the transferred asset may be impaired.

Segment reporting
Operating segments are presented from a management perspective, which means they are presented on the same basis used for internal reporting. The basis for identifying reportable segments is the internal reporting, whereby the reporting is received 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.

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 and reporting currency.

Transactions and balance-sheet items
Transactions in foreign currency are translated into the functional currency using the applicable exchange rate on the transaction date. 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 the statement of comprehensive income. Operating items are recognised in operating profit, while other items are recognised as financial income or expense.

Translation of foreign subsidiaries
The assets and liabilities of foreign subsidiaries are established in the respective functional currency, meaning 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) at the closing day rate and any exchange differences arising are recognised in other comprehensive income. All items in the income statement 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.

Revenues
Group revenue consists mainly of own products and products where Sobi holds the distributions and/or licensing agreements, revenues from manufacturing and from royalty agreements.

Revenues include invoiced gross revenue for contracted 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 his normally arises when the products have been delivered from the company's consignment stock to the end customer. The commitments associated with the contracts between Sobi and the customers consist mainly of distinct goods that are delivered to the customer against payment. The products are not customized and are of benefit to the customers in the condition they are delivered. The products are thus considered to be distinct and separately identifiable. Upon delivery, the customer normally takes over the responsibility for the goods, depending on the shipping terms, and then receives an unconditional obligation to pay. The Group applies standardised payment terms that vary between countries. Usually, payment conditions of 30 to 90 days are applied.
The price of the goods is identified in contract. The benefits are partly variable before deductions are made for discounts under agreements and for pharmaceutical taxes. Where these cannot be reliably estimated, an assessment is made and the amounts are reserved in the balance sheet.

Contract manufacturing revenue (ReFacto) is recognised when the products have been delivered to the customer, meaning the customer has taken control over the products. Payment terms are 90 days.

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

Royalty revenue is recognised according to agreement. Revenue is recognized monthly over time, with quarterly reconciliation and invoicing. ding to agreement, Sobi is entitled to royalties on sold goods. Accrued royalties, which are also classified as contractual assets according to IFRS 15, are recognised in the balance sheet under prepaid expenses and accrued income. Standardised payment terms are 45 days after the end of the quarter.

Sobi has no contractual agreements where performance obligations extend beyond 12 months after 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 taken place and the revenue is certain to materialise.Due to various agreement formulations, the initial license fee can be recognised in two ways. The revenue is either recognised directly when the license fee is received, or allocated over its estimated duration. In 2017 and 2018, Sobi did not recognise any licence fees or milestone payments.

Service fees are remuneration for sales and marketing services related to some Partner Products during a contractual term. Revenue is recognised over time.

When the Group has undertaken to carry out research and development assignments and receives payment for services provided by the Group, this is recognised over time as the assignments are carried out. 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 requirements associated with the grant and when it can be established with certainty that the subsidy will be received. Grants received are recognised in the balance sheet as deferred income and recognised in the period in which 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 financed with government grants.

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 on cash-flow hedges in equity are reclassified to other operating income/expenses in the period in which the hedged item impacts earnings. For more information, see Notes 8 and 9.

Classifications
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.

Intangible assets
Amortisation of intangible assets
Amortisation of product 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.

Note 2, cont.

Goodwill
Goodwill consists of the amount by which the cost exceeds the fair value of the Group's share of the acquired subsidiary/associated company's net identifiable assets on the acquisition date. Goodwill on acquisition of a subsidiary is recognised as an intangible asset. When associated companies are acquired, goodwill is included in the value of the holding in the associated company. Goodwill is tested annually for impairment and recognised at cost less any accumulated impairment. Gains or losses on the disposal of an entity include the remaining carrying amount of goodwill attributable to the discontinued unit.

Product and marketing rights
Product and marketing rights are recognised 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 useful life, based on the expected earnings of each product and marketing right. Amortisation is classified as selling expenses. For more information, see Note 4.

Licenses och patent
The cost and amortisation of licenses are treated in the same way as product and marketing rights above. 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 is relocated. Amortisation commences when the asset is available for use.

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

All property, plant and equipment 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 will accrue to the Group and the cost of the asset can be measured reliably. All other forms of repair and maintenance are recognised as costs in profit or loss as incurred.

Depreciation of property, plant and equipment
Property, plant and equipment are depreciated according to plan over their estimated useful life. Depreciation is calculated on a straight-line basis over the asset's 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 property, plant and equipment 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.

Leased assets are classified in the consolidated financial statements as either finance or operating leases. Leased non-current assets where Sobi is responsible for the same risks and rewards as direct ownership are classified as finance leases. The asset is recognised as a non-current asset in the balance sheet. Corresponding obligations for future lease payments are recognised as current or non-current liabilities. The leased assets are depreciated according to plan, while the lease payments are recognised as interest and repayment of debts. Leased assets where the lessor essentially retains ownership of the asset are classified as operating leases and the lease payment is expensed on a straight-line basis over the term of the lease. For more information, see Note 10.

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 depreciated are also tested annually for impairment since the carrying amount is significant for the Group. Other assets that are depreciated 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 calculating the value in use, future cash flows that the asset is expected to generated are discounted at a rate equivalent to Sobi's weighted average cost of capital (WACC).

When assessing goodwill impairment, this is grouped at the lowest levels for which there are separately identifiable cash flows. 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. Impairments of assets other than goodwill are reversed if there has been any change in the conditions used to determine the recoverable amount. Reversal amounts do not exceed the carrying amount that would have been recognised, less depreciation, if no impairment had been performed. Impairment testing of goodwill, product and marketing rights, and development projects is described in Note 17.

Financial instruments
A financial instrument is a contract that gives rise to a financial asset in a company and a financial liability or an equity instrument in another company. Financial instruments include contract-based rights to receive cash, such as trade receivables.

Note 2, cont.

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. 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 in 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 in the balance sheet include such assets as cash and cash equivalents, trade receivables and endowment policies. Financial liabilities mainly include trade payables, liabilities to Sanofi and Novimmune, the latter recognised under other liabilities, and loans.

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 trade and other receivables and cash and cash equivalents. These are measured at amortised cost less any impairment. The maturities of trade receivables are mainly short, which is why the value is initially recognised at nominal amounts without discounting. Any impairment of trade 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 trade receivables based on expected future losses, which are assessed individually like trade 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, trade 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. Derivatives
Derivatives are only used as financial security, not for speculative purposes. Sobi differentiates between derivatives included in a effective hedging relationship and other derivatives held for sale. Derivatives are measured at fair value in the balance sheet, both initially and in subsequent revaluations, 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 the recognition of derivatives that meet the criteria for hedge accounting.

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

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 recognised in profit or loss 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 revaluation effect 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.

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.

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 operating activities less selling expenses. Obsolescence risk and established 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 in 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 in 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 in the balance sheet as a financial asset and a provision. 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 in the balance sheet.

Cash-based programmes for employees are treated as a provision until the programme expires.

Taxes

Taxes in the statement of comprehensive income comprise current and deferred tax. Current tax is tax that will be paid or received in the current year, and current tax attributable to previous years. Deferred tax is calculated using the liability method, based on temporary differences between the carrying amounts of assets and liabilities and their corresponding tax bases. Deferred tax is measured using the tax rates and tax rules enacted or substantively enacted on the balance-sheet date.

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 under other comprehensive income or equity. See also Notes 16 and 21.

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 2018, five people in the Norwegian subsidiary and two people in the Swedish Parent Company were covered by defined-benefit plans, while other employees are covered by defined-contribution plans.

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 costs for the defined-contribution plans are charged to earnings as they are earned. Pension commitments are calculated without discounting, since the payments for these plans fall due within 12 months.

Commitments 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 2005–2018, 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 commitments are recognised in the balance sheet as the net total of the estimated present value of the commitments 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 costs and commitments are calculated according to the applicable principles of IAS 19. This calculation is performed annually by independent actuaries.

The company's commitments are measured at the present value of expected future payments. When discounting commitments in Sweden, a discount rate equal to the interest on mortgage bonds with a maturity corresponding to the relevant commitments is applied. The most important actuarial assumptions are described in Note 28.

Actuarial gains and losses may arise in connection with the determination of the present value of the commitments 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 expense items in the pension costs 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 commitments. 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 in the balance sheet, since they are a long-term holding, and measured at fair value, while the pension commitment 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. 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, whereby market-related conditions are taken into account. The 2018 share programme, which covers the CEO, senior executives and managers, includes a revenue component 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, distributed 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 requirement. The shares are delivered to the employee when vested under the framework of the programmes.

The Group also has four long-term cash-based incentive programmes that do not constitute share-based remuneration. Three of these comprise all employees in the US and one of them relates to a number of senior executives in Sweden. Since remuneration under these programmes is contingent on 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 achievement and how much has been earned. The net of these effects is recognised as a personnel cost in consolidated profit or loss.

The social security costs are revalued 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.

Note 2, cont.

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.

Parent Company's accounting policies
The Annual report for Swedish Orphan Biovitrum AB (publ), the Parent Company, has been prepared according to the Swedish Annual Accounts Act, the Swedish Financial Reporting Board's recommendation RFR 2 Accounting for Legal Entities and statements from the Financial Reporting Board. 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 Swedish pension commitments Vesting Act when calculating defined-benefit pension plans, which is a prerequisite for tax deductibility. The most significant differences compared with the requirements under IAS 19 are how the discount rate is established, that the calculation of the defined-benefit commitment 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. Refer to Note 29 for more information.

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

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 materialise. If, in subsequent periods, the initial assessment needs to be revised, the acquisition cost must be adjusted.

Group contributions
Sobi applies the alternative rule and, consequently, reports all group contributions received/provided as appropriations.

Accounting principles of the Parent Company
The Parent Company´s financial statements are prepared in accordance with the Swedish Financial Reporting Board´s recommendations RFR 2, Reporting by legal Entities, and the Annual Accounts Act.

The Parent Company's functional currency is Swedish kronor (SEK), which is also the presentation currency for the Parent Company and the Group. The financial statements are consequently presented in SEK.

All amounts are stated in thousands of Swedish kronor (SEK thousands) unless otherwise stated. Assets and liabilities are measured at historical cost, except for certain financial assets and liabilities, which are measured at fair value.

In order to prepare the financial statements in accordance with generally accepted accounting principles, the Board of Directors and management make estimates and assumptions that affect the company's earnings and financial position, as well as other information disclosed. These estimates and assumptions are based on historical experience and are regularly revised.

Judgements made by management in the application of IFRS that have a significant impact on the financial statements and estimates made have not resulted in any material adjustments to the financial statements of subsequent years. The accounting policies stated above are applied consistently in the financial statements that are published, and are based on IFRS.

The figures for previous years in the tables and notes have been adjusted due to changes in the current and deferred tax for previous years, but that were identified during the year.

The amounts and figures in parenthesis are comparative figures for 2017. See also Note 4.

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 and financial position. The risks can be divided into operational risks and financial risks. Financial risks refer to a potentially negative impact on the financial position 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 is also responsible for the Group's financing, ensuring that solutions are in place for liquidity monitoring and payments, continuously monitoring financial risk and supporting the business operations in finance-related issues.

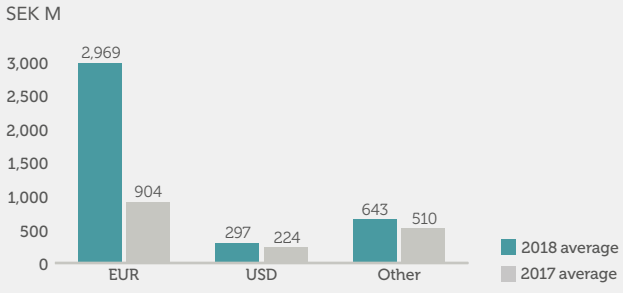
The finance policy, which is adopted by the Board, establishes the division of responsibilities and control of financial matters between the Board, CEO, CFO and the treasury function. The Board has appointed an Audit Committee tasked with, among other things, monitoring the structure of the finance policy and, if necessary, suggesting changes to the Board. The main objective of the finance policy is to maintain a low level of financial risk and to manage risk safely.

Financial risk factors
Currency risk – Commercial transaction risk
Commercial transaction risk is the risk that changes in exchange rates will have a negative impact on operating profit during the period until a transaction is settled. Since the subsidiaries largely have commercial flows in their local currencies, this risk is limited. This risk is significant for the Parent Company since the Parent Company has considerable commercial flows in foreign currencies, mainly EUR and USD, which are not naturally matched with Sobi's functional currency (SEK). The Parent Company mainly purchases in EUR and USD and invoices the internal distribution companies in their domestic currency. The most significant currency surplus is EUR, and arises because most of Sobi's subsidiaries have EUR as their functional currency. This risk is managed by limiting the net exposure, meaning the net of all positive and negative exposures in each currency, and by investing in financial instruments, such as currency futures.

Some of this transaction risk is managed by applying hedge accounting, using cash-flow hedges of highly probable inflows in USD, mainly in relation to Elocta and Alprolix. This means that the effect of the remeasurement of liabilities related to Elocta and Alprolix to Sanofi are recognised in other comprehensive income, and accumulated profit or loss from these remeasurements are reclassified to profit or loss when the hedged inflows affect profit or loss. See Notes 17 and 27 for more information about these liabilities.

The currencies with the largest net exposures are shown in the diagram below. The amounts shown in the diagram correspond to the Group's net annual volumes.

Commercial transaction exposure



Currency risk – Financial transaction risk
Financial transaction risk refers to the risk of changes in exchange rates having a negative impact on net financial items. Financial transaction risk is managed at central level by the treasury function of the Parent Company. This is carried out by generally denominating the loans and investments of subsidiaries in their local currencies with the Parent Company, and that external loans and investments are mainly made by the Parent Company.

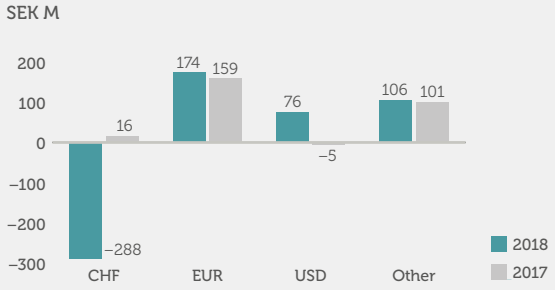
Note 3, cont.

3

This risk is managed by matching all transactions in their respective currencies, including receivables, liabilities and other items that are restated in net financial items, and by limiting any net exposure of a sufficiently large amount, compared with a fixed measure according to the finance policy, by investing in financial instruments, such as currency futures. The currencies with the largest net exposures are shown in the diagram below. The amounts shown in the diagram correspond to the net amounts (including derivatives) that, in average over the year, were restated in net financial items, and net amounts on the balance-sheet date. Total exposure amounted to SEK 644 M (271). An instantaneous and permanent change of +/– 10 per cent in all rates against the SEK would have an impact of +/– SEK 64 M (27) on financial profit before tax.

The high exposure towards CHF at year-end 2018 was temporary and resulted from the acquisition of the rights for emapalumab. The derivatives outstanding on the balance-sheet date are presented in the table below. The increase of the derivatives in USD and EUR is attributable to hedging of future transactions related to the acquisition of Synagis.

Financial transaction exposure



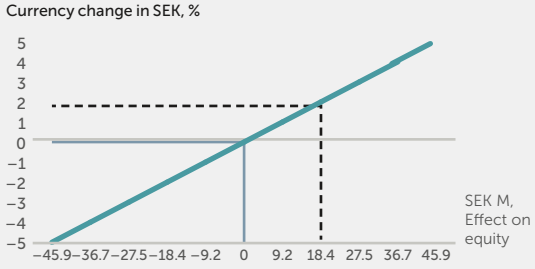
Outstanding derivatives (nominal amounts in millions, local currency)

	2018	2017
USD	880	–30
EUR	–417	–29
CHF	–29	–
GBP	–	–1
CAD	–5	–5

Currency risk – translation exposure

Translation risk is the risk that fluctuations in exchange rates will have a negative impact on equity when the balance sheets and income statements of foreign subsidiaries are translated into SEK. The currency risk in equity is controlled by ensuring that the subsidiaries' equity is kept at a reasonable level. The diagram of translation risk shows the company's sensitivity to this risk. The diagram shows how the translation effect on the Group's equity would be positive if the SEK weakened, and vice versa. If the SEK, for example, were to weaken 2 per cent against all currencies, the translation effect on consolidated equity would be SEK 18.4 M (3.4).

Translation risk



Interest rate risk

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

Sobi's financing sources primarily consist of equity, cash flow from operating activities and borrowings. In the case of interest-bearing borrowings, the Group is exposed to interest-rate risk. Sobi's long-term interest-bearing financing comprises an undrawn revolving credit facility of SEK 1,000 M with Svenska Handelsbanken AB (publ) and Danske Bank A/S, Denmark, Swedish branch. The original term of this facility was three years, but has now been extended to 27 June 2020. In November 2018, Sobi raised a new credit facility of EUR 870 M with BNP Paribas FORTIS SA/NV, Danske Bank A/S, Skandinaviska Enskilda Banken AB (publ) and Svenska Handelsbanken AB (publ). This facility is divided into three tranches with maturities ranging from three to five years. One of the tranches is a four-year revolving credit facility of EUR 335 M and the other two tranches are credit facilities of five years and EUR 335 M, and three years and EUR 200 M, respectively.

There were no outstanding interest-rate derivatives on the balance-sheet date. The liability to Bioverativ is non-interest bearing by agreement, but is discounted in the financial statements and therefore recognised as an interest expense.

The sensitivity to interest-rate changes on earnings is measured by assuming a sustained interest-rate change of 1 percentage point. At 31 December 2018, such a change would have had an annual impact of SEK 0 M (0) on net financial items. At 31 December 2018, Sobi's interest-bearing liabilities amounted to SEK 4 M (7).

Credit risk

Credit risk refers to the risk of loss if a counterparty does not meet its obligations. Credit risk can be divided up into credit risk in trade receivables, and financial credit risk.

