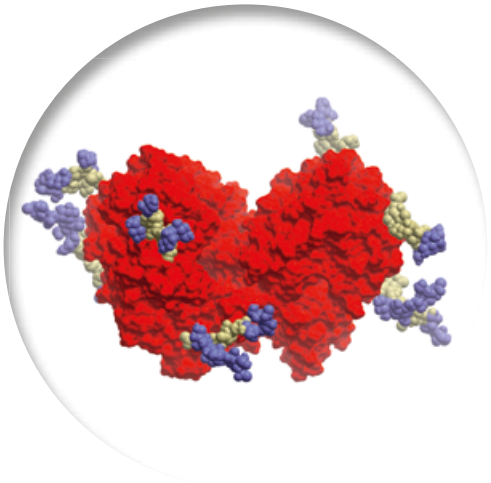
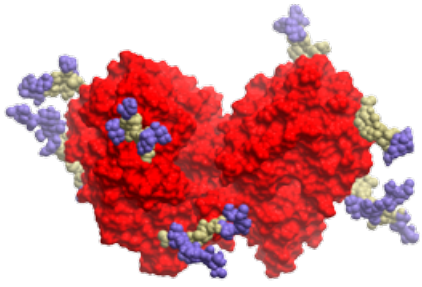
sobi
Pioneer in Rare Diseases



# Building on our strengths

ANNUAL AND SUSTAINABILITY REPORT 2017

**Forward-looking statements**
This report includes forward-looking statements. Actual results may differ from those stated. Internal factors such as the successful management of research programmes and intellectual property rights may affect future results. There are also external conditions such as the economic climate, political changes and competing research programmes that may affect Sobi's results.



Sobi™ is an international biotechnology company dedicated to rare diseases.

Our mission is to transform the lives of people with rare diseases by providing innovative therapies in our focus areas."

Guido Oelkers, CEO

# Contents



This is Sobi's Annual and Sustainability Report 2017. The audited Annual Report includes pages 56–107. The Sustainability Report is found on pages 12–13, 36–47, and 123–132 and consist of the Company and the Group's legally required sustainability report according to the Annual Accounts Act, 6 chap. 11§ .

## INTERVIEW 8

**CEO and Chairman**

Sobi operates throughout the entire value chain, from early research, over to clinical development and into the commercial market. "We can add significant value to our partnerships by leveraging all our competencies, making us the partner of choice for a range of companies with innovative products", says Guido Oelkers, CEO.

## STRATEGY 10

Sobi's growth strategy builds on the company's strengths and aims to capitalise on the potential in haemophilia and the rare disease areas. We also aim to strengthen our pipeline and build a foundation for self-sustained R&D.

# HAEMOPHILIA


Sobi introduced recombinant extended half-life factor products to Europe in 2016 and the Middle East in 2016–2017. The products have been well received in the haemophilia community.

# INNOVATION


Building on a strong legacy in biotechnology, Sobi aims to have a transformational impact in the rare-disease space.

# SPECIALTY CARE 22

Sales for the newly formed business area Specialty Care reached SEK 2,829 M in 2017. Sobi is exploring several opportunities for growth that build on the company's strengths in patient-centric development and commercialisation.


# SUSTAINABILITY

# REPORTING 54

Our rapid growth continued throughout 2017, with a remarkable financial performance and a resulting strong financial position.

# This is Sobi

Sobi is an international rare-disease company dedicated to making a significant difference for individuals with rare diseases by providing access to innovative treatments.

## OUR VISION

To be recognised as a global leader in providing access to innovative treatments that make a significant difference for individuals with rare diseases.

## OUR MISSION

We transform the lives of people with rare diseases by providing innovative therapies in our focus areas.

We are growing our haemophilia business to become a leading player in the EMENAR[1] region.

We look to become the preferred partner for the development and commercialisation of products in specialty care.

We continue to identify and develop innovative treatments through a self-sustained R&D organisation funded by growth in our business areas.

1. Europe, Middle East, North Africa and Russia.

**Strong and growing portfolio**
We operate through two business areas: Haemophilia and Specialty Care. Our research and product portfolio is primarily focused on haemophilia and specialty care, including inflammation and genetic and metabolic diseases. In Haemophilia, we aim for a leadership position in Europe, the Middle East and North Africa. In Specialty Care, we aim to grow our portfolio to leverage our competence in rare-disease and niche indications, and thereby build on the capital generated in Haemophilia.

**Integrated biotechnology company**
As an integrated biotechnology company, we have in-house capabilities that encompass the entire value chain, from research, through preclinical and clinical development, biologics manufacturing and supply, regulatory affairs to patient access and distribution. The integrated approach is a prerequisite for providing proprietary drugs, and an enabler for partnerships throughout all stages of drug development.

**Preferred partner**
With our dedication and strong capabilities across the entire value chain, proven track record of bringing rare-disease products to the complex European market through a multi-faceted environment, and a demonstrated inherent ability to grow our North American portfolio, we aim to become the preferred partner for pharmaceutical companies with strong franchises and promising drug candidates in rare-disease and niche indications.

**Growing international presence**
With our head office in Stockholm, Sweden, the Sobi organisation spans 19 countries, delivering treatments to patients in over 70 countries across the globe. Europe is the core market for the Haemophilia franchise. The Sobi strategy for growth is aimed at balancing this geographic footprint by expanding Specialty Care in other markets including North America.

**Win-win collaborations**
We put the needs of patients first, in the knowledge that this will create long-term, sustainable value for everyone. Through strategic partnerships with multiple stakeholders, we believe it is possible to create a win-win environment for all parties – patients, healthcare systems, budget holders, our employees, investors and the pharmaceutical industry – and deliver new treatments to patients.

**Responsible pricing**
An effective treatment is one that not only provides a medical benefit but is also both available in the country where the patient lives and is affordable in the healthcare system. One of the most crucial factors to ensure patient access to treatment is responsible pricing. That means balancing the role of a sustainable company with being a sustainable part of the healthcare system.

**Partnership is key**
In 2017, the European Commission authorised 14 medicines with an orphan designation and the US Food and Drug Administration (FDA) approved 18 new orphan drugs. The main driver of this growth is successful legislation, combined with technological and scientific advancements, academic partnerships and the increasing availability of infrastructure, together with patient-led international collaborations which have helped to spur momentum worldwide.

**An urgent need for treatments for rare diseases**

A rare disease affects a small percentage of the population, and is often serious, life-threatening or chronically debilitating. Many rare diseases manifest in childhood, and are present throughout a person's life. The causes of many rare diseases remain unknown, and they are often not curable with current interventions or medications; this results in a substantial unmet medical need and immense costs for healthcare systems, societies and families. In Europe and North America, an estimated 60 million people are impacted by one of approximately 7,000 known rare diseases.

The rarity of each disease, the extreme variability of the clinical manifestation, the common effects on different organs and the lack of broad recognition of the diseases often result in delayed diagnosis, a lack of medicinal products and restricted access to care. That is why rare diseases are a prime example of an area that can benefit from collaboration between academia, authorities, healthcare providers, patient advocacy groups and drug development companies. Legislation in the European Union, the United States and other regions aims to stimulate research and development, and the availability of treatments for rare conditions.

# Year in brief

## 2017

- Guido Oelkers appointed President and CEO.
- Total revenues increased to SEK 6,511 M (5,204), an increase of 25 per cent.
- Total product revenues increased to SEK 5,917 M (4,548), an increase of 30 per cent.
- Gross margin increased to 72 per cent (70).
- EBITA amounted to SEK 2,053 M (1,543).
- Ended the year with a cash position of SEK 1,478 M (786).

### NEW LEADERSHIP

Guido Oelkers succeeded Geoffrey McDonough as President and Chief Executive Officer in May 2017. A new leadership structure was introduced during the year as an Executive Committee replaced the former Executive Leadership Team as the Group's decision-making body.

The new Executive Committee includes Norbert Oppitz as new Head of Specialty Care; Armin Reininger as Head of Medical and Scientific Affairs and Torbjörn Hallberg as new General Counsel and Head of Legal Affairs assuming his position in 2018. The Head of EMENAR Hege Hellström; Head of North America Rami Levin and Head of Haemophilia Philip Wood, were all promoted to the Executive Committee. The two remaining committee members are Milan Zdravkovic as Head of Research & Development and Chief Medical Officer, and Mats-Olof Wallin as Chief Financial Officer.

### Key figures

| SEK M | 2013 | 2014 | 2015 | 2016 | 2017 |
|---|---|---|---|---|---|
| Total revenue[1] | 2,177 | 2,607 | 3,228 | 5,204 | 6,511 |
| Gross profit | 1,284 | 1,548 | 2,007 | 3,651 | 4,657 |
| Gross margin, % | 59 | 59 | 62 | 70 | 72 |
| Operating expenses | 1,351 | 1,873 | 1,861 | 2,518 | 3,057 |
| EBITA | 211 | –44 | 433 | 1,543 | 2,053 |
| EBIT | –67 | –325 | 146 | 1,133 | 1,600 |
| Profit/loss for the year | –92 | –270 | 83 | 802 | 1,149 |
| Earnings per share, SEK | –0.35 | –1.01 | 0.31 | 2.99 | 4.27 |
| Cash flow from operations | 185 | 234 | 507 | 343 | 1,333 |
| Equity per share, SEK | 17.5 | 16.6 | 17.3 | 19.8 | 24.6 |
| Equity assets ratio, % | 73 | 71 | 56 | 54 | 61 |
| Dividend | 0 | 0 | 0 | 0 | 0 |
| No. of employees (full-time equivalent) | 546 | 589 | 702 | 760 | 800 |

1. Full-year 2016 revenue includes a one-time credit in Q1 of SEK 322 M relating to the first commercial sales of Elocta, and a one-time credit in Q2 of SEK 386 M relating to the first commercial sales of Alprolix.

### Revenue, Business area

Haemophilia

SEK 3,088 M

Specialty Care

SEK 2,829 M

## Business highlights Haemophilia

- Outstanding sales growth.
- Elocta® launched in 22 countries, Alprolix® launched in 14.
- Long-term improvements in joint health demonstrated for haemophilia A patients after prophylactic treatment with Elocta.
- Higher capacity of drug substance-manufacturing for Elocta approved by the EMA.
- Elocta and Alprolix approved in Saudi Arabia. Alprolix approved in Kuwait.
- New dosing regimen for Alprolix to dose 14 days or longer was approved by the European Medicines Agency (EMA).
- The first patients were enrolled in the RelTIrate study evaluating immune tolerance induction with Elocta.

## Business highlights Specialty Care

- The business area Specialty Care was established in Q2.
- Double-digit growth for Kineret® and Orfadin®.
- Solid uptake of the new oral suspension and 20 mg capsule formulations of Orfadin.
- New Orfadin formulations approved in Saudi Arabia, Canada, Algeria and Tunisia.
- Orfadin once-daily dosing approved in the EU and US.
- Kineret approved in Canada for the treatment of NOMID.

## Business highlights Pipeline

- First patient randomised in the anaGO study to evaluate efficacy and safety of anakinra for the treatment of acute gout.
- First patient randomised in the ana-STILL's study evaluating safety and efficacy of anakinra in the treatment of Still's disease.
- FDA granted orphan drug designation for SOBI003 for the treatment of MPS IIIA.
- Haemophilia development portfolio expanded by adding rFIXFc-XTEN to the collaboration agreement with Bioverativ (now a Sanofi company).
- Bioverativ initiated phase 1/2 trial with next generation EHL product in haemophilia A, rFVIIIFc-VWF-XTEN (BIVV001).

### Overview of most important products by revenue

| SEK M | 2017 | 2016 | Change |
|---|---|---|---|
| **Haemophilia** | | | |
| Elocta | 1,557 | 267 | 483% |
| Alprolix | 363 | 60 | 500% |
| Royalty[1] | 1,168 | 1,525 | –23% |
| **Total** | **3,088** | **1,853** | **67%** |
| **Specialty Care** | | | |
| Orfadin | 862 | 770 | 12% |
| Kineret | 1,142 | 1,001 | 14% |
| Xiapex | 164 | 153 | 7% |
| Other | 661 | 772 | –14% |
| **Total** | **2,829** | **2,695** | **5%** |
| **ReFacto** | | | |
| ReFacto | 559 | 569 | –2% |
| Royalty | 34 | 88 | –61% |
| **Total** | **594** | **656** | **–10%** |
| **Grand total** | **6,511** | **5,204** | **25%** |

**Haemophilia:**
**Elocta** is used to treat haemophilia A and **Alprolix** to treat haemophilia B.

**Specialty Care:**
Proprietary products or products where Sobi has global or regional rights. Includes **Orfadin** for treatment of hereditary tyrosinaemia type 1 (HT-1) and **Kineret** for the treatment of autoinflammatory conditions. **Xiapex®** is approved for the treatment of Dupuytren's contracture and Peyronie's disease in the EU and marketed by Sobi on behalf of Endo Pharmaceuticals. Sobi also markets some 30 products on behalf of partners in Europe, the Middle East, North Africa and Russia.

**Manufacturing**
Sobi has been manufacturing the active ingredient in the haemophilia treatment **ReFacto AF®** for the global market on behalf of Pfizer for almost 20 years.

# Interview with CEO and Chairman

## Building on our strengths

"There will be a stronger focus on execution and external growth."

*Guido Oelkers, CEO*

**How would you describe 2017?**

***Håkan Björklund (HB):*** It was a very good year for Sobi, a year in which we saw a significant increase for Alprolix and Elocta. It was also a year when we changed CEO. Geoffrey McDonough made an amazing effort guiding Sobi to the very strong position we have today, something for which I am very grateful. Now we are gearing up with Guido Oelkers as new CEO with the aim of taking the company to its next phase. It really has been an exciting year.

***Guido Oelkers (GO):*** Sobi has a great team in place that has delivered tremendous growth over the past year. Group revenues increased by 25 per cent to SEK 6,511 M with an organic growth of 45 per cent, excluding one-time items.

The two haemophilia products, Elocta and Alprolix, have shown stellar performance with 487 per cent growth in sales, and they still hold great promise. We have formed a new Specialty Care unit that has a very attractive position in the industry from which it can grow.

In 2018, we expect to continue to deliver significant growth and achieve revenues of SEK 7,500 to 7,700 M[1].

**In what way has a new CEO affected the company and what should be expected going forward?**

***HB:*** A new CEO will always make changes and there have been quite a few already. They have been positive ones, but a high-paced environment puts pressure on the organisation. Growing a company is a team effort, and we have been very successful so far.

Guido and I have a close dialogue, but it is his task to execute on the strategy that the Board has adopted. He is a very active person, so we will see more things happening over time. I expect Sobi to continue to develop organically and through in-licensing, collaborations and acquisitions.

**Guido, what attracted you to Sobi and what are your main aspirations for the company?**

***GO:*** Sobi is a biotech company that has managed to transition from a company with assets primarily in the development stage into a successful commercial company. That attracted me. We have a commercial as well as an innovation platform from which we can grow and become recognised as a global leader.

One of our main ambitions in the longer term is to achieve self-sustained R&D, with proprietary products that are able to propel the company, something that both requires and results in further growth. We need to identify and develop new, effective treatments.

In Haemophilia, our near-term focus will be on commercial effectiveness and further expansion across our territories.

In Specialty Care, our aim is to develop the unit into the preferred partner for pharmaceutical companies with drugs that can really make a difference for individuals with rare diseases.

We have learnt a lot during our years as a pioneer in the rare-disease space that other companies can benefit from.

An important aspect is the fact that Sobi operates throughout the entire value chain, from early development and biological manufacturing, over to clinical development and into the commercial market. We know how to navigate regulatory affairs and how to form fruitful relationships with the research and medical communities. We can add significant value for our partners by leveraging all our competencies, which should make us the partner of choice for a range of companies with innovative products.

**What were the main achievements in 2017?**

***GO:*** We have achieved a successful launch of Elocta and Alprolix, and established a good position for the products in our main markets. Our track record of very strong quarter-on-quarter growth shows that we have managed to deliver consistently on our launch strategy.

We have also managed the patent expiry of Orfadin well. Building on our understanding of patient needs and the relationships we have formed over the years, we have been able to achieve double-digit growth even during a rather challenging year.

We have also seen double-digit growth for Kineret and have identified potential for further significant expansion. We started studies in acute gout and Still's disease – indications that explore the great potential of IL-1 inhibition and that, if the results are positive, can become very important additions to the product.

1. The outlook was published on 22 February 2018.

Another exciting development is the initiation of our inhibitor study with Elocta, named RelTIrate. Our aim here is to eliminate inhibitors. Should we be successful in demonstrating this, it will be important news because it would significantly improve and facilitate treatment for patients who develop inhibitors.

Overall, the company is in very good shape. We have profitable growth and we are in a strong position to continue to grow and strengthen our business.

**What are the main priorities for 2018?**

***HB:*** Elocta and Alprolix – the main priority is to increase sales in existing and new markets.

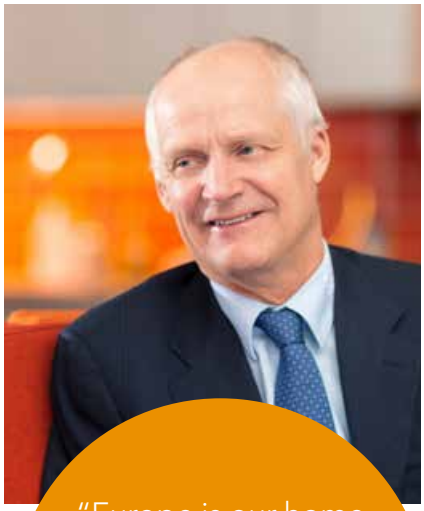
***GO:*** Yes, the number one priority is to continue to grow Haemophilia. We have only begun to reach our full potential in a few markets and new markets are also coming on stream. Long term, we want to achieve a leadership position in our region: this means that we aim to establish Elocta and Alprolix as the standard of care.

We also want to enhance our operations in Specialty Care. In 2018, we are aiming for a strong growth for Kineret and further growth for Xiapex. We are also actively seeking external growth opportunities to reinforce our product portfolio with assets that complement our areas of focus. We are looking for opportunities where we can utilise our strengths as a company, which are positive for our bottom line and which increase our geographical footprint. Financial discipline will be key as we develop the company further.

***HB:*** Long term, we need to focus on our pipeline, which includes acquiring projects and products of some size. To leverage our unique capabilities, it should be a rare-disease treatment or possibly something within a specialist indication with a small patient group. We are a rare-disease company, and want to remain so.

Europe is our home market, but we also want to strengthen our operations in the United States because it is the most important rare-disease market. Therefore, we would like our operations to better reflect the fact that these markets are rather equal in size. Europe and the US are therefore our main priorities.

***GO:*** With the ambition to become a global leader, sustainability is a vital part of our vision and overall corporate strategy. We will sharpen our sustainability programme, developed during the year, so that we can continue to reinvest in developing new therapies for rare diseases and serve our communities for many years to come.



"Europe is our home market, but we also want to strengthen our operations in the United States."

*Håkan Björklund, Chairman*

**In 2017, Sobi evolved the company strategy. In which ways has the strategy changed?**

***HB:*** Long term, our aim is to build a leading rare-disease company and to do it by building on the strengths we already have.

***GO:*** The company is evolving, and we aim to continue doing so at a rapid pace. Haemophilia is driving growth and transforming us into a much more commercial company than we have been previously. We are in a fairly classic development phase for companies that are growing quickly. There will be a stronger focus on execution to bring about change within the next two years. We are still a small company though, but we will not let that stop us from taking action. We need to step up throughout the organisation to reach our goal to be recognised as a global leader.

**How do you prepare and equip the organisation to be able to participate in and drive the evolution?**

***GO:*** As we are progressing, we will need additional skills. We are becoming more commercial, which is reflected in a greater empowerment of our local country organisations. In 2017, we evolved our previous CARE values (Collaborative, Accountable, Respectful, Engaged) that have been central in how we operate, to better align with our current ambitions. To ensure that more patients can benefit from our advanced therapies and to support our ambitions to grow, we have agreed on the values Care, Ambition, Urgency, Ownership and Partnership. These will help us to develop our leadership and entrepreneurship, and to become an even more formidable competitor.

Going forward, we will continue to develop the organisation and our individuals, and I feel confident that we have a great team in place. I would like to thank everyone within Sobi for all the work they have put in over a demanding and eventful year, and for their continuing dedication and commitment.

Finally, I would like to thank our shareholders for their support and trust in us during 2017 and beyond.

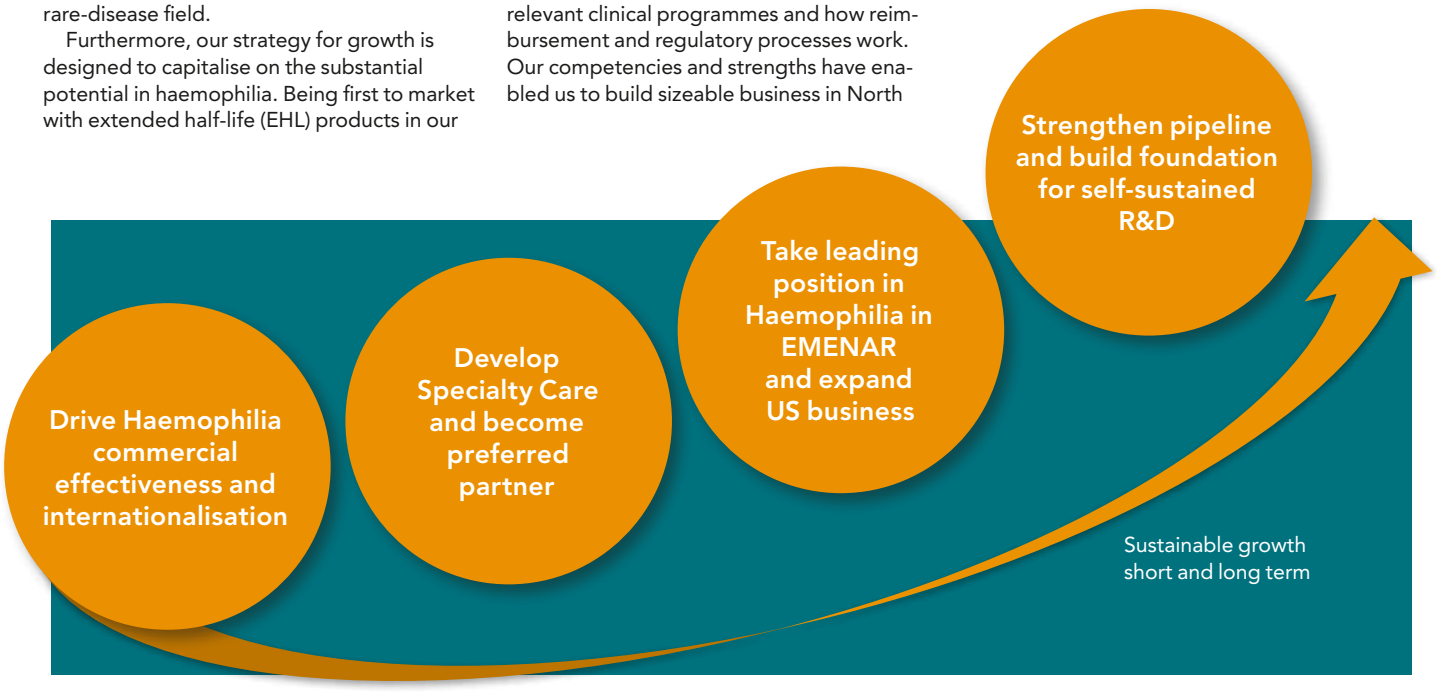
# Strategy

**Building on strengths to propel growth**
We will continue to build on our strong position that covers the entire value chain for treatment of rare diseases in EMENAR and North America. Sobi offers an integrated process, from in-house research and development in protein characterisation, biologics manufacturing and industrialisation, to commercialisation of products for rare diseases. Partnering with stakeholders and facilitating effective and timely rare-disease therapy development, including an extensive and robust distribution network, creates unique opportunities for us to add value to the rare-disease field.