Sobi's credit risk is mainly related to trade receivables. On the balance-sheet date, these amounted to SEK 1,665 M (1,129), of which SEK 518 M (290) was past due, see Note 23 for information about overdue trade receivables. Sobi's customers are mainly hospitals and government administrations, which means that these are largely funded by the government of each respective country. If Sobi deems that a claim will not be honoured, provisions for expected credit losses must be made in accordance with the principles described in Note 2. At 31 December 2018, these amounted to SEK 70 M (35). Normally there is no collateral for the credit risk associated with trade receivables.

Credit rating reports are obtained for both distribution agreements and individual transactions, when the customer is not previously known or when other circumstances give rise to uncertainty regarding creditworthiness. Credit reports must be obtained from a market-recognised rating agency. A credit limit is established for every customer, and continuously monitored and evaluated.

In its finance 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 mainly conducted with banks with a high official credit rating. Investment of any surplus liquidity are made 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 banks, financial institutions and enterprises 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 the investments can be converted into liquid funds at any given time.

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 finance policy. Both short and long-term forecasts of the Group's liquidity are regularly compiled to ensure there is sufficient cash and undrawn credit facilities to meet the needs of the day-to-day operations. According to the policy, there must also be a liquidity reserve the size of which should be based on a proportion of annual sales. The liquidity reserve comprises bank balances, current investments and the undrawn amount of the granted credit facilities. At 31 December 2018, the company's undrawn granted credit facilities totalled SEK 10,075 M (1,135).

Note 3, cont.

The long-term financing sources comprise a revolving credit facility of SEK 1,000 M with Handelsbanken and Danske Bank that expires on 27 June 2020, and a new credit facility of EUR 870 M that Sobi raised in November with BNP Paribas FORTIS SA/NV, Danske Bank A/S, Skandinaviska Enskilda Banken AB (publ) and Svenska Handelsbanken AB (publ). See more above, under the section on interest-rate risk.The credit agreements contains customary terms regarding limitations on the Group's net debt to EBITDA ratio and interest coverage ratio. The credit agreements also contain limitations with regard to any significant changes in the company's ownership structure (change of control). These credit conditions have been met. Sobi also has a SEK 135 M overdraft facility with Handelsbanken, with a term of more than three months. The facilities, as well as the overdraft facility, were undrawn on the balance-sheet date. The new liabilities have been raised to finance the acquisition of Synagis.

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 2018	Less than 1 year	Between 1–2 years	Between 2–5 years	More than 5 years
Derivatives	8,181	—	—	—
Trade payables	486,972	—	—	—
Other liabilities[1]	3,639,695	1,130,357	599	—
Total	**4,135,843**	**1,130,357**	**599**	**—**

AT 31 DECEMBER 2017	Less than 1 year	Between 1–2 years	Between 2–5 years	More than 5 years
Loans payable	2,624	—	—	—
Trade payables	358,449	—	—	—
Other liabilities[1]	1,624	3,700	1,707,761	—
Total	**362,967**	**3,700**	**1,707,761**	**—**

1. Other liabilities mainly pertain to the liability to Sanofi. The liability to Sanofi is recorded at the nominal amount according to the contract. Repayment of the liability to Sanofi in USD will mainly take place via royalty revenue in USD, see Note 17.

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 arising by changing the dividend to shareholders, repaying capital to shareholders, issuing new shares or selling assets to reduce debt.

The Group's equity/assets ratio forms the basis of the Group's capital structure assessment. The company's target is an equity/assets ratio of at least 40 per cent. At 31 December 2018, the equity/assets ratio was as follows:

	2018	2017
Equity	9,040,097	6,700,524
Total assets	17,183,157	10,902,907
Equity/assets ratio, %	52.6	61.5

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.

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 the Group makes the assessment that a receivable will not paid, a provision for expected credit loss will be made in accordance with principles described in Note 2. When revenue is recognised, each agreement is interpreted separately and the company makes an assessment if any remining commitments exists.

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 remuneration corresponding to actual and estimated discounts to public and private customers, pharmaceutical taxes, and adjustments for deliveries where control has not yet been transferred to the buyer.

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 of calculating indirect production costs, including the utilisation rate, lead times etc., 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 collaborative 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. There has been no write-down of intangible assets in 2018.

Costs for internal development and payments for projects and substances under agreement with third parties are expensed continuously 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.

ESTIMATES AND ASSUMPTIONS

Intangible assets

The Group's intangible assets are essentially attributable to goodwill, development projects, licence, product and marketing rights. Goodwill arose on the acquisition of Swedish Orphan. Annual impairment testing of goodwill, development projects, product rights and marketing rights is based on their recoverable amounts, including essential 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 Decmber 2018, Sobi's goodwill amounted to SEK 1,554 M (1,554). The testing did not indicate any 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.

Note 4, cont.

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 expenses, 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. Use of rights is not consumed in a manufacturing process but rather over a useful life which 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 expansion of the applicable areas for the pharmaceutical. If the company's assumptions regarding product development and expansion of the applicable areas for a pharmaceutical prove to be incorrect, this may 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. It is currently possible in Sweden to use any future tax losses for an unlimited period of time. Deferred tax assets on losses in countries other than Sweden that arose in 2018 are recognised when it is likely that they can be deducted against future gains. Foreign tax rates were used for measurement.

Assumptions for the calculation of pension benefits
The actuarial calculation of pension commitments and pension costs is based on the actuarial assumptions specified in Notes 2 and 29.

Inventories
Obsolescence
Inventories consist of raw materials for production, manufactured semi-finished and finished products of Alprolix, Ammonaps, Elocta, Kepivance, Kineret, Orfadin and Xiapex, and inventories of finished goods for other products. There is no obsolescence provision for these inventories. Stock levels for Kepivance are expected to last for several years. The stocked product durability can vary over time. This could lead to an increased risk of obsolescence when a significant change in demand for a product, or a change in durability, could result in impairment. Products not approved at quality inspection are directly expensed.

Other stock mainly consists of ReFacto. Production of ReFacto has two components: cultivation and purification. If a certain portion of the stock is not approved by Sobi's and/or Pfizer's quality department, the material is immediately expensed. The obsolescence assessment is regularly updated based on historical obsolescence or sales forecasts. Sobi is part of the pharmaceutical industry, which is regulated and controlled by several authorities in and outside Sweden. The company collaborates with external partners, both Swedish and foreign, who control and evaluate the business. All finished stock is measured continuously with respect to the shelf life limits of drugs.

5 Distribution of operating revenue

GROUP	2018	2017
Operating revenue by major revenue type		
Product sales	7,361,979	4,746,175
Manufacturing	435,846	559,295
Royalty[4]	1,341,067	1,202,660
Service fee	–	2,701
Total	9,138,892	6,510,831

GROUP	2018	2017
Revenues by geographic market[1]		
Europe[2]	6,026,271	3,784,036
MENAR[3]	381,249	271,806
North America	1,309,099	1,168,279
RoW	81,206	84,050
Total	7,797,825	5,308,171
Royalty[4]	1,341,067	1,202,660
Total	9,138,892	6,510,831

The Group's and Parent Company's financial accounts do not include revenues for 2018 or 2017 relating to performance obligations made in previous years. Furthermore, there are no customer agreements with performance obligations reported in the balance sheet.

In 2018, revenues for the Parent Company, Swedish Orphan Biovitrum AB (publ), amounted to SEK 8,221 M (5,756) of which SEK 4,554 M (2,732) pertained to sales to Group companies.

PARENT COMPANY	2018	2017
Operating revenue by major revenue type		
Product sales	6,444,314	3,991,714
Manufacturing	435,846	559,295
Royalty[4]	1,341,067	1,202,660
Service fee	–	2,701
Total	8,221,227	5,756,370

PARENT COMPANY	2018	2017
Revenues by geographic market[1]		
Europe[2]	8,518,162	3,453,619
MENAR[3]	259,604	157,498
North America	1,021,189	857,941
RoW	81,206	84,652
Total	6,880,160	4,553,710
Royalty[4]	1,341,067	1,202,660
Total	8,221,227	5,756,370

1. The geographic distribution is based on where end-customers are located.
2. Sales in Sweden amounted to SEK 199 M (165).
3. Middle East, North Africa and Russia.
4. Royalty revenue includes royalties related to our haemophilia products that are not attributable to a specific region according to the distribution above; royalty on Sanofi's sales of Eloctate and Alprolix amounted to SEK 1,340 M (1,168). Royalty revenue from Pfizer's sales of ReFacto amounted to SEK 1 M (34). Estimated non-invoiced accrued royalty income is to be classify as contractual assets in accordance with IFRS 15. The balance as of December 31 2018 is included in the balance sheet in prepaid expenses and accrued liabilities and specified in note 24. See also note 2 section revenue.

Revenue per business area (Group)

SEK 000s	2018	2017
Elocta	3,261,126	1,557,476
Alprolix	973,782	362,798
Manufacturing	435,846	559,295
Royalty	1,341,067	1,202,660
Haemophilia	6,011,821	3,682,229
Orfadin	899,404	861,866
Kineret	1,319,735	1,141,938
Other	907,932	824,798
Specialty Care	3,127,071	2,828,602
Total revenues	9,138,892	6,510,831

6 Segment reporting

The Group reports one operating segment, sales of pharmaceuticals. The basis for identifying reportable segments is the internal reporting, whereby the reporting is received 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 2018 Sobi's largest customers were Sanofi, with sales of SEK 825 M (691), and Pfizer, with sales of SEK 446 M (594), corresponding to 9 and 5 per cent respectively of the company's total revenue for 2018. Most of the non-current assets are in Sweden.

7 Depreciation and amortisation of assets[1]

GROUP	2018	2017
Depreciation/amortisation according to plan by type of asset		
Licenses and patents	−38,571	−38,766
Product and marketing rights	−386,596	−386,594
Capitalised expenditures	−23,447	−15,492
Plant and machinery	−18,878	−15,001
Equipment, tools and fixtures and fittings	−14,759	−15,599
Other non-current assets	−2,351	−2,525
Total	**−484,602**	**−473,977**
Depreciation/amortisation according to plan by type of function		
Cost of goods	−12,819	−14,412
Selling and administrative expenses	−462,921	−453,538
Development costs	−8,834	−6,027
Total	**−484,574**	**−473,977**
Impairment by type of asset[1]		
Licenses and patents	—	−12,000
Total	**—**	**−12,000**
Impairment by type of function[1]		
Selling and administrative expenses	—	−12,000
Total	**—**	**−12,000**

PARENT COMPANY	2018	2017
Depreciation/amortisation according to plan by type of asset		
Licenses and patents	−6,484	−6,669
Product and marketing rights	−262,216	−262,213
Capitalised expenditures	−23,447	−15,321
Plant and machinery	−18,509	−14,652
Equipment, tools and fixtures and fittings	−9,636	−11,371
Other non-current assets	−524	−524
Total	**−320,816**	**−310,750**
Depreciation/amortisation according to plan by type of function		
Cost of goods	−12,762	−14,355
Selling and administrative expenses	−299,407	−290,553
Development costs	−8,647	−5,842
Total	**−320,816**	**−310,750**
Impairment by type of asset[1]		
Licenses and patents	—	−12,000
Total	**—**	**−12,000**
Impairment by type of function		
Selling and administrative expenses	—	−12,000
Total	**—**	**−12,000**

1. See Note 17 for further information.

8 Other operating income

GROUP	2018	2017
Re-invoiced costs to partners	5,212	—
Exchange-rate gains[1]	—	—
Other	932	471
Total	**6,144**	**471**

PARENT COMPANY	2018	2017
Re-invoiced costs to partners	5,181	—
Exchange-rate gains[1]	—	—
Other	—	120
Total	**5,181**	**120**

1. Exchange-rate effects are recognised net and in 2018 constituted a gain, see Note 9.

9 Other operating expenses

GROUP	2018	2017
Exchange-rate losses on operating receivables/liabilities[1]	−2,473	−52,541
Utrangerar/avyttring av anläggningstillgångar	−3,983	—
Other	−30	−207
Total	**−6,486**	**−52,748**

PARENT COMPANY	2018	2017
Exchange-rate losses on operating receivables/liabilities[1]	−4,717	−39,824
Utrangerar/avyttring av anläggningstillgångar	−2,858	—
Total	**−7,575**	**−39,824**

1. Exchange-rate effects are recognised net and in 2018 they generated a loss as they also did in 2017, hence appearing under note 9.

10 Lease payments for operating leases

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

	Group		Parent Company	
	2018	2017	2018	2017
Within 1 year	81,160	69,395	60,644	59,144
Between 1–5 years	293,046	251,080	222,145	224,121
Later than 5 years	24,493	64,492	14,914	64,492
Total	**398,699**	**384,967**	**297,703**	**347,757**
Rental costs for the year	75,558	72,530	59,441	58,120

10

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

	Group		Parent Company	
	2018	2017	2018	2017
Within 1 year	12,099	6,082	318	318
Between 1–5 years	14,974	8,898	159	477
Later than 5 years	—	—	—	—
Total	**27,073**	**14,980**	**477**	**795**
Lease payments for the year	11,018	11,565	318	323

The decisive factor in the classification of leases is to what extent the economic risks and benefits associated with ownership of the leased object are retained by the lessor or transferred to the lessee. For property, assessments of the lease contract must be made both for the building and the land. Sobi mainly bases its position on the fact that the present value of the minimum lease payments does not represent a significant portion of the fair value of the property and that there is no compelling evidence of a financial lease.

As set out in Note 2 Accounting policies, the new reporting standard IFRS 16 Leasing will come into effect on 1 January 2019 and supersede IAS 17 Leases. The standard establishes new accounting requirements for lessees and stipulates that all lease contracts are to be recognised in the lessee's balance sheet as a lease liability and a corresponding right-of-use asset. Previous lease payments will be replaced with depreciations and interest expense. For more information about the new standard, including the choice of transition method and the effects of the transition on the Group's financial statements and key figures, see Note 2 Accounting policies.

The Group's balance sheet with the closing balances at 31 December 2018, transition effect/IFRS adjustment and opening balances on 1 January 2019 is presented below.

Amounts in SEK M	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			
Shareholders' equity	**9,040**		**9,040**
Long-term liabilities			
Long-term liabilities	3	320	323
Long-term liabilities, non-interest bearing	1,189	–2	1,187
Total long-term liabilities	**1,192**	**318**	**1,510**
Current liabilities			
Current 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**

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

Number of employees[1]

GROUP	2018	of whom women, %	of whom men, %	2017	of whom women, %	of whom men, %
Sweden	468	64	36	451	64	36
Denmark	15	60	40	14	59	41
Finland/Baltics	9	56	44	9	57	43
Norway	5	80	20	7	71	29
The UK	45	56	44	51	47	53
France	54	61	39	38	63	37
Germany	45	64	36	35	66	34
Italy	44	55	45	36	47	53
Greece[2]	4	75	25	2	100	0
Spain	35	60	40	29	52	48
Belgium	22	45	55	16	38	62
Russia	5	60	40	6	83	17
Switzerland	13	48	52	9	42	58
Austria	6	67	33	4	71	29
Central and Eastern Europe	21	52	48	16	50	50
The US	80	54	46	48	54	46
Canada	5	40	60	6	33	67
United Arab Emirates	26	15	85	23	17	83
Total	**902**	**59**	**41**	**800**	**59**	**41**

1. At 31 December 2018, the number of full-time employees was 902, while the number of persons employed on the same date was 935.
2. The Greek company was formed on 20 April 2017.

Gender composition of the Board and management

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

GROUP	2018	2017
Board		
Men	5	4
Women	3	2
Total	**8**	**6**
CEO and senior executives		
Men	9	7
Women	2	2
Total	**11**	**9**

GENDER COMPOSITION EMPLOYEES

59% ♀ ♂ 41%

Salaries, other remuneration and social security costs

GROUP AND PARENT COMPANY	2018 Salaries and remuneration	2018 Social security costs	2017 Salaries and remuneration	2017 Social security costs
Parent Company	444,204	280,780	427,440	243,525
(of which pension cost)	—	*(89,426)*		*(78,864)*
Subsidiaries	647,450	125,341	500,024	91,861
(of which pension cost)	—	*(30,044)*		*(24,050)*
Group, total	1,091,654	406,121	927,464	335,386
(of which pension cost)	—	*(119,470)*		*(102,914)*

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

	2018 Board and CEO	2018 Other employees	2017 Board and CEO	2017 Other employees
Parent Company				
Salaries and other remuneration	20,489	423,715	16,573[1]	410,867
(of which bonus)	*(6,278)*	*(69,197)*	*(4,065)*[1]	*(52,312)*
Subsidiaries				
Salaries and other remuneration	—	647,450	14,732[1]	485,292
(of which bonus)	—	*(144,734)*	*(1,841)*[1]	*(84,261)*
Group, total	**20,489**	**1,071,165**	**31,305**	**896,159**
(of which bonus)	*(6,278)*	*(213,931)*	*(5,906)*	*(136,573)*

1. 2017 includes both former CEO Geoffrey McDonough and current CEO Guido Oelkers. The former CEO's salary, bonus and severance pay were mostly paid by the US subsidiary, where the former CEO also has his domicile.

Guidelines and remuneration 2018

The Annual General Meeting 2018 resolved on guidelines for remuneration for the Management as set forth below which shall apply until the annual general meeting 2019. The Management is defined as the managing director of Swedish Orphan Biovitrum AB (publ) and the executives who report to the managing director and are members of the senior management.

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. Remuneration for the Management is designed on a total remuneration approach. The position of total remuneration should be market competitive without being leading 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 should enable international hiring and should support diversity within the Management. The remuneration may consist of the following components:

- A, Fixed Base Pay
- B, Variable Pay – so-called Short Term Incentives
- C, Long Term Incentives
- D, Pensions
- E, Other Benefits

To the extent a member of the Board of Directors carries out work for the company or for another group company, in addition to the board work, consulting fees and/or other remuneration for such work may be payable.

Note 11, cont.