Furthermore, our strategy for growth is designed to capitalise on the substantial potential in haemophilia. Being first to market with extended half-life (EHL) products in our territories povides Sobi with a unique opportunity to secure a strong market position in haemophilia and generate significant revenue and earnings. From this advantageous position, we can continue to invest in the haemophilia space. The first milestone in this regard is the advancement of the XTEN-programmes in collaboration with Bioverativ during the year.

Within Speciality Care, we have extensive experience of successful partnerships in rare diseases. Sobi has a proven commercial track record across many treatment areas and specialist indications. We know how to design relevant clinical programmes and how reimbursement and regulatory processes work. Our competencies and strengths have enabled us to build sizeable business in North America and EMENAR with Kineret and Orfadin as showcase examples. Specialty Care's setup makes Sobi an attractive partner for European as well as North American biotech companies.

With a solid foundation as a fully integrated company, we are ready to take on a larger part of the value chain in later-stage development of new treatments to broaden the Specialty Care portfolio and thereby better balance our overall business operations, while ensuring sustainable growth in both the short and long term.




**Capitalise on the substantial potential in Haemophilia.**
Our EHL products are the first advances in many years in the haemophilia space. Securing a broad and rapid launch has been a high priority for the company. We aim to further develop our position in the field through continued dedication to advancing care and by developing follow-on compounds.

**Establish Specialty Care as a strong business area.**
Our market organisation is well equipped to manage a larger portfolio. We are exploring different growth opportunities in Specialty Care, building on our capabilities of bringing products to patients in a complex market.

**Expand in certain regions.**
We aim to rebalance our geographic footprint by scaling up and advancing operations in certain of our existing regions, particularly in North America. The goal is for our portfolio to reflect the geographical balance seen in the rare-disease domain between Europe and North America.

**Strengthen the late-stage R&D pipeline.**
We aim to strengthen our late-stage R&D pipeline and fuel proprietary product development, with the aim of producing commercially viable products that are able to propel the company. We are exploring different opportunities, primarily within existing therapeutic areas.

# Overarching goals and financial outlook

| Operational targets 2017 | Outcome |
|---|---|
| **Meet or exceed operational targets:** | |
| • Expand market shares for Elocta, Alprolix, and Orfadin Oral Suspension and 20 mg capsule | ✓ |
| • Meet contract delivery for ReFacto | ✓ |
| **Expand portfolio through synergistic new indications, partnerships and acquisitions.** | (✓) |

**Operational targets 2018**

**Strengthen commercial focus**
- Increase sales of Elocta and Alprolix in existing and new markets
- Increase sales of Kineret in existing markets and in applications

**Expand our commercial portfolio through new in-licensing, acquisitions or partnerships focused on Europe and North America.**

| Pipeline targets 2017 | Outcome |
|---|---|
| **Ensure key pipeline inflection points are met:** | |
| • Complete enrolment in the anaGo study | |
| • Initiate the anaStill's study | ✓ |
| • Initiate two Elocta immune tolerance studies in collaboration with Bioverativ | ✓ |

**Pipeline targets 2018**

**Progress development towards a self-sustained R&D pipeline**
- Begin SOBI003 first in human phase 1/2 study
- Complete enrolment into the RelTIrate study
- Phase 2 Gout (anakinra) key results for phase 3 decision

**Expand R&D pipeline with new late-stage assets.**

**Financial outcome 2017**

**Revenues SEK 6,511 M**
**Gross margin 72%**
**EBITA SEK 2,053 M**

**Financial outlook 2018[1]**

**Revenues SEK 7,500–7,700 M**
**Gross margin at least 70%**
**EBITA SEK 2,500–2,700 M**

1. Expected outcome published on 22 February 2018.

## SOBI'S VALUE CREATION

True availability and access to treatment for patients is what brings long-term value to the patients we serve, our employees, partners and shareholders. The capabilities that make this possible are our knowledge of biologics manufacturing and industrialisation, our in-house research and development competencies within protein characterisation, and our ability to provide access to treatments for rare-disease patients. We believe that our ability to partner and to pioneer with different stakeholders – and bring together all the opportunities that exist to facilitate effective and timely rare-disease therapy development – creates unique opportunities to add value to the rare-disease field.

**Drivers**
- Increased global understanding and knowledge of treatments for rare diseases
- Market development
  – Strong market growth expected
  – National health budgets
  – Competitors
- Expectations of improved efficiency
- Digitalisation

**Vision** To be recognised as a global leader in providing access to innovative treatments that make a significant difference for individuals with rare diseases.

**Mission** We make a real difference to the lives of people with rare diseases by providing innovative therapies in our focus areas. These people cannot wait, so we must have a sense of urgency in our work.


**Input**
- Capital provided by investors and owners
- Manufacturing facilities
- Skilled workforce
- Partner products
- Patient journey insights
- Intellectual properties
- Partnerships, relationships and networks

### Sobi's business model

Sobi's business model for value creation is founded on a fully integrated process that includes Innovation, Biologics Manufacturing & Supply as well as Commercialisation and Patient access to treatment.

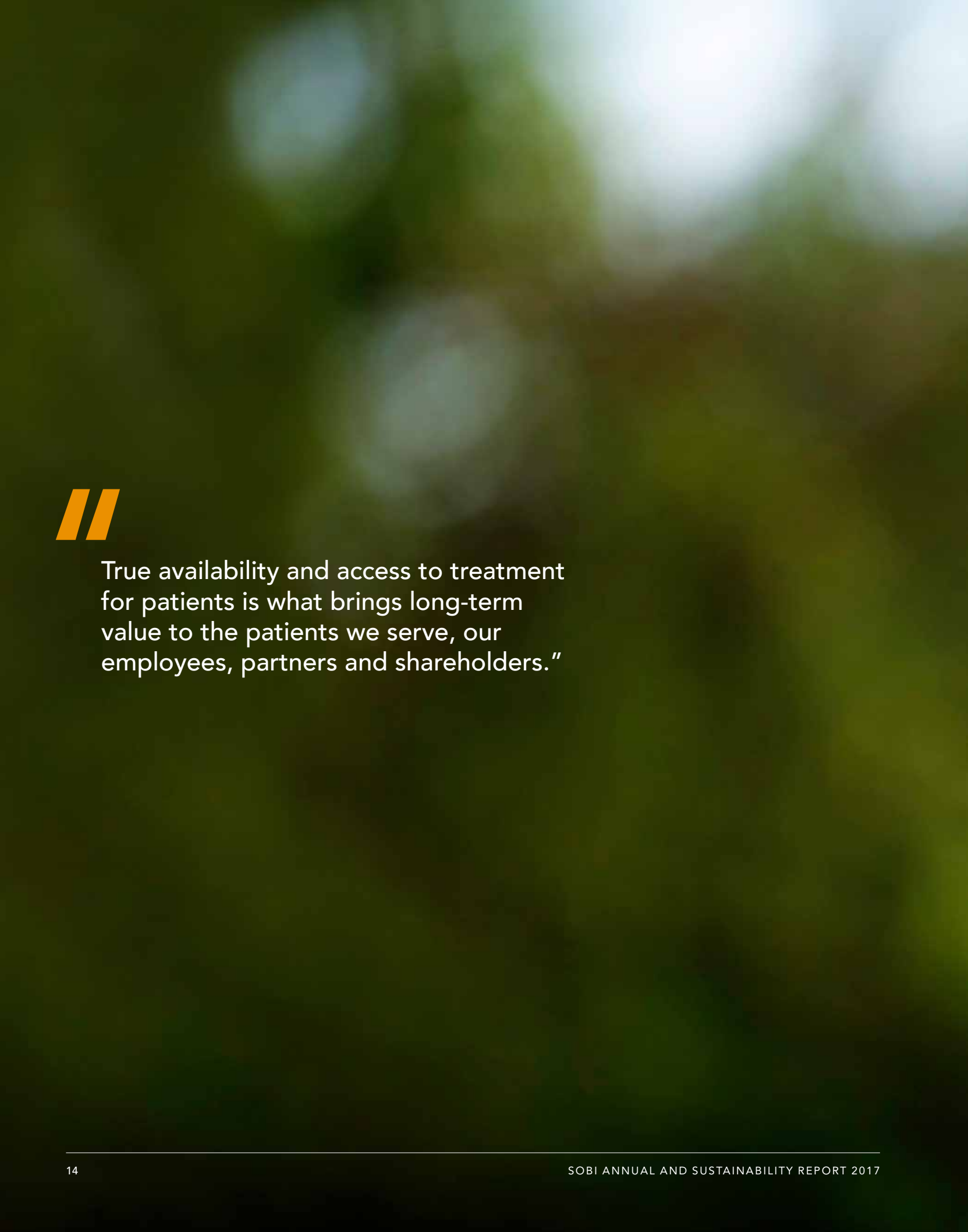
1. Read more about Sobi's innovation model on page 32.

### Output

- Sustainable growth, short- and long-term
- Returns to investors and shareholders
- Returns to partner companies
- Efficient, innovative processes and platforms
- Strong R&D pipeline
- High-quality speciality care products
- Job creation and productivity
- Engaged and skilled people
- Global access to treatments of rare diseases

### Value for stakeholders

| | | |
|---|---|---|
| **Countries** | 72 | Number of countries to access Sobi's treatments. |
| **Employees** | 850 | Number of people employed by Sobi by year-end 2017. |
| **Products** | 39 | Number of products commercialised by Sobi; proprietary and partner products. |
| **Tax** | SEK 252 M | Total corporate income tax for 2017, to be paid in 2018. |
| **R&D** | SEK 908 M | Reinvestment in R&D to deliver potential future treatments for rare diseases. |
| **Shareholders** | 4.27 | Earnings per share (SEK). |



"True availability and access to treatment for patients is what brings long-term value to the patients we serve, our employees, partners and shareholders."

Business area

# Haemophilia

**Sobi introduced recombinant extended half-life products into Europe in 2016 and the Middle East in 2016 and 2017. The products have been well received in the haemophilia community, and experience in a real-world setting is rapidly increasing in these regions, building on even longer experience from the US market.**

Only an estimated 25 per cent of the people living with haemophilia across the globe have access to satisfactory levels of treatment. The availability of treatment is concentrated in Europe and North America, which have 37 and 44 per cent of the market respectively.

Clotting-factor therapies are the treatment of choice in haemophilia, using either recombinant or plasma-derived factor. Treatment is provided as prophylaxis to prevent bleeds, or on demand to stop a bleed or allow surgery to be performed.

Prophylactic treatment is key to a successful long-term treatment outcome in children and adults with severe haemophilia. It offers significant protection, minimising the number of bleeding episodes and reducing the risk of joint damage and life-threatening soft-tissue bleeds.[1] The use of prophylaxis in haemophilia is estimated to be around 40–60 per cent in Europe and North America.[2]

A European retrospective study[3] that assessed haemophilia care in seven countries before the introduction of extended half-life (EHL) treatments showed that treatment practice varied widely between countries. It also showed that patients treated both on-demand and prophylactically experienced bleeds, emphasising the need for further improvement in the standard of care. Even when prophylaxis is the norm, it appears that treatment is left at a minimal acceptable level or even lower, which increases the risk of joint injury and limits the ability for people with haemophilia to live full and active lives.

The development of antibodies (inhibitors) that neutralise the effect of clotting-factor therapy is one of the most serious complications in haemophilia treatment, making standard replacement therapy ineffective, increasing the risk of severe bleeding and morbidity, decreasing quality of life and increasing healthcare costs.[4] To resume treatment, those affected need to go through a burdensome and very costly immune tolerance induction treatment (ITI), requiring large amounts of traditionally used factor treatment often up to twice daily over a long time. Around 30 per cent of people on replacement therapy develop antibodies.[5]

1. Carcao M. Haemophilia. 2014;20(4):99-105

2. World Federation of Hemophilia. Report on the Annual Global Survey 2016. Available at: http://www1.wfh.org/publications/files/pdf-1690.pdf. Accessed on: 6 March 2018

3. Berntorp E, et al. Haemophilia. 2017;23(1):105-114
4. Krishnamoorthy et al. Cell Immunol. 2016; 301:30-3
5. Christoph Königs et al. EAHAD18-ABS-1138.

**EHL products**
Beginning in 2016, Sobi became the first company to make recombinant extended half-life (EHL) coagulation factor concentrate available for the treatment of haemophilia A in Europe and parts of the Middle East, with the launch of Elocta, and one of the first for haemophilia B with the launch of Alprolix. The products were first approved in the US in 2014, where they are marketed by Bioverativ, a Sanofi company, (previously Biogen) under the names Eloctate® and Alprolix, helping create an extensive bank of real-world experience in these treatments.

EHL treatments can achieve higher factor levels in the blood for longer than traditionally used factor treatments when used at the same dose and same frequency.[1] This characteristic addresses the challenges that arise when intensifying prophylactic treatment with traditionally used clotting factors, such as increased treatment burden, compliance, higher factor consumption and associated cost implications.

Moreover, EHL treatment creates an opportunity to individualise prophylactic treatment to meet the individual patient's needs, improving the clinical outcome. Interim data from the ASPIRE study[2] first published on-line in 2017, show continuous improvement in joint health over a nearly three-year period with prophylactic treatment with Elocta, regardless of prior treatment regimen, severity of joint damage or target joints. Improvements were most notable in haemophilia A patients with poor joint health.

1. Berntorp E, Negrier C, Gozzi P et al. Haemophilia 2016; 22(3):389-96. 2. Oldenburg et al. Haemophilia 2018; 24(1):77-84.

"EHL treatment creates an opportunity to individualise prophylactic treatment to meet the individual patient's needs, and thereby has the potential to improve the clinical outcome."

Armin Reininger, Head of Medical and Scientific Affairs

## EXTENDED HALF-LIFE TECHNOLOGIES

**Fc fusion**
Sobi's products Elocta and Alprolix are approved in Europe and the Middle East for the treatment of haemophilia A and haemophilia B respectively in children, adolescents and adults.

The products achieve extended half-life by fusing an Fc fragment, part of immunoglobulin, to a recombinant clotting factor. While the clotting-factor part of Elocta and Alprolix retains the procoagulant activity, the Fc region binds to the neonatal Fc receptor (FcRn). This receptor is expressed throughout life and is part of a naturally occurring pathway that protects immunoglobulins from lysosomal degradation by cycling these proteins back into circulation, resulting in their long plasma half-life[1].

Elocta and Alprolix bind to FcRn, utilising this same natural pathway to delay degradation and allow for longer plasma half-life than endogenous FVIII and FIX. This makes it possible to achieve substantially higher clotting-factor levels in the body than with the same dosage of traditionally used clotting-factor concentrates, which is important for effective prevention of bleeds. The prolonged half-life also makes it possible to reduce the frequency of intravenous injections needed for prophylactic treatment. While Fc fusion technology has been used for more than 15 years, Bioverativ and Sobi have optimised the technology and are the first companies to utilise it in the treatment of haemophilia.

Furthermore, there are preliminary preclinical and clinical data on the immune tolerance effects of Fc fusion that indicate relatively short immune tolerance induction (ITI) treatment for patients who have developed antibodies to standard clotting-factor treatment, possibly due to immunomodulatory effects attributed to the Fc domain of the molecule[2, 3]. Sobi started a study called ReITIrate in 2017 to investigate Elocta's potential as an ITI treatment.

**PEGylation**
Other pharma companies are using a technique called PEGylation, in which a compound called polyethylene glycol (PEG) is conjugated to clotting factors to extend the half-life of the clotting factor.

**Albumin fusion**
A third approach to extend the half-life of clotting factors is fusion with recombinant albumin, which is a protein that occurs naturally in the blood.

1. Roopenian and Akilesh 2007.
2. Krishnamoorthy et al. Cell Immunol. 2016; 301:30-3
3. Malec Haemophilia 2016

With the first EHL treatments coming on the market in 2014, Sobi and Bioverativ, a Sanofi company, have gained considerable experience from the real-world use of EHL products in general, and Elocta and Alprolix specifically. Apart from the growing body of data around efficacy both products display a good safety profile.

Other EHL products have entered or are under review to enter European markets. Gene therapy and other technologies are maturing and may offer treatment alternatives in the future.

**The launch of Elocta – an update**
Commercial access to Elocta for people with haemophilia A in Europe was achieved in January 2016. It was subsequently approved in Kuwait in November 2016, and then in Saudi Arabia in May 2017. By the end of 2017, reimbursement had since been secured in 22 markets. Sales increased to SEK 1,557 M from SEK 267 M in 2016, an increase of nearly 500 per cent (excluding royalties).

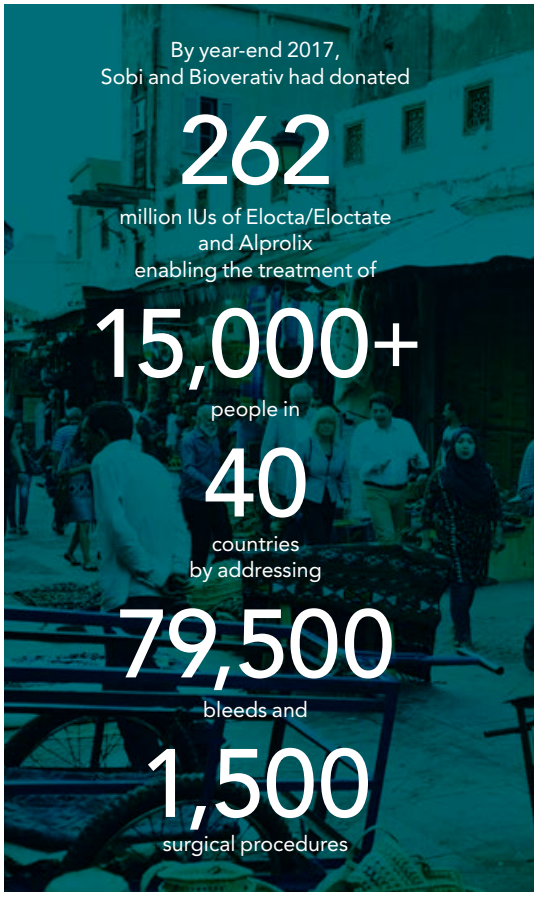
**The launch of Alprolix – an update**
Commercial access to Alprolix for people with haemophilia B in Europe was first achieved in May 2016. By the end of 2017, reimbursement had been secured in 14 markets. Among the important milestones in 2017 were the approvals in Kuwait and Saudi Arabia, as well as the EMA approval for the potential to dose Alprolix every 14 days or longer. Sales increased to SEK 363 M from SEK 60 M in 2016, an increase of 500 per cent (excluding royalties).

**Manufacturing of clotting factors**
We have more than 35 years of experience in developing therapies for haemophilia. Together with Biogen we developed the process for large-scale manufacturing of Alprolix, based on our experience from the manufacturing the active ingredient ReFacto in Pfizer's haemophilia product ReFacto AF, is produced according to Good Manufacturing Practice (GMP) in our biologics facility in Stockholm, Sweden. As the global supplier, we receive manufacturing revenues as well as royalties on Pfizer's sales of ReFacto AF. Manufacturing capacity was increased during 2017, enabling us to deliver higher volumes of the drug. Total revenues from ReFacto AF decreased by 10 per cent to SEK 594 M. This is an effect of the royalty to Sobi on sales on ReFacto AF outside of the US ceasing on 1 June 2016.

**Financial performance of the business area**

SEK 3,088 M

Total revenue for the Haemophilia business unit was SEK 3,088 M, up 67 per cent from SEK 1,853 M in 2016.




# First choice in Saudi Arabia

At King Faisal Specialist Hospital & Research Centre (KFSHRC), where 40 per cent of people with haemophilia in Saudi Arabia are treated, most of the patients with haemophilia A are now treated with Elocta.

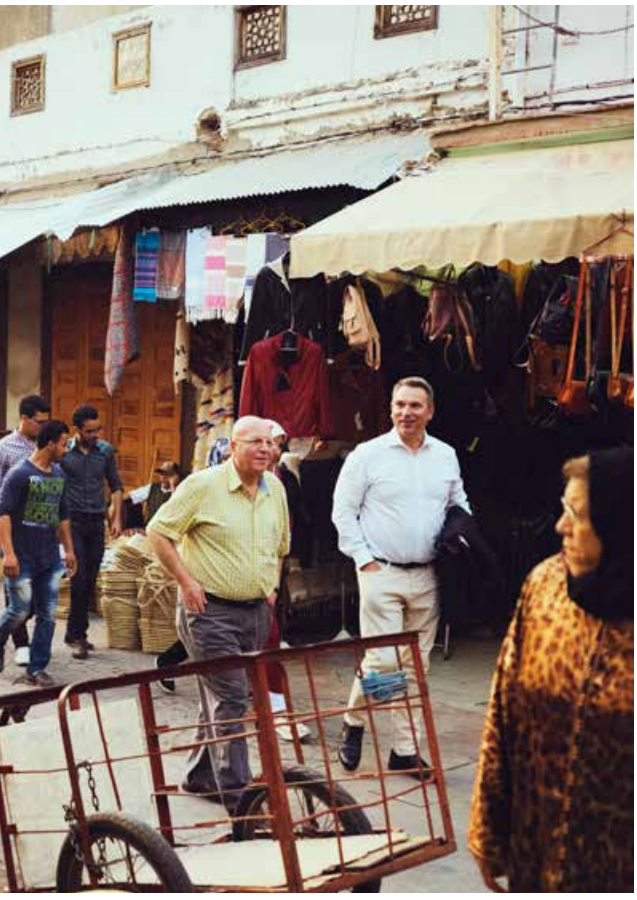
Key to this success was the fact that Sobi's team got an early start. From its formation in 2012, our local team dedicated itself to building trust and explaining the extended half-life products to medical experts, hospital physicians and budget holders. Discussions examined the challenges facing patients.

"Since Elocta was seen as a new and innovative product in Saudi Arabia due to its ability to extend half-life, we were allowed a fast track lane for approval, meaning that the market approval and the reimbursement approval were handled in parallel", says Ahmad Abu-Dahad, Director Sobi Middle East.

The product's ability to help improve both the short and long-term quality of life for patients with haemophilia A convinced King Faisal Hospital & Research Center to adopt Elocta as its primary product.

Aside from Elocta as the primary treatment, the hospital uses one other treatment. Previously, the hospital provided two different short-acting treatments.

*Ahmad Abu-Dahad, Director Sobi Middle East.*



## HUMANITARIAN AID DONATION REPORT

An estimated 400,000 people are living with haemophilia. Around 300,000 of them live in areas with limited access to diagnosis and treatment.