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

2018	Basic salary/fees	Bonus	Pension cost	Other benefits	Share programmes	Total
Chairman 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
Group Management, 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, comprising ten individuals in addition to the CEO, at December 2018. The tabel shows the Company's costs (excluding social security costs). For more information about the Board fees, see the Corporate Governance Report.
2. At the AGM 2018, David Allsop and Elisabeth Svanberg were elected as new Board members.
3. See also allotment and fulfillment of long-term incentive programmes for the 2015 share programme.
4. Base pay and benefits include an agreed severence pay of SEK 4,463 K.

2017	Basic salary/fees	Bonus	Pension cost	Other benefits	Share programmes	Total
Chairman of the Board						
Håkan Björklund[2]	1,327					1,327
Other Board members						
Helena Saxon	513					513
Hans GCP Schikan	553					553
Lennart Johansson	522					522
Matthew Gantz	502					502
Annette Clancy[3]	510					510
Jeffrey Jonas[4]	145					145
Theresa Heggie[5]	110					110
Group Management, 2017						
Guido Oelkers, Chief Executive Officer from 22 May 2017	5,126	3,585	1,497	171	2,772	13,151
Other senior executives (8 people)[6]	7,765	3,953	1,069	901	3,777	17,465
Former Chief Executive Officer and other senior executives						
Geoffrey McDonough, Chief Executive Officer until 21 May 2017	15,141[8]	2,321	144	780	5,785[7]	24,171
Other former senior executives (7 people)[6]	16,763[9]	5,046	7,414[9]	546	3,632[7]	33,402
Total	**48,977**	**14,905**	**10,124**	**2,398**	**15,966**	**92,370**

1. Other senior executives refers to Sobi's Executive Committee, comprising eight individuals in addition to the CEO, at December 2017. The table shows the company's costs (excluding social security costs). For more information about Board fees, see the Corporate Governance Report.
2. The fee comprises the Board Chairman fee excluding social security costs. The gross payment to the Chairman's company was SEK 1,744,000, including compensation for social security costs.
3. The fee comprises the Board fee excluding social security costs. The gross payment to the Board member's company was SEK 670,000, including compensation for social security costs.
4. Board member Jeffrey Jonas stepped down from the Board in connection with the AGM in May 2017.
5. Board member Theresa Heggie left the Board on 7 April 2017.
6. In 2017, Sobi established a new management structure: an Executive Committee to replace the former Executive Leadership Team in its existing form. The Executive Committee is Sobi's decision-making body. Remuneration to senior executives in 2017 includes members of the Executive Leadership Team, up to and including the date on which the new management structure was established, and members of the Executive Committee for the period thereafter until the end of the year.
7. See also allotment and fulfilment of long-term incentive programmes for the 2014 share programme.
8. Base pay includes an agreed severance payment of SEK 11,757 K.
9. Base pay and pension cost include an agreed severance payment of SEK 10,066 K

Note 11, cont.

Fixed base pay
The fixed base pay of the Management should be based on competence, responsibility and performance. The company uses an international evaluation system in order to evaluate the scope and responsibility of the position. .

Variable pay
The annual short-term incentive plan is based on the achievement of annual performance objectives (corporate and individual). Payment is based on achievement of the 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. The Short-Term Incentives are limited to 75 per cent of the annual gross salary for the managing director and 60 per cent of the fixed annual salary for the other members of the management.

Long-term incentives
The company can introduce long-term incentive programmes for all or some of its employees. The objectives 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 executives and top talent, to offer participants to take part in the company's long-term success and value creation, and to contribute to a competitive total remuneration.

Pensions
The preferred pension plan design is defined contribution . If the operating environment requires the establishment of a defined benefit pension plan by law or other regulations, such a plan may be established. The defined benefit level should in such cases 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 fixed base pay for two years. In addition to this restriction, the total severance payment shall be limited to the existing monthly salary for the remaining months up to the age of 65.

Additional compensation may also be paid out in extraordinary circumstances, provided that such arrangement is made for management recruitment or retention purposes and is agreed on an individual basis. Such extraordinary arrangements shall be in line with market practice and may for example include a one-time cash payment, a support package including relocation and tax filing support, retention bonus or severance payment in case of a change of control, or similar.

Deviations from the guidelines
The Board of Directors may resolve to deviate from the guidelines if the Board of Directors, in an individual case, is of the opinion that there are special circumstances justifying that.

Senior executives' employment conditions and remuneration
Sobi aims to offer market terms that enable the company to recruit and retain competent personnel (for complete proposal regarding Guidelines for remuneration for the Management 2019, see the Director's report).

Remuneration to Directors elected by the AGM is paid in accordance with the decision of the AGM of 2018. No pensions are paid to the Board.

The CEO's remuneration is reviewed and proposed by the Chairman of the Board together with the Remuneration Committee and approved by the Board. Remuneration to other members of Group Management is proposed by the CEO in close cooperation with the Remuneration Committee and approved by the Board. Remuneration to the CEO and other senior executives consists of fixed salary, variable remuneration in the short and long term, other benefits and pensions. Other senior executives refer to those persons who together form the Group Management.

Fixed salary
Each senior executive's areas of responsibility, experience and performance have been taken into account in determining the fixed salary. Fixed salary is reviewed every year.

Short-term variable remuneration
For the CEO and former CEO, short-term variable remuneration in 2018 was capped at 75 per cent of the annual gross salary. Variable remuneration is based on Group targets and individual targets defined by the Board. For other senior executives, short-term variable remuneration is capped at 60 per cent of the fixed salary and is based on targets at Group and individual targets. There are regular status reviews of the expected outcome throughout the year and reserves are adjusted monthly. An assessment of the variable salary is made on each reporting date.

Retirement benefits
The CEO is entitled to a defined contribution pension amounting to 30 per cent of the basic salary. Sobi has paid out a premium of SEK 2,516 K for 2018. 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 commitment of 27 per cent of the pensionable salary, including ITP.

In connection with the transition from the defined benefit pension to defined contribution pension, some individual agreements have been made with former senior management members with percentages higher than 27 per cent. Members of Group Management who are employed in other countries receive pension terms according to market practice in the country of employment.

Incentive programmes
At the balance-sheet date, Sobi had 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 2015–2018 Annual General Meetings adopted the Board's proposals 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 performance share programmes for 2015–2018 are structured according to similar principles.

- The programmes have a three-year vesting period.
- These programmes require a personal investment in Sobi shares, although not in the 2017 and 2018 Management Programmes, which requires no personal investment in Sobi shares.
- Employees are entitled to matching shares free of consideration. Some employees may also be entitled to performance shares if the performance criteria are met. The number of performance shares that employees are entitled to receive differs according to the organisational level.
- The employee must be permanently employed during the entire vesting period and not sell the investment shares during this period in order to receive matching and potential performance shares.
- The performance targets are that the share price will increase by a certain percentage over a three-year period, and for the 2017 and 2018 management programme that actual annual revenue during the vesting period will meet or exceed the budget for annual revenue.
- Employee eligibility differs between the programmes, as does the formulation of the performance target.

Note 11, cont.

2015 Share Programme (paid in 2018)
The 2015 share programmes expired in 2018. For 2015, the Board resolved that the following performance conditions and other vesting terms were fully met when the 2015 share programme was redeemed on 19 August 2018. In the management programme for senior executives and managers, 356,200 shares with a market value of SEK 94.8 M were allotted. In the employee programme, 48,586 shares with a market value of SEK 13 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.

The Board also resolved that the following performance conditions and other vesting terms were fully met when the share programme for former CEOs was redeemed on 24 September 2018. 235,767 shares with a market value of SEK 61.7 M were allotted to former CEO, based on the length of service during the programme period. The performance target was that the share price, adjusted for any dividends, must exceed the threshold of 20 per cent. If the share price increased between 20–100 per cent, a proportional number of performance shares would be allotted.

11

2015 Cash-Based Programme (paid in 2018)
The 2015 AGM approved a long-term cash-based programme for all employees in the US. 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. In addition, sales must be 95–105 per cent relative to the average budget over a three-year period. The programme expired in 2018 and the outcome related to the share price performance was 50 per cent, the outcome related to sales was achieved in full.

2016 Share Programme
The 2016 AGM approved a long-term share programme covering former CEO, senior executives and managers, and a programme for other employees. Participation 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 one matching share for each saving share, plus additional performance shares contingent on the achievement of a certain share price performance. For maximum allotment of performance shares, the price of Sobi's ordinary share, adjusted for any dividends, must increase by at least 75 per cent. If the share price, adjusted for any dividends, has increased by 15–75 per cent, programme participants will receive straight-line allotment of performance shares.

Participants in the 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 allotment possible in the management and employee programme is 179,853 performance shares and 94,999 matching shares.

When Sobi's 2016 Share Programme was introduced, a number of employees, including former CEO and other senior executives in the Group, were legally prohibited from participating in the programme as they were in possession of insider information at that 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. For more information, refer to the 2016 Annual Report.

2016 Cash-Based Programme
In 2016, the design of the cash-based programme covering all employees in the US and Canada was adjusted. 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 North America's annual sales must be at least 95 per cent in relation to the budget over a four-year period.

2016 Share Programme

	Number of performance shares	Number of matching shares	Value in SEK
Other senior executives in the Group (0)	0	0	0
Total	**0**	**0**	**0**

2017 Share Programme
The 2017 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 on a certain share price performance. For a maximum allotment of 60 per cent of performance shares, the price of Sobi's ordinary share, adjusted for any dividends, must increase by at least 50 per cent. If the share price, adjusted for any dividends, has increased by 15–50 per cent, the programme participants will receive a straight-line allotment of performance shares. For a maximum allotment of the remaining 40 per cent of performance shares, actual annual revenue during the vesting period must meet or exceed the budget for annual revenue. The performance target was achieved for 2017 and 2018. The maximum possible allotment of shares is 776,075. Participants in the 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 45,030.

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 North America's annual sales must be at least 95 per cent in relation to the budget over a four-year period.

Note 11, cont.

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 on a certain share price performance. For a maximum allotment of 60 per cent of performance shares, the price of Sobi's ordinary share, adjusted for any dividends, must increase by at least 50 per cent. If the share price, adjusted for any dividends, has increased by 15–50 per cent, the programme participants will receive a straight-line allotment of performance shares. For a maximum allotment of the remaining 40 per cent of performance shares, actual annual revenue during the vesting period must meet or exceed the budget for annual revenue. The performance target for 2018 was achieved. The maximum possible allotment of shares is 746,563. Participants in the 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 41,054. During the roll-out of the 2018 share programme, a number of employees were insiders and not therefore able 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.

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 North America's annual sales 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
CEO and other senior executives in the Group, (5)	223,357	—	7,364,080
Total	223,357	—	7,364,080

2018 Share Programme

	Number of performance shares	Number of matching shares	Value in SEK
CEO and other senior executives in the Group, (9)	247,030	—	11,820,401
Total	247,030	—	11,820,401

11

Expensing of the 2016–2018 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 2018
2016 Share Programme	28 Oct 2016	28 Oct 2019	94,999	179,853	36	94.05	33.34	n/a	5	274,852	29,180
2017:1 Share Programme, All employees	9 May 2017	9 May 2020	45,030	n/a	36	136.85	n/a	n/a	5	45,030	1,900
2017:2 Share Programme, Management	9 May 2017	9 May 2020	n/a	776,075	36	n/a	54.95	136.85	6	776,075	136,464
2018:1 Share Programme, All employees	11 May 2018	11 May 2021	41,054	n/a	36	184.32	n/a	n/a	7	41,054	272
2018:2 Share Programme, Management	11 May 2018	11 May 2021	n/a	746,563	36	n/a	79.75	184.32	7	746,563	26,686

1. Fair value of performance shares linked to share price development, see section 2017 and 2018 Share Programme above.
2. Fair value of performance share associated with income, see section 2017 and 2018 Share Programme 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 last three years.

12 Remuneration of auditors

GROUP	2018	2017
EY		
Auditing assignments[1]	–4,972	–4,782
Audit activities in addition to the auditing assignment	–1,428	–681
Tax consultancy	–94	–81
Other services	–625	–332
Total EY	**–7,119**	**–5,876**

PARENT COMPANY	2018	2017
EY		
Auditing assignments[1]	–2,242	–1,921
Audit activities in addition to the auditing assignment	–1,332	–593
Tax consultancy	–59	–81
Other services	–625	–332
Total EY	**–4,257**	**–2,927**

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	2018	2017
Raw materials and consumables	–2,056,110	–1,509,077
Other external costs	–1,860,260	–1,499,690
Costs for remuneration of employees	–1,615,638	–1,363,445
Depreciation/amortisation and impairment[1]	–484,574	–485,977
Other operating expenses	–199,868	–145,226
Total	**–6,216,450**	**–5,003,415**

PARENT COMPANY	2018	2017
Raw materials and consumables	–1,995,014	–1,516,485
Other external costs	–1,645,936	–1,565,730
Costs for remuneration of employees	–765,095	–711,675
Depreciation/amortisation and impairment[1]	–320,816	–322,750
Other operating expenses	–193,577	–133,824
Total	**–4,920,438**	**–4,250,464**

1. 2017 includes an impairment of SEK 12 M related to one of the early-phase clinical programmes, no similair impairment occurred during 2018.

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	2018	2017
Interest income[1]	2,742	1,219
Exchange-rate gains[2]	16,684	–
Total	**19,426**	**1,219**

PARENT COMPANY	2018	2017
Interest income, Group companies	20,016	11,258
Interest income, other	1,396	398
Exchange-rate gains[2]	13,400	–
Total	**34,812**	**11,656**

1. According to effective interest method.
2. Exchange-rate effects are recognised net and comprised a gain in 2018, but a loss in 2017, see Note 15. SEK –48 M (0) is attributable to derivatives valued at fair value through profit and loss. Other items are valued at amortised cost using the effective interest method.

15 Financial expenses

GROUP	2018	2017
Interest expense, borrowings[1]	–16,086	–13,886
Interest expense[1,2]	–40,377	–50,085
Exchange-rate losses[3]	–	–3,389
Management costs[1]	–2,173	–1,277
Other	–1,023	–524
Total	**–59,659**	**–69,161**

PARENT COMPANY	2018	2017
Interest expense, Group companies	–10,557	–8,945
Interest expense, borrowings[1]	–15,960	–13,886
Interest expense, other[1,2]	–40,192	–50,085
Exchange-rate losses[3]	–	–1,588
Management costs[1]	–2,173	–1,277
Other	–596	–518
Total	**–69,478**	**–76,299**

1. According to effective interest method.
2. Pertains to interest expense on loans from Sanofi.
3. The figures include realised and unrealised currency effects of SEK 0 M (8) from derivatives. For 2018, SEK 0 M (8) attributable to derivatives, is measured at fair value through profit and loss. Other items are valued at amortised cost using the effective interest method.

16 Income tax

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

GROUP	2018	2017
Current tax		
Tax expense/income for the period[1]	–765,090	–209,067
Adjustment of tax attributable to prior years	–1,465	–61
Total current tax reported for the Group	**–766,555**	**–209,128**
Deferred tax		
Excess depreciation	–65,024	–213,400
Change in depreciation method	19,729	19,729
Inventory	64,961	–4,331
Acquired product rights	48,976	38,148
Other intangible assets	–7,584	–3,720
Trade receivables	12,374	1,671
Provision for pensions	2,553	8,299
Tax loss carry-forward	25,650	–15,447
Pharmaceutical tax	3,139	1,233
Other	–2,159	–6,865
Total deferred tax reported for the Group	**102,615**	**–174,683**
Total tax reported for the Group	**–663,940**	**–383,811**

PARENT COMPANY	2018	2017
Current tax		
Tax expense/income for the period[1]	–698,446	–146,855
Adjustment of tax attributable to prior years	–1,402	64
Total current tax reported for the Parent Company	**–699,848**	**–146,791**
Deferred tax		
Change in depreciation method	19,729	19,729
Provision for pensions	2,863	9,094
Tax loss carry-forward	–	–15,447
Other	–957	1,240
Total deferred tax reported for the Parent Company	**21,635**	**14,616**
Total tax reported for the Parent Company	**–678,213**	**–132,175**

Reconciliation of effective tax

GROUP	2018	2017
Profit before tax	**3,081,735**	**1,532,423**
Tax at applicable tax rate for the Parent Company[2]	–677,982	–337,133
Effect of changed tax rate in Sweden[3]	41,455	–
Effect of changed tax rate in the US	–	–28,424
Effect of foreign tax rates	–11,496	–12,141
Trade receivables	4,555	–
Provision for pensions	4,494	6,608
Non-deductible expenses	–24,364	–19,318
Non-taxable income	–	2,241
Deductible costs, not recognised in profit or loss	433	1,710
Taxable income, not recognised in profit or loss	–	–19
Adjustment of tax attributable to prior years	–1,465	–61
Other	430	2,726
Recognised effective tax for the Group	**–663,940**	**–383,811**

PARENT COMPANY	2018	2017
Profit before tax	**3,059,976**	**–375,662**
Tax at applicable tax rate for the Parent Company[2]	–673,195	82,646
Effect of changed tax rate in Sweden[3]	–843	–
Write-down of shares in subsidiaries	–	–220,000
Provision for pensions	4,494	6,608
Controlled Foreign Company taxation	–1,845	–
Non-deductible expenses	–5,423	–1,897
Non-taxable income	–	1
Deductible costs, not recognised in profit or loss	–	404
Adjustment of tax attributable to prior years	–1,402	64
Recognised effective tax for the Parent Company	**–678,213**	**–132,175**

1. In addition to current tax recognised in earnings, tax on the Parent Company's cash-flow hedges in other comprehensive income reduced the current tax liability by SEK 39 M (–42).
2. Applicable tax rate for the Swedish Parent Company is 22 per cent (22).
3. In 2018, a decision was made in Sweden to lower the tax rate to 21.4% from 2019, and to 20.6% from 2021. The entire effect of the revaluation of deferred tax liabilities and tax assets was recognised during the year.