In 2014, Sobi and Bioverativ (formerly Biogen) committed to produce up to a total of 1 billion international units (IUs) of clotting-factor therapy for humanitarian aid programmes in the developing world. Creating a predictable supply of factor over a 10-year period allows healthcare systems to plan in a way that fosters better care. Surgical procedures can be planned and prophylactic treatment becomes a real possibility.

The World Federation of Hemophilia (WFH) is leading efforts to improve access to haemophilia treatment and raise the standard of care for people with haemophilia in the developing world. Over five years, 500 million IUs will be donated to the WFH Humanitarian Aid Program to support these efforts.

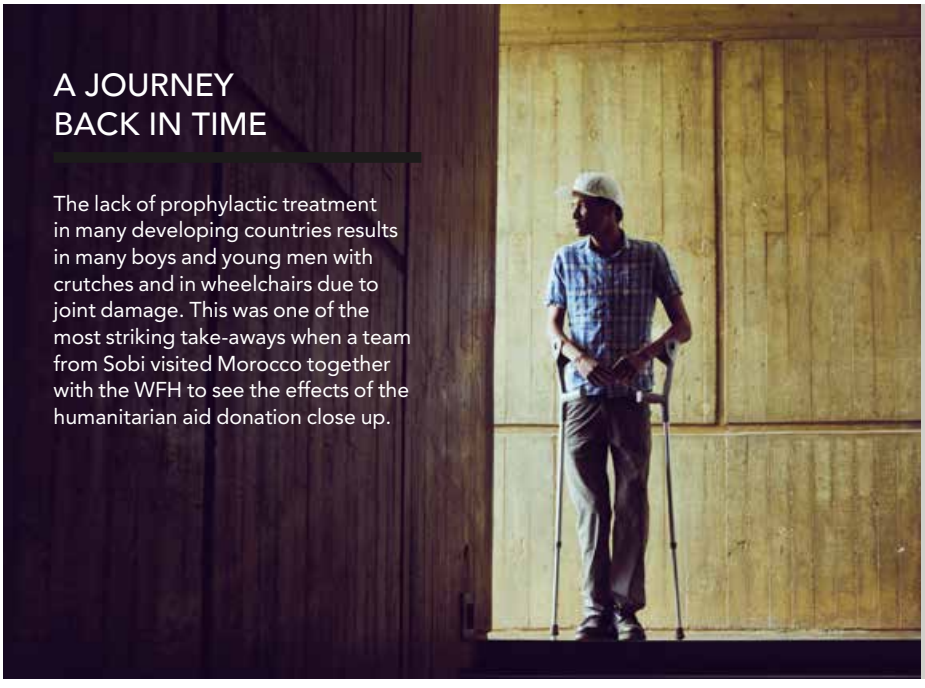
# 14% to 39%

Importantly, the percentage of children who receive treatment through the donation programme in these countries has almost tripled, from 14 to 39 per cent. The number of injections used in prophylactic treatment is rising steadily, and these are currently approaching half of the treatments. The number of people receiving prophylactic treatment is gradually increasing. Many of these are young children, making it possible to minimise joint damage.[1]

1. World Federation of Haemophilia - Humanitarian Aid Program end of 2017

## A JOURNEY BACK IN TIME

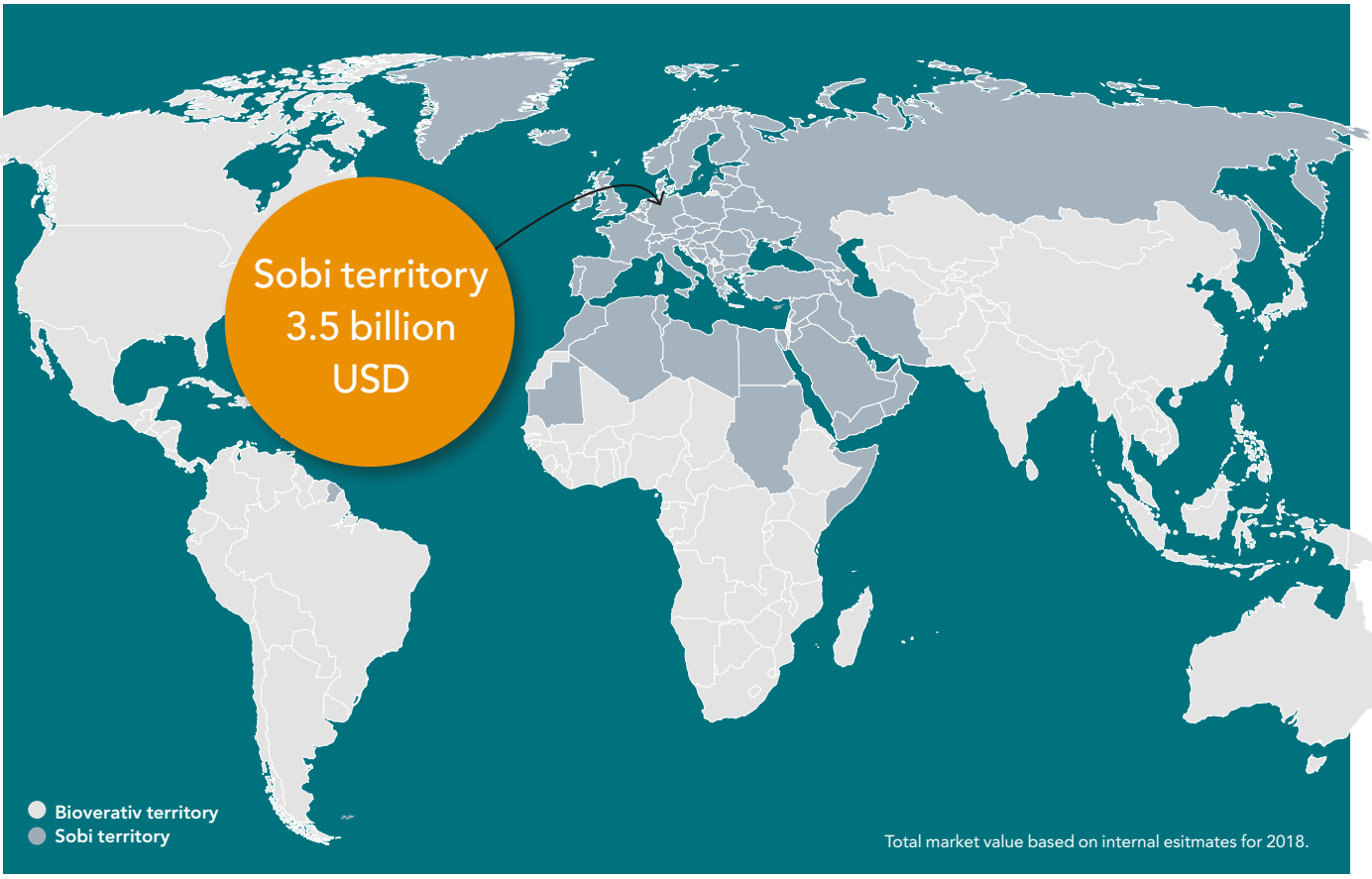
The lack of prophylactic treatment in many developing countries results in many boys and young men with crutches and in wheelchairs due to joint damage. This was one of the most striking take-aways when a team from Sobi visited Morocco together with the WFH to see the effects of the humanitarian aid donation close up.



"Sobi's commitment to the WFH Humanitarian Aid Program is about making a real difference with our donations, and demonstrating a true commitment to the haemophilia community and patients."

Guido Oelkers, CEO

**Global distribution of haemophilia products provided by Sobi and Bioverativ**




## ABOUT THE SOBI AND BIOVERATIV COLLABORATION

Sobi and Bioverativ, a Sanofi company, collaborate on the development and commercialisation of Elocta/Eloctate and Alprolix. Sobi has final development and commercialisation rights in its territory – essentially Europe, most Middle Eastern markets, North Africa and Russia.

Bioverativ 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.

*The financial terms of the agreement between the companies are described in more detail in Note 18.*

## 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. Eloctate is approved for the treatment of haemophilia A in the United States, Japan, Canada, Australia and other countries, and marketed by Bioverativ.

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

# Driving conversion in a fragmented market

Providing access to treatment at a local level starts with getting market approval and reimbursement. Thereafter comes the less formal but just as important work of sharing information about the treatments.

Sobi has put a lot of effort into educating physicians about the safety and efficacy of the new EHL treatments Elocta and Alprolix, backing up clinical data with real-world experience, striving to make them feel confident about converting patients to these newer technologies. Sobi has also educated others involved in patient care, such as nurses, pharmacists and physical therapists. People with haemophilia often assume great responsibility for their treatment, seeing their physician only on an annual basis.

"The haemophilia market is a conservative and rather cautious market," says Hege Hellström, Head of Sobi's EMENAR region. "We had done a lot of preparatory work, but it was not until late 2016 and 2017 that we really started to see market-share growth. A lot of centres and markets have now started to actively convert patients to modern EHL treatments. Once physicians are convinced, we see something of a roll-out starting."

Europe is far from a homogeneous market though. In some countries, centres are free to suggest treatment. In Germany for example there are 18 approved products and many patients are still on traditionally used treatments. In France, relatively few are on prophylaxis and most are only treated on-demand. In some other markets, it is decided centrally what treatments are chosen, sometimes through a tender. Patients are actively kept on the currently recommended treatment. This is the case for example in the United Kingdom and the Republic of Ireland.

"In early 2018, the Republic of Ireland became the first country in Europe where all people with haemophilia A or B treated with replacement clotting factors will be treated with the newest generation of treatments, EHL therapies – and specifically Elocta and Alprolix," says Neil Dugdale, General Manager UK & Republic of Ireland.

As a new entrant into the commercial haemophilia market, Sobi needed to build trust in the company and our dedication to the community, something the teams across Europe have done successfully. Sobi UK has been selected as the number one company in haemophilia in the UK for two years in a row, as rated by an independent annual survey.

Marketing regulations also differ between markets, making it necessary to adjust activity plans accordingly. In France, it is permissible to talk to physicians about a product before it is granted reimbursement, an opportunity Sobi took up.

"We needed to set out early to build trust and confidence among stakeholders," says Sofiane Fahmy, General Manager Sobi France. "After market approval we could move on to talking about the characteristics of the product, paving the way for a successful launch."

Within six months of launch, Elocta had become the second most commonly used haemophilia A treatment in France. By the end of 2017, it was the leading treatment; significant market shares had also been achieved in other markets in Europe and the Middle East.

"Our approach has been a global strategy guided by country-specific needs."

Hege Hellström, Head of EMENAR, and Philip Wood, Head of Haemophilia

## 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. Bioverativ holds the marketing rights for the United States, Canada, Japan, Australia, New Zealand, Brazil and other countries.

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

## THE MOST COMMON RARE DISEASE IN THE WORLD[1]

Affecting 400,000 people across the globe, haemophilia is the most common rare disease in the world[1]. 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 Hemophilia estimates that approximately 185,000 people are currently diagnosed with haemophilia A and B worldwide.

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

1. World Federation of Hemophilia. Report on the Annual Global Survey 2016. Available at: http://www1.wfh.org/publications/files/pdf-1690.pdf. Accessed on: 6 March 2018

Business area

# Specialty Care

Growth in the newly formed business area Specialty Care reached 5 per cent in 2017. Ambitions for the unit are higher than this, as Sobi explores several opportunities for growth that build on proven capabilities in bringing products to patients in complex markets.

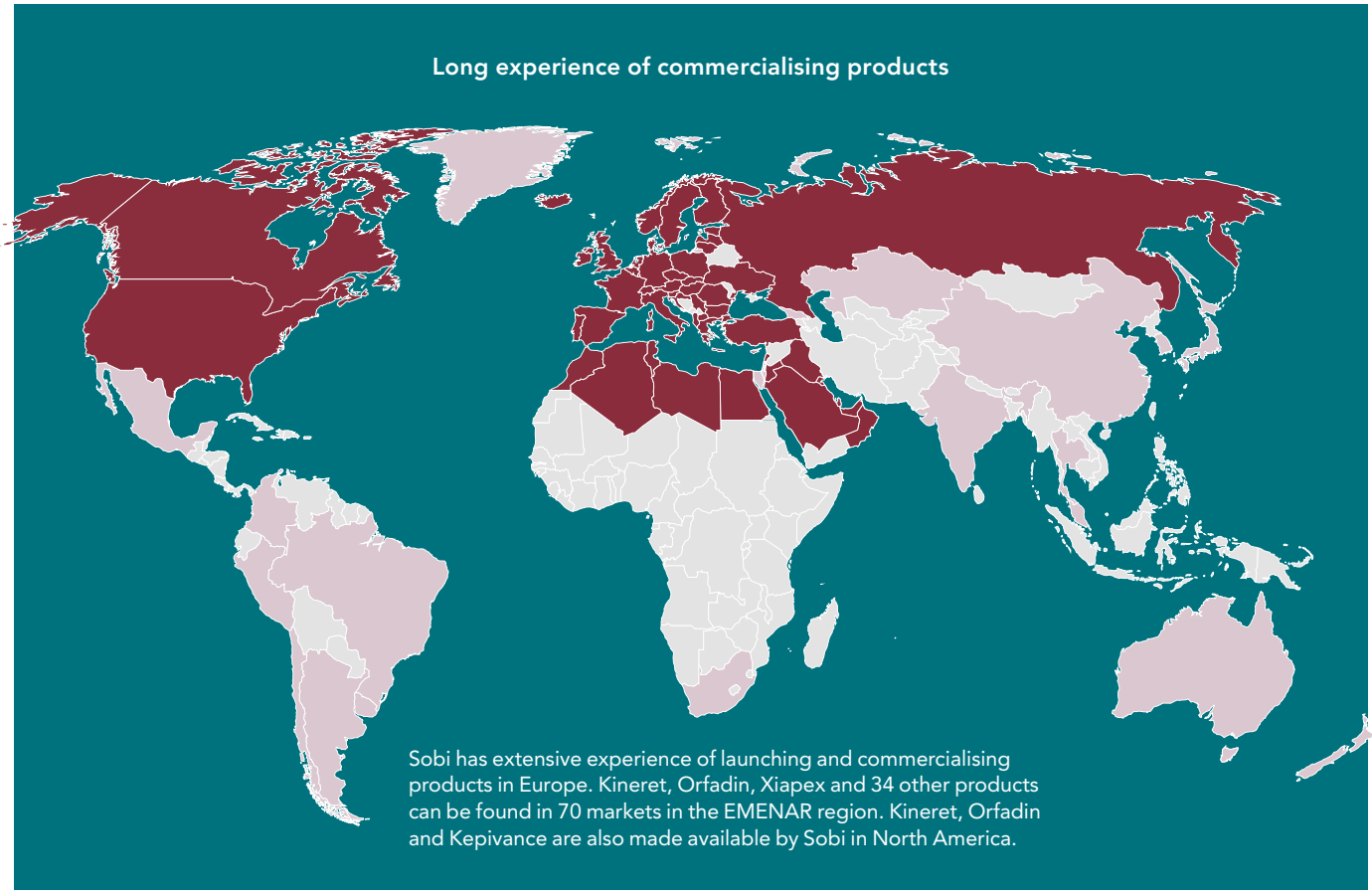

The business area Specialty Care was formed during 2017 by merging Sobi operations in Partner Products, Genetics & Metabolism and Inflammation. The focus is on rare diseases and niche indications, and the products aim to make a significant difference for patients.

The unit has a distribution network across EMENAR and North America used to sell both proprietary and partner products. Sales in 2017 amounted to SEK 2,829 M. The unit's largest products are Kineret and Orfadin, representing 40 and 30 per cent of sales respectively, followed by Xiapex representing 6 per cent. The portfolio currently consists of 37 products.

We are actively seeking new products for our Specialty Care portfolio, to enhance efficiency and 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.

Based on more than 25 years of experience, we offer partners strong collaborative skills and well-developed processes that efficiently manage partnerships covering several markets with efficient distribution and extensive market knowledge.

Our organisation has a competitive advantage thanks to our ability to launch products




rapidly in both larger and smaller markets, offering our partners an efficient path to market. We have a thorough understanding of local regulatory environments and the drivers among payers and healthcare providers in various markets.

Partnerships span over many years: apart from strategies for regulatory approval, pricing and reimbursement, they may include launch preparations, marketing activities, tender management and efficient logistics. We assume a comprehensive responsibility for products to ensure that medical needs are met in the best possible manner.

Our current organisation has offices in 19 countries, managing products in over 70 countries. Markets are evolving in many countries as their standards of living rise. We are looking to match increased demand with a greater market presence, particularly in more populous countries.

**Better meeting patient needs**

In recent years, we have employed active strategies to address patient needs even better. 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.

Sobi also supports rare-disease communities in various ways, for example through ambassador programmes, financial support to bridge reimbursement, or educational tools for healthcare providers, children and adults.

**Financial performance of the business area**

SEK 2,829 M

Total revenue for the Specialty Care business unit was SEK 2,829 M, up 5 per cent from SEK 2,695 M in 2016.

"Understanding the rare disease space also gives us capabilities to leverage in specialty-care and niche indications"

Norbert Oppitz,
Head of Specialty Care

The Orfadin Ambassador programme in the US allows patients and caregivers to connect with other people who have experience of living with HT-1. For a patient population of 1000 people worldwide, this is a rare opportunity.

**Orfadin**

Before Orfadin was first launched in 2002, few patients living with hereditary tyrosinaemia type 1 (HT-1) would celebrate their second birthday. Today, thanks to improved new-born screening, effective treatment and dietary management, we are seeing patients with HT-1 reach an age where they are starting their own families.

Sobi has worked closely with the HT-1 community to help people to manage their disease not just at diagnosis but throughout their lives. We made a commitment to make treatment as simple as possible, and in recent years we have developed new formulations to achieve this goal on several fronts.

Firstly, as new-born screening for HT-1 has improved and patients are being identified at birth, we developed a liquid formulation of Orfadin that makes it easy to administer a precise dose to infants and young children. Secondly, because patients are growing up and becoming adults, we have developed a 20 mg capsule, allowing patients to reduce the number of capsules they take each day. Lastly, we have conducted studies allowing Orfadin to be taken as a once-daily dosing option for patients five years of age and older. These new dosing options are unique to Sobi and a result of our insights concerning the medical needs of these patients.

In 2017, competition entered the nitisinone market in the US, Canada and Europe in the form of generic treatments. Our commitment to the community and our understanding of patient needs have proven valuable not only to HT-1 patients but also to Sobi. Despite the new generics, Orfadin sales continued to increase during 2017, driven by the launch of the new formulations and comprehensive patient support services.

## ORFADIN®

People with HT-1 are unable to break down an amino acid called tyrosine. Toxic by-products are formed and accumulate in the body, which can cause liver, renal and neurological complications. In the most common form of the disease, symptoms arise within the first six months of the child's life.

Orfadin (nitisinone) blocks the breakdown of tyrosine, thereby reducing the amount of toxic tyrosine by-products in the body. Patients must maintain a special diet in combination with Orfadin treatment as tyrosine is not adequately broken down.

Orfadin is a proprietary product, developed and marketed globally by Sobi. Orfadin is available in five dosage strengths: 2 mg, 5 mg, 10 mg, 20 mg capsules and 4 mg/ml oral suspension.

*For full European prescribing information, please visit the EMA website.*
*For full US prescribing information please see orfadin.com*

**Kineret**
Kineret is a biologic that can reduce the activity of interleukin-1 (IL-1), a key mediator of inflammation in autoinflammatory and autoimmune diseases. Kineret blocks the biological activity of IL-1a and IL-1b 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.

In 2017, Sobi started clinical trials for acute gout (phase 2) and Still's disease, including SJIA and adult onset Still's disease (AOSD) (phase 3). The Still's study (anaSTILLs), is required for approval in the US market.

In 2013, at the time we received the CAPS (cryopyrin-associated periodic syndrome) indication in Europe, we made a fundamental revision of our strategy for Kineret. A focused and tailored patient and customer-centric organisation was formed to meet market needs in the best way possible. Listening to healthcare providers and patients has helped us better meet their needs and take an important role in the market, one which has also resulted in steadily increasing product sales.

Increasing interest in and understanding of the IL-1 field is supporting the growth of Kineret.

Our work with Kineret in the US is described below.

## KINERET®

Kineret (anakinra) 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 systemic juvenile idiopathic arthritis (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.*

# Developing Kineret's market potential in the US

In 2014, the US team decided to take a closer look at how we could improve the Kineret business from a relatively flat business to a growing and thriving one. Sobi in North America was established in 2012 and the full rights for Kineret were bought in 2013. At that time there was little understanding of patient needs: half of the people prescribed the drug did not even start treatment due to reimbursement issues. Making matters worse, half of those who actually started dropped out during the first two months.

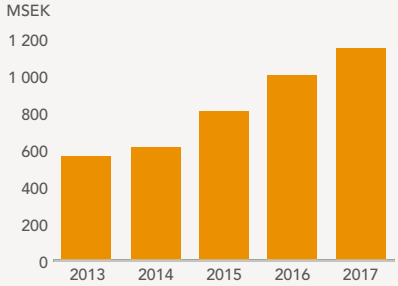
"We set out to better understand the patients and the market, and then we leveraged that understanding to bring about change," says Rami Levin, Head of Sobi North America. "Our goals were twofold – to remove the barriers that were preventing patients from starting treatment, and to understand and address treatment challenges so that patients could stay on treatment."

To allow more patients to access the treatment, Sobi applied a rare-disease approach, addressing doctors who were familiar with the treatment and working together with them to identify appropriate patients.

Sobi also invested in supporting patients through the very complex reimbursement process and launched the Kineret On Track patient support programme, which includes nurse support, training on how to inject the drug, assistance in applying for reimbursement, and financing until reimbursement is received. The changes Sobi enacted increased both retention and compliance for Kineret by about 15 percentage points each.

"I cherish the fact that we have strengthened our relationships with the rheumatoid arthritis and NOMID communities. And I am also proud that we so strongly have contributed to the growth of Kineret", says Rami.

**Five-year global Kineret sales[1]**




1. Sales in the US and EMENAR follow the same trend.

"We set out to better understand the patients and the market, and then use that understanding to bring about change"

Rami Levin,
Head of North America

**Xiapex**
Xiapex was first granted marketing authorisation by the European Commission for the treatment of the disabling hand condition Dupuytren's contracture in 2011. In 2015, the treatment was approved in Europe for Peyronie's disease, a condition resulting in an abnormally curved penis.

Since 2013, when we partnered with Auxilium, now Endo International, for Xiapex, sales of the product have grown by an average of 36 per cent per year (CAGR). In 2017, sales increased by 7 per cent to SEK 164 M with growth stemming from both indications

During 2017, people in England with Dupuytren's contracture were given access to Xiapex on the National Health Service for the first time after a recommendation from the National Institute for Health and Care Excellence (NICE), offering an alternative to surgery.

Dupuytren's contracture is believed to be more common than Peyronie's disease, and has less stigma attached. In 2017, we continued to raise awareness about Peyronie's disease, a hidden condition that is not spoken about publicly. More men were subsequently given access to treatment.

## XIAPEX®

Sobi and the specialty pharmaceutical company Endo International are partners for the commercialisation of Xiapex (collagenase clostridium histolyticum). Sobi has the exclusive rights to commercialise Xiapex for the treatment of Dupuytren's contracture and Peyronie's disease in 71 Eurasian and African countries. Sobi is the Marketing Authorisation Holder (MAH) for Xiapex in the 28 EU Member States, as well as Norway and Iceland. Xiaflex® is the trade name for Xiapex used in the United States.