17 Intangible assets and impairment testing

GROUP	Goodwill	Licenses and patents	Product and marketing-rights	Capitalised expenditures[4]	Ongoing capitalised expenditures[4]	Total
1 January–31 December 2017						
Opening accumulated cost	1,554,158	573,097	6,738,415	126,426	30,072	9,022,168
Acquisitions[1]	—	—	59,017	12,414	20,491	91,922
Impairments[3]	—	–12,000	—	—	—	–12,000
Exchange differences	—	15	—	–69	—	–54
Closing cost	**1,554,158**	**561,112**	**6,797,432**	**138,771**	**50,563**	**9,102,036**
Opening accumulated amortisation and impairment	—	–349,033	–1,785,651	–81,474	—	–2,216,158
Amortisation	—	–38,766	–386,594	–15,492	—	–440,852
Exchange differences	—	–13	—	58	—	45
Closing accumulated amortisation and impairment	**—**	**–387,812**	**–2,172,245**	**–96,908**	**—**	**–2,656,965**
Closing carrying amount	**1,554,158**	**173,300**	**4,625,187**	**41,863**	**50,563**	**6,445,071**
1 January–31 December 2018						
Opening accumulated cost	1,554,158	561,112	6,797,432	138,771	50,563	9,102,036
Acquisitions[2]	—	—	4,186,179	15,861	26,767	4,228,807
Scrapping[3]	—	–10,988	—	—	—	–10,988
Reclassification	—	—	–75,069	72,130	–1,797	–4,736
Exchange differences	—	9	–59,019	59	—	–58,951
Closing cost	**1,554,158**	**550,133**	**10,849,523**	**226,821**	**75,533**	**13,256,168**
Opening accumulated amortisation and impairment	—	–387,812	–2,172,245	, –96,908	—	–2,656,965
Amortisation	—	–38,571	–386,596	–23,447	—	–448,614
Scrapping[3]	—	8,154	—	—	—	8,154
Exchange differences	—	–8	—	–59	—	–67
Closing accumulated amortisation and impairment	**—**	**418,237**	**–2,558,841**	**–120,414**	**—**	**–3,097,492**
Closing carrying amount	**1,554,158**	**131,896**	**8,290,682**	**106,407**	**75,533**	**10,158,676**

1. In 2017, acquisitions relate to the right to participate in the rFIXFc-XTEN programme SEK 56 M, LMS (training system) for SEK 7 M and other minor investments totalling SEK 29 M divided between the various intangible items.
2. In 2018, acquisitions relate mainly to the investment of CHF 450 M in Emapalumab, additional acquisition costs of CHF 2.6 M, and investments primarily in IT. Se vidare under Avtal med Novimmune.
3. 2018: Refers to scrapping of completed distribution agreements. 2017: Pertains to impairment of one of the early-phase clinical programmes.
4. Capitalised expenditures comprises IT projects and costs to relocate manufacturing of active substance. Items under capitalised expenditures are amortised according to plan.

Note 17, cont.

PARENT COMPANY	Licenses and patents	Product and marketing rights	Capitalised expenditures[4]	Ongoing capitalised expenditures[4]	Total
1 January–31 December 2017					
Opening accumulated cost	76,785	4,792,343	119,517	29,988	5,018,633
Acquisitions[1]	—	59,017	12,414	20,491	91,922
Impairments[3]	–12,000	—	—	—	–12,000
Closing cost	**64,785**	**4,851,360**	**131,931**	**50,479**	**5,098,555**
Opening accumulated amortisation and impairment	–18,448	–660,558	–77,628	—	–756,634
Amortisation	–6,669	–262,213	–15,321	—	–284,203
Closing accumulated amortisation and impairment	**–25,117**	**–922,771**	**–92,949**	—	**–1,040,837**
Closing carrying amount	**39,668**	**3,928,589**	**38,982**	**50,479**	**4,057,718**
1 January–31 December 2018					
Opening accumulated cost	64,785	4,851,360	131,931	50,479	5,098,555
Acquisitions[2]	—	—	15,861	26,767	42,628
Scrapping[3]	–10,988	—	—	—	–10,988
Reclassification	—	–75,069	72,130	–1,797	–4,736
Closing cost	**53,797**	**4,776,291**	**219,922**	**75,449**	**5,125,459**
Opening accumulated amortisation and impairment	–25,117	–922,771	–92,949	—	–1,040,837
Amortisation	–6,484	–262,216	–23,447	—	–292,247
Scrapping[3]	8,154	—	—	—	8,154
Closing accumulated amortisation and impairment	**–23,447**	**–1,184,987**	**–116,396**	—	**–1,324,830**
Closing carrying amount	**30,350**	**3,591,304**	**103,526**	**75,449**	**3,800,629**

1. In 2017, acquisitions relate to the right to participate in the rFIXFc-XTEN programme SEK 56 M, LMS (training system) for SEK 7 M and other minor investments totalling SEK 29 M divided between the various intangible items.
2. In 2018, acquisitions relate to investments, mainly in IT.
3. 2018: Refers to scrapping of completed contracts. 2017: Pertains to impairment/scrapping of one of the early-phase clinical programmes.
4. Capitalised expenditures comprises IT projects and expenditures for transfer of technology in manufacturing of active substance. Items under capitalised expenditures are amortised according to plan.

Impairment testing of intangible assets

Goodwill

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

Cash flows are based on financial plans that have been established by management covering a four-year period. The financial plans have been drawn up based on past performance, experiences and market expectations. The plans includes assumptions about the current product development and future product launches. The financial planning also includes assumptions of price trends, sales performance and cost trends. Cash flows beyond a four-year period have been extrapolated using an estimated growth rate of 2 per cent. On 31 December 2018, Sobi's goodwill amounted toSEK 1,554 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, %	2018	2017
Growth rate beyond the initial five-year period	2	2
Discount rate before tax	11.5	11.9
Discount rate after tax	9.0	9.2

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:* 6.4 per cent (6.3).
- *Beta coefficient:* Sobi's beta coefficient is calculated at 1.31 (1.31).
- *Interest expense:* according to Sobi's borrowing costs.
- *Tax rate:* according to tax rates in Sweden.

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.

Development projects and product rights

Development projects and product rights are tested annually for impairment. Separate impairment testing has been carried out for each product and project. The assessment of the value of development projects and product rights is based on the value in use for each 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.

Key parameters for impairment testing of development projects are future cash flows from the individual asset, the probability of achieving positive outcomes in clinical trials, and assumptions of the best commercial outcome. Future cash flows are estimated with regard to project development in the short and long-term and adjusted for the likelihood of the project being commercialised. The earlier in the chain of development the project is, the higher the risk. As it passes through the defined development phases, the likelihood of reaching the market increases. The likelihood of a project successfully coming through the relevant development phase is assessed on the basis of the project's scientific potential to have a positive outcome in the individual phase of the development process. A best-case assumption is made on the basis of the parameters that have the greatest effect on whether the project will develop into a drug with the highest commercial potential, and on the basis of what is reasonable to assume about the project's scientific profile using the information currently available. The forecast period is based on the product's estimated market life.

In the impairment testing of product and marketing rights, a number of assumptions are made. The assumptions are forecasts of future sales revenue, costs attributable to each product, product life and the discount rate. In cases where the contract for product and marketing rights exceed four years, the term of contract is used as the remaining life. The impairment testing of product and marketing rights did not indicate any impairment.

Note 17, cont.

Impairment in 2018
There has been no write down of intangible assets 2018.
In 2017, Sobi's assessment of the value of one of the early-phase clinical programmes indicated an impairment of SEK 12 M. The impairment had a negative impact on intangible assets.

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, PREVIOUS BIOVERATIV
Bioverativ was created as a spin-off from Biogen's haemophilia business and separated from Biogen on 1 February 2017. Bioverativ is a Sanofi company located in Massachusetts, US. Sanofy has during 2018 acquired Bioverativ. Sanofi will continue to collaborate with Sobi in our joint development programmes.

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 with Sanofi in place for the XTEN-programmes[5] BIVV001 and BIVV002.

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 on the next page.

Sobi opted 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. Reimbursement of development activities that only benefited Sobi's territory was 100 per cent.

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 which 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
The total liability for the development and commercialisation of Elocta is USD 211 M. On 24 November 2015, Sobi and Sanofi announced that the European Commission had approved Elocta for the treatment of haemophilia A 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 January 2016, Sobi credited retroactive royalty revenue of SEK 322 M against the liability. At 31 December 2018, the remaining liability was SEK 412 M (USD 46 M), corresponding to the discounted value of the nominal liability, which amounted to USD 46 M.

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 had 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 retroactive royalty revenue of SEK 386 M against the liability. At 31 December 2018, the remaining liability was SEK 692 M (USD 77 M), corresponding to the discounted value of the nominal liability, which amounted to USD 79 M.

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 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.

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.

Percentage rates for royalties and reimbursement between the companies

		Percentage rates after the first commercial sales in Sobi's territory if Sobi exercises its opt-in right[3]		
	Method	Base rate, %[3]	Adjusted royalty rate during repayment period[3]	Net royalty payment during repayment period[4], %
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[1] from Sanofi's distribution territory[2]	Royalty on net profit	50	Base rate minus 15%	35

1. Net profit relates to Sanofi's revenue before tax from distributors (third parties), less costs incurred by Sanofi for supporting this sale.
2. Sanofi's distribution territory pertains to the territory in which sales are conducted through a third party.
3. Base rate impacts earnings. Repayment of the liability comprises the difference between the base rate and the adjusted royalty.
4. Actual payments that impact cash flow.
5. XTEN is Sanofi's development programme. Sobi has chosen to add this programme to the collaboration agreement, but has not yet exercised its opt-in right.

Note 17, cont.

AGREEMENT WITH NOVIMMUNE

Emapalumab

Sobi has acquired the global rights to emapalumab from Novimmune. On 20 November 2018, emapalumab was approved by the US Food and Drug Administration (FDA). The agreement stipulates an initial cash payment CHF 50 M (SEK 450 M) (paid in Q3 2018), with additional payments of CHF 400 M (SEK 3,600 M) up to an eight-year period. The agreement includes milestone payments for approval in the US and the EMA, respectively, of USD 1 M per milestone. In addition, minor amounts will be payable provided that certain criteria are met. Sobi holds assets of approximately SEK 4,127 M and liabilities of SEK 3,649 M in relation to emapalumab.

Upon the completion of all payments, Sobi will acquire the intellectual property rights for emapalumab, including patents, data and know-how. Either party has the option of bringing forward the date of the additional payments to any time after 1 July 2019. A non-binding letter of intent regarding a possible subsequent acquisition of emapalumab has also been signed.

18 Property, plant and equipment

GROUP	Plant and machinery	Equipment, tools, fixtures and fittings	Other non-current assets	Construction in progress	Total
1 January–31 December 2017					
Opening accumulated cost	435,449	225,281	15,361	14,770	690,861
Acquisitions	28,636	9,854	2,762	6,271	47,523
Reclassification	—	542	—	—	542
Write-offs	–922	–1,752	–2,886	—	–5,560
Exchange differences	36	9	—	—	45
Closing cost	**463,199**	**233,934**	**15,237**	**21,041**	**733,411**
Opening accumulated depreciation and impairment	–377,473	–187,929	–4,436	—	–569,838
Amortisation	–15,001	–15,599	–2,525	—	–33,125
Reclassification	—	–542	—	—	–542
Write-offs	922	1,713	1,721	—	4,356
Exchange differences	–13	–67	—	—	–80
Closing accumulated amortisation and impairment	**–391,565**	**–202,424**	**–5,240**	**—**	**–599,229**
Closing carrying amount	**71,634**	**31,510**	**9,997**	**21,041**	**134,182**
1 January–31 December 2018					
Opening accumulated cost	463,199	233,934	15,237	21,041	733,411
Acquisitions	2,476	9,629	1,913	26,494	40,512
Reclassification	33,191	6,343	—	–38,968	566
Write-offs	–33,312	–6,439	–5,520	—	–45,271
Exchange differences	73	1,372	–13	—	1,432
Closing cost	**465,627**	**244,839**	**11,617**	**8,567**	**730,650**
Opening accumulated depreciation and impairment	–391,565	–202,424	–5,240	—	–599,229
Amortisation	–18,878	–14,759	–2,351	—	–35,988
Reclassification	—	–565	—	—	–565
Write-offs	33,288	6,069	2,694	—	42,051
Exchange differences	–39	–658	77	—	–620
Closing accumulated amortisation and impairment	**–377,194**	**–212,337**	**–4,820**	**—**	**–594,351**
Closing carrying amount	**88,433**	**32,502**	**6,797**	**8,567**	**136,299**

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 2017					
Opening accumulated cost	430,119	199,766	5,210	14,770	649,865
Acquisitions	28,557	2,583	—	6,271	37,411
Disposals	–922	—	—	—	–922
Closing cost	**457,754**	**202,349**	**5,210**	**21,041**	**686,354**
Opening accumulated depreciation and impairment	–371,582	–173,525	–1,560	—	–546,667
Amortisation	–14,653	–11,371	–524	—	–26,548
Disposals	922	—	—	—	922
Closing accumulated depreciation and impairment	**–385,313**	**–184,896**	**–2,084**	**—**	**–572,293**
Closing carrying amount	**72,441**	**17,453**	**3,126**	**21,041**	**114,061**
1 January–31 December 2018					
Opening accumulated cost	457,754	202,349	5,210	21,041	686,354
Acquisitions	—	—	—	26,494	26,494
Reclassification	33,191	5,778	—	–38,968	1
Disposals	–33,312	–5,668	—	—	–39,580
Closing cost	**457,633**	**202,459**	**5,210**	**8,567**	**674,169**
Opening accumulated depreciation and impairment	–385,313	–184,896	–2,084	—	–572,293
Amortisation	–18,509	9,636	–524	—	–28,669
Disposals	33,288	5,668	—	—	38,956
Closing accumulated depreciation and impairment	**–370,534**	**–188,864**	**–2,608**	**—**	**–562,006**
Closing carrying amount	**87,099**	**13,595**	**2,602**	**8,567**	**111,863**

18
19

19 Participations in Group companies

PARENT COMPANY	2018	2017
Accumulated cost		
At beginning of year	4,059,768	4,059,573
Investment[1]	592,273	195
Total	**4,652,041**	**4,059,768**
Accumulated impairment		
At beginning of year	–1,177,435	–177,435
Impairment for the year	—	–1,000,000
Total	**–1,177,435**	**–1,177,435**
Carrying amount at end of period	**3,474,606**	**2,882,333**

1. Investment for the year relates to the acquisition of the perpetual rights to emapalumab from Novimmune SA, which was conducted by the subsidiary in Switzerland.

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
Swedish Orphan Biovitrum International AB, 556329–5624, Stockholm, Sweden	100	100	2,655,588
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			
SOBI Middle East FZ-LLC, 91193, Dubai, United Arab Emirates	1,000	100	132
Arexis AB, 556573-5130, Stockholm, Sweden	1,000	100	225,137
Sobi, Inc EIN 68-0682244, Delaware, USA	1,000	100	7
Swedish Orphan Biovitrum s.r.o, 28171276, Prague, Czech Republic[2]	1	1	8
BVBA Swedish Orphan Biovitrum, 0536.217.087, Brussels, Belgium	100	100	165
Swedish Orphan Biovitrum AG, 284,917,678, Lucerne, Switzerland	100	100	592,996
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
Total			**3,474,606**

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.

20 Financial assets

GROUP	2018	2017
Accumulated cost		
At beginning of year	35,155	1,956
Endowment insurance[1]	14,320	32,391
Financial receivables	2,036	1,356
Returned deposit	–1,339	–619
Derivatives	5,268	—
Other	—	71
Accumulated cost	**55,440**	**35,155**
Carrying amount at end of period	**55,440**	**35,155**

PARENT COMPANY	2018	2017
Accumulated cost		
At beginning of year	32,392	1
Endowment insurance[1]	14,320	32,391
Derivatives	5,268	—
Accumulated cost	**51,979**	**32,392**
Carrying amount at end of period	**51,979**	**32,392**

21 Deferred tax assets and liabilities

Recognised deferred tax assets and liabilities

GROUP 2018	Deferred tax assets	Deferred tax liabilities	Net
Excess depreciation	—	–532,304	–532,304
Inventory	180,890	—	180,890
Acquired product rights	—	–202,930	–202,930
Other intangible assets	61,029	—	61,029
Trade receivables	14,045	—	14,045
Provision for pensions	13,969	–135	13,834
Pharmaceutical tax	5,929	—	5,929
Tax loss carry-forward[1]	26,379	—	26,379
Other	3,248	–3,107	141
Total	**305,489**	**–738,476**	**–432,987**
Offsetting	–74,655	74,655	—
Tax assets/liabilities, net	**230,834**	**–663,821**	**–432,987**

1. Deferred tax on loss carry-forward for the year relates to losses accumulated during the year that are expected to be utilized before they expire, see also Note 4.

Note 21, cont.

GROUP 2017	Deferred tax assets	Deferred tax liabilities	Net
Excess depreciation	—	–467,280	–467,280
Change in depreciation method	—	–19,729	–19,729
Inventory	115,929	—	115,929
Acquired product rights	—	–251,906	–251,906
Other intangible assets	68,613	—	68,613
Trade receivables	1,671	—	1,671
Provision for pensions	11,390	—	11,390
Pharmaceutical tax	2,669	—	2,669
Other	3,573	–1,233	2,340
Total	**203,845**	**–740,149**	**–536,303**
Offsetting	–72,416	72,416	—
Tax assets/liabilities, net	**131,429**	**–667,733**	**–536,303**

The Parent Company's total deferred tax assets/liabilities amounted to SEK 11 M (–10), comprising a deferred tax liability of SEK 12 M (9) related to pension provisions, a deferred tax asset of SEK 2 M (2) related to trade receivables, a deferred tax liability of SEK –3 M (–1) related to derivatives and a deferred tax liability of SEK –1 M (–1) related to restoration reserve. Deferred tax was calculated using the new tax rates introduced in Sweden during the year, see Notes 2 and 16.

Change in deferred tax on temporary differences and loss carry-forward

GROUP 2018	Amount at beginning of year	Recognised in profit or loss	Recognised in other comprehensive income	Amount at end of year
Excess depreciation	–467,280	–65,024	—	–532,304
Change in depreciation method	–19,729	19,729	—	—
Inventory	115,929	64,961	—	180,890
Acquired product rights	–251,906	48,976	—	–202,930
Other intangible assets	68,613	–7,584	—	61,029
Trade receivables	1,671	12,374	—	14,045
Provision for pensions	11,390	2,553	–109	13,834
Tax loss carry-forward[1]	—	25,650	729	26,379
Pharmaceutical tax	2,669	3,139	121	5,929
Other	2,340	–2,159	–40	141
Total	**536,303**	**102,615**	**701**	**–432,987**

1. Deferred tax on loss carry-forward for the year relates to losses accumulated during the year that are expected to be utilized before they expire, see also Note 4.

GROUP 2017	Amount at beginning of year	Recognised in profit or loss	Recognised in other comprehensive income	Amount at end of year
Excess depreciation	–253,880	–213,400	—	–467,280
Change in depreciation method	–39,458	19,729	—	–19,729
Inventory	120,260	–4,331	—	115,929
Acquired product rights	–290,054	38,148	—	–251,906
Other intangible assets	72,333	–3,720	—	68,613
Trade receivables	—	1,671	—	1,671
Provision for pensions	2,805	8,299	286	11,390
Tax loss carry-forward	15,368	–15,447	79	—
Pharmaceutical tax	1,358	1,233	78	2,669
Other	9,607	–6,864	–404	2,340
Total	**–361,661**	**–174,683**	**39**	**–536,303**

22 Inventories

GROUP	2018	2017
Raw materials and consumables	17,165	20,905
Work in progress	581,185	536,603
Finished goods and goods for resale	685,762	495,760
Total	**1,284,112**	**1,053,268**

The cost of inventories recognised as an expense is included in cost of goods sold and amounted to SEK 2,056,110 K (1,516,822). 2017 included a one-off adjustment of stock of SEK 59 M in connection with the delayed release of the pharmaceutical substance for Kineret manufactured in 2016.

PARENT COMPANY	2018	2017
Raw materials and consumables	17,165	20,905
Work in progress	581,185	536,603
Finished goods and goods for resale	472,462	336,166
Total	**1,070,812**	**893,674**

The cost of inventories recognised as an expense is included in cost of goods sold and amounted to SEK 1,995,014 K (1,516,485). 2017 included a one-off adjustment of stock of SEK 59 M in connection with the delayed release of the pharmaceutical substance for Kineret manufactured in 2016.

23 Trade and other receivables

GROUP	2018	2017
Trade receivables	1,734,990	1,164,054
Minus: Provision for expected credit losses	−69,782	−35,038
Trade receivables, net	**1,665,208**	**1,129,016**
Tax assets	14,817	25,232
Other receivables	77,919	38,732
Total other receivables	**92,736**	**63,964**
Total trade and other receivables	**1,757,944**	**1,192,980**

PARENT COMPANY	2018	2017
Trade receivables	597,693	413,296
Minus: Provision for expected credit losses	−8,097	−7,594
Trade receivables, net	**589,596**	**405,702**
Tax assets	670	22,261
Other receivables	56,319	30,831
Total other receivables	**56,989**	**53,092**
Total trade and other receivables	**646,585**	**458,794**

Sobi's clients are primarily hospitals and government authorities. The large client 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 for an expected credit loss shall be made in accordance with the principles described in Note 2. This note also includes information on client's payment conditions.

At 31 December 2018, overdue customer receivables for the Group amounted to SEK 518 M (291), on which SEK 70 M (35) are included in the provision for future credit losses. The year's profit has been affected by confirmed credit losses of SEK 2.525 M, of which SEK 1.015 M are attributed to the parent company.

The new accounting standard IFRS 9 Financial Instruments came into effect on 1 January 2018. New accounting principles for expected credit losses are applied to trade receivables and contract assets when IFRS 15 is applied.

Sobi has analysed the effects of the introduction of IFRS 9 on the Group's financial statements, and this did not result in any material impact on the opening balances in 2018.

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

Provision for expected credit losses

GROUP	2018	2017
At beginning of year	−35,038	−49,279
Provision for expected credit losses	−40,805	−10,566
Reversed provisions	6,061	24,807
At end of year	**−69,782**	**−35,038**

PARENT COMPANY	2018	2017
At beginning of year	−7,594	−12,799
Provision for expected credit losses	−2,258	−2,296
Reversed provisions	1,755	7,501
At end of year	**−8,097**	**−7,594**

Note 23, cont.

Past due trade receivables

GROUP	2018	2017
Not past due	1,147,113	838,737
Past due 1–30 days	371,251	183,050
Past due 31–90 days	80,146	68,366
Past due 91–120 days	10,283	11,954
Past due > 121 days	56,415	27,273
Total	**1,665,208**	**1,129,016**

PARENT COMPANY	2018	2017
Not past due	439,469	335,870
Past due 1–30 days	142,159	62,111
Past due 31–90 days	5,630	5,754
Past due 91–120 days	1,718	–
Past due > 121 days	620	1,967
Total	**589,596**	**405,702**

Recognised amount per currency for trade and other receivables

GROUP	2018	2017
AUD	3,461	10,459
CHF	44,405	20,333
CZK	1,639	2,088
DKK	34,338	24,786
EUR	1,134,478	661,603
GBP	122,402	101,106
NOK	37,947	35,945
PLN	3,957	5,129
RON	9,677	10,248
SEK	191,285	167,292
USD	161,938	150,155
Other currencies	12,417	3,834
Total	**1,757,944**	**1,192,980**

PARENT COMPANY	2018	2017
AUD	3,461	10,459
CHF	38,400	20,333
CZK	1,283	1,799
DKK	33,763	24,619
EUR	294,391	172,013
GBP	–	–
NOK	37,835	35,404
PLN	3,957	5,129
RON	9,677	10,248
SEK	191,751	167,292
USD	25,838	9,631
Other currencies	6,229	1,865
Total	**646,585**	**458,794**

24 Prepaid expenses and accrued income

GROUP	2018	2017
Accrued royalty revenue[1]	364,250	327,390
Prepaid lease payments	172	176
Prepaid rents	21,743	16,174
Prepaid insurance expenses	854	14,469
Accrued interest income	42,969	2,884
Prepaid IT licenses	18,394	11,229
Prepaid fees, regulatory authorities	18,987	16,975
Other accrued income[1]	–	179
Other prepaid expenses	93,741	42,850
Total	**561,110**	**432,326**

PARENT COMPANY	2018	2017
Accrued royalty revenue[1]	364,250	327,390
Prepaid rents	15,693	15,012
Prepaid insurance expenses	–	13,343
Accrued interest income	42,969	2,884
Prepaid IT licenses	18,394	11,229
Prepaid fees, regulatory authorities	18,987	16,975
Other prepaid expenses	71,489	31,361
Total	**531,782**	**418,194**

1. These are classified as contract assets according to IFRS 15.

25 Cash and cash equivalents

	2018		2017	
GROUP	Fair value	Carrying amount	Fair value	Carrying amount
Cash and cash equivalents	2,998,742	2,998,742	1,478,496	1,478,496
Total	**2,998,742**	**2,998,742**	**1,478,496**	**1,478,496**

	2018		2017	
PARENT COMPANY	Fair value	Carrying amount	Fair value	Carrying amount
Cash and cash equivalents	2,761,759	2,761,759	1,381,369	1,381,369
Total	**2,761,759**	**2,761,759**	**1,381,369**	**1,381,369**

Cash and cash equivalents relate to the holding of funds in bank accounts.

26 Financial assets and liabilities per category (Group)

	Assets measured at amortised cost	Assets measured at fair value through profit or loss	Derivatives	Total
31 December 2018				
Assets in the balance sheet				
Trade receivables	1,665,208	—	—	1,665,208
Endowment insurance	—	46,711	—	46,711
Derivatives[1]	—	—	14,924	14,924
Fair value hedges	—	5,268	—	5,267
Cash and cash equivalents	2,998,742	—	—	2,998,742
Total	**4,663,950**	**51,978**	14,924	**4,730,852**
31 December 2017				
Assets in the balance sheet				
Trade receivables	1,129,016	—	—	1,129,016
Endowment insurance	—	32,391	—	32,391
Derivatives	—	—	5,095	5,095
Cash and cash equivalents	1,478,496	—	—	1,478,496
Total	**2,607,512**	**32,391**	**5,095**	**2,644,998**

	Liabilities measured at amortised cost	Other financial liabilities	Derivatives	Total
31 December 2018				
Liabilities in the balance sheet				
Finance leases	3,986	—	—	3,986
Derivatives[2]	—	—	8,181	8,181
Trade payables	486,972	—	—	486,972
Other liabilities	4,887,001	—	—	4,887,001
Total	**5,377,959**	—	**8,181**	**5,386,140**
31 December 2017				
Liabilities in the balance sheet				
Finance leases	—	6,668	—	6,668
Derivatives	—	—	2,624	2,624
Trade payables	—	358,449	—	358,449
Other liabilities	—	1,646,728	—	1,646,728
Total	**—**	**2,011,845**	**2,624**	**2,014,469**

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

1. Of the 2018 derivatives, SEK 8 M (5) is measured at fair value through profit and loss, SEK 7 M (0) is included in cash flow hedges.
2. Derivatives on the liability side consist of SEK 5 M (0) hedged at fair value and SEK 3 M (0) included in cash flow hedges.

Financial instruments measured at fair value

The following table shows financial instruments measured at fair value, based on their classification in the fair value hierarchy. The different levels are defined as follows:

- Level 1: Quoted prices in active markets for identical assets or liabilities.
- Level 2: Observable data for the asset or liability other than the quoted prices included in Level 1.
- Level 3: Inputs for the asset or liability that are not based on observable market data.

AT 31 DECEMBER 2018	Level 1	Level 2	Level 3	Total
Financial assets measured at fair value through profit or loss				
Derivatives held for sale		2,445		2,445
Derivative instruments used for hedging purposes		4,298		4,298
Total assets		**6,743**		**6,743**

Note 26, cont.

AT 31 DECEMBER 2017	Level 1	Level 2	Level 3	Total
Financial assets measured at fair value through profit or loss				
Derivatives held for trading	—	2,471	—	2,471
Total assets	—	**2,471**	—	**2,471**

All derivatives are measured at fair value based on market data in accordance with IFRS. At 31 December 2018, the carrying amount of derivatives in the balance sheet was SEK 7 M (2), see also Note 26.

27 Other liabilities, current and non-current

GROUP	2018	2017
Current		
Liability to Sanofi Genzyme	676,778	579,895
Liability to Novimmune	3,639,695	—
Non-invoiced goods received	28,826	14,678
Other	114,003	67,539
Total	**4,459,302**	**662,112**
Non-current		
Liability to Sanofi Genzyme	427,699	1,066,833
Total	**427,699**	**1,066,833**

PARENT COMPANY	2018	2017
Current		
Liability to Sanofi Genzyme	676,778	579,895
Non-invoiced goods received	28,826	14,678
Other	25,724	12,535
Total	**731,328**	**607,108**
Non-current		
Liability to Sanofi Genzyme	427,699	1,066,833
Total	**427,699**	**1,066,833**

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 Genzyme'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 in the balance sheet (USD 46 M for Elocta and USD 77 M for Alprolix). The right to market the products in certain markets, recorded as intangible assets, is initially recognised at the same value as the liabilities. The costs correspond to the discounted liability, and the difference compared with nominal amounts gives rise to deferred tax in the financial statements. The risk associated with currency effects on these liabilities is reduced by applying hedge accounting. This is done by hedging highly probable future inflows in USD using cash flow hedges, and the effect of the remeasurements of the liabilities is reflected in other comprehensive income. If full payment has not been made within six years of the first commercial sale of each product, Sanofi Genzyme is entitled to request that Sobi pay the remaining amount within 90 days of the sixth anniversary of Sanofi Genzyme's first commercial sale. Liability of CHF 450 M to Novimmune pertains to the acquisition of the license agreement for Emapalumab. The liability is classified as current, since additional payments may be accelerated by either party at any time after 1 July 2019. The liability is non-interest-bearing.

28 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 2018, five people in the Norwegian subsidiary and two people in the Swedish Parent Company were covered by defined-benefit plans, while other employees were covered by defined-contribution plans.

Defined-contribution plan by Alecta and pension benefits
For white-collar employees in Sweden, the ITP 2 plan's defined-benefit pension commitments 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 2018 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 25 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 commitments 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 2018, Alecta's surplus in the form of the collective funding ratio was 142 per cent (154).

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 commitments are calculated annually on the balance-sheet date, based on actuarial principles. Sobi has a defined-benefit pension plan for the subsidiary in Norway and for two individuals in the Parent Company in Sweden.

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

Pension costs are recognised under the items of selling expenses, 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 assumptions: 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 most significant in the Swedish plan, in which inflation increases result in higher sensitivity to changes in the 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.

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Note 28, 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) 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.

Both the Swedish and Norwegian plans are based on final salary.

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

1 JANUARY–31 DECEMBER 2018	Present value of commitments	Fair value of plan assets	Total
At beginning of year	**–41,414**	**32,775**	**–8,639**
Current service cost	–2,267	—	–2,267
Interest expense	–990	—	–990
Revaluations:			
Return on plan assets, excl. amounts included in interest expense	—	801	801
Changed financial assumptions	–449	–62	–511
Experience-based assumptions	5,363	–1,613	3,750
Contributions:			
Employer	908	470	1,378
Settlements	—	–170	–170
Exchange differences	–422	238	–185
At end of year	**–39,271**	**32,439**	**–6,832**

1 JANUARY–31 DECEMBER 2017	Present value of commitments	Fair value of plan assets	Total
At beginning of year	**–40,639**	**29,679**	–10,960
Current service cost	–1,859	—	–1,859
Interest expense	–983	—	–983
Revaluations:			
Return on plan assets, excl. amounts included in interest expense	—	732	732
Changed financial assumptions	–1,251	20	–1,231
Experience-based assumptions	1,447	1,362	2,808
Contributions:			
Employer	1,020	1,658	2,678
Settlements	—	–219	–219
Exchange differences	852	–456	395
At end of year	**–41,414**	**32,775**	**–8,639**

Net obligation per country

	2018	2017
Sweden	614	–744
Norway	–7,446	–7,895
Total	**–6,832**	**–8,639**

Actuarial assumptions on the balance-sheet date

SWEDISH PENSION PLAN	2018	2017
Discount rate, %	2.3	2.5
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	2018	2017
Discount rate, %	2.6	2.3
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

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. 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 asset class

	2018	Quoted, %	2017	Quoted, %
Equity funds[1]	12,050	100	10,878	100
Interest-bearing securities	16,652	100	18,070	100
Properties	813	—	1,016	—
Other funds	2,844	—	2,669	—
Other	80	—	142	—
Total	**32,439**		**32,775**	

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.

Sensitivity analysis

	2018	2017
Pension commitment under current assumptions	39,271	41,413
Discount rate –0.5%	43,025	45,870
Discount rate +0.5%	35,546	37,482
Inflation +0.5%	43,204	45,699
Inflation –0.5%	38,644	39,489
Life expectancy after retirement –1 year	36,415	38,867
Life expectancy after retirement +1 year	40,835	43,335

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 in the balance sheet.

Other information

For the 2019 financial year, contributions to plans for post-employment benefits are expected to be SEK 1,439 K (1,362). The weighted average maturity of the commitment is an estimated 30.2 years.

Note 28, cont.

29 Provisions

	Group		Parent Company	
	2018	2017	2018	2017
Provision at beginning of year	97,955	44,389	82,443	33,060
Endowment insurance[1]	14,320	32,391	14,320	32,391
Cash-based incentive programme[2]	–16,817	16,817	–16,817	16,817
Commitments, leases	–455	2,725	–	–
Restoration reserve[3]	176	171	176	175
Changes in pension commitments	–1,806	–2,321	–	–
Other	4,106	3,783	–	–
Provisions at 31 December	**97,479**	**97,955**	**80,122**	**82,443**

1. On the balance-sheet date, endowment insurance amounted to SEK 47 M.
2. Cash-based incentive programme 2017 related to programme that will be vested during 2019 and hence has been reclassified during 2018. See Note 11.
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 2018, the company recognised a provision of SEK 33 M in the balance sheet.

	Group		Parent Company	
	2018	2017	2018	2017
Non-current portion	95,643	94,172	80,122	82,443
Current portion	1,836	3,783	–	–
Total provisions	**97,479**	**97,955**	**80,122**	**82,443**

30 Accrued expenses and deferred income

GROUP	2018	2017
Provision for vacation pay and bonuses, incl. social security contributions	322,041	239,469
Accrued social security contributions	139,336	119,066
Accrued royalty expense	183,961	112,849
Accrued manufacturing costs	107,473	46,014
Accrued R&D costs	128,548	64,960
Accrued interest expense	3,996	175
Accrued consulting and travel costs	59,126	23,351
Accrued discounts	260,190	176,099
Pharmaceutical tax	139,777	111,261
Accrued costs for audit and Annual Report	3,187	4,700
Accrued costs of items sold	23,377	10,426
Co-Promotion	76,677	–
Other accrued expenses	162,606	210,308
Total	**1,610,295**	**1,118,678**

PARENT COMPANY	2018	2017
Provision for vacation pay and bonuses, incl. social security contributions	181,706	146,223
Accrued social security contributions	83,360	51,856
Accrued royalty expense	183,961	112,849
Accrued manufacturing costs	107,473	46,014
Accrued R&D costs	99,012	64,960
Accrued interest expense	3,996	175
Accrued consulting and travel costs	29,328	7,295
Accrued discounts	65,656	30,633
Pharmaceutical tax	52,714	14,517
Accrued costs for audit and Annual Report	1,164	2,756
Accrued costs of items sold	4,106	–
Co-Promotion	76,369	–
Other accrued expenses	80,616	205,552
Total	**969,462**	**682,830**

31 Pledged assets and contingent liabilities

GROUP	2018	2017
Pledged assets		
Endowment insurance	46,711	32,391
Other pledged assets	739	686
Total	47,450	33,077

PARENT COMPANY	2018	2017
Pledged assets		
Endowment insurance	46,711	32,391
Other pledged assets	43	43
Total	46,754	32,434

PARENT COMPANY	2018	2017
Contingent liabilities		
Guarantee commitment	96,127	36,835
Total	96,127	36,835

Guarantees for 2018 for the 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.