Xiapex is used to treat Dupuytren's contracture and Peyronie's disease in adults. Dupuytren's contracture is a condition where one or more fingers are bent forwards toward the palm and cannot be fully straightened.

Peyronie's disease is a condition in which men develop plaques of fibrous, scar-like tissue in their penis, causing it to become abnormally curved.

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

Long experience from working with partners in a complex environment.

# Biologics Development and Supply

**Sobi's expertise and capacity within biologics development and supply not only brings stable revenue through manufacturing of the drug substance for ReFacto AF, but also supports Sobi's development capabilities, ensuring scale-up and industrialisation. Our network of contract manufacturing organisations ensures reliable supply of Sobi's products in the markets.**

We have extensive expertise within biologics development and supply, and a long history as a reliable supplier of biopharmaceuticals. In the 1980s, the predecessors of Sobi were pioneers in the development and manufacturing of biopharmaceuticals using recombinant protein technologies. One of these drugs was a recombinant factor VIII called ReFacto/ReFacto AF for the treatment of haemophilia A, a drug substance we have been manufacturing for Pfizer since 1998.

Today, manufacturing of this drug substance constitutes the major part of operations, but the unit also manufactures other proprietary drug substances for use in clinical trials and manages the external manufacturing of Group products. The unit's overall objective is to enable business in Sobi.

Apart from manufacturing, the unit also develops biological manufacturing processes and manages the upscaling from pilot plant to commercial facilities. With a commercial mind-set from the outset, we ensure that development programmes lead to robust processes tailored for large scale and volumes. Key competencies include process development, protein characterisation and quality control strategies for drug substances and drug products.

We play an active role in the Swedish government's national programme for method development and manufacturing of biologics, which aims to make Sweden a leader in the field. During 2017, we were involved in three nationally funded collaborations.

**Manufacturing of proprietary drugs**

In 2017, we manufactured material for the planned clinical studies with our candidate drug SOBI003 using a proprietary process developed in-house.

**External Manufacturing**

The External Manufacturing unit is responsible for the supply of drugs within the group. In 2017, an important task was to ensure sufficient volumes of Elocta and Alprolix in our territories to guarantee the success of launches. During the year, we received approval from the European Medicines Agency for higher capacity drug-substance manufacturing for Elocta, providing a consistent and reliable supply across our territories.

In 2017, the transfer of the production of Kineret's biologic drug substance to Pfizer's manufacturing site in Strängnäs, Sweden, was approve by the US and European medicines agencies. This capacity increase will support growth in potential new indications which are under exploration.

## HIGH-PACED KINERET TRANSFER

**At the end of 2017, the transfer of the manufacturing of Kineret drug substance to our new manufacturing partner was approved by both the US and the European medicines agencies, ahead of schedule. The transfer will expand capacity significantly, improve access for patients and support the growth of Kineret in existing and planned indications, as well as increasing cost efficiency for Sobi.**

Ann-Britt Vikström, Project Manager for the technology transfer of the production of Kineret drug substance, says the EMA approved the transfer to a new production site without a single question, something Sobi's regulatory department described as "extraordinary" for a biotech product.

"We always aim to avoid questions, but you can never really be certain," says Ann-Britt. "Everybody has worked intensively throughout the project, setting up strategies both to achieve efficiency and meet all the agency requirements."

Kirsti Gjellan, Head of Biologics Development and Supply, adds: "This project goes to show how our long-standing partnership with Pfizer has paved the way to an excellent collaboration and how valuable our knowledge in biological manufacturing is. The approval of Pfizer as the drug substance (DS) manufacturer for Kineret will secure the supply of product to our patients now and in the future, and improve our operational effectiveness."

It was in the spring of 2016 that Sobi decided to transfer the production of Kineret drug substance to Pfizer's manufacturing site in Strängnäs, Sweden.


Ann-Britt Vikström, Project Manager

## 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. It is vital to have full control of the entire chain, as biologics often require cold-chain supply to ensure product integrity and quality. See Sustainability from page 38 for more information.

"With a commercial mind-set from the outset, we ensure that development programmes lead to robust manufacturing processes tailored for large scale and volumes."

Kirsti Gjellan, Head of Biologics Development and Supply

# Innovation

Expanding the number of programmes, particularly those in clinical development, is a priority for the company. In 2017, we paved the way for our most advanced early-stage programme, SOBI003, to move into clinical studies during 2018.

**Broad scope and focus**
Our research and development (R&D) capabilities span from the discovery phase, through clinical development, to post-approval clinical studies in a real-world setting. We are currently running pre-clinical research programmes, clinical development programmes and studies in a real-world setting – studies in phase 1 through phase 4.

Expanding the number of programmes, we have proven our ability to successfully in-license innovation from outside Sobi. Our two haemophilia products Elocta and Alprolix, as well as Orfadin, Kineret and other partner products, all originate from other companies and have evolved into successful lines under Sobi's stewardship. An additional core strength is our heritage of working with bio-pharmaceutical drugs based on recombinant proteins.

We focus our efforts on selected therapeutic areas, where we can make a difference and where we have the potential to become leaders within haemophilia and specialty care including inflammation, and genetics and metabolic diseases. This focus improves our ability to comprehend, assess and leverage the science of intended drugs. A greater understanding of patient needs facilitates the identification and assessment of unmet medical needs.

**Adding value for patients**
At Sobi, we apply a complete life-cycle management approach to our therapies to generate more value for patients. Even after

a therapy is approved and launched, we continue with research and development. This can involve adding new indications, new formulations and real-world data to approved therapies. As an example, Kineret was originally approved for rheumatoid arthritis. Sobi continued to study and develop Kineret, which is also approved for CAPS, a group of rare, inherited auto-inflammatory disease, and NOMID, the most severe form of CAPS. Treatment with Kineret has led to a transformational improvement in quality of life for people with NOMID and CAPS. Two new studies are investigating the potential of Kineret for patients with Still's disease in the US and acute gout. Similarly, we are investigating the potential effects of Elocta in immune tolerance induction for people with haemophilia A who are affected by inhibitors.

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

**SOBI003**

SOBI003 is our most advanced early-stage project. It is being developed for mucopolysaccharidosis (MPS) type IIIA or Sanfilippo A syndrome, a progressive, life-threatening and rare inherited metabolic disorder affecting children from early age. The body is unable to break down long chains of sugar molecules, resulting in the accumulation of heparan sulphate in lysosomes and affecting the central nervous system where it causes severe progressive degeneration.

With approximately 1,000–2,000 persons living with the disease in the EU and US, MPS IIIA is a rare disease. It is usually identified at two to four years of age and the lifespan of someone with MPS IIIA usually does not extend past the end of the second or beginning of the third decade of life. There is currently no approved treatment for MPS IIIA. During 2017, SOBI003 was granted orphan status by the US Food & Drug Administration, adding to the previously granted orphan designation in the EU. SOBI003 is preparing to enter phase 1/2 clinical studies during 2018, being tested on patients for the first time.

SOBI003 has been developed in-house by Sobi. The technology that allows the potential disease-modifying effects is a proprietary modification of the glycan sugar molecule. All product development and manufacture of medicine for clinical trials has been carried out under the direction of Sobi. Development of the clinical studies has been done in collaboration with patient organisations and healthcare authorities.

## Our innovation pipeline as per 31 December 2017

| Therapeutic area/Indication | Product/Project | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Phase 4 |
|---|---|---|---|---|---|---|
| Haemophilia A | Elocta/ASPIRE* | | | | ■ | |
| Haemophilia A | Elocta/PUP[1]* | | | | ■ | |
| Haemophilia A | XTEN/BIVV001[2] | | ■ | | | |
| Haemophilia A | Elocta/A-SURE | | | | | ■ |
| Haemophilia A | Elocta/RelTIrate | | | | | ■ |
| Haemophilia A | Elocta/verITI8 | | | | | ■ |
| Haemophilia A and B | Elocta/Alprolix/PREVENT | | | | | ■ |
| Haemophilia B | Alprolix/B-YOND* | | | | ■ | |
| Haemophilia B | Alprolix/PUP[1]* | | | | ■ | |
| Haemophilia B | XTEN/BIVV002[2] | ■ | | | | |
| Acute gout | Kineret/anaGO[3] | | | ■ | | |
| Still's disease | Kineret/anaSTILLs | | | | ■ | |
| Alkaptonuria | Orfadin/SONIA2 | | | | ■ | |
| MPSIIIA | SOBI003[4] | ■ | | | | |
| Anti-C5 | SOBI005 | ■ | | | | |
| Anti-IL-1 | SOBI006 | ■ | | | | |

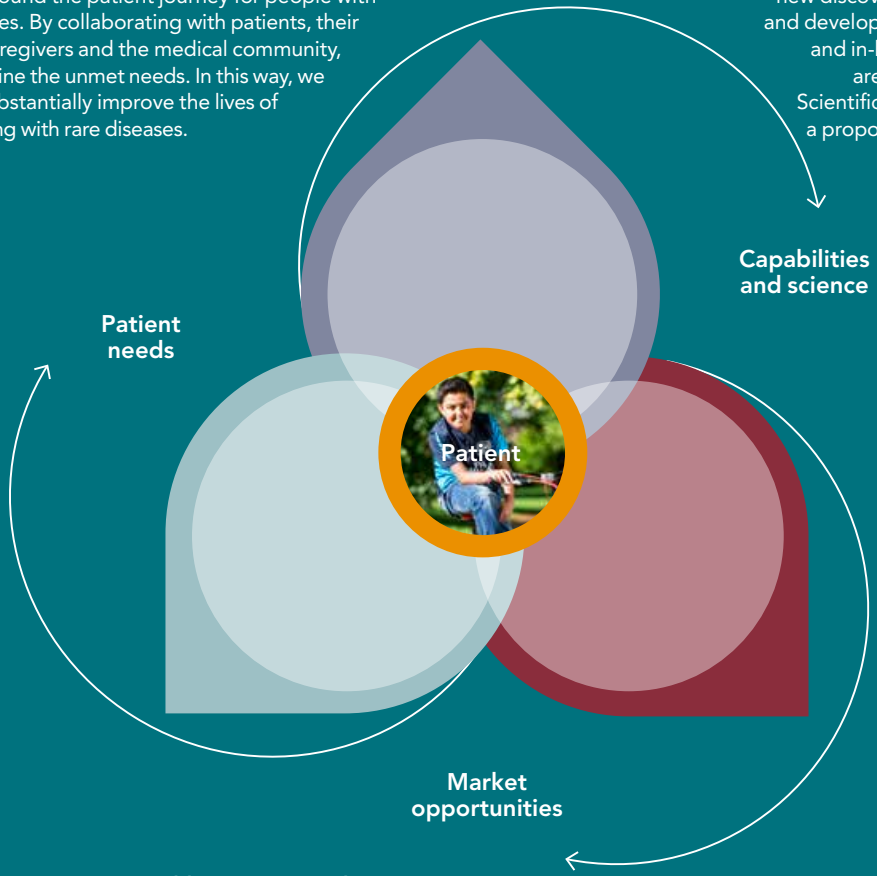
* Extension trial for an already approved indication
1. PUP = Previously untreated patients
2. Bioverativ development programme. Sobi has elected to add programmes to the collaboration agreement but not yet opted in
3. First patient dosed on 30 December 2016.
4. Moving into clinic during 2018

# Sobi's innovation model

Using a multi-disciplinary approach, cross-functional teams map and evaluate new R&D projects by applying the three steps of Sobi's innovation model: patient needs, scientific knowledge and Sobi's capabilities and estimated market opportunities. This ensures that new projects are aligned with the strategy and build on Sobi's strengths, and keeps the focus on projects with favourable risk profiles.

**Patient needs**
By defining the unmet needs, our innovation model revolves around the patient journey for people with rare diseases. By collaborating with patients, their families, caregivers and the medical community, we can define the unmet needs. In this way, we strive to substantially improve the lives of people living with rare diseases.

**Development and skills aligned**
Our R&D approach provides an interface between new discoveries and integrated research and development processes. Acquisitions and in-licensing of projects/products are also included in this process. Scientific and technological aspects of a proposed research or development plan must be aligned with our capabilities and skill sets.




**Sustainable access to medicines**
By identifying relevant stakeholders at each stage of the patient journey, we aim to secure optimal outcomes along the development pathway. We also facilitate each step on the way to market, resulting in smoother – and ideally faster – development and delivery to patients.

# Milan Zdravkovic

Head of
Research & Development
and Chief Medical Officer

**What is your background?**
I am a medical doctor with more than 18 years in the industry bringing new molecules to market for the benefit of patients.

When Milan joined Sobi in late 2016, he came from a position as Corporate Vice President at Novo Nordisk where he had been working in several areas including diabetes, growth hormone deficiency, obesity and immunology.

**What attracted you to Sobi?**
When I interviewed for the position, I thought it was a good match with the culture. I liked the inclusiveness, the way you work together and that everyone really sees to the needs of the patients. Secondly, I thought the pipeline was interesting, with opportunities to bring the preclinical assets forward, and ramp up our life-cycle-management activities. Finally, the company has a degree of financial strength that is necessary to enable R&D. Those were the three main factors.

**What constitutes a good innovation climate and how is that achieved?**
On one hand, you need to reward ideas and in parallell maintain certain rigours around your decision making. It is important to strike the right balance here. When evaluating the portfolio, you also need to set up the right criteria and goals to ensure that you are getting an answer to your most important questions first – that helps you decide what molecules to move on or move out.

**What are the key success factors for an R&D organisation?**
To demonstrate that we create value for the organisation and for the patients. It requires the right people, which we have: people who are hungry to achieve something; they want to push, and they like to collaborate and challenge the norms. Then you spice this up with good decision making and transparency around how decisions are taken.

**Which areas are you working to improve within Sobi?**
I have spent time with the organisation creating transparency around the assets and how they are prioritised. We have defined goals and instilled more accountability for everyone. And finally we want to have fun and to appreciate people for their achievements.

**What areas do you want to focus on going forward?**
We need to focus on what we are really good at, on our DNA: large molecules and putting patient needs in the centre.

The organisation is good at cooperating with other companies. Most of our products and projects are in-licensed or developed in collaboration with others. That is certainly another of our strengths. We need to ensure that we move the pipeline forward. This is going to be a very important success factor for our organisation.

**How would you describe your leadership style?**
I am very open and clear. As a leader I really believe in being inclusive, and basing my decisions on a sound set of values. I work with delegation combined with holding people accountable for moving things forward.

# Innovative technologies

Sobi has developed two proprietary technologies that extend the duration of activity of bio-pharmaceutical drugs. Both technologies may be combined with a variety of differ3ent biological substances to form new drugs with attractive characteristics, which meet significant medical needs. The technologies have been named Elvera™ and Modifa™.

**Elvera**
Elvera is an innovative recombinant polymer mimetic technology that exploits the characteristics of a naturally occurring human protein domain to protect active biological molecules and to extend their circulatory half-life and target tissue exposure. Elvera can be used to fine-tune the pharmacokinetic properties of all types of therapeutic proteins. Furthermore, the technology results in improved stability and reduced non-specific clearance of biologicals such as therapeutic enzymes. Since the resulting protein is fully human, it is not only expected to be well tolerated, it is also fully biodegradable, setting it apart from the commonly used chemical conjugation of PEG to increase half-life. It is a versatile technology which through its tuneable nature can achieve longer or shorter circulation time in the body and may also improve the solubility of drugs.

Elvera can be applied to create biological drugs in all Sobi's therapeutic areas. It may be used to create recombinant fusions for the potential treatment of haemophilia, genetic metabolic diseases and inflammatory conditions.

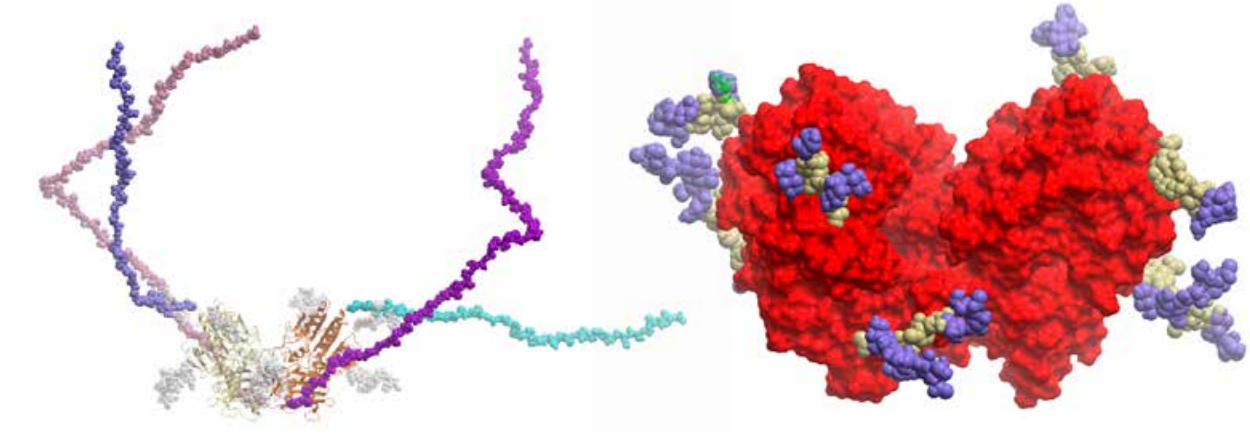
Sobi has applied for patents on Elvera both regarding composition of matter and methods.

**Modifa**
Modifa works by modifying glycans, a type of sugar molecule that is present in peptides and proteins, and causes the peptide or protein to leave the body rapidly through the liver. With this modification, the protein molecules stay longer in the circulation and as a result, their distribution may be altered, thereby enabling penetration of the blood-brain barrier or distribution to hard-to-reach tissues such as cartilage and bone.

Sobi is using the technology in the development of SOBI003, where Modifa is applied to the enzyme sulfamidase in an effort to treat the rare serious genetic disease Sanfilippo syndrome A (MPSIIIA) caused by mutations which result in shortage of this enzyme (see page 31). The technology's ability to help proteins penetrate the blood-brain barrier may prove to be a breakthrough in developing treatments for many serious conditions.

The technology is based on chemistry that is flexible and adaptable.

Sobi has applied for patents on Modifa both regarding composition of matter and methods.



Elvera is an innovative recombinant polymer mimetic technology that can help protect active biological molecules and extend their circulatory half-life and target tissue exposure.

By modifying glycan sugar molecules, Modifa can help protein molecules to circulate longer, thereby enabling penetration of the blood-brain barrier or distribution to hard-to-reach tissues such as cartilage and bone.


"As patients who have not had access to treatments before are given the opportunity to live longer lives, the medical need changes and new challenges are presented."

# Sustainability

## Sobi contributes to a sustainable future as part of our vision of becoming a global leader in providing access to innovative treatments that make a significant difference for individuals with rare diseases.

The Group's overall objective from a sustainability perspective is tied to this overall vision: to contribute to the societies in which Sobi operates by improving access to treatment of rare diseases. A sustainable business entails a commitment to responsibility for patients and employees, reduced environmental impact from operations and treatment, as well as long-term sustainable profitability.

## Our values

Sobi's values are the starting point for our approach to sustainability. The Code of Conduct & Ethics also contains policies guiding sustainability activities. Together these provide a solid foundation for our work with sustainability.

We care about our world, but primarily we care about people – in particular, people with rare diseases and our colleagues at Sobi. During 2017, we evolved our previous CARE values (Collaborative, Accountable, Respectful, Engaged) which have been central to who we are and the way we work. 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 new values that build on the CARE values. These are Care, Ambition, Urgency, Ownership and Partnership. They will help us to develop the spirit of leadership and entrepreneurship that we need to become recognised as a leader in rare diseases.

**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.

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

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

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

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




# Material sustainability issues

Sobi's material sustainability issues were developed during 2017. Based on ongoing input from external stakeholders and an internal analysis of the growth strategy, the Executive Committee approved an updated materiality analysis. Sobi's material sustainability issues have been clustered in relation to their potential to create value, ability to support a responsible business, and expectations to adhere to laws, regulations and society's expectations.

The materiality analysis forms the basis for Sobi's sustainability programme. The programme is under development and current initial activities aim to define the overall objective, targets and indicators to further drive performance.

| | Material issues |
|---|---|
| **Value creation** | • Improving global access to treatments for rare diseases<br>• Quality and supply chain management<br>• Strategic research and development |
| **Compliance and ethics** | • Regulatory and legal environment<br>• Developing our people<br>• Ethical practices and collaborations |
| **Responsibility** | • Environmental impact<br>• Patient and customer integrity<br>• Responsible tax<br>• Anti-corruption<br>• Anti-competitive practices |

## Contribution to the UN's Sustainable Development Goals

The United Nations' Sustainable Development Goals are 17 global goals, approved by more than 150 countries in 2015, to be reached before the end of 2030. Sobi recognises the important role of business in the achievement of these goals. Based on the growth strategy and the materiality analysis, Sobi has identified nine goals to which our operations contribute the most. The most strategic global goal for Sobi is number three "Good health and well-being" and specifically target 3.8: Achieve 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. For Sobi, this is sustainability.

### UN'S SUSTAINABLE DEVELOPMENT GOALS

Sobi has identified that, through our actions, we are able to influence a number of the Sustainable Development Goals.

## Value creation

### Improving global access to treatments for rare diseases

Access to treatments for rare diseases is provided through the business areas Haemophilia and Specialty Care. An integrated approach is required to ensure that patients can access treatment and achieve the best possible outcomes. Successfully providing such treatment requires comprehensive and sustainable solutions in several dimensions, including access to early diagnosis and treatment, a long-term commitment to the community and healthcare systems, and responsible pricing. With a strong focus on patient and medical needs, responsible pricing, adaptive regulatory pathways, partners for manufacturing and an extensive and efficient distribution network, we work continuously to shorten the time it takes for products to reach patients.

**Responsible pricing**
An effective treatment is one that not only provides a medical benefit but is also both available in the country where the patient lives and is affordable in the healthcare system. One of the most crucial factors to ensure patient access to treatment is responsible pricing.

Sobi is committed to playing an active role in the dialogue with stakeholders, governments and healthcare systems, to ensure that patients get timely and sustainable access to required medicines, irrespective of where they live and irrespective of the level of development of the local healthcare system. We aim to set prices at a local level according to local needs and preconditions. Our ambition is to work with local health communities to improve health policies and to ensure sustainable access to treatment.

**Bridging and access programmes**
Sobi acknowledges the fact that where the local government and/or healthcare system has not yet included therapies in their local healthcare provisions, patients suffering from rare conditions do not have access to the same quality of treatment as other patients. In these situations, Sobi is committed to working with governments in finding a way to secure that patients get access to treatments through bridging programmes, to bridge access until reimbursed access is secured. In developing and emerging markets, Sobi also works with governments and local and international patient organisations, to fulfil a humanitarian aid need, while working with key stakeholders to build and lay the foundation to move from donation to sustainable reimbursed access by governments and/or healthcare systems.

In the US, Sobi provides financial assistance for people in need of treatment with Orfadin and Kineret, to bridge access until reimbursement is in place. Sobi is also bridging access in other countries based on individual patient need and engages in dialogue with authorities to adapt local regulations – a successful approach that has provided access to treatment in Chile.

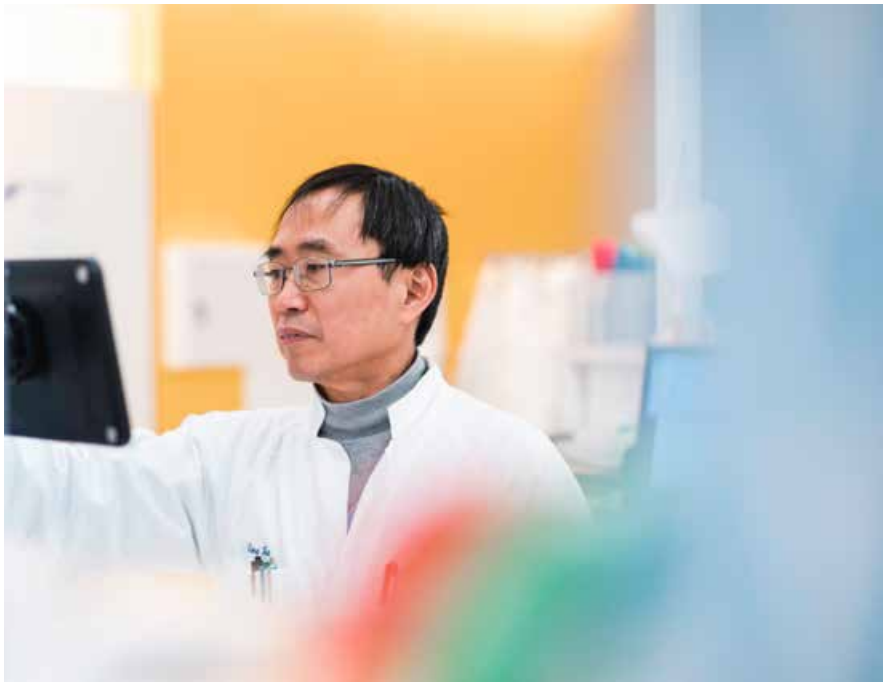
Since 2015, Sobi in collaboration with Bioverativ, a Sanofi company, has contributed to providing access to a predictable supply of innovative and effective haemophilia treatment to people in developing countries. The companies have pledged to donate up to 1 billion international units of clotting factor between 2015 and 2025. Of these, 500 million have been earmarked for the World Federation of Hemophilia, which is working to ensure a sustainable shift and predictable access to treatment in local markets.

In several European countries with developed healthcare systems but limited budgets, the volumes of factor replacement necessary to treat haemophilia effectively are not available, despite minimum treatment recommendations. In order to bridge the gap between the recommendations and current access in those countries, the European Haemophilia Consortium (EHC) has developed the Procurement of Affordable Replacement Therapies – Network of European Relevant Stakeholders (PARTNERS) programme, in which Sobi is a key player. This is a new and innovative approach to the sustainable procurement of treatment products for haemophilia A and B in select countries meeting EHC-specified criteria and located both inside and outside the EU.

"I have treated patients with HT-1 with Orfadin for over 20 years thanks to the support of Sobi. I am grateful for Sobi's initiative to work towards securing sustainable treatment for these patients."

Dr Dweikat, Jerusalem

## Quality and supply chain management



**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.

Counterfeit pharmaceuticals are a growing worldwide problem. To combat this hazardous and illegal business, governments all over the world are introducing regulations and systems to detect and prevent the distribution of counterfeit products. Sobi's products have not yet been subject to falsification. All Sobi products will be serialised from February 2019.

**Enabling global access to treatments**
We market and sell products in more than 70 countries, typically in small volumes aimed for a small number of patients. Because patient safety is our single most important responsibility, ensuring that patients never risk being without their medication is paramount because it could cause life-threatening situations. We have therefore built up robust supply and distribution processes covering all our markets.

Manufacturing of our products for which Sobi is Market Authorisation Holder is performed by 15 contract manufacturing organisations (CMOs) in Europe and the US, all of which fully comply with good manufacturing practices (GMP) ensuring that all products are produced and controlled according to quality standards for pharmaceuticals.

**Full control of supply and distribution**
Our Logistics Development and Supply unit is responsible for managing the global CMO network and ensuring uninterrupted, reliable and sustainable transportation of products. Biologics are sensitive and often require cold-chain supply to ensure product integrity and quality. It is vital to have full control of the entire supply and distribution chain – from manufacturing to patient.

The manufacturing process itself contains three steps: manufacturing of drug substance, manufacturing of drug product and finally the packaging of finished goods. Depending on the product, there can be different partners for each step or the same partner for several steps. All manufacturers of products for which Sobi is Market Authorisation Holder are required to meet our Code of Conduct and Ethics. Manufacturers are normally contracted long-term and are monitored closely. For products sold on a partner basis, we strive to ensure that all providers comply with the code.

Distribution is characterised by collaboration and strong commitment to patient health. We assume responsibility for ensuring the right products of specified quality arrive in the right quantities at distribution units, ensuring their quick and efficient physical delivery to patients when an order arrives. Our Transport and Trade Compliance unit ensures that trade laws and regulations are followed.


*By 2019, all Sobi products will have a unique identity code.*

*"Patient safety is our most important responsibility", Arvid Cronlund, Head of Drug Safety.*

## Strategic research & development

Research and development activities are of strategic importance for us in our efforts to improve global access to innovative treatments for rare diseases. In these activities, we strive to maintain the highest ethical, technical and scientific standards.

Our ambition is to become a long-term global leader in the rare-disease field. Making a difference to individuals with rare diseases requires us to remain relevant to them throughout their lives. Therefore, we need to reinvest in research and development to be able to continue to provide innovative treatments. We liaise with physicians, payers and patient groups to obtain a good understanding of patients' and society's needs, and design our research and development projects based on the knowledge gained.

**An integrated company**
Our expertise includes an understanding of the elements needed to successfully scale up and prepare for commercial production. A holistic view of the process, with integrated development and manufacturing approaches, supports our ability to reduce the overall time from early development to products reaching the patients, without compromising safety.

As a mid-sized rare-disease company, our partnerships are key to building a successful pipeline. Our expertise in biologics and protein engineering, in collaboration with partner companies, has allowed us to design and produce therapeutic proteins with the potential to transform the lives of rare-disease patients – our partnership with Bioverativ regarding the development of Alprolix and Elocta being an example of such a collaboration. We are also developing platforms aimed at extending the time molecules circulate in the body (half-life), which may present both us and other partners with even more opportunities to develop novel and clinically relevant treatments for rare and other diseases (see page 34).

**Responding to patient insights**
In order to make a significant difference for individuals with rare diseases, we are also developing existing drugs to meet new medical needs. As patients who have not had access to treatments before are given the opportunity to live longer and healthier lives, the medical need changes and new challenges are presented. Orfadin, our treatment for HT-1, has allowed people living with the disease to become adults. To meet the needs of adulthood, new formulations of Orfadin better suited to adults have been developed and introduced.

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.

**Positioning Sweden as a leader in biologics**
We are also participating in the Swedish government's strategic programme in life sciences to support the future development and production of biologics in Sweden, aimed at positioning Sweden as a leading nation in this field. The programme runs over a period of eight years, until 2024, with government funding of SEK 320 million as well as private funding.

**Exploring new technologies**
We are working jointly with academia and participated in three centres and projects focused on development and manufacturing of biologics in 2017. Sobi contributes through financial "in-kind" funding and competence. The initiative has allowed us to explore new technologies that are expected to have an impact on development and manufacturing lead times. The academic network provided through this partnership also allows us to connect with students and graduates, both equally benefiting from competence and experience sharing.

> "We have been pioneers in haemophilia for the past 35 years – We intend to continue bringing innovation to the community for at least another 35 years to come."
>
> Philip Wood, Head of Haemophilia

## Compliance and ethics

### Regulatory and legal environment

We operate in a highly regulated environment and are subject to laws and regulations governing research, production and marketing. There is also a general trend towards greater awareness of liability issues and legal risk as well as increased transparency requirements. In parallel, our operating environment is constantly changing, requiring an adaptive and agile approach towards evolving regulatory and legal requirements as well as to stimulate innovation.

Sobi manages regulatory and legal engagement through various internal processes and control measures, such as continuous scientific, regulatory and compliance training. The aim is to secure high-quality research, considering all relevant precautionary principles, and production as well as transparent and comprehensive marketing. During 2017, no incidents of non-compliance concerning marketing communications have been identified or reported.

### Developing our people

To continue building a company that remains innovative and high-performing while growing, we aim to foster a strong culture and create and sustain an organisation where continuous learning is key.

**Culture-supported performance**
We seek to engage our people in high-performing teams to deliver in a competitive market and to reach challenging goals in a way that is aligned with corporate objectives and values. Training in our culture and values (see page 36) plays a vital role in building the business.

We strive to promote a performance-based culture based on individual accountability, mandate and ownership. A critical factor in these efforts is to set, and continuously support, individual goals linked to strategic business objectives. However, performance is not only about what individuals achieve but also how these objectives are achieved.

We are committed to providing a safe and healthy workplace for our

**850**

people around the world.

Our people are expected to achieve individual and team performance goals in line with the corporate values. We endeavour to offer competitive salaries and benefits, which are individually determined. We perform regular benchmarks to ensure that compensation is on a par with similar companies.

**Competence development**
sInnovation is essential for a growing and research-based company such as Sobi. An adaptive and agile approach to respond to our evolving requirements is important to stimulate innovation. Through feedback and cross-functional teams we aim to develop a change-ready mind-set across our organisation, a learning process that is dependent on individuals across Sobi being engaged in and committed to our shared day-to-day operations.

Professional development for all employees is seen as essential for both development of Sobi's product portfolio as well as the organisation as a whole. In 2017, we implemented a training matrix system across the organisation in line with regulatory requirements, to serve as a comprehensive platform for ensuring individualised and specialised training as well as evidence of learning.

During the year, 99.1 per cent of all employees received a regular performance and career development review. In 2017, Sobi employees spent on average 26 hours completing training through e-learning. This does not include on-the-job or standard operating procedure (SOP) training or external training opportunities.

**Safe and healthy labour practices**
We are committed to providing a safe and healthy workplace for our 850 people around the world. Activities to protect labour rights are based on our responsibilities as an employer, and we encourage suppliers and partners to adopt socially responsible labour practices as well. We respect the international labour standards set forth by the International Labour Organization (ILO) and complies with national labour laws.

The Environmental, Health and Safety (EHS) Policy and guidelines aim to promote a working culture where every employee and manager is personally responsible for ensuring a safe and healthy workplace, through preventive measures and regular training.

The health and safety committee represents all employees in Sweden. Country managers have the overall responsibility for health and safety within their own operations.

Investigating and identifying the cause(s) of an accident, dangerous situation or near miss makes it possible to take action to prevent a similar occurrence in the future. All employees are required to report EHS-related incidents to their employer. In 2017, 23 accidents were reported, none of which led to sick leave.

**Diversity supports growth**
We have expanded internationally in recent years. The successful incorporation of new knowledge and influences is building the future company. The combination of rare-disease competencies and specific therapeutic knowledge has guided the recruitment process.

Our business relies on the knowledge and competence of our people. Competitive terms of employment are a prerequisite for recruiting and retaining high-calibre people. We endeavour to offer competitive salaries and benefits, individually determined and adapted to the local labour market.

We are committed to providing equal employment opportunities regardless of race, age, gender, religion, national origin, sexual orientation or physical ability. During 2017, focus was placed on strengthening the general knowledge about Sobi's Code of Conduct & Ethics and non-discrimination policies. Sobi's guidelines clearly position against sexual harassment. Sobi's Compliance Hotline is a third party whistle-blower service available to all Sobi employees which offers the option of reporting an issues anonymously. In 2017, there was no incident of discrimination.

We believe that diversity among people contributes to progress and mutual enrichment. Of the total number of people in 2017 (2016), 41 (42) per cent were men and 59 (58) per cent women. The corresponding figures for the Executive Committee and Board of Directors (excluding employee representatives) were 78/22 per cent and 67/33 per cent respectively.

## Ethical practices and ethical collaborations

Sobi promotes business ethics by enforcing compliance with our corporate principles, and by supporting a culture that promotes an open discussion of ethics in our operations and among key stakeholders.

**Ethical standards across the value chain**
We work actively to prevent all forms of corruption and to ensure compliance with our ethical standards across the value chain. There is a zero-tolerance policy towards bribery, supported by the Sobi Code of Conduct and Ethics and the Sobi Global Policy on Anti-Corruption, which have both been translated into relevant business processes, such as those governing interactions with healthcare professionals and organisations.

**Engagement with organisations**
To develop and deliver treatments that help meet the needs of patients and their families, our organisation strives to learn from them about their challenges, and the success and limitations of current treatment options. For this purpose, we collaborate with stakeholders throughout the value chain: from research and clinical programmes to patient access and pricing. Collaborations span all stakeholders, including national and regional patient organisations, governments and healthcare systems.

There are company-wide guidelines in all business areas that support compliance with the regulations regarding ethics and transparency in engagement with external organisations.

**Ethical research standards**
The safety of individuals who take part in clinical trials is of the utmost importance, building on rigorous, scientifically based evaluations by clinical experts in cooperation with regulatory authorities, independent ethics committees and stakeholders. To guide the ethical conduct of all research involving humans, we apply the Declaration of Helsinki's principles for medical researchers. All Sobi-sponsored clinical studies are conducted and reported in accordance with applicable law and the international Good Clinical Practice (GCP) standard. We collaborate to a substantial extent with contract research organisations (CROs) when conducting clinical trials. 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.

## Responsibility

### Environmental impact

Proactive environmental management is part of a sustainable business. We meet our environmental responsibility by performing risk assessments and acting to reduce these risks even further, managing chemicals and waste by phasing out chemicals of high concern, and working with energy and water consumption plans in our production facilities. Environmental considerations are integrated into activities and operational control, and formal responsibility has been delegated across the line organisation. We strive to comply with all environmental laws and regulations.

All employees are required to undergo annual Environmental Training, covering risk assessment, greenhouse gas emissions and the management of chemicals and waste in the environment.

**Chemicals management**
Chemical regulations, aimed to eliminate adverse effects on the environment and human health, are extensive and continuously expanding. The handling of chemicals in R&D and manufacturing processes within Sobi follows clear instructions, with annual risk assessments and internal audits of processes carried out.

**Pharmaceuticals in the environment**
The environmental hazard of a specific drug refers to its inherent properties, such as toxicity, the ability to be broken down by nature and the capacity to be stored in the fat of animals. 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 these are unlikely to pose any significant risk to the environment.

**Energy use and greenhouse emissions**
Business travel is one of the largest sources of greenhouse gas emissions from our activities. As operations expand, face-to-face meetings with the multidisciplinary teams across the organisation are important to achieving operational goals. The importance of complying with the Travel Policy, which calls for consideration of virtual meetings when possible, is emphasised continuously and the company provides tools for virtual meetings.

We are committed to improving energy efficiency at our sites, and regularly review and monitor the operating costs of our buildings. An energy management plan for the production facility in Stockholm has contributed to reduced energy and water consumption relative to production capacity: although production volumes of ReFacto AF increased by 15 per cent, consumption of energy increased by only 0.8 per cent.

### Patient and customer integrity

It is important that customers, clinical trial subjects, staff and others we interact with can rely on Sobi managing and processing personal data in a responsible and safe manner, and in accordance with applicable laws and regulations. Emerging EU legislation imposes additional requirements on businesses processing personal data. To comply with these new requirements, we have assessed our framework and made necessary adjustments: for example 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. We have adopted a governance model that supports the compliant use of data and have provided relevant training to the organisation. An updated data privacy organisation will secure compliance from 2018.

In 2017, we had one Data Breach incident documented.

### Responsible tax

Sobi pays corporate taxes in a responsible way. This means paying taxes where profits are earned in accordance with international transfer pricing rules. It means having a balanced tax risk profile and not engaging in tax-avoidance activities, as well as keeping tax levels stable and predictable, insofar as prevailing business conditions permit.

## Anti-corruption and anti-competitive practices

An open dialogue on ethical issues provides the foundation for our efforts to prevent corruption. The dialogue is supported by annual training for all people, where the Code of Conduct and Ethics and other related procedures are translated into a business context; completion of this training is a prerequisite to be eligible for and receive incentive payments. In 2017, 100 per cent of the employees participated in the training. No cases of corruption where reported during the year. Zero cases of non-compliance with laws and regulations within the economic and social area were reported.

**Transparency in business operations**
In the rare-disease community, collaborations between authorities, healthcare professionals, companies and patient organisations have always been a cornerstone for the development of new and better treatments. Such collaboration needs to be carried out in a correct and transparent manner. By further increasing transparency the community can achieve an even stronger basis for continued collaboration with positive impacts on the quality of research, development and manufacturing.

Sobi has had a programme for Health Care Compliance (HCC) in place for quite some time. HCC 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 programme contains policies and controls aimed at minimising the risk of corruption.

We support 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.

**Procurement**
We procure materials, goods and services from more than 1 000 suppliers. Establishing good relationships with these suppliers promotes sustainability and responsibility in the industry. We strive to apply consistent rules to all suppliers based on our Code of Conduct and Ethics. Our authorisation and sign-off procedures also reflect our anti-corruption commitment and help to ensure that we enter agreements and perform procurements in a transparent and responsible manner. During 2017, all new suppliers were screened based on requirements in our Code of Conducts and Ethics.

Purchasing can be divided into two main categories: products governed by international and national regulatory requirements and standards, and products of a general nature for all companies regardless of industry. Purchases in the first category are made after careful evaluation according to our governing documents and procedures, followed by continuous assessments. In the second category, the company procures goods at the best terms, balancing price and quality in consideration of the relevant industry's standards of responsibility. We also work with due diligence to ensure that service providers comply with our anti-corruption standards.

# Sustainability and risk management

The aim of our approach to risk management is to identify the risks that could affect the company's ability to achieve our business goals, and to proactively manage those risks in a professional manner to safeguard the company's ability to execute on the strategy.

Sobi has a business-integrated risk management process. Business intelligence, risk management and business continuity management are all integrated into the strategy and business planning process as part of the regular corporate planning procedure. The risk management process is linked in an integrated and seamless way to all units and other processes – quality evaluation, financial planning and strategy – within the company.

During the year, some areas became more important to address to reduce the potential risk impact. Competition in commercial markets, especially in Haemophilia and for Orfadin, was one such area. Another is the continued need to balance the development portfolio in terms of the developmental stages. For this reason, a clear strategic direction aimed at acquiring new programmes, projects or treatments through in-licencing or acquisition has been announced.

The assessment of sustainability risks is an integrated part of Sobi's risk management process. The sustainability risk table identifies material risks in relation to our identified sustainability issues. Read more on pages 126–127.

# A strong heritage in biologics and rare disease

**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 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 with Syntonix (subsequently Bioverativ) is signed 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 lists 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 studies 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**
The decision is taken to initiate final registration studies for rFIXFc after safety and efficacy in previously treated (PTPs) haemophilia B subjects is established in phase 1/2a clinical studies.

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 studies, A-LONG and B-LONG.

**2011**
Data from the rFVIIIFc haemophilia phase 1/2 study shows an approximately 1.7-fold increase in half-life compared with Advate®, 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.

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


**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 studies 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 the Sobi territories. Sobi also adds a potentially longer-acting haemophilia A candidate, rFVIIIFc-VWF-XTEN to the agreement with Biogen.

The Kiobrina project was 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 a 20 mg capsule 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 Bioverativ. The first patients are recruited to the clinical studies anaGO and anaSTILLs 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.

# Sobi's share

## 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 200 per cent.

In 2017 the highest price paid was SEK 143.80 on 5 June, and the lowest was SEK 106.10 on 25 January. Sobi's market capitalisation at year-end 2017 was SEK 30.6 billion. Over the past five years, the share price has risen 202 per cent.

**Turnover and trading locations**
The Sobi share is traded on several exchanges and trading platforms. In 2017, official trading accounted for 92 per cent of turnover in the share, of which the Nasdaq Stockholm accounted for 47 per cent. Unofficial "off-book" trade in what are called "dark pools", private trading forums, represented 8 per cent of trading in the share, with the largest number of trades on UBS MTF.

The average daily turnover in the Sobi share was 704,589 shares in official trading. In 2017, a total of 176.9 million shares were traded, corresponding to a value of approximately SEK 46.1 billion.

**Share capital**
At year-end, the total number of ordinary shares outstanding in Sobi was 272,507,708. Each ordinary share carries one vote. All C shares were converted during the year.

At year-end, the share capital was SEK 149,526,711, distributed between 272,507,708 shares with a par value of approximately SEK 0.55.

**Largest shareholders at 31 December 2017[1]**

| Shareholders | Number of A shares | Share capital, % | Share votes, % |
|---|---|---|---|
| Investor AB | 107,594,165 | 39.48 | 39.48 |
| Swedbank Robur fonder | 14,945,541 | 5.48 | 5.48 |
| Mellon Omnibus 15%, Agent F ITS clients | 12,263,370 | 4.50 | 4.50 |
| Fjärde AP fonden | 11,653,245 | 4.28 | 4.28 |
| AMF Försäkring och Fonder | 9,186,284 | 3.37 | 3.37 |
| Lannebo fonder | 9,034,328 | 3.32 | 3.32 |
| SEB Investment Management | 6,827,457 | 2.51 | 2.51 |
| Handelsbanken fonder | 6,300,097 | 2.31 | 2.31 |
| Gladiator | 4,650,000 | 1.71 | 1.71 |
| Swedish Orphan Biovitrum AB (publ) | 3,249,870 | 1.19 | 1.19 |
| JPM Chase NA | 3,204,789 | 1.18 | 1.18 |
| Länsförsäkringar fondförvaltning AB | 3,048,381 | 1.12 | 1.12 |
| Afa Försäkring | 2,843,306 | 1.04 | 1.04 |
| Goldman Sachs & Co. LLC, W9 | 2,541,494 | 0.93 | 0.93 |
| State Street Bank and Trust Co. | 2,185,930 | 0.80 | 0.80 |
| **Total 15 largest shareholders** | **199,528,257** | **73.22** | **73.22** |
| Other | 72,979,451 | 26.78 | 26.78 |
| **Total** | **272,507,708** | **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 2,175,157 shares, or 0.8 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 22,938 (32,397). The largest shareholder, Investor AB, held 39.5 per cent (39.6) of the shares. Swedish legal entities, including institutions and funds, held 75.9 per cent (77.2). Treasury shares held by Swedish Orphan Biovitrum AB (publ) at year-end totalled 3,249,870 common shares.

During the year, 478,154 shares were used for allotment under two performance-based long-term share programmes.