32 The share

At year-end, Sobi's share capital amounted to SEK 149,947 M distributed between 273,322,117 shares with a par value of about SEK 0.55. All shares issued on the balance-sheet date were ordinary shares. Ordinary shares carry one vote per share. At the balance-sheet date, the company held 3,423,726 ordinary shares in treasury. The Equity item corresponds to 1.3 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.

	2018	2017
Earnings attributable to Parent Company shareholders	2,417,795	1,148,612
Weighted average number of ordinary shares outstanding (000s)	269,524	269,020
Undiluted earnings per share (SEK per share)	8.97	4.27
Diluted earnings per share (SEK per share)	8.93	4.25

33 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.

34 Proposed appropriation of profit

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

SEK	
Share premium reserve	4,277,038,162
Retained earnings	121,508,296
Profit for the year	2,381,763,358
Total	6,780,309,816

The Board of Directors proposes that no dividend be distributed for the 2018 financial year.

The Board proposes that the share premium reserve and retained earnings at their disposal, of SEK 6,780,309,816 be carried forward.

35 Events after the balance-sheet date up to 27 March 2019

- Sobi completed the acquisition of the Synagis US rights from AstraZeneca and exercised authorisation to issue shares. The upfront consideration payable at closing of the acquisition, announced on 24 January 2019, corresponds to approximately US 1.5 B (SEK 13.8 B) consisting of cash and 24,193,092 newly issued Sobi common shares.
- In connection to the acquisition from AstraZeneca of the rights to Synagis in the US, Sobi announced a new number of shares and votes due to the issue of 24,193,092 new common shares. Thereafter, the total number of shares and votes amounts to 297,515,209. At 31 January 2019, the company held 3,423,726 common shares in treasury.
- The US Food and Drug Administration granted Breakthrough Therapy Designation (BTD) for MEDI8897.
- Christian Dreger (Head of Northern Europe, Middle East and Russia), Sofiane Fahmy (Head of Southern & Western Europe and North Africa) and Paula Treutiger (Head of Communications & Investor Relations) were appointed to the Executive Committee in January 2019. Hege Hellström (Head of EMENAR) left the Executive Committee and the company in January 2019.

For more information, refer to the Directors' Report.

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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 Directors' 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 9 May 2019 for adoption.

Stockholm, 27 March 2019

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

Bo-Gunnar Rosenbrand
Employee representative

Guido Oelkers
Chief Executive Officer

Our auditor's report was submitted on 12 April 2019
Ernst & Young AB

Björn Ohlsson
Authorised Public Accountant

Letter from the Chairman

2018 was an extremely eventful year for Sobi. It was also an extremely successful year in two key ways.

Looking at Sobi's success in both sales and in business development during 2018, it is clear that the company has delivered on its strategy. The progress so far bodes well for continued growth in the years ahead.

Product sales have matched or exceeded expectations across the board, with outstanding growth in Haemophilia, increased sales for Kineret and a stable performance for Orfadin.

Just as importantly, Sobi has completed two business development deals. These are in line with the strategy adopted in September 2017. The acquisitions represent both the first stage in the realisation of Sobi's growth strategy and an important diversification for the company.

We have seen a number of additional hires in the management team, making it more international and diversified. Diversity, in senior management, across the company and within the Board itself, is something we see as adding value to Sobi, and is something we will continue to work with over the coming years.

Contributing to society

Sobi's overall objective from a sustainability perspective is tied to the vision of contributing to the societies in which it operates by improving access to treatment of rare diseases. This requires a commitment to responsibility for patients and employees, reduced environmental impact from operations and treatment, as well as long-term sustainable profitability.

The Board monitors and supports Sobi's ongoing efforts to reduce the company's impact on the environment. Sobi's operations are not seen as having a significant environmental impact, but the company still looks continuously at how energy and water consumption can be reduced further. To reduce the impact of business travel, which accounts for our largest contribution to greenhouse gas emissions, the option of virtual meetings is both promoted and facilitated.

Compliance remains a major issue for all companies today. As far as Sobi is concerned, there can be only one standard: to be completely compliant with all rules and regulations in every jurisdiction where the company operates. Nothing else is acceptable.

There is also the question of how people behave towards each other. One example is sexual harassment, which is unacceptable in all its forms. To assist in ensuring compliance, Sobi provides a a third-party whistle-blower service available to all employees, enabling anonymous reports of any possible violation of the Code of Conduct & Ethics, any law, or any company policy.

These are all issues in which the Board will continue to work with Sobi's senior management.

Looking forward

I see the acquisitions of 2018 as the first stage in the diversification of Sobi's business base. Sobi has been incredibly successful in Haemophilia and we expect this to continue, with strong growth for current products and promising follow-up compounds. The business development activities last year will ensure a more diverse portfolio.

I expect diversification efforts to continue, to create a broader yet still focused product portfolio. I also expect Sobi to add to the R&D pipeline, bringing in not only products that can be launched immediately but also late-stage products that can be brought to patients within a couple of years. We have not seen the end of business development activities.

Research and development remain very important, and Sobi will continue to develop its own products. But it is also obvious that you cannot do everything on your own. To be able to bring in successful projects or products from outside, you need to have strong in-house R&D. Otherwise you cannot evaluate these projects adequately, nor contribute to the further development of them going forward. You cannot have your own R&D in one silo and in-licensing in another. These competences go together.

Partnership is a skill, a very important skill that you need to develop throughout the organisation. Throughout its history, Sobi has been very good at working with a variety of partners, to achieve good results for everyone.

Partnership is also one of Sobi's values, together with Urgency, Ownership, Ambition and, of course, Care. These are values that I see truly as underpinning the way everyone at Sobi thinks and works. Values are significant only if they are an integral part of a company's culture, and not just words in a presentation or on a piece of paper. Many companies have failed because they have not preserved and nurtured their culture throughout periods of great change. I have confidence in Sobi's culture. It will provide guidance and support for everyone across the company during the challenges and opportunities ahead.

Board supporting growth journey

As well as providing oversight and governance, the Board is also here to support management in developing the company.

To enhance our abilities in these areas, we brought in two new Board members in 2018. David Allsop brings additional commercial competence, and Elisabeth Svanberg strengthens our medical expertise. Their talents help ensure we have a well-rounded, diverse and expert Board.

To wrap up, 2018 was a fantastic year for Sobi. On behalf of the Board, I'd like to thank everyone across Sobi for their commitment and hard work. But this is not the end. It is not even the end of the beginning. We will all need to work hard in 2019 and beyond for Sobi to develop as we know it can. This requires all of us to do our best, no matter where in the organisation we are.

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 2018 financial year is part of Sobi's Directors' 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 Chairman 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 not found that the composition of shareholders justifies any special measures for shareholders being able to take part in 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.

2018 AGM

The AGM was held on 9 May 2018 in Stockholm. The Meeting was attended by 264 shareholders (169), in person or by proxy. This represented 69.6 per cent (65.2) of the total number of votes. Lawyer Eva Hägg was elected to chair the Meeting.

The full minutes and information from the 2018 AGM are available at www.sobi.com.

2019 AGM

The Annual General Meeting will be held on Thursday, 9 May 2019 at Grand Hôtel, Stockholm. More information about the AGM can be found on page 134.

Shareholders, share capital, the share and voting rights

At year-end, Sobi had a total of 23,435 (22,938) shareholders. Investor AB was the largest shareholder, with 39.4 per cent (39.5) of the share capital and 39.4 per cent (39.5) of the votes. The 15 largest shareholders accounted for 73.8 per cent (72.7) of the share capital and 73.8 per cent (72.7) of the votes. No shareholder other than Investor AB has 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 authorisation to the Board of Directors

In order to secure commitments under long-term incentive programmes, the AGM on 9 May 2018 adopted (i) a private placement of redeemable and convertible C shares, (ii) authorisation of 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 144,808 of Sobi's own shares in order to cover some expenses, mainly social security contributions, that may arise due to the 2015 Share 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 2018, Sobi held 3,423,726 ordinary shares in treasury. In 2018, 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 50.

Dividend policy
One of Sobi's most important business objectives is to create long-term shareholder value. This can take the form of increased share value and dividends. 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;
- the dividend's impact on liquidity; and
- the company's equity ratio target.

The Board proposes that no dividend be paid for 2018. 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 regulations
- 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 26 April 2013, the Nomination Committee shall consist of four members: the Chairman of the Board, and one representative from each of the company's three largest shareholders 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 2019 AGM, the Nomination Committee has had the following composition: Petra Hedengran, Investor AB, Nomination Committee Chairperson, Lennart Francke, Swedbank Robur Fonder AB, Javiera Ragnartz, AMF & AMF Funds and Håkan Björklund, Chairman of the Board of Sobi. Prior to the 2019 AGM, the Nomination Committee held two minuted meetings with telephone contact between these meetings. As a basis for its work, the Nomination Committee has taken note of the Chairman's account of the Board's work. The Committee has also prepared recommendations to the AGM regarding Board members, the remuneration of Board and Committee members, the appointment of auditors and their fees, the Chairman of the AGM and changes to the Instructions and Statutes for the Nomination Committee.

3. Board/Chairman 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 and products in various phases of clinical and preclinical development. It is therefore crucial that Board members have extensive, in-depth experience of 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 management, acquisitions, divestments and major investments. The Board approves 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, Chairman 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 Corporate Governance Code as a diversity policy. The objective of the policy is that the Board shall have an appropriate composition with regard to the company's business, stage of development and situation in general, characterised by versatility and breadth in respect of the competence, experience and

Nomination Committee prior to the 2019 AGM

Name/Representing	Votes 31 Dec 2018, %	Votes 31 Aug 2018, %
Petra Hedengran (Chairperson of the Nomination Committee) Investor AB	39.4	39.4
Lennart Francke Swedbank Robur Fonder AB	4.7	4.6
Javiera Ragnartz AMF & AMF Funds	2.6	2.0
Håkan Björklund Chairman of Swedish Orphan Biovitrum AB (publ)	0.0	0.0
Total	46.7	46.0

background of members elected by the AGM, and that efforts shall be made to achieve an even gender distribution. As mentioned in the Nomination Committee's motivated opinion to the 2018 AGM, the Nomination Committee has in its work considered the importance of an effective composition of the Board with regard to diversity, in respect of aspects such as gender, nationality and professional experiences, and considered that it is important to achieve and maintain an even gender distribution. The current composition of the Board of Directors is the result of the Nomination Committee's work prior to the 2018 AGM.

The 2018 AGM resolved in accordance with the Nomination Committee's revised proposal, to the effect that from the 2018 AGM the Board has consisted of eight members elected by the AGM (six re-elected and two newly elected at the 2018 AGM) and two employee representatives appointed by the trade union organisations (plus two deputies for the employee representatives). Three of eight members elected by the AGM are women.

For more information about the Board, refer to pages 116–117.

Resolutions 2018 AGM

The following resolutions were adopted by the 2018 AGM:

- Re-election of six Board members
- New election of two Board members
- Re-election of the Chairman
- Re-election of EY as auditor
- Adoption of remuneration of the Board and auditors
- Adoption of proposed guidelines for remuneration of senior executives
- Board and CEO discharged from liability for the 2017 financial year

Chairman of the Board

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

Independent

The company fulfils 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 111 shows the independence of the Board members on the publication date of this report.

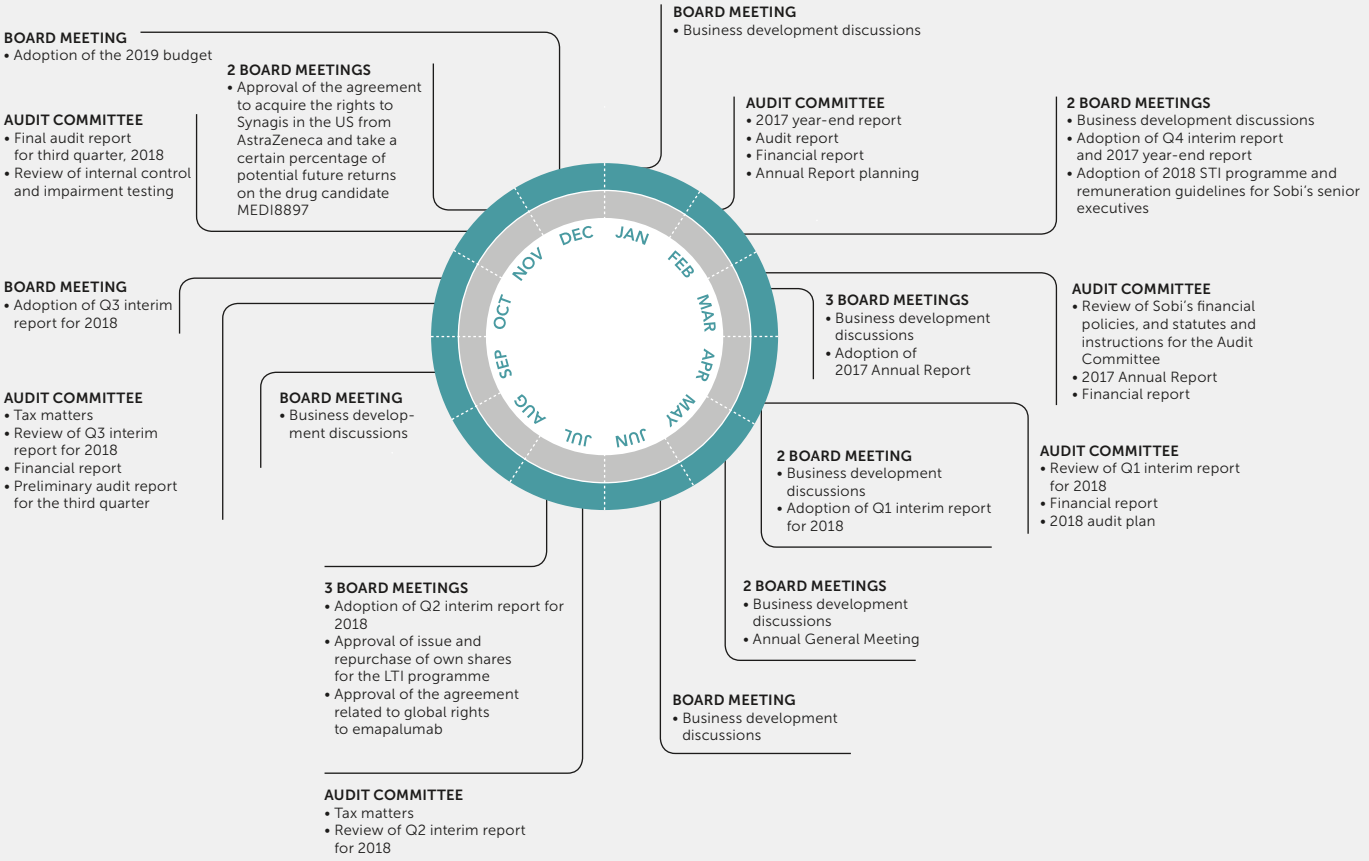
Number of meetings

The Board shall meet at least four to six times a year, usually 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 2019, the Board has scheduled a total of 10 meetings.

The Board's work in 2018

In 2018, the Board held a total of 19 meetings, of which ten were scheduled and nine extra meetings. Sobi's CEO and President attends Board meetings, as does Sobi's General Counsel, who has served as secretary at

Important events in Board work in 2018



the meetings. Other Sobi employees have attended in a reporting capacity. The number of extra Board meetings was motivated by discussions concerning strategic projects. The agenda items are shown in the illustration on page 110.

Board fees

At the AGM on 9 May 2018, the Board resolved that for the period until the next AGM, a fee of SEK 465 K would be paid to each of the AGM-elected Board members except for the Chairman, who would be paid a fee of SEK 1,325 K. Fees for Audit Committee work were adopted as follows: SEK 125 K to the Chairman and SEK 75 K to each of the other members. Fees for the Compensation & Benefits Committee's work were adopted as follows: SEK 80 K to the Chairman and SEK 40 K to each of the other members. Fees for Scientific Committee work were adopted as follows: SEK 80 K to the Chairman and SEK 40 K to each of the other members. In 2018, Board fees of SEK 5,105 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, refer to 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 Chairman initiates and leads the evaluation of the Board's work. The evaluation includes questionnaires and discussions. In 2018, the Board members answered written questionnaires. As part of the evaluation process, the Chairman also held individual discussions with individual Board members. The evaluations were discussed at a Board meeting. The Chairman presented the results of the evaluations for the Nomination Committee.

4. Audit Committee

The Committee's main task is to deal with 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 (Chairman)
- Hans GCP Schikan
- Helena Saxon

Sobi's CFO serves as secretary to 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 elected auditors attended five of the meetings. The agenda items are shown in the illustration on page 110. 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 review and proposals on remuneration of senior executives and recommendations concerning 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 (Chairman)
- Helena Saxon
- David Allsop
- Matthew Gantz

David Allsop and Matthew Gantz were elected to the Compensation & Benefits Committee on 9 May 2018.

Sobi's Head of HR serves as secretary to the Committee, but is not a member. The Compensation & Benefits Committee met five times during the year. At these meetings, the Committee discussed and followed up annual salary revisions and bonus outcome for the CEO and senior executives, and proposed guidelines and allocations 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 2019 for adoption by shareholders. The Board members' attendance and remuneration for Committee meetings is presented in the table below.