**Dividend**
The Board proposes that no dividend be paid for 2017. 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
- Focussing 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 on Nasdaq Stockholm**

| SEK 1,000 | 2013 | 2014 | 2015 | 2016 | 2017 |
|---|---|---|---|---|---|
| A shares | 22,446 | 43,445 | 100,369 | 131,644 | 86,178 |

In 2017, the average daily trading volume in number of shares for the Sobi share on Nasdaq Stockholm was 704,589 shares.
Source: SIX Trust

**Shareholder categories**

| 31 Dec. 2017 | % of capital |
|---|---|
| Foreign shareholders | 18.8 |
| Swedish shareholders | 81.2 |
| Of which: | |
| Institutions | 94.6 |
| Private persons | 5.4 |

Source: Euroclear

**Key data per share**

| SEK | 2013 | 2014 | 2015 | 2016 | 2017 |
|---|---|---|---|---|---|
| Earnings/loss per share | –0.35 | –1.01 | 0.31 | 2.99 | 4.27 |
| Equity per share | 17.5 | 16.6 | 17.3 | 19.8 | 24.6 |
| Market price, Series A-share, 31 Dec., last paid price, SEK | 66.75 | 79.35 | 134.6 | 106.7 | 112.3 |
| P/E ratio | –190.7 | –78.6 | 434.2 | 35.7 | 26.3 |
| Number of shares at 31 Dec. | 270,389,770 | 270,785,950, | 271,822,806 | 272,010,948 | 272,507,708 |

**Analyst coverage during 2017**
The following research analysts followed Swedish Orphan Biovitrum (Sobi) during 2017. For a current list, visit sobi.com

| | |
|---|---|
| Carnegie | Erik Hultgård |
| Danske Bank | Lars Hevreng |
| Deutsche Bank | Richard Parkes |
| Handelsbanken | Peter Sehested |
| Jefferies | Eun K. Yang |
| Nordea | Hans Mähler |
| Pareto Securities | Peter Östling |
| Rx Securities | Samir Devani |
| SEB | Richard Koch |

**Recommendations from analysts, %**

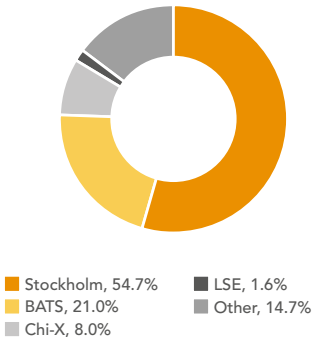
| | 2015 | 2016 | 2017 |
|---|---|---|---|
| Buy | 75 | 73 | 56 |
| Hold | 25 | 9 | 33 |
| Sell | 0 | 18 | 11 |

Source: Based on analyst reports

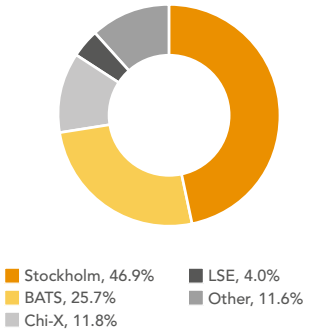
**Brief facts, the Sobi share**

| | |
|---|---|
| Listing | Nasdaq Stockholm |
| Number of shares (A shares) | 272,507,708 |
| Market capitalisation, at year end | SEK 30.6 billion |
| Ticker | SOBI |
| ISIN | SE0000872095 |
| CUSIP | 870321106 |

**Trading places 2016**

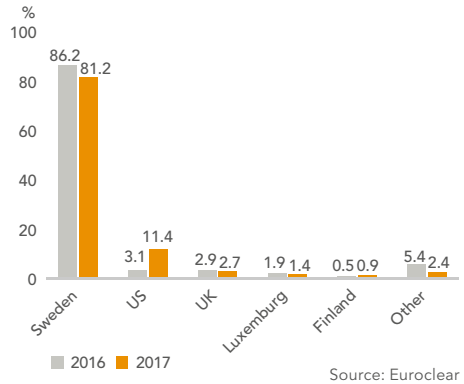



**Trading places 2017**



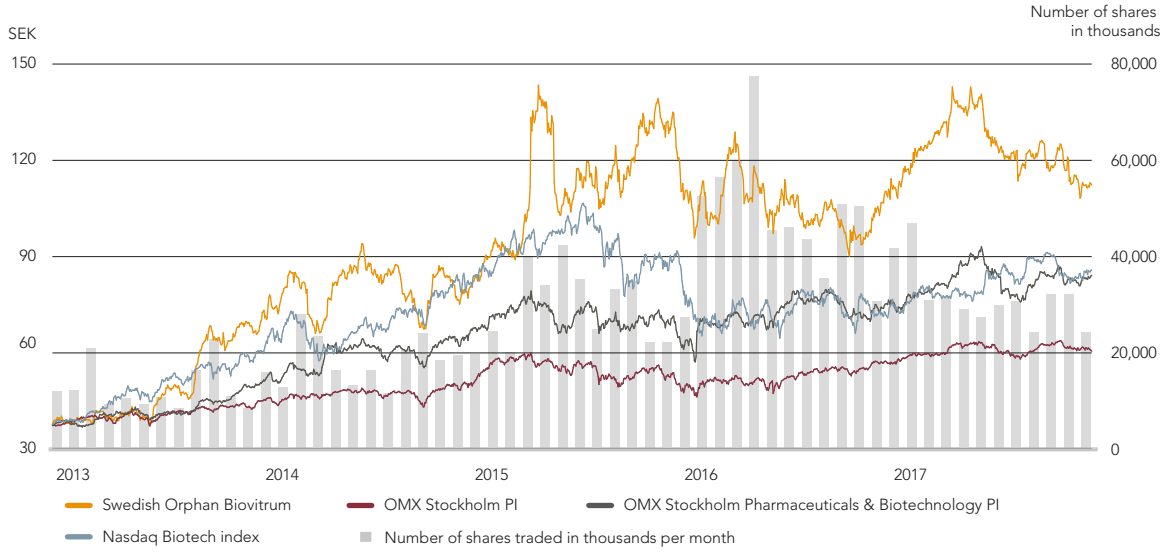

Source: Fidessa

**Shareholders by country**




Source: Euroclear

**Sobi share price and trading volume 2013–2017**




## CONTACT DETAILS

**For more information about Sobi's American Depositary Receipt (ADR), contact:**
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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 Jörgen Winroth, Head of Investor Relations.

# Five-year summary – Group development

| | 2013 | 2014 | 2015 | 2016 | 2017 |
|---|---|---|---|---|---|
| **Income statement, SEK M** | | | | | |
| Operating revenue[1] | 2,177 | 2,607 | 3,228 | 5,204 | 6,511 |
| Gross profit | 1,284 | 1,548 | 2,007 | 3,651 | 4,657 |
| EBITDA[2] | 241 | –12 | 465 | 1,574 | 2,086 |
| EBITA[2] | 211 | –44 | 433 | 1,543 | 2,053 |
| EBIT (Operating profit) | –67 | –325 | 146 | 1,133 | 1,600 |
| Profit/loss for the year | –92 | –270 | 83 | 802 | 1,149 |
| **Capital, SEK M** | | | | | |
| Total assets | 6,525 | 6,375 | 8,315 | 9,974 | 10,903 |
| Capital employed[2] | 5,550 | 5,326 | 5,508 | 5,880 | 6,716 |
| Equity | 4,745 | 4,497 | 4,678 | 5,365 | 6,701 |
| Cash and cash equivalents | 445 | 519 | 904 | 786 | 1,478 |
| Net cash (–)/net debt (+)[2] | 352 | 298 | –82 | –282 | –1,472 |
| **Cash flow, SEK M** | | | | | |
| Cash flow from operating activities before changes in working capital | 166 | 299 | 411 | 642 | 1,431 |
| Cash flow from operating activities | 185 | 234 | 507 | 343 | 1,333 |
| Cash flow from investing activities | –405 | –184 | –143 | –158 | –139 |
| Cash flow from financing activities | 207 | 20 | 22 | –308 | –500 |
| Change in cash and cash equivalents | –13 | 70 | 386 | –123 | 694 |
| **Key figures, %** | | | | | |
| Gross margin[2] | 59 | 59 | 62 | 70 | 72 |
| Return on capital employed[2] | –1.2 | –6.1 | 2.6 | 19.3 | 23.8 |
| Return on equity[2] | –1.9 | –5.8 | 1.8 | 16.0 | 19.0 |
| Equity ratio[2] | 73 | 71 | 56 | 54 | 61 |
| Debt/equity ratio[2] | 37 | 41 | 77 | 86 | 63 |
| **Share ratio, SEK** | | | | | |
| Earnings/loss per share | –0.35 | –1.01 | 0.31 | 2.99 | 4.27 |
| Equity per share[2] | 17.5 | 16.6 | 17.3 | 19.8 | 24.6 |
| Dividend | — | — | — | — | — |
| Cash flow per share[2] | 0.0 | 0.3 | 1.4 | –0.5 | 2.5 |
| Cash flow from operating activities per share[2] | 0.7 | 0.9 | 1.9 | 1.3 | 4.9 |

1. Full year 2016 revenues include a one time credit in Q1 of SEK 322 M relating to the first commercial sales of Elocta, and a one time credit in Q2 of SEK 386 M relating to first commercial sales of Alprolix.
2. Sobi presents certain financial measures in the annual report that are not defined according to IFRS, so called alternative performance measures. These have been noted in the table above and further information on why these are considered important, and how they are calculated, can be found in Definitions at the end of this report.

# Reporting

## Contents

# CFO's statement

## Outstanding performance powers growth

Sobi's outstanding financial performance in 2017 shows how we continue to grow substantially in terms of volume and size. We have established our haemophilia products as leaders in the market, and seen double-digit growth in two key Specialty Care products. This exceptional growth and the resulting strong financial position give Sobi the platform we need to pursue growth.

Our rapid growth continued throughout 2017, with a remarkable financial performance. This was the third consecutive year in which we over-delivered on our financial targets. Our total revenue for 2017 was SEK 6,511 M, up 25 per cent on the year before. Excluding the one-time credits we received in 2016, there was a 45 per cent increase year-on-year. Our gross margin increased by 72 per cent thanks to an improved product mix.

EBITA reached more than SEK 2 billion, which is more than our total revenue figure for 2012. Over the past five years, our revenues have grown by an average of more than 30 per cent per annum. Excluding the one-time credits 2016, which were of a non-cash-flow nature, 2017 EBITA was up 146 per cent on 2016.

We have strengthened our balance sheet significantly, with operating cash flow of more than SEK 1.3 billion. We were also able to pay off our bank loan, and now have a net cash position of SEK 1.5 billion.

**Successful launches in Haemophilia**

We had fantastic growth in our haemophilia products, Elocta® and Alprolix®, in 2017. Product sales for the full-year reached SEK 1,557 M (267) for Elocta and SEK 363 M (60) for Alprolix. The successful launches of both products, together with higher royalties from our collaboration partner Bioverativ, a Sanofi company, due to higher sales in its territories, were the key drivers for this excellent increase in revenue. Over the year, our Haemophilia franchise grew 67 per cent with full-year revenues of SEK 3,088 M (1,853), including royalties.

**Double-digit growth for two Specialty Care products**

Our new Specialty Care business area also performed strongly, demonstrating how it will contribute to our future growth. The core products Orfadin® and Kineret® had double-digit growth in 2017, with increases of 12 per cent and 14 per cent respectively. Xiapex® revenues increased by 7 per cent during 2017.

Total revenue for Specialty Care reached SEK 2,829 M for the full year.

**Financial strength to pursue growth**

We are all very proud of the financial results we were able to achieve in 2017 and the strong financial position in which Sobi is today. Sobi has repaid the entire bank loan of SEK 500 M during the year. This means the company and the balance sheet can afford both to support internal projects and to seize external opportunities, allowing the company to fulfil the strategic direction of pursuing possibilities for further growth.

We now are well placed to continue to grow the company, both organically and through business development activities.

Mats-Olof Wallin, CFO

# Directors' Report

## Highlights 2017

**Financial highlights**

- Total revenue was SEK 6,511 M (5,204), an increase of 25 per cent. Adjusted for one-time credits in 2016, this was an increase of 45 per cent.
- Product sales amounted to SEK 5,917 M (4,548), an increase of 30 per cent.
- The gross margin was 72 per cent (70).
- EBITA was SEK 2,053 M (1,543).
- Profit for the year amounted to SEK 1,149 M (802), corresponding to earnings per share of SEK 4.27 (2.99).
- Cash flow from operating activities amounted to SEK 1,333 M (343).

**Business highlights**

- By the end of the year, Elocta was reimbursed in 22 countries and Alprolix in 14 countries.
- First patients enrolled in the ReITIrate study evaluating immune tolerance induction with Elocta.
- Haemophilia development portfolio expanded by the addition of rFIXFc-XTEN[1] for subcutaneous haemophilia B treatment.
- Orfadin oral suspension and 20 mg capsules approved on several markets.
- The anaGO and anaSTILLs studies with Kineret were initiated.
- Kineret was approved for treating NOMID in Canada.
- SOBI003 was awarded orphan drug designation for the treatment of MPS IIIA in the US.
- Guido Oelkers took over as CEO on 22 May 2017 and appointed a new Executive Committee during the year.
- The new business area Specialty Care was established.

## Sobi's operations

Sobi is an international healthcare company dedicated to rare diseases. Our mission is to make a real difference to the lives of people with rare diseases by providing innovative therapies in our focus areas. The product portfolio is primarily focused on haemophilia and specialty pharmaceuticals. Partnership in the development and commercialisation of specialty pharmaceuticals is an important part of our strategy.

In 2017, the Company generated revenue through:

- Sales of proprietary products, marketing rights for Elocta and Alprolix, and royalty revenue from Bioverativ's sales of Eloctate® and Alprolix.
- Sales of products for which Sobi holds the distribution and/or licensing agreements in Europe, the Middle East, North Africa and Russia.
- Sales of the drug substance for ReFacto AF®/Xyntha® to Pfizer, and royalties from Pfizer's US sales of ReFacto AF/Xyntha.

1. XTEN is a Bioverativ development programme. Sobi has elected to add the programmes to the collaboration agreement but not yet opted in.

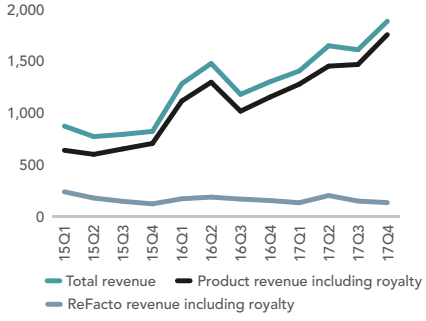
### Key figures

| SEK M | 2017 | 2016 |
|---|---|---|
| Operating revenue | 6,511 | 5,204 |
| Gross profit | 4,657 | 3,651 |
| Gross margin, %[1] | 72 | 70 |
| EBITA [1] | 2,053 | 1,543 |
| EBIT (Operating profit) | 1,600 | 1,133 |
| Profit for the year | 1,149 | 802 |
| Earnings per share, SEK | 4.27 | 2.99 |

1. APM (Alternative Performance Measures).

See page 53 for a five-year summary of revenue, expenses and earnings.

### Revenue trend, SEK M




### Revenue by product category

| SEK M | 2017 | 2016 |
|---|---|---|
| Haemophilia | 3,088 | 1,853 |
| Specialty Care | 2,829 | 2,695 |
| ReFacto | 594 | 656 |
| **Total revenue** | **6,511** | **5,204** |

**Operating revenue**
Revenue increased to SEK 6,511 M (5,204) in 2017. Product sales increased by 30 per cent to SEK 5,917 M (4,548).

*Haemophilia*
Sales in the area of Haemophilia, with the products Elocta and Alprolix, showed growth of 67 per cent, increasing to SEK 3,088 M (1,853). Sales for the comparative year 2016 included one-time credit of SEK 322 M, related to the first commercial sales of Elocta, and a one-time credit of SEK 386 M, related to the first commercial sales of Alprolix. The growth came mainly from France, Italy, the UK and Germany.

Royalty revenue from Bioverativ's sales of Eloctate and Alprolix accounted for SEK 1,168 M (1,525) of the revenue. Product sales related to haemophilia amounted to SEK 1,920 M (327) during the year, with sales of Elocta accounting for SEK 1,557 M (267) of the figure. Sales of Alprolix amounted to SEK 363 M (60) for the year. At year-end, Elocta was reimbursed in 22 countries in Europe, while Alprolix was reimbursed in 14 countries, with the addition of Bulgaria and Greece towards the end of the year.

*Specialty Care*
The Specialty Care business area was formed in 2017 by merging Sobi's operations in Partner Products, Genetics & Metabolism and Inflammation. Specialty Care focuses on rare diseases and niche indications, where there is a great medical need.

The business area has its own distribution networks across Europe, the Middle East, North Africa and North America, which it uses to sell both proprietary and other products. Sales for Specialty Care, comprising the products Orfadin, Kineret, Xiapex and Kepivance® and a large number of products distributed on behalf of partners, increased by 5 per cent to SEK 2,829 M (2,695).

Full-year sales of Orfadin amounted to SEK 862 M (770), an increase of 12 per cent, with strong growth in North America and EMENAR. The growth in North America is largely attributable to the launch of 20 mg capsules and oral suspension. EMENAR performed strongly in all markets, particularly in the Middle East, North Africa and Russia. In 2017, the Orfadin patent expired and competition entered the nitisinone market in the US, Canada and Europe in the form of generic treatments. Despite the new generic treatments, Orfadin sales continued to increase during 2017, driven by the launch of the new formulations and comprehensive patient support services.

The year's revenue from sales of Kineret amounted to SEK 1,142 M (1,001), an increase of 14 per cent, with continuing volume growth in North America and EMENAR. This growth was mainly driven by increasing interest in the area of interleukin-1.

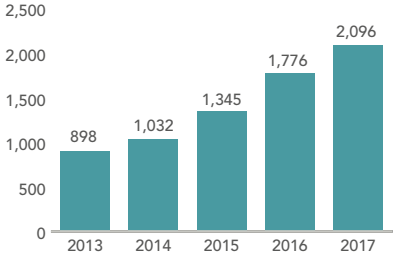
Revenue from Xiapex amounted to SEK 164 M (153), an increase of seven per cent. The growth was driven by good uptake in both Dupuytren's contracture and Peyronie's disease, particularly in less mature markets.

*ReFacto*
The ReFacto business area's total revenue from manufacturing and royalties amounted to SEK 594 M (656). Manufacturing revenue declined by 2 per cent to SEK 559 M (569), while royalty revenue declined by 61 per cent to SEK 34 M (88) due to the expiration of Sobi's rights to royalty revenue on sales outside the US on 1 June 2016. The present supply agreement for ReFacto AF/Xyntha runs until 31 December 2023, with an option to renew. Sobi's royalty agreement for ReFacto in the US remains valid until January 2018.

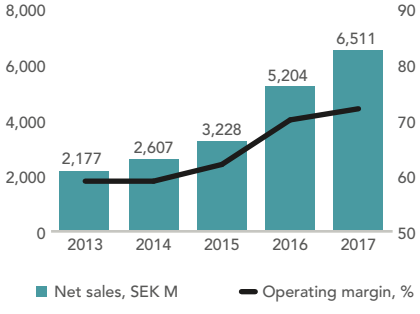
**Gross margin**
The gross margin increased to 72 (70) per cent thanks to an improved product mix driven by a continued strong development of Elocta and Alprolix.

**Expenses**
Operating expenses increased to SEK 3,057 M (2,518). The increase was partly due to higher selling and administrative expenses associated with the strengthening of Sobi's management team and strategic initiatives for future development. The increase is also reflective of investments to support the continuing launch of Elocta and Alprolix. Selling and administrative expenses amounted to SEK 2,096 M (1,776).

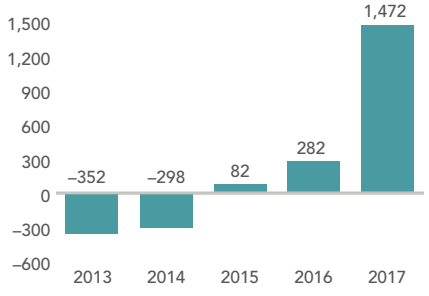
**Selling and administrative expenses, SEK M**




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




**Net cash (+)/net debt (–), SEK M[1]**




1. APM

Other factors that contributed to the increase in operating expenses were higher R&D expenses reflecting clinical operations for Elocta, Sobi's share of Bioverativ's development costs for Elocta and Alprolix, early development programmes and the programme for Kineret, anaGO, for acute gout. Research and development expenditure amounted to SEK 908 M (778).

Operating expenses also include costs of SEK 84 M (36) for the long-term incentive programmes. Cash flow is not affected by these programmes until they are vested, and then as social costs.

Other operating income and expenses amounted to SEK –52 M (36). Operating revenues and expenses for this year and the previous year are related to currency effects.

### Earnings

Earnings before amortisation of intangible assets (EBITA) amounted to SEK 2,053 M (1,543). Amortisation of intangible assets was SEK 453 M (410), including a write-down of a clinical programme at an early stage of SEK 12 M. EBIT amounted to SEK 1,600 M (1,133).

### Net financial items

Net financial items for 2017 amounted to SEK –68 M (–85) of which SEK –50 M (–51) relates to interest to Bioverativ and SEK –14 M (–29) to interest on external loans. This derives primarily from the redemption in 2016 of a bond which has resulted in reduced interest costs. The net financial items included exchange gains/losses of SEK –3 M (5). Net financial items comprised finance income of SEK 1 M (8) and finance costs of SEK 69 M (93). In addition to currency effects, net financial items consisted of interest income and interest expenses.

### Taxes

Current tax for the year amounted to SEK –209 M (–82), while deferred tax was SEK –175 M (–164). Total tax recognised for the Group was SEK –384 M (–246). Deferred tax for the previous year has been adjusted during 2017 by a net amount of SEK –7 M as a result of the return to the residual value method of depreciation in Q2 2016 and deferred tax on cash flow hedges for which the tax is now assessed as non-temporary. The adjustments have affected deferred tax in both the Parent Company and the Group, but have not had any effect on taxes paid. See also notes 16 and 21.

### Other comprehensive income

Other comprehensive income amounted to SEK 147 M (–170) (net) and consisted of cash flow hedges attributable to future inflows in USD, current tax on these hedges, exchange differences and revaluation of the pension obligations and deferred tax on these.

### Cash flow and investments

Cash flow from operating activities amounted to SEK 1,333 M (343). Cash flow from investing activities was SEK –139 M (–158).

An increase in working capital had an effect of SEK –98 M (–300 ) on cash flow. The increase was mainly attributable to trade receivables and increased inventories as a result of

### Five-year summary, Group

| SEK M | 2017 | 2016 | 2015 | 2014 | 2013 |
|---|---|---|---|---|---|
| Operating revenue | 6,511 | 5,204 | 3,228 | 2,607 | 2,177 |
| Cost of goods and services sold | –1,854 | –1,554 | –1,221 | –1,059 | –893 |
| Research and development expenditure | –908 | –778 | –513 | –501 | –456 |
| Operating profit (EBIT) | 1,600 | 1,133 | 146 | –325 | –67 |
| Net financial | –68 | –85 | –61 | 5 | –56 |
| Profit for the year | 1,149 | 802 | 83 | –270 | –92 |
| Earnings per share, SEK | 4.27 | 2.99 | 0.31 | –1.01 | –0.35 |
| Earnings per share after dilution, SEK | 4.25 | 2.98 | 0.31 | –1.01 | –0.35 |
| Number of shares, thousands | 272,508 | 270,390 | 270,390 | 270,390 | 270,390 |
| Equity/assets ratio[1] | 61% | 54% | 56% | 71% | 73% |

1. APM.

### Revenue by product category (Group)

| SEK M | 2017 | 2016 |
|---|---|---|
| Elocta | 1,557 | 267 |
| Alprolix | 363 | 60 |
| Royalty revenue | 1,168 | 1,525 |
| **Haemophilia** | **3,088** | **1,853** |
| Orfadin | 862 | 770 |
| Kineret | 1,142 | 1,001 |
| Xiapex | 164 | 153 |
| Other | 661 | 772 |
| **Specialty Care** | **2,829** | **2,695** |
| Manufacturing revenue | 559 | 569 |
| Royalty revenue | 34 | 88 |
| **ReFacto** | **594** | **656** |
| **Total revenue** | **6,511** | **5,204** |

### Product sales by region (Group)

(Excluding royalty revenues)

| SEK M | 2017 | 2016 | Change |
|---|---|---|---|
| Europe | 3,784 | 2,222 | 70% |
| MENAR[1] | 272 | 302 | –10% |
| North America | 1,168 | 1,002 | 17% |
| Rest of world | 84 | 66 | 27% |
| **Total** | **5,308** | **3,592** | **48%** |

1. Middle East, North Africa and Russia

### Source of revenue by business line (Group)

| Haemophilia | Specialty Care | ReFacto |
|---|---|---|
| Alprolix | Akynzeo® | Manufacturing |
| Elocta | Ammonaps® | Royalty |
| Royalty | Ferriprox® | |
| | Kepivance | |
| | Kineret | |
| | Orfadin | |
| | Ruconest® | |
| | Valeant portfolio | |
| | Xiapex | |
| | Yondelis® | |
| | Other | |

increased sales. At the same time, these were offset by an increased tax liability as the Parent Company is now in a tax position, see under Parent Company.

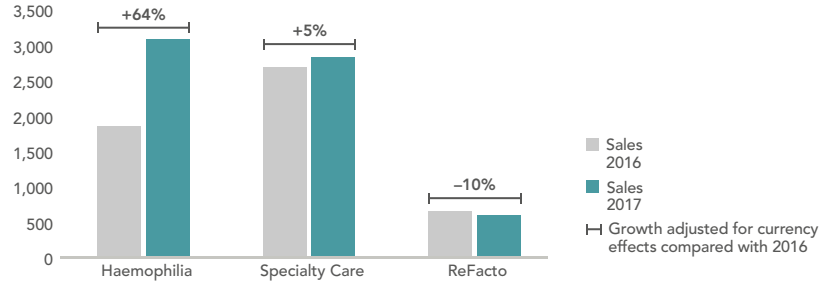
**Financial position**
At 31 December 2017, cash and cash equivalents and short-term investments amounted to SEK 1,478 M (786).

In December, the credit facility with an original maturity in June 2019, was restructured from the previous utilised and repaid credit facility of SEK 500 M and revolving credit facility of SEK 500 M to a revolving credit facility of SEK 1,000 M, which has not been utilised to date. During the year, Sobi also used the option to extend the credit facility by one year. The measures will reduce the Company's interest expenses, increase financial flexibility and reduce refinancing risk.

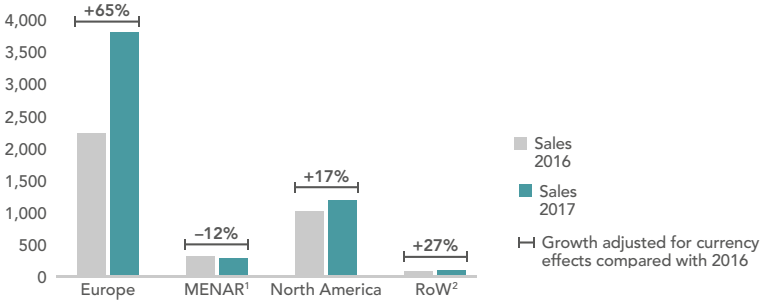
Net cash on 31 December 2017 was SEK 1,472 M, compared with SEK 282 M on 31 December 2016. The liability to Bioverativ is a non-interest-bearing liability, but is recognised at a discounted value and therefore carries an accounting interest cost. This liability is not included in net cash/debt.

**Equity**
The Group's equity amounted to SEK 6,701 M (5,365) as per 31 December 2017. In addition to the result for the year, the change includes costs for share programmes and hedge accounting. Closing balance 2016 has been adjusted with net SEK 11 M, see note 21 for more information.

**Revenue by product category, SEK M**




**Product sales by region (excluding royalty revenues), SEK M**




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

**Parent Company**
The Parent Company's business model is to develop, register, distribute and market drugs for rare diseases. The Parent Company's revenue amounted to SEK 5,756 M (4,594) in 2017. The operating profit was SEK 1,600 M (1,206). Profit for the year totalled SEK –508 M (51), including excess depreciation of SEK –970 M, a Group contribution of SEK 59 M and a non-tax deductable write-down of SEK 1,000 M. At 31 December 2017, cash and cash equivalents were SEK 1,381 M (662) and equity amounted to SEK 5,436 M (5,755). The change was attributable to profit for the year, costs associated with the Company's share programmes, sales of own shares and hedge accounting including current tax. The opening balance for 2016 has been adjusted by a net amount of SEK 11 M, see note 21.

After impairment testing, the Parent Company has written down the value of the shares in the subsidiary Swedish Orphan Biovitrum International AB by SEK 1,000 M. The impairment is the result of a reduction in the underlying projected cash flows from Swedish Orphan Biovitrum International AB, which has a negative effect on the value of the Parent Company's shares in the subsidiary. These cash flows are only internal within the Group.The impairment does not affect the Group's earnings or financial position, mainly because surplus values of assets in the Group are depreciated according to plan annually.

## Development
Sobi's development projects include pipeline programmes in the areas of haemophilia, inflammation and genetic and lysosomal diseases. Sobi is also conducting a number of projects focused on the further development of existing products.

In haemophilia, development consists of expanded clinical trial activity to strengthen the already extensive evidence for Sobi's approved haemophilia products. The ReITIrate study is evaluating immune tolerance induction with Elocta. Sobi is also conducting preclinical development of the XTEN technology in partnership with Bioverativ for the purpose of producing the next generation of treatments for haemophilia A and haemophilia B.

Two clinical programmes are in progress in the area of inflammation, aimed at studying new applications for Kineret – acute gout and

Still's disease. The anaGO phase 2 trial is to evaluate the safety and efficacy of Kineret for the treatment of acute gout. The ana-STILLs phase 3 trial is to evaluate the safety and efficacy of Kineret for the treatment of Still's disease.

The earlier pipeline programme explored potential new product candidates for the treatment of inflammatory conditions where interleukin (IL-1) is involved. SOBI006 is based on the Affibody platform.

A clinical programme is in progress in the area of genetics. A collaboration study designed to examine the use of nitisinone in patients with alkaptonuria (AKU) is in progress. Surveillance studies to assess the long-term efficacy and safety of Orfadin in HT-1 are in progress.

Clinical studies are about to be conducted for SOBI003, a product candidate for the treatment of the lysosomal storage disease MPS IIIA.

The product candidate SOBI005 is part of the programme for complement-related diseases.

**Regulatory approvals**

- EMA approved the possibility of dosing Alprolix at 14-day intervals for hemophilia B.
- Elocta and Alprolix were approved in Saudi Arabia.
- Kineret was approved in Canada for the treatment of systemic multi-inflammatory disease with neonatal debut (NOMID).
- Orfadin capsules and oral suspension were approved in Canada for the treatment of hereditary tyrosinaemia type 1 (HT-1) in combination with a restrictive intake of tyrosine and phenylalanine.
- Orfadin capsules were approved in Saudi Arabia, Algeria and Tunisia for the treatment of HT-1. Algeria and Tunisia are the first approvals for Orfadin in North Africa.
- The European Commission and the FDA approved a reduced dosing frequency of Orfadin to twice daily for patients who are five years of age or older. The FDA also approved the storage of Orfadin capsules (all strengths) at room temperature (25° C or lower) for up to 45 days during use.
- SOBI003 received orphan drug status (ODD) in the United States for the treament of mucopolysaccharide type IIIA (MPS IIIA).

**First patients enrolled in 24-month real-world study evaluating effectiveness of Elocta**

The first patients have been enrolled in the A-SURE study. A-SURE is a 24-month real world study evaluating the effectiveness of Elocta compared with conventional FVIII products in the prophylactic treatment of patients with haemophilia A in Europe.

**Sobi and Bioverativ present new long-term safety and efficacy data for Elocta and Alprolix**

New haemophilia data was presented at the 10th Annual Congress of the European Association for Haemophilia and Allied Disorders (EAHAD). Data on the long-term safety and efficacy of Elocta and Alprolix and an updated analysis of data from the ASPIRE and B-YOND studies were presented.

**New Alprolix data published in The Lancet Haematology**

Results from the Kids B-LONG phase 3 clinical study, which studied Alprolix in previously treated children with severe haemophilia B, were published in The Lancet Haematology. The primary outcome measure of the trial was development of inhibitors, and no patients treated with Alprolix in the study developed inhibitors.

**New Alprolix data published in Thrombosis and Haemostasis**

Interim results from the B-YOND extension study, which studies Alprolix in previously treated patients with severe haemophilia B, were published in the March 2017 issue of Thrombosis and Haemostasis. The study results reinforce the long-term safety and efficacy of prophylactic treatment with Alprolix over a median duration of more than three years in adults/adolescents and more than a year and a half in children under twelve years of age.

**Haemophilia B development portfolio expanded with rFIXFc-XTEN**

Sobi opted to add the novel development candidate rFIXFc-XTEN, for subcutaneous treatment of haemophilia B, to the collaboration agreement with Bioverativ.

**ASPIRE and B-YOND studies showed improvement of affected joints**

Follow-up data from the ASPIRE and B-YOND continuation studies, showed improvements in the haemodialysis assessment of haemophilia with a lower number of haemorrhages per year, especially in the worst affected joints of people receiving prophylactic treatment with Alprolix and Elocta, was presented by Sobi and Bioverativ at the International Society on Thrombosis and Haemostasis (ISTH) Congress 2017 in Berlin.

**ReITIrate study launched**

The first patients were enrolled in the ReITIrate study evaluating immune tolerance induction with Elocta.

**Bioverativ initiated XTEN molecule studies**

Bioverativ initiated the phase 1/2 study for rFVIIIFc-VWF-XTEN within haemophilia A. rFVIIIFc-VWF-XTEN is the next generation of extended half-life products. Sobi is collaborating with Bioverativ in the XTEN programme.

**Start-up of pipeline programmes for acute gout and Still's disease**

The first patients have been randomised in the two Kineret clinical development programmes, for the purpose of evaluating two new potential areas of application: acute gout and Still's disease.

**First patient randomised in the anaGO phase 2 study**

The first patient was randomised in the anaGO phase 2 study to evaluate efficacy and safety of Kineret (anakinra) in the treatment of acute gout.

## Other information

**Company management changes**

Guido Oelkers succeeded Geoffrey McDonough as President and CEO with effect from 22 May 2017. Guido Oelkers joined Sobi from a previous role as CEO of BSN Medical GmbH. He has extensive experience from pharmaceutical and healthcare companies.

A new Executive Committee was established and replaced the Executive Leadership Team as decision-making body. The Executive Committee consists of:

**CEO:** Guido Oelkers

**CFO:** Mats-Olof Wallin

**General Counsel and Head of Legal Affairs:** Torbjörn Hallberg
*(took office in January 2018)*

**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 & Scientific Affairs:** Armin Reininger

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

From the previous management team, Fredrik Berg, former Chief Legal Officer, retired and thus left the company. In addition, former Chief Operations Officer – Alan Raffensperger, former Head of Human Resources – Dennis Pedersen, former Chief Patient Access Officer – Wills Hughes Wilson, and former Head of Business Development – Stefan Fraenkel left Sobi during the year.

**Sustainability Reporting**
In accordance with the Annual Accounts Act Sobi is required to produce a legal sustainability report. The legal sustainability report is found on pages 12–13, 36–47 and 123–132 in the Annual and Sustainability Report which has been prepared in accordance with the GRI Standards.

**Corporate Governance**
In accordance with the Annual Accounts Act, Sobi is required to produce a corporate governance report. In accordance with the Annual Accounts Act, 6 chapter 8§, Sobi has chosen to prepare a corporate governance report, separate from the annual report, which can be found on pages 108–113.

**Environmental regulation**
Although the Company is not certified, Sobi's environmental management system is based on the ISO 14001 standard. Management has established an environmental policy to further underscore the importance of environmental work. The policy can be found on the Company's website www.sobi.com. Sobi's production facility in Stockholm holds a permit for hazardous operations for facilities that produce organic substances through industrial-scale biological reactions. Compliance with the permit conditions is disclosed annually in an environmental report to the local supervisory authority. In Solna, the Company has facilities that are subject to a reporting obligation for the professional production, through chemical or biological reactions, of organic or inorganic substances in trial, pilot or laboratory scale or other non-industrial scale production. The conditions for this permit mainly relate to water emissions and include a requirement to adjust the pH of the process water. No breaches of the conditions were reported by any of the facilities in 2017. 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 had any adverse impact on Sobi's competitiveness or operations to date, the Company cannot predict the impact of future regulations.

## Share capital and ownership
Sobi's share capital was SEK 149,526,711 divided into 272,507,708 shares, with a quota value per share of approximately 0.55 SEK. On 31 December 2017, there were a total number of outstanding shares of 272,507,708 ordinary shares, each with one vote. On 31 December 2017, Investor AB was the single largest shareholder in Sobi, with a total of 107,594,165 shares, representing 39.48 per cent of the votes and 39.48 per cent of the capital.

## Conversion of shares
The Annual General Meeting on 4 May 2017 authorised the Board to decide to issue C shares and repurchase the issued C shares for the purpose of hedging long-term incentive programmes. The Meeting also adopted the Board's proposal concerning the transfer of shares. On 31 December 2017, Sobi held 3,249,870 ordinary shares. All previously issued C-shares were converted into ordinary shares during 2017. For more detailed information about the total number of shares in the Company, the number of shares by category and the number of votes carried by the shares, see the section on shares on page 50.

## Guidelines and remuneration 2018
The Board of Directors proposes that the Annual General Meeting resolves on guidelines for remuneration for senior executives as set forth below which shall apply until the 2019 Annual General Meeting. Senior executives are defined as the CEO of Swedish Orphan Biovitrum AB (publ) and the executives who report to the CEO and who are members of 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 senior executives is based 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 senior executives. 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.

**Fixed Base Pay**
The fixed base pay of senior executives 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 CEO and 60 per cent of the fixed annual salary for the other senior executives.

**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 the opportunity to take part in the Company's long-term success and value creation, and to contribute to a competitive total remuneration.

For more 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.

1. A defined contribution pension plan determines the contribution paid to the plan for every employee.

## 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 work 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 in the organisation. Sobi has the following values: 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 2017, the number of full-time equivalent was 800 (760), of whom 451 (433) were based in Sweden. Salaries and other benefits amounted to SEK 927 M (793), with the Parent Company accounting for SEK 427 M (367) of the amount.

Of the total number of employees in 2017, 59 per cent were female and 41 per cent were male. All employees are treated equally and offered the same opportunities regardless of age, gender, religion, sexual orientation, 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.

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

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

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

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

**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 arrangements are made for senior executive recruitment or retention purposes and are 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.

**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 amounts are at the disposal of the Annual General Meeting:

| SEK | |
|---|---|
| Share premium reserve | 4,231,346,499 |
| Retained earnings | 763,083,789 |
| Profit for the year | –507,835,892 |
| **Total** | **4,486,594,396** |

The Board proposes that no dividend be paid for the financial year 2017.

The Board proposes that the available funds of SEK 4,486,594,396 be carried forward.

## Events after the reporting date, up to 27 March 2018

- The FDA approved an application for a clinical trial and granted Fast Track status the product candidate SOBI003 for the treatment of MPS IIIA.
- Elocta was reimbursed in Poland and Slovakia.
- Sobi signed a two-year agreement with the Health Services Executive in Ireland to provide Elocta and Alprolix to all patients who had previously been treated with factor replacement therapy.
- The European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a favourable opinion for Kineret (anakinra) in the treatment of Stills disease.
- Henrik Stenqvist was appointed Chief Financial Officer (CFO) when Mats-Olof Wallin, current CFO, retires in July 2018.
- Sobi launched Ravicti® in Europe and advances the care for patients with Urea Cycle Disorders.
- New market data was received from the pharmaceutical industry association in France after the end of the financial year which indicates that the provision made by Sobi's French subsidiary for pharmaceutical tax may be too high. One component in the calculation of pharmaceutical tax is based on the development of the French market. Preliminary prognoses from an independent organisation in France are submitted to the industry body during the financial year, and provide a foundation for pharmaceutical tax provisions. In February 2018, the industry body reported that the growth figure on which the received forecasts were based could be too high. A final figure for pharmaceutical tax will be received during the second quarter of 2018, at which point the provision in the annual report will be adjusted, if required, and reported.

## Outlook for 2018[1]

Sobi expects revenue for the full year 2018 to be in the range of SEK 7,500–7,700 M. The gross margin is expected to be at least 70 per cent, while EBITA for the full year is expected to be in the range of SEK 2,500–2,700 M.

For information regarding forward looking statements, see inside front cover.

1. At current exchange rates.
This outlook was published on 22 February 2018.

## Risk management

Sobi work according to an integrated risk management process which contributes to our ability to achieve defined goals and pursue the strategy adopted for the business. Each operational unit works actively to identify any uncertainties concerning the ability to achieve defined goals. These are also assessed when they could potentially disrupt operations in the short or long term. The risks are quantified against relevant values for operations in order to prioritise and handle the risks in a commercial manner. By identifying risks and getting the management Group to determine strategic priorities for risk management, we achieve a dynamic process in which uncertainties and unexploited opportunities concerning the Company's strategy can be identified and managed. Sobi's Chief Risk Officer reports the current risk status to the management Group and a review of this process is presented to the Board.

As part of the strategic work on risk management, the Company's critical flows are identified and business continuity plans are implemented. For circumstances that fall within the framework of our definition of a crisis, there is a crisis management policy and a crisis management team composed of members of the Company's management Group. The strategic crisis management team works with operational crisis management groups for each business area within the Company to ensure that the Company's values are observed in both the short and long term.

### Key risk areas

Research and development of new drugs, and regulations regarding research and development, manufacturing, testing, marketing and sales of pharmaceutical products are complex and can change over time. A summary of the main operational risks is presented below. The risks are not ranked in any particular order, but are categorised and described.

### Operational risks

| Risk | Description of risk | Management and comments |
|---|---|---|
| Drug development | Drug development until launch is a capital-intensive, complex and risk-prone process. The probability of reaching the market increases as the project advances through the development process. However, the risks remain substantial up to and including phase 3 clinical studies, while costs increase at a faster rate when the project moves into the later clinical phases. | Sobi currently has a number of projects in clinical development and several projects in preclinical development. Sobi's innovation model (see page 32) is used to determine the attractiveness of a project and its risk profile. |
| Obtaining and retaining authorisation for new products | Sobi must be able to demonstrate that drug candidates maintain high quality, are safe and have the intended effect with sufficient, well-controlled preclinical and clinical studies. Preclinical and clinical development is a time-consuming process that is affected by a number of factors, including those beyond the Company's control, such as changed regulatory requirements. Before the launch of a drug, it must be demonstrated that the drug meets the stringent proof of quality, safety and efficacy requirements imposed by regulators in the countries or regions where 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, which in the best of worlds can result in faster development and availability, or the discovery of new opportunities. |
| Collaboration and partnerships | The strategy includes entering into collaborative agreements on joint development and/or authorisation with other pharmaceutical and biotech companies for the development and launch of some of Sobi's products. These partners still have considerable power of decision in terms of the efforts and resources to be devoted to the projects, depending on the nature of the agreement between the parties. | A structured flow of information is crucial for a successful partnership.<br>The success of such collaborations will largely depend on the joint work of Sobi's partners or licensees. Sobi sets up Joint Steering Committees in all partnership agreements in order to guarantee ongoing coordination and the sharing of information. |
| | Collaborations in respect of patient organisations, academic institutions, healthcare personnel or other relevant groups depend on the counterparts, knowledge, desire and regulatory guidelines that govern how these collaborations are to be implemented. | Sobi strives to maintain and preserve long-term engagement and collaboration. We support and collaborate with many different patient organisations, both nationally and regionally, in order to achieve our shared goal, to achieve the best possible outcome for patients with rare diseases.<br>There are Group-wide guidelines to guarantee compliance with the requirements for ethics and transparency in all of Sobi's business areas. |
| Intellectual property protection and patent risks | Sobi's success is largely dependent on 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. | Sobi's success will largely depend on its protection. Sobi has a number of technology licenses of importance to the operations, and the Company is expected to obtain additional licenses in the future. 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 through, for example, confidentiality agreements with employees, consultants and partners. |

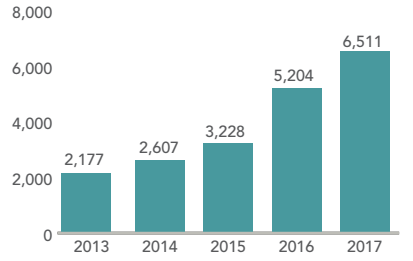
| Risk | Description of risk | Management and comments |
|---|---|---|
| Biologics manufacturing and quality | The manufacture of Sobi's products requires all manufacturing processes, methods and equipment to be compliant with Good Manufacturing Practice (GXP) guidelines. The GMP guidelines control all aspects of the pharmaceutical manufacturing process, including quality control and quality assurance, manufacturing processes and documentation. Sobi's production facilities may be inspected at any time by the regulators or the Company's customers. | In 2017, Sobi introduced a system, Qase (abbreviation of Quality Case Management), to manage Non Conformances (NC) as well as Corrective and Preventive Actions (CAPAs). All GMP, GDP, GVP and GCP-related cases are now registered and managed in this system. From 2018, all inspections will be managed in this system.<br>Internal GXP audits have been completed according to the 2017 plan within areas covering product supply and distribution set-up, Quality Assurance, Quality Control and IT systems. Any actions arising from audit activities have been followed up in the CAPA system. |
| | Sobi collaborates in the manufacturing of drugs with other pharmaceutical companies as a customer and is dependent on the partners' facilities meeting GMP requirements as well as being well maintained and available. | The GMP guidelines apply to Sobi and its distributors, contract laboratories and suppliers. Sobi conducts extensive audits of its distributors, contract laboratories and suppliers. For Sobi's external network, a total of 54 GXP have been performed during 2017. All audits have resulted in approving the auditee as an approved supplier. |
| | The company's production and its research and development involve the controlled use of biological and hazardous material and waste. | Sobi is subject to laws and regulations governing the use, manufacture, storage, handling and disposal of such hazardous material and waste. |
| **External risks** | | |
| 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 ensure that we remain at the forefront of technology development, Sobi cooperates with many different groups, for example, within the framework of the Swedish strategic cooperation program in life science to support future development and production of biological drugs. |
| | The Company's products under development may be exposed to competition from similar products or entirely new product concepts that can demonstrate better value. | Sobi initiates collaborations with external research groups at the forefront of medical development in order to increase opportunities for gaining access to target proteins that can be developed into competitive medical treatment options. |
| Product counterfeiting | Prescription drugs are increasingly being challenged by illegally produced pharmaceutical products (and by access to pirated products in some distribution channels). | Sobi's products have not yet been the subject of pirating. Sobi is involved in global work that has been initiated to investigate product traceability. To minimise the risk of counterfeiting, all Sobi's distribution processes comply with good distribution practice.<br>Since 2017, Sobi has been using the TraceLink system to manage the serial numbers of all products. This system meets the needs of regulators in the markets where we operate. By 2019, all Sobi products will have a unique identity code. |
| **Ethical and compliance risks** | | |
| | Areas such as social responsibility and sustainable business play an increasingly significant role in companies' competitiveness and profitability. | Sobi's Risk and Regulatory Compliance Committee continuously monitors the development and implementation of the Company's regulatory compliance programme, which aims to reduce Sobi'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. |
| **Financial risks** | | |
| Currency risks | The Company's operations are exposed to currency risk. Most of the Company's expenses are incurred in SEK, while a significant portion of revenue is generated in other currencies. As a result of the Company's international expansion, lower exchange rates for 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. | For more information about financial risks, see note 3. |