		Remuneration, (SEK 000s)						Attendance[1]			
	Independent	Fees	Audit Committee	Compensation & Benefits Committee	Scientific Committee	Other[6]	Total	Board	Audit Committee	Compensation & Benefits Committee	Scientific Committee
David Allsop[4]	x	310	–	27	–	30	367	8/10	–	2/5	–
Håkan Björklund	x	1,308	–	80	–	–	1,388	19/19	–	4/5	–
Annette Clancy	x	452	–	–	80	60	592	19/19	–	–	3/3
Matthew Gantz	x	452	–	27	–	132	610	18/19	–	2/5	–
Lennart Johansson	[2]	452	125	–	–	–	577	16/19[5]	6/6	–	–
Helena Saxon	[2]	452	75	40	–	–	567	16/19[5]	6/6	5/5	–
Hans GCP Schikan	x	452	75	–	40	60	627	19/19	6/6	–	3/3
Elisabeth Svanberg[4]	x	310	–	–	27	40	377	10/10	–	–	2/3
Pia Axelson	[3]	–	–	–	–	–	–	18/19	–	–	–
Bo-Gunnar Rosenbrand	[3]	–	–	–	–	–	–	19/19	–	–	–

1. The figures in the table show the totals for attendance/meetings. In 2018, the Board held a total of 19 meetings, of which ten were scheduled and nine were extra meetings. In 2018, the Audit Committee held six meetings, the Compensation & Benefits Committee held five meetings and the Scientific Committee held three meetings.
2. Board member does not qualify as independent in relation to major shareholders.
3. Employee representative.
4. David Allsop and Elisabeth Svanberg were elected as new, ordinary Board members at the AGM on 9 May 2018.
5. The members have full attendance, but were not permitted to attend three meetings because they are not independent members.
6. 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.

For information about salaries and remuneration of the CEO and senior executives, see Note 11.

6. Scientific Committee

The Scientific Committee's task is to provide advice on scientific matters, to evaluate the company's research strategies and to follow up and report to the Board on scientific trends and new fields of research. The Scientific Committee consists of three members who are all independent in relation to management:

- Annette Clancy (Chairman)
- Hans GCP Schikan
- Elisabeth Svanberg

Elisabeth Svanberg was elected to the Scientific Committee on 9 May 2018.

Sobi's CEO and the Head of Research and Development/Chief Medical Officer took part in the meetings, but are not formal members. The Head of RD/CMO serves as Secretary to the Committee but is not a member.

In 2018, the Committee held three meetings. The following issues were discussed at these meetings:

- Development of the company's R&D pipeline
- R&D organisation
- Review of individual projects
- Review and follow-up of the organisation's objectives
- 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 on page 111.

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 2018, the Executive Committee held one meeting every month For more detailed information about the Executive Committee, refer to pages 118–119.

Each year, the Board defines the division of work between the Board, the Chairman and the CEO. Operational management is based on the decision-making procedure adopted by the Board, which is reflected in the organisational form and governance model according to which Sobi works and is managed.

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 salary component for the CEO is 75 per cent of the annual salary, and 60 per cent for the 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 2019 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:

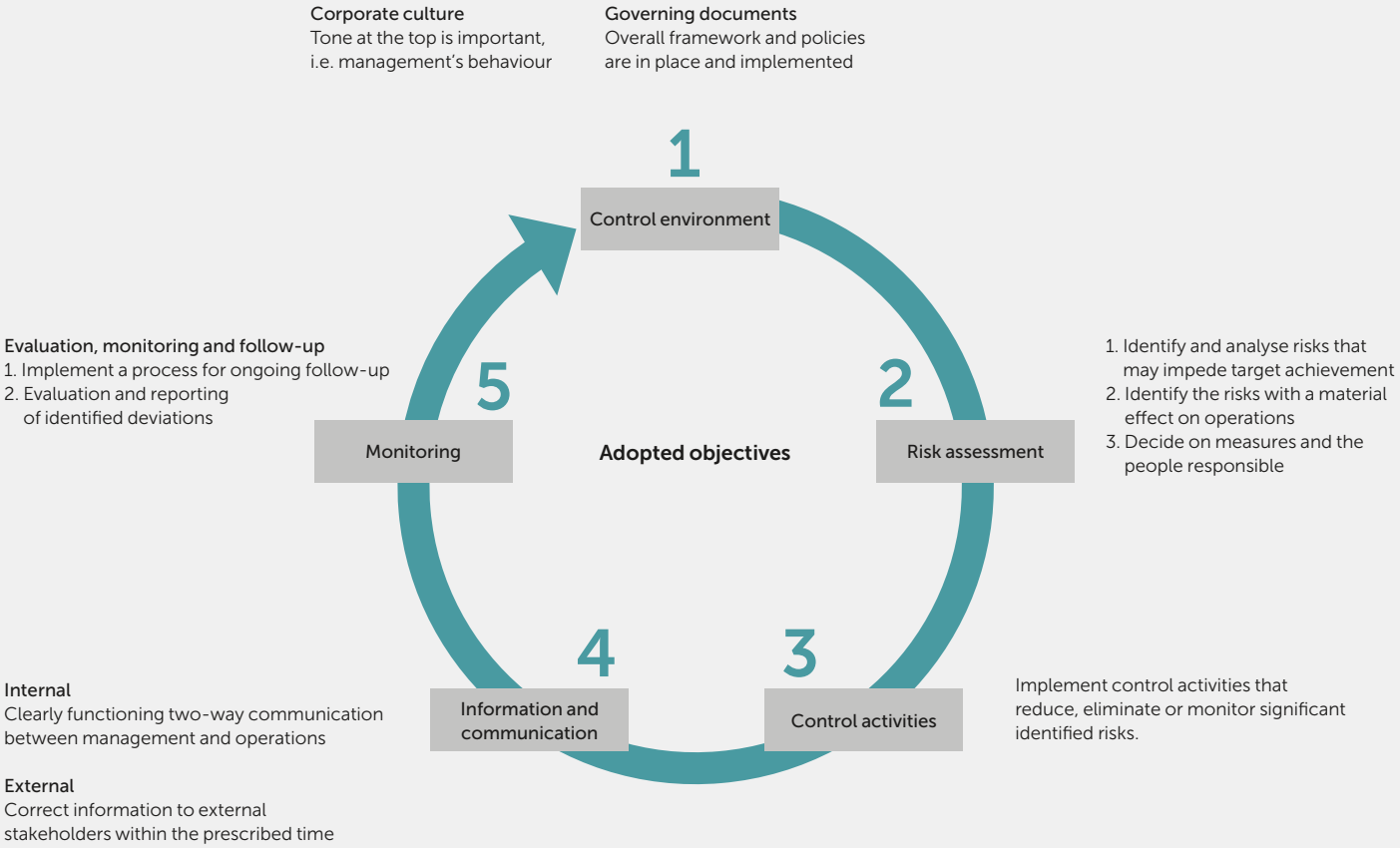
- The Group's mission, vision, strategies, objectives and values.
- Sobi's Code of Conduct and Ethics.
- Organisational structure and descriptions of positions.
- Administrative processes, guidelines and instructions such as authorities, authorisation instructions, risk management policy, purchasing 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. Sobi's risk management process aims to help the company's operations create profitable business opportunities combined with good evaluation of risk, and to ensure and strengthen stakeholders' faith in Sobi, in order to support the operations in executing the defined business strategy. The risk management process contributes with structures and systems to proactively identify and manage risks which could have a negative effect on the business's ability to achieve its set targets. Material risks identified by Sobi are described on pages 58–63

Risk assessment, as part of risk management, is carried out to identify and analyse risks so that decisions can be taken on actions to ensure good control of identified risks and, if required, actions to reduce risk. In terms of this report, the operational units carry out risk assessments together with the responsible controllers, to identify, analyse and ensure a correct evaluation of risks within the accounting and reporting processes.

Sobi's COSO framework



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 measures for identified deficiencies. Activities include analytical monitoring and comparison of financial results, reconciliation of accounts, monitoring, reconciliation of Board decisions, approval and reporting of business transactions and partnership agreements, mandate and authorisation instructions, and accounting and valuation 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 through a variety of control measures, including the monitoring of forecasts and budgets, earnings and balance-sheet analyses, reconciliations, as well as trend analysis and market intelligence. The results of this work are reported 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 management level, then 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 updates on the Group's financial 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 of 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 provided is evaluated regularly. The company's external auditor reports their observations and their assessment of internal control to the Audit Committee.

Activities in 2018 to strengthen internal control

- Developed and launched a digital accounting manual for the Group (Finansportalen).
- Local visits by the internal control function to different chosen subsidiaries.
- Implementation of a new budget system.
- Creation of Group-wide policies.
- Identification of key processes for the finance function.
- Preparation of a new risk-management process for the Group.

Activities in focus for 2019 to further strengthen internal control

- Implementation of the new risk-management process for the Group.
- Monitor and support the Group's accounting functions.
- Continued work to conduct process analyses within the financial function.
- Implement control activities that reduce, eliminate or monitor identified material risks.

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 of the stock exchange on which its shares are traded, or generally accepted practices on the share market.

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 2018 on pages 108-114 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, April 12, 2019
Ernst & Young AB

Björn Ohlsson
Authorised Public Accountant

The board

Lennart Johansson

Born 1955.

Board member since 2010.

MBA from Stockholm School of Economics.

Other appointments: Member of the management team and Senior Advisor at Patricia Industries (division of Investor AB). Chairman of the board of Fastighets AB Tingshuset 13, board member of Vectura Fastigheter AB, HI3G, Chalmers Ventures, Atlas Antibodies AB, Bonesupport AB, and deputy board member of Mölnlycke Health Care.

Previous appointments: Chairman 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: 20,000

Helena Saxon

Born 1970.

Board member since 2011.

MSc from Stockholm School of Economics.

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

Previous appointments: 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

Pia Axelson

Born 1962.

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

Employee Representative.

Laboratory engineer.

Shares: 6,935

Hans GCP Schikan

Born 1958.

Board member since 2011.

Pharm D, Utrecht University.

Other appointments: Chairman of the Board of Directors of Interna, The Netherlands and Complix, Belgium. Member of the Board of Directors of Vicore Pharma, Sweden, Therachon, Switzerland as well as of the Dutch Top Sector Life Sciences & Health, The Netherlands. Advisor to various organisations in Life Sciences & Health.

Previous appointments: 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

Bo-Gunnar Rosenbrand

Born 1963.

Board member since 2006.
Deputy board member 2001–2005.
Representative of the council for negotiation and cooperation.
Employee Representative.

Laboratory engineer.

Shares: 9,759 (including shareholdings of related physicals)

Annette Clancy

Born 1954.

Board member since 2014.

BSc Hons Pharmacology from Bath University UK.

Other appointments: Non executive Chairman of the Board, Enyo SA and Lysogene SA. Member of the Board of Directors, Obseva SA.

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

Shares: 3,414

Håkan Björklund

Born 1956.

Chairman. Board member since 2016.

Ph.D., Associate Professor from Karolinska Institutet in Stockholm.

Other appointments: Industry Executive at Avista Capital Partners.

Previous appointments: CEO of Nycomed. Member of the Board of Directors of several international life science companies including Alere, Coloplast, Danisco, and Lundbeck. Between 2001 and 2007, Håkan Björklund also served as member of the Board of Directors for Biovitrum.

Shares: 15,800

Matthew Gantz

Born 1965.

Board member since 2012.

BA Princeton University and MBA from Harvard Business School.

Other appointments: CEO of OxThera AB. Member of the board for Pennsylvania Life Sciences Association and Marine Corps Scholarship Foundation.

Previous appointments: 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

Elisabeth Svanberg

Born 1961

Board member since 2018.

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

Other appointments: Chief Development Officer at Ixaltis SA in France since 2016. Member of the Board of Directors of PledPharma AB.

Previous appointments: Board member of Follicum AB and of the Swedish American Chamber of Commerce New York. Head of the Established Products Group at Janssen Pharmaceuticals 2014–2016. Head of Medical Affairs for the Intercontinental region at Bristol Myers Squibb (BMS) in the US 2007–20014. Leading roles in R&D for metabolic diseases at Serono International, Switzerland, 2000–2007.

Shares: 260

David Allsop

Born 1963

Board member since 2018.

BSc Hons Chemistry from Coventry University, UK.

Other appointments: Director and sole employee in U-R-NOT Ltd., through which Mr Allsop offers advisory services to the pharma industry.

Previous appointments: More than 30 years' of experience from research as well as marketing within the pharmaceuticals and health care industries. International experience from the pharmaceutical and biotechnology industry and a commercial and general management background. Until January 2018, Head of International in Amicus Therapeutics Ltd. A number of senior positions in Biogen 1998–2015.

Shares: 0

Executive committee


TORBJÖRN HALLBERG


ANNE MARIE DE JONGE SCHUERMANS


GUIDO OELKERS


HEGE HELLSTRÖM


RAMI LEVIN

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 appointments: Chairman of the Advisory Committee of Zentiva Group, Industrial Advisor EQT

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 and Sartorius AG.

Shares: 49,000

Torbjörn Hallberg

General Counsel and
Head of Legal Affairs

Born 1969

Employed since 2018

Master of Laws from University of Lund, Sweden.

Previous positions: VP, General Counsel, Emerging Markets, Takeda Pharmaceuticals. Senior Director and Senior Corporate Counsel, Takeda Pharmaceuticals. Corporate Counsel, Nycomed Pharma. Corporate Counsel, Ferring Pharmaceuticals. Senior Associate/Lawyer, Advokatfirman Lindahl.

Shares: 3,500

Hege Hellström[1]

Head of EMENAR

Born 1965

Employed since 2013

BSc in Bioengineering, Oslo, Norway.

Previous positions: Global Head Cardiovascular, Sanofi, VP Renal Europe and Head of Regional Liaisons, Sanofi. VP Renal and Endocrine Europe, Genzyme. General Manager Benelux, Genzyme. 13 years at Baxter in different leadership roles.

Shares: 60,767

Anne Marie de Jonge Schuermans

Head of Technical Operations

Born 1972

Employed since 2018

PhD from Swiss Federal Institute of Technology Zurich (ETHZ); M.Sc. 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: Biogen, VP for Global Supply Chain Operations & Strategic Partnerships, and Executive Board Member of Biogen International GmbH; more than 15 years of experience in the healthcare industry from Biogen, Stryker and Novartis.

Shares: 0

Rami Levin

Head of North America

Born 1969

Employed since 2014

MBA from Rekanati Business School, Tel-Aviv University, Israel. BSc in Biology, Tel-Aviv University, Israel.

Other assignments: Board of advisors of "Life Science Cares", Corporate alliance member for Global Genes, Corporate council member for the National Organization for Rare Disorders (NORD), Regional chamber representative for the Swedish American Chamber of Commerce.

Previous positions: Various senior roles within Merck since 1998, most recently as VP of Marketing (US). Managing Director Scandinavia, Global Marketing Head, Business Unit Manager. Product Manager, Schering AG.

Shares: 0

1. Christian Dreger (head of Northern Europe, Middle East & Russia), Sofiane Fahmy (Head of Southern and Western Europe & North Africa) and Paula Treutiger (Head of Communications & Investor Relations) was appointed to be part of Sobi's Executive Committee in January 2019. Hege Hellström (Head of EMENAR) resigned from the Executive Committee in January 2019.


NORBERT OPPITZ


HENRIK STENQVIST


PHILIP WOOD


ARMIN REININGER


FREDRIK WETTERLUNDH


MILAN ZDRAVKOVIC

Norbert Oppitz

Head of Specialty Care

Born 1967

Employed since 2017

Business Administration, FH Rhenania Palatina/Mainz, Germany.

Previous positions: Executive Committee member in charge of Latin America, BSN Medical. Executive Committee member Emerging Markets, Endo Pharmaceuticals. Head of Latin America, Takeda/Nycomed. Country management roles at Roche Pharmaceuticals and Aventis Pharma.

Shares: 10,000

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 Hemophilia, Baxter. Head of Global Medical Affairs Hematology, Baxalta. Head of Medical Affairs EMEA Hematology, 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 and MedCap AB.

Previous positions: CFO Recipharm, CFO Meda, CFO Pharmalink, Regional Finance Director AstraZeneca, Finance Director Astra Export &Trading, Financial Manager, Astra Hungary.

Shares: 13,000

Fredrik Wetterlundh

Head of Human Resources

Born 1966

Employed since 2018

Degree in HR Management from the University of Lund, Sweden.

Previous positions: Global Human Resources Lead at Pfizer. Senior HR roles in AstraZeneca, Kraft Foods as well as Codan Group.

Shares: 7,000

Philip Wood

Head of Haemophilia

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.

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 2018. The annual accounts and consolidated accounts of the company are included on pages 50–106 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 2018 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 2018 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the group.

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

Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Key Audit Matters

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters. For each matter below, our description of how our audit addressed the matter is provided in that context.

We have fulfilled the responsibilities described in the Auditor's responsibilities for the audit of the financial statements section of our report, including in relation to these matters. Accordingly, our audit included the performance of procedures designed to respond to our assessment of the risks of material misstatement of the financial statements. The results of our audit procedures, including the procedures performed to address the matters below, provide the basis for our audit opinion on the accompanying financial statements.

Valuation of product and market rights and goodwill

Description	How our audit addressed this key audit matter
Per 31 December 2018 the majority of (57 per cent or SEK 9,485 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 or 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 claw back taxes and discounts exist as conditions for certain products. Net sales are reported after deductions from claw back taxes and discounts. Therefore, an estimate of the unsettled revenue adjustments for claw back taxes and discounts needs to be made at year end. The unsettled revenue adjustments recorded at 31 December 2018 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 30 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.

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 [A-B]. 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 2018 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 2018 and has been the company's auditor since the 8th of May 2014.

Stockholm, April 12, 2019
Ernst & Young AB

Björn Ohlsson
Authorized Public Accountant

Sustainability management

Our sustainability work and programme are based on a number of material sustainability issues. These are divided into two focus areas: Value creation and Our responsibility. These were defined in a materiality analysis we performed in 2016 and updated in 2017 and 2018.

Stakeholders and materiality analysis
In 2016 we performed a comprehensive materiality analysis including web surveys and targeted interviews with internal and external stakeholders to identify and prioritise our most important sustainability issues. Based on input from external stakeholders and an internal analysis of the revised corporate strategy, the materiality analysis was updated in both 2017 and 2018. For 2019 our ambition is to do a more comprehensive update of our materiality analysis, including external stakeholders.

Important external stakeholders that we are listening to:
- Patient organisations
- Families and carers
- Pharmaceutical companies
- Governments and government agencies
- Regulatory authorities
- Healthcare systems
- Budget holders and insurers
- Academic researchers
- Centres of expertise
- Specialist physicians and nurses
- Investors and analysts
- Shareholders

Stakeholders engaging with Sobi discuss the following sustainability areas:

Internal stakeholders
- Access to healthcare and medicine
- Product safety and quality
- Ethics, safety, transparency in clinical trials
- Engagement with patient organisations
- Anti-corruption
- Responsible marketing and sales activities
- Research and development
- Sustainable supply chain
- Diversity and equal opportunity
- Employee recruitment, development, retention

External stakeholders
- Access to healthcare and medicine
- Sustainable supply chain
- Ethics, safety, transparency in clinical trials
- Regulatory and legal environment
- Responsible marketing and sales activities
- Product safety and quality
- Pharmaceuticals in the environment
- Engagement with patient organisations
- Anti-corruption
- Research and development

Sustainability programme

Sobi's overall objective from a sustainability perspective is tied to the overall mission: to contribute to the societies in which Sobi operates by improving access to treatment for rare diseases. True availability and access to treatment for patients is what brings long-term value to the patients we serve, our employees, partners and shareholders.

In 2017 we started to develop a sustainability programme based on Sobi's material sustainability issues. Our ambition is to further develop the programme, include activities and follow-up on our key performance indicators in 2019. The sustainability programme will make it possible for Sobi to follow progress towards the overall sustainability objectives and vision.

Value creation

Read more on our strategic sustainability issues on page 15–17, 30–31 and 34–35.

Material issue	Description	Sustainability objectives	Key performance indicator
Improving global access to treatments for rare diseases	Our aim is to make our treatments accessible to an increasing number of people around the world, as well as shorten the time it takes for products to reach patients. This requires a strong focus on patient and medical needs, responsible pricing, adaptive regulatory pathways, partners for manufacturing, and an extensive and efficient distribution network.	Ensure that Sobi's products are made available to patients through local healthcare budgets.	Products receiving regulatory approval, pricing and reimbursement in new markets.
Strategic research and development	Research and development are of high strategic importance in order to improve our treatments. We strive to maintain the highest ethical, technical and scientific standards. Our approach is holistic and we work closely with patients throughout their lives, and collaborate with academia, partners and governments to find new solutions and technologies. We secure intellectual property rights and reinvest in the development of new innovative treatments.	Invest in R&D to build pipeline.	Amount of investment in R&D in relation to revenue. Development of pipeline e.g. number of projects moving into clinical phase during 2019.
Quality and supply chain management	The quality and supply of our products are essential to enable global access to treatments. Since Sobi market and sell products in more than 70 countries, typically in small volumes aimed for a small number of patients, patient safety as in both quality and access is fundamental. We have built a robust supply and distribution processes covering all our markets to ensure that patients never risk being without their medication, which in some cases can be life-threating.	Our products are to improve the lives of rare disease patients and their families.	Number of suppliers subject of audits applying under the GMP/GDP guidelines. Percentage of significant product and service categories for which drug safety impacts are assessed for improvement.
We make it happen	Sobi's employees are the enablers that allow us to achieve our mission of transforming the lives of people with rare diseases and delivering on a strategy for increasing growth. It is our everyday behaviour and achievements that matter the most in shaping the future of our company. In the organisation we focus on developing strong leadership, culture-supported performance, equal opportunities and professional development for everyone, and a safe and healthy workplace.	Engaged and skilled people who are offered a safe and developing workplace free from discrimination.	Employee turnover in percentage. Average hours of training per year per employee.

Our responsibility

Read more on our responsibility issues on pages 40–41.

Material issue	Sustainability objectives	Key performance indicator
Regulatory and legal environment	Always be compliant with laws and regulation.	Percentage of employees who have completed education in Sobi's Code of Conduct and Ethics.
Ethical practices and collaborations	Always be compliant with Code of Conduct and Ethics.	
Patient and customer privacy	Always secure patient privacy.	
Anti-corruption and fair competition	Always be compliant with laws, regulations Code of Conduct and Ethics.	
Responsible tax	Paying taxes where profits are earned.	Margin where profit is earned.
Environmental impact	Reduce Sobi's environmental impact.	Reduced water and power consumption in relation to production.

Sustainability governance and organisation

Sobi's Board of Directors holds 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 approves Sobi's sustainability programme, ensures compliance, and decides on overall objectives and implementation of the sustainability programme.

All sustainability activities are guided by the Code of Conduct and Ethics and the other sustainability related policies. The Head of Communications and Investor Relations is responsible for communication and operationalisation of the programme in close collaboration with the business units.

Compliance risks and management

Compliance risks and the assessment of their impact are an integral element of Sobi's risk management process. In the compliance risk table, material risks are identified in relation to our responsibility issues in the sustainability strategy. For a description of our general Sustainability risks and the areas of our compliance risks that coincide with operational risks, see pages 58–63.

Sustainability performance 2018

Sobi is committed to report on progress regarding material issues related to economic, social and environmental performance. The sustainability notes found below complement the performance reporting found in the Sustainability section of this report. Reported data covers all Sobi's business operations unless otherwise stated.

Sustainability notes

Economic Performance

Direct Economic Value Generated

SEK 000s	2018
Revenues	9,138,892
Operating costs	3,601,156
Employee wages & benefits	1,091,654
Payments to providers of capital	14,577
Payments to government[1]	20,185
Community investments[2]	3,732

Calculation is based on the consolidated statement of comprehensive income 2018.

1 Costs to governmental health care agencies whereof the largest i FDA and EMA.
2. Community investments is based on costs to support to Patients Organisations during 2018, the three largest ones consists of European Haemophilia Consortium (EHC), Irish Haemophilia society and EURORDIS, Rare Disease Europe.

Indirect economic impact

NUMBER	2018	2017	2016
Total MIUs delivered	362	262	146
Total patients treated	16,885	15,072	12,311
Acute bleeds treated	37,896	40,557	33,876
Surgeries	461	709	719
Paediatric patients, %	39	39	28

Sobi and Sanofi have pledged to donate up to 1 billion IUs of coagulation factor to humanitarian aid between 2015–2025.

500 million IUs have been allocated in support of the World Federation of Hemophilia's (WFH) humanitarian aid work. Sobi's indirect economic impact is reported in accordance with the WFH:s progress report for this programme. The impacts are the result of Sobi's and Sanofi's contribution to the programme.

In developing countries and growth markets, Sobi works in collaboration with regulators and international patient organisations to meet humanitarian needs. Sobi donates drugs to patients with rare diseases in cases where humanitarian aid has been considered necessary.

Environmental Performance

Carbon dioxide emissions (CO_2)

METRIC TONNES	2018	2017	2016
Indirect emissions from energy	213	221	222
Emissions from travel	1,110	983	1,112

Reported emissions reflects only operations in Sweden, comprising just over half of Sobi employees. Travelling emissions include emissions from business travel and company cars.

Waste

METRIC TONNES	2018	2017	2016	2015	2014
Recycled waste	24	50	46	68	52
Hazardous waste	18	22	16	13	13
Landfill	0.1	0.1	0.0	1.6	0.1
Total waste	**42**	**72**	**62**	**82**	**65**

Waste reporting is based on Sobi's facilities in Solna and Stockholm, Sweden. Waste data does not include waste from marketing and sales offices.

Social performance

Employees per region 2018

REGION	New employee hires	Female	Male	Employees 2018
Sweden	77	324	172	496
EMENAR (Europe, Middle East, North Africa, Russia) (excluding Sweden)	93	196	158	354
North America (USA & Canada)	44	45	40	85
Total	**214**	**565**	**370**	**935**[1]

1. Per year-end 2018, the number of full-time equivalent employees was 902, while the number of persons employed at the same date was 935.

New hires

	Female				Male				
REGION	Under 30 years old	30–49 years old	50 years and older	Female Total	Under 30 years old	30–49 years old	50 years and older	Male Total	Total
Sweden	7	33	11	51	3	14	9	26	77
EMENAR (Europe, Middle East, North Africa, Russia) (excluding Sweden)	7	38	10	55	3	29	6	38	93
North America (USA & Canada)	1	16	6	23	1	16	4	21	44
Total	**15**	**87**	**27**	**129**	**7**	**59**	**19**	**85**	**214**

Turnover 2018

EMPLOYEES	2018	2017
Number of employees[1]	935	812
Departures	109	90
Turnover	11.6%	11.1%

1. Mean number of employees during the year, including only permanent contracts.

Employees and contract type 2018

EMPLOYEES	Male	Female	Total
Permanent contract	363	549	912
Temporary contract	7	16	23

EMPLOYEES	Sweden	Other region	Total
Permanent contract	482	430	912
Temporary contract	14	9	23

Employee numbers are expressed as head count. Sobi has no employees working part-time. Some employees have been granted a part-time equivalent employment type due to issues such as child care.

All employees in the Swedish operations (representing approximately 57 per cent of all employees) are covered by collective bargaining agreements.

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.

Alprolix®
EU – indicated for the treatment and prophylaxis of bleeding in patients with haemophilia B (congenital factor IX deficiency). Alprolix can be used for all age groups.

Elocta®
EU – indicated for the treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency). Elocta can be used for all age groups.

Gamifant®
US – (emapalumab-lzsg) is an interferon gamma (IFNγ)–blocking antibody indicated for the treatment of adult and pediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy.

Kineret®
EU and Australia – indicated in adults for the treatment of the signs and symptoms of rheumatoid arthritis (RA), in adults, adolescents, children and infants aged 8 months and older for the treatment of CAPS and in adults, adolescents, children and infants aged 8 months and older for the treatment of Still's disease.

USA – indicated in adults for the treatment of the signs and symptoms of RA, and the treatment of neonatal-onset multisystem inflammatory disease (NOMID).

Canada – indicated for the treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) in adults, adolescents, children and infants aged eight months and older and for active RA in patients 18 years of age or older.

Orfadin®
EU and Canada – indicated for the treatment of adult and paediatric (in any age range) patients with confirmed diagnosis of hereditary tyrosinemia type 1 (HT 1) in combination with dietary restriction of tyrosine and phenylalanine.

US and Australia – indicated for the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

	Approval (A), Pricing (P) and Reimbursement (R)					
Region	Alprolix	Elocta	Kineret	Gamifant	Orfadin capsules	Orfadin oral suspension
EU and EFTA states	A	A	A	MAA submitted to EMA August 2018	A	A
Austria	APR	APR	APR		APR	APR
Belgium	APR	APR	APR		APR	APR
Bulgaria	APR	APR	APR		APR	APR
Croatia	A	APR	APR		APR	APR
Cyprus	A	A	AR		A	A
Czech Republic	A	APR	APR		APR	AP
Denmark	APR	APR	APR		APR	APR
Estonia	A	A	AR		AR	AR
Finland	A	APR	APR		APR	APR
France	APR	APR	APR		APR	APR
Germany	APR	APR	APR		APR	APR
Greece	APR	APR	APR		APR	APR
Hungary	APR	APR	APR		AR	AR
Iceland	A	A	APR		APR	APR
Ireland	APR	APR	APR		APR	APR
Italy	APR	APR	APR		APR	APR
Latvia	A	A	AR		A	A
Liechtenstein	APR	APR	APR		APR	APR

	Approval (A), Pricing (P) and Reimbursement (R)					
Region	**Alprolix**	**Elocta**	**Kineret**	**Gamifant**	**Orfadin capsules**	**Orfadin oral suspension**
Lithuania	A	A	APR		APR	A
Luxembourg	APR	APR	APR		APR	APR
Malta	A	A	A		A	A
Netherlands	APR	APR	APR		APR	APR
Norway	APR	APR	APR		APR	APR
Poland	A	APR	APR		APR	AP
Portugal	A	APR	APR		APR	APR
Romania	AP	AP	A		APR	A
Slovakia	APR	APR	APR		APR	APR
Slovenia	APR	APR	APR		APR	AP
Spain	A	APR	APR		APR	APR
Sweden	APR	APR	APR		APR	APR
UK	APR	APR	APR		APR	APR
Europe – other						
Russia					APR	APR
Switzerland	APR	APR	APR		APR	APR
Turkey						
Ukraine					APR	APR
North America						
Canada			APR		APR	
Mexico					APR	APR
US			APR	APR	APR	
Asia						
Kuwait	APR	APR				
Israel			APR		APR	APR
Japan					APR	APR
Saudi Arabia	APR	APR			APR	APR
United Arab Emirates	APR	APR				
Africa						
Algeria					APR	
Jordan					APR	
Tunisia					APR	APR
South America						
Argentina					APR	
Chile					APR	
Australia			APR		APR	

Global Reporting Initiative Index

Sobi's Sustainability Report 2018 is defined in the GRI Index below. Its main components are found in the following sections of the Annual and Sustainability Report 2018:

- Business Model is found in the section Sobi's Value Creation, pages 12–13.
- Description of sustainability approach, activities and performance 2018 are found on pages 15–17, 30–31 and 34–41.
- Information on objectives and targets on Sustainability issues is reported in the Sustainability management section and non-financial notes, on pages 123–129.
- Information on the structure of the Sustainability Report is found in the section Sustainability Management, on pages 123–129.

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. The 2018 sustainability report was published in April 2019.

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 pages 123–125. All page references below refer to pages in Sobi's 2018 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 Sustainability Report, please contact info@sobi.com.

GRI Standard	Disclosure	Page reference	Comment	UN Global Compact
STANDARD DISCLOSURES				
Organisational Profile				
GRI 102: General Disclosures	102-1 Name of the organisation	74		
	102-2 Activities, brands, products, and services	2–5, 10–14, 52		
	102-3 Location of headquarters	74		
	102-4 Location of operations	15–17, 34–35, 82, 97		
	102-5 Ownership and legal form	74		
	102-6 Markets served	128–129		
	102-7 Scale of the organisation	2–5, 82		
	102-8 Information on employees and other workers	85		Principle 6
	102-9 Supply chain	34–35		
	102-10 Significant changes to the organisation and its supply chain	6–7		
	102-11 Precautionary Principle or approach	40–41, 58–63		
	102-12 External initiatives	40–41, 58–63		
	102-13 Membership of associations		See www.sobi.com for current list of memberships.	
Strategy				
GRI 102: General Disclosures	102-14 Statement from senior decision-makers	6–7, 49		
Ethics and Integrity				
GRI 102: General Disclosures	102-16 Values, principles, standards, and norms of behaviour	36–37, 56		Principle 10
Governance				
GRI 102: General Disclosures	102-18 Governance structure	108–113, 125		
Stakeholder Engagement				
GRI 102: General Disclosures	102-40 List of stakeholder groups	123		
	102-41 Collective bargaining agreements	127		
	102-42 Identifying and selecting stakeholders	123–125		Principle 3
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Auditor's report on the statutory sustainability statement

To the general meeting of the shareholders of Swedish Orphan Biovitrum AB (publ), corporate identity number 556038-9321

Engagement and responsibility
The Board of Directors are responsible for the statutory sustainability statement for the year 2018 on pages 12–13, 15–17, 30–31, 34–41, 58–63 and 123–133 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, April 12, 2019
Ernst & Young AB

Björn Ohlsson
Authorized Public Accountant

2019 Annual General Meeting

2019 Annual General Meeting
Swedish Orphan Biovitrum AB (publ) will hold its Annual General Meeting on Thursday, 9 May 2019, in Grand Hôtel, S. Blasieholmshamnen 8, 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 Friday 3 May 2019. Shareholders must notify the company of their intention to participate no later than Friday, 3 May 2019 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 Friday, 3 May 2019. 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 2019

January–March Interim Report	25 April
Annual General Meeting	9 May
Capital markets day	14 May
January–June Interim Report	17 July
January–September Interim Report	31 October

The Annual Report can be downloaded in PDF format from www.sobi.com, as well as previous annual reports, interim reports and press releases.

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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 revenues less cost of goods and services sold.

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.

EBITDA
Earnings before interest, tax, depreciation and amortisation.

Equity per share
Equity divided by the number of shares.

Equity ratio
Equity divided by total assets.

Gross margin
Gross profit as a percentage of sales.

Net cash (–)/debt (+)
Interest-bearing non-current and short-term liabilities minus cash and bank balances.

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 (0.66%) plus Beta (1.31) multiplied with a risk premium (6.36). 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 22% 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, which can be used by people of all ages.

Acute gout
An autoinflammatory disease and intensely painful and disabling inflammatory arthritis involving one or several joints. Gout is also a disease associated with multiple comorbidities, which may limit the use of some conventional treatment regimens.

AnaGO
A randomised double-blind, multicentre phase 2 study conducted in North America which studied two dose levels of anakinra in comparison to intramuscular triamcinolone for the treatment of acute gout.

AnaSTILLS
A randomised, double-blind, multicentre study being conducted in North America studying two subcutaneous dose levels of anakinra, in comparison to placebo for the treatment of Still's disease.

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.

CHMP
The Committee for Medicinal Products for Human Use at the European Medicines Agency.

EC
European Commission.

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, which can be used by people of all ages. 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.

EMENAR
Abbreviation for business region including Europe, Middle East, North Africa and Russia.

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. An application to the EMA was submitted in August 2018.

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 infection, 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
A single dose extended half-life anti-RSV F monoclonal antibody being developed for the prevention of lower respiratory tract infections (LRTI) caused by RSV in all infants entering their first RSV season[1] and children with chronic lung disease or congenital heart disease entering their first and second RSV season. Engineered to have a long half-life so that only one dose will be needed for the entire RSV season, MEDI8897 is being developed for passive immunisation of a broad infant population.

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.

ReITIrate
An open-label, multicentre study designed to investigate the 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.

SOBI003
A product candidate and a chemically modified variant of a recombinant human sulfamidase, using Sobi's proprietary glycan modification technology Modifa™, 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 LRTI caused by RSV 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 that acts as a prophylaxis against serious RSV disease. It is the only medicine approved for the prevention of serious RSV disease.

UCD
Urea cycle disorders are a group of serious conditions in which patients suffer from deficiencies in the enzymes required to remove ammonia from the blood stream.

XTEN
XTEN is a technique used to extend the half-life of proteins.

WFH
World Federation of Hemophilia, an international not-for-profit organisation.

1. The RSV season usually occurs from early fall until late spring and peaks during the winter.

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