# Consolidated statement of comprehensive income

| AMOUNTS IN SEK THOUSANDS | Note | 2017 | 2016 |
|---|---|---|---|
| | 1–4 | | |
| Operating revenue | 5–6 | 6,510,831 | 5,204,340 |
| Cost of goods and services sold | | –1,853,998 | –1,553,823 |
| **Gross profit** | | **4,656,833** | **3,650,517** |
| | | | |
| Selling and administrative expenses | 12 | –2,096,470 | –1,776,261 |
| Research and development expenditure | | –907,721 | –777,587 |
| Other operating income | 8 | 417 | 36,670 |
| Other operating expenses | 9 | –52,748 | –225 |
| **Operating profit** | 7, 10, 11, 13, 17, 18, 29 | **1,600,365** | **1,133,114** |
| | | | |
| Finance income | 14 | 1,219 | 7,925 |
| Finance costs | 15 | –69,161 | –93,060 |
| **Net financial items** | | **–67,942** | **–85,135** |
| **Profit before tax** | | **1,532,423** | **1,047,979** |
| | | | |
| Income tax expense | 16 | –383,811 | –246,344 |
| **Profit for the year**[1] | | **1,148,612** | **801,635** |
| **Other comprehensive income**[2] | | | |
| *Items that will not be reclassified to profit or loss* | | | |
| Actuarial gains/losses on defined-benefit plan | | –1,042 | 1,231 |
| *Items that may be reclassified subsequently to profit or loss* | | | |
| Translation differences | | –1,258 | 4,869 |
| Cash flow hedges | | 191,856 | –226,019 |
| Tax effect of cash flow hedges | | –42,208 | 49,724 |
| **Other comprehensive income** | | **147,348** | **–170,195** |
| **Comprehensive income for the year**[2] | | **1,295,960** | **631,440** |
| | | | |
| Earnings per share, SEK | 33 | 4.27 | 2.99 |
| Earnings per share after dilution, SEK | 33 | 4.25 | 2.98 |
| | | | |
| Number of shares (ordinary) | | 272,507,708 | 270,389,770 |
| Average number of shares | | 269,020,363 | 268,362,041 |
| Number of C shares held in treasury | | — | 1,621,178 |
| Number of ordinary shares held in treasury | | 3,249,870 | 1,610,086 |
| Number of shares after dilution | | 269,975,826 | 269,252,883 |
| Average number of shares after dilution | | 270,003,546 | 269,218,052 |

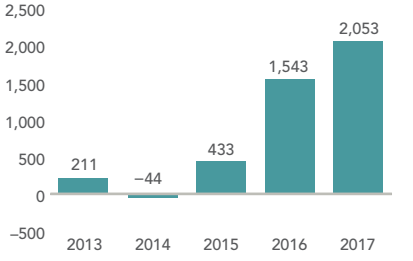
1. Everything attributable to the Parent Company's shareholders.
2. In accordance with the revised IAS 1, all non-shareholder changes in equity are presented in the consolidated statement of comprehensive income. Translation differences are entirely related to shares in foreign subsidiaries.

**Operating revenue, SEK M**



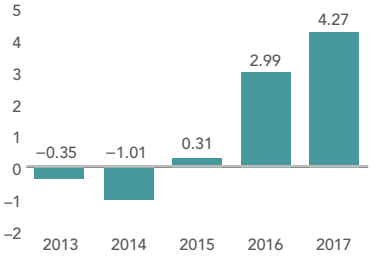

**Operating revenue**
Revenue for the full-year amounted to SEK 6,511 (5,204) M, an increase of 25 per cent.

**EBITA[1], SEK M**




**EBITA**
EBITA for the year increased with 33 per cent to SEK 2,053 M compared to 2016.

**Earnings per share[1], SEK**



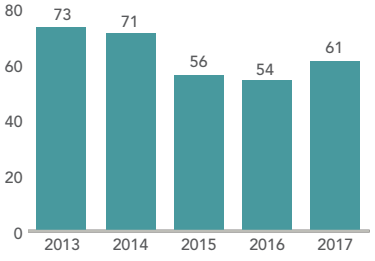

1. Alternative Performance Measures (APM)

# Consolidated balance sheet

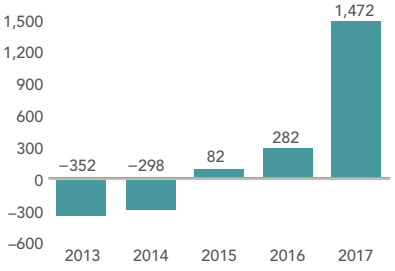
| AMOUNTS IN SEK THOUSANDS | Note | 31 Dec 2017 | 31 Dec 2016 |
|---|---|---|---|
| ASSETS | 1–4 | | |
| **Non-current assets** | | | |
| Intangible assets | 17 | 6,445,071 | 6,806,010 |
| Property, plant and equipment | 18 | 134,182 | 121,023 |
| Financial assets | 20 | 35,155 | 1,956 |
| Deferred tax assets | 21 | 131,429 | 133,897 |
| **Total non-current assets** | | **6,745,837** | **7,062,886** |
| | | | |
| **Current assets** | | | |
| Inventories | 22 | 1,053,268 | 870,046 |
| Trade receivables | 23, 26 | 1,129,016 | 768,765 |
| Other receivables | 23 | 63,964 | 75,543 |
| Prepayments and accrued income | 24 | 432,326 | 411,109 |
| Cash and cash equivalents | 25, 26 | 1,478,496 | 785,790 |
| **Total current assets** | | **4,157,070** | **2,911,253** |
| **TOTAL ASSETS** | | **10,902,907** | **9,974,139** |
| | | | |
| **EQUITY AND LIABILITIES** | | | |
| **Equity** | | | |
| Share capital | | 149,527 | 149,254 |
| Other capital reserves | | 5,023,557 | 4,983,959 |
| Other reserves | | –20,386 | –167,734 |
| Retained earnings | | 399,214 | –402,148 |
| Profit for the year | | 1,148,612 | 801,635 |
| **Equity attributable to Parent Company shareholders** | | **6,700,524** | **5,364,966** |
| | | | |
| **Liabilities** | | | |
| *Non-current liabilities* | | | |
| Deferred tax liabilities | 21 | 667,733 | 495,558 |
| Liability to Bioverativ | 26, 27 | 1,066,833 | 1,808,916 |
| Liabilities to credit institutions | 26, 27 | 5,044 | 502,216 |
| Provisions | 29, 30 | 97,955 | 44,389 |
| **Total non-current liabilities** | | **1,837,565** | **2,851,079** |
| | | | |
| Current liabilities | | | |
| Trade payables | 26 | 358,449 | 280,173 |
| Tax liabilities | | 225,579 | 15,801 |
| Liability to Bioverativ | 26, 28 | 579,895 | 496,697 |
| Other liabilities | 26, 28 | 82,217 | 156,123 |
| Accruals and deferred income | 31 | 1,118,678 | 809,300 |
| **Total current liabilities** | | **2,364,818** | **1,758,094** |
| **TOTAL EQUITY AND LIABILITIES** | | **10,902,907** | **9,974,139** |

For information about the Group's pledged assets and contingent liabilities, see note 32.

**Equity/assets ratio[1], %**




**Net cash (+)/net debt (–)[1], SEK M**




**Net cash**

Net cash increased during the year from SEK 282 to 1,472 M.

**Net cash (+)/net debt (–)**

| SEK M | 2013 | 2014 | 2015 | 2016 | 2017 |
|---|---|---|---|---|---|
| Cash and cash equivalents | 445 | 519 | 904 | 786 | 1,478 |
| Interest bearing debt | 798 | 818 | 822 | 504 | 7 |
| **Net cash (+)/net debt (–)** | **–352** | **–298** | **82** | **282** | **1,472** |

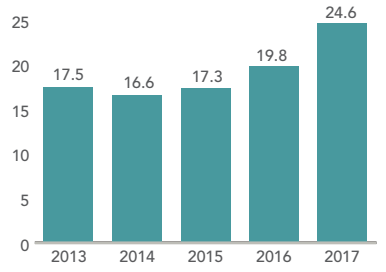
1. APM

# Consolidated statement of changes in equity

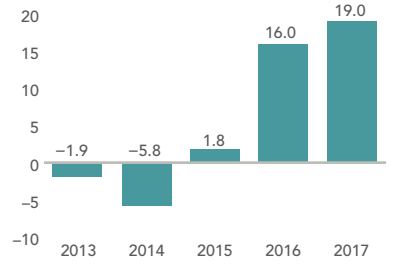
| AMOUNTS IN SEK THOUSANDS | Share capital | Other capital reserves | Other reserves | Retained earnings | Total equity |
|---|---|---|---|---|---|
| **Opening equity, 1 Jan 2016** | **149,150** | **4,928,765** | **2,461** | **–402,044[1]** | **4,678,332** |
| **Comprehensive income** | | | | | |
| Profit for the year | — | — | — | 801,635[1] | 801,635 |
| **Other comprehensive income** | | | | | |
| Cash flow hedges | — | — | –176,295 | — | –176,295 |
| Actuarial loss/gain | — | — | 1,231 | — | 1,231 |
| Exchange differences | — | — | 4,869 | — | 4,869 |
| **Total comprehensive income** | **—** | **—** | **–170,195** | **801,635** | **631,440** |
| **Shareholder transactions** | | | | | |
| Issue/repurchase of shares | 104 | — | — | –104 | — |
| Sale of ordinary shares | — | 23,500 | — | — | 23,500 |
| Share programmes | — | 31,694 | — | — | 31,694 |
| **Total shareholder transactions** | **104** | **55,194** | **—** | **–104** | **55,194** |
| **Closing equity, 31 Dec 2016** | **149,254** | **4,983,959** | **–167,734** | **399,487** | **5,364,966** |
| **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 | — | — | 149,648 | — | 149,648 |
| 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[2]** | **1,547,826** | **6,700,524** |

1. Deferred tax has been adjusted during the year related to change in depreciation method and cash flow hedges. The adjustments have been reported against retained earnings and have affected deferred tax in both Group and Parent Company but has not had any effect on paid tax. See note 21.

**Equity per share[1], SEK**




**Return on equity[1], %**




**Return on equity**
Return on equity increased from 16.0 to 19.0 per cent compared to last year.

1. APM

**[2]Other reserves**

| SEK THOUSANDS | 2017 | 2016 |
|---|---|---|
| Translation differences | –21,453 | –20,195 |
| Pensions in accordance with IAS 19 | –26,273 | –25,231 |
| Cash flow hedges | 27,543 | –122,105 |
| Other | –203 | –203 |
| **Closing balance 31 Dec 2017** | **–20,386** | **–167,734** |

**Cash flow hedges**

| SEK THOUSANDS | 2017 | 2016 |
|---|---|---|
| Opening balance, cash flow hedges | –122,105 | 54,190 |
| Changes in value for the year, hedging instruments | 149,648 | –176,295 |
| **Closing balance, cash flow hedges** | **27,543** | **–122,105** |

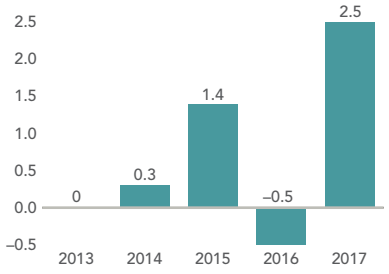
Regarding cash flow hedges SEK 12,662 K (–4,955) is transferred to the Income statement.

# Consolidated cash flow statement

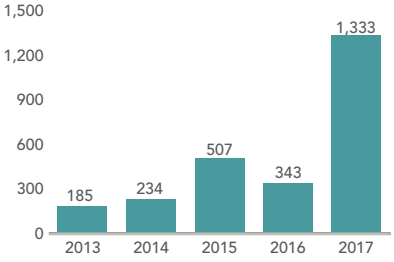
| AMOUNTS IN SEK THOUSANDS | Note | 2017 | 2016 |
|---|---|---|---|
| **Operating activities** | | | |
| Profit for the year | | 1,148,612 | 801,635 |
| Adjustments for non-cash items | | 282,377 | –159,175 |
| **Cash flow from operating activities before changes in working capital** | | **1,430,989** | **642,460** |
| | | | |
| **Cash flow from changes in working capital** | | | |
| Decrease (+)/Increase (–) in inventories | | –183,222 | –94,192 |
| Decrease (+)/Increase (–) in operating receivables | | –369,889 | –618,765 |
| Increase (+)/Decrease (–) in operating liabilities | | 455,064 | 413,354 |
| **Cash flow from operating activities** | | **1,332,942** | **342,857** |
| | | | |
| **Investing activities** | | | |
| Acquisition of intangible assets[1] | 17 | –91,922 | –118,657 |
| Acquisition of property, plant and equipment | 18 | –47,523 | –45,808 |
| Acquisition of financial assets | 20 | –737 | –100 |
| Disposal of property, plant and equipment | 18 | 1,204 | 6,555 |
| **Cash flow from investing activities** | | **–138,978** | **–158,010** |
| | | | |
| **Financing activities** | | | |
| Sale of shares | | — | 23,500 |
| Proceeds from borrowings | 27 | — | 496,914 |
| Repayment of loans[2] | 27 | –500,000 | –828,000 |
| **Cash flow from financing activities** | | **–500,000** | **–307,586** |
| | | | |
| **Change in cash and cash equivalents** | | **693,964** | **–122,739** |
| **Cash and cash equivalents at beginning of year** | | **785,790** | **903,660** |
| **Exchange differences in cash flow** | | **–1,258** | **4,869** |
| **Cash and cash equivalents at end of year** | | **1,478,496** | **785,790** |

1. The largest investments during the year relate to the right to participate in the rFIXFc-XTEN programme, amounting to SEK 56 M, and LMS (education system) for SEK 7 M, see note 17.
2. Amortisation of loan liabilities relates to the disposal 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 amounted to SEK 694 M including repayment of bank loans of SEK 500 M.

1. APM

# Consolidated cash flow statement, contd.

**Supplemental disclosures to the consolidated cash flow statement**

| AMOUNTS IN SEK THOUSANDS | Note | 2017 | 2016 |
|---|---|---|---|
| Interest and tax paid and received | | | |
| Interest received | | 1,219 | 1,427 |
| Interest paid | | 13,886 | 27,772 |
| | | | |
| Corporate tax paid | | 28,421 | 10,812 |
| | | | |
| **Adjustments for non-cash items** | | | |
| Depreciation, amortisation and impairment of non-current assets | 7, 17, 18 | 485,977 | 440,710 |
| Revaluation of non-current liabilities | | — | 670 |
| Pensions | 29 | –1,042 | 2,851 |
| Cost of share programmes[1] | | 39,598 | 31,694 |
| Deferred tax | 21 | 174,683 | 164,190 |
| Elocta and Alprolix[2] | | –437,660 | –811,832 |
| Other items | | 20,821 | 12,542 |
| **Total** | | **282,377** | **–159,175** |

1. IFRS 2-expenses associated with the share programmes recognised in equity.
2. Refers to royalty revenues used to settle the liability to Bioverativ and interest expenses relating to the liability to Bioverativ.

# Parent Company income statement

| AMOUNTS IN SEK THOUSANDS | Note | 2017 | 2016 |
|---|---|---|---|
| | 1–4 | | |
| Operating revenue | 5–6 | 5,756,370 | 4,593,940 |
| Cost of goods and services sold | | –1,861,398 | –1,469,991 |
| **Gross profit** | | **3,894,972** | **3,123,949** |
| | | | |
| Selling and administrative expenses | 12 | –1,400,380 | –1,218,391 |
| Research and development expenditure | | –854,862 | –729,241 |
| Other operating income | 8 | 120 | 29,922 |
| Other operating expenses | 9 | –39,824 | — |
| **Operating profit** | 7, 10, 11, 13, 17, 18 | **1,600,026** | **1,206,239** |
| | | | |
| Profit from participations in Group companies | 19 | –1,000,000 | — |
| Finance income | 14 | 11,656 | 21,883 |
| Finance costs | 15 | –76,299 | –94,819 |
| **Net financial items** | | **–1,064,643** | **–72,936** |
| **Profit after financial items** | | **535,383** | **1,133,303** |
| | | | |
| Group contributions | | 58,956 | 105,334 |
| Excess depreciation | | –970,000 | –1,154,000 |
| **Appropriations** | | **–911,044** | **–1,048,666** |
| **Profit/loss before tax** | | **–375,661** | **84,637** |
| Income tax expense | 16 | –132,175 | –33,380 |
| **Profit/loss for the year** | | **–507,836** | **51,257** |

# Parent Company statement of comprehensive income

| AMOUNTS IN SEK THOUSANDS | 2017 | 2016 |
|---|---|---|
| Profit/loss for the year | –507,836 | 51,257 |
| *Items that may be reclassified subsequently to profit or loss* | | |
| Cash flow hedges | 191,856 | –226,019 |
| Tax effect of cash flow hedges | –42,208 | 49,724 |
| **Other comprehensive income** | **149,648** | **–176,295** |
| **Comprehensive income for the year** | **–358,188** | **–125,038** |

# Parent Company balance sheet

| AMOUNTS IN SEK THOUSANDS | Note | 31 Dec 2017 | 31 Dec 2016 |
|---|---|---|---|
| **ASSETS** | 1–4 | | |
| **Non-current assets** | | | |
| *Intangible assets* | 17 | | |
| Patents, licences, trademarks and similar rights | | 4,057,718 | 4,261,999 |
| *Property, plant and equipment* | 18 | | |
| Plant and machinery | | 72,441 | 58,536 |
| Equipment, tools, fixtures & fittings | | 20,579 | 29,891 |
| Construction in progress | | 21,041 | 14,770 |
| *Financial assets* | | | |
| Investments in subsidiaries | 19 | 2,882,333 | 3,882,138 |
| Other non-current financial receivables | 20 | 32,392 | 1 |
| **Total non-current assets** | | **7,086,504** | **8,247,335** |
| | | | |
| **Current assets** | | | |
| *Inventories* | 22 | | |
| Raw materials and consumables | | 20,905 | 25,557 |
| Work in progress | | 536,603 | 433,243 |
| Finished goods and goods for resale | | 336,166 | 307,584 |
| *Current receivables* | | | |
| Trade receivables | 23 | 405,702 | 280,249 |
| Other receivables | 23 | 53,092 | 54,532 |
| Receivables from Group companies | | 901,936 | 725,626 |
| Prepayments and accrued income | 24 | 418,194 | 399,373 |
| Cash and cash equivalents | 25 | 1,381,369 | 662,110 |
| **Total current assets** | | **4,053,967** | **2,888,274** |
| **TOTAL ASSETS** | | **11,140,471** | **11,135,609** |

| AMOUNTS IN SEK THOUSANDS | Note | 31 Dec 2017 | 31 Dec 2016 |
|---|---|---|---|
| **EQUITY AND LIABILITIES** | | | |
| **Equity** | | | |
| *Restricted equity* | | | |
| Share capital | | 149,527 | 149,254 |
| Statutory reserve | | 800,257 | 800,257 |
| **Total restricted equity** | | **949,784** | **949,511** |
| | | | |
| *Unrestricted equity* | | | |
| Share premium reserve | | 4,231,347 | 4,191,749 |
| Retained earnings | | 763,083 | 562,451 |
| Profit for the year | | –507,836 | 51,257 |
| **Total unrestricted equity** | | **4,486,594** | **4,805,457** |
| **Total equity** | | **5,436,378** | **5,754,968** |
| | | | |
| **Untaxed reserves** | | | |
| Excess depreciation | | 2,124,000 | 1,154,000 |
| **Total untaxed reserves** | | **2,124,000** | **1,154,000** |
| | | | |
| **Liabilities** | | | |
| *Non-current liabilities* | | | |
| Deferred tax liabilities | 21 | 10,196 | 24,813 |
| Liability to Bioverativ | 27 | 1,066,833 | 1,808,916 |
| Liabilities to credit institutions | 27 | — | 496,914 |
| Other provisions | 30 | 82,443 | 33,060 |
| **Total non-current liabilities** | | **1,159,472** | **2,363,703** |
| | | | |
| *Current liabilities* | | | |
| Trade payables | | 312,771 | 257,038 |
| Liabilities to Group companies | | 628,848 | 549,753 |
| Tax liabilities | | 189,064 | 40 |
| Liability to Bioverativ | 28 | 579,895 | 496,697 |
| Other liabilities | 28 | 27,213 | 100,484 |
| Accruals and deferred income | 31 | 682,830 | 458,926 |
| **Total current liabilities** | | **2,420,621** | **1,862,938** |
| **TOTAL EQUITY AND LIABILITIES** | | **11,140,471** | **11,135,609** |

For information about the Group's pledged assets and contingent liabilities, see note 32.

# Parent Company statement of changes in equity

| | Restricted equity | | Unrestricted equity | | |
|---|---|---|---|---|---|
| AMOUNTS IN SEK THOUSANDS | Share capital | Statutory reserve | Share premium reserve | Retained earnings, and profit for the year | Total equity |
| **Opening equity, 1 Jan 2016** | **149,150** | **800,257** | **4,156,272** | **715,350[1]** | **5,821,029** |
| Cash flow hedges | — | — | — | –176,295 | –176,295 |
| Issue/repurchase of shares | 104 | — | — | –104 | — |
| Sale of own shares | — | — | — | 23,500 | 23,500 |
| Share-based payment to employees | — | — | 35,477 | — | 35,477 |
| Profit for the year | — | — | — | 51,257[1] | 51,257 |
| **Closing equity, 31 Dec 2016** | **149,254** | **800,257** | **4,191,749** | **613,708[2]** | **5,754,968** |
| | | | | | |
| **Opening equity, 1 Jan 2017** | **149,254** | **800,257** | **4,191,749** | **613,708** | **5,754,968** |
| Cash flow hedges | — | — | — | 149,648 | 149,648 |
| Issue/repurchase of shares | 273 | — | — | –273 | — |
| Sale of own shares | — | — | — | — | — |
| Share-based payment to employees | — | — | 39,598 | — | 39,598 |
| Profit for the year | — | — | — | –507,836 | –507,836 |
| **Closing equity, 31 Dec 2017** | **149,527** | **800,257** | **4,231,347** | **255,247[2]** | **5,436,378** |

1. Deferred tax has been adjusted during the year related to change in depreciation method and cash flow hedges. The adjustments have been reported against retained earnings and have affected the tax in both Group and Parent Company but has not had any effect on paid tax. See note 21.

| [2]Cash flow hedges | 2017 | 2016 |
|---|---|---|
| Opening balance, cash flow hedges | –122,105 | 54,190 |
| Changes in value for the year, hedging instruments | 149,648 | –176,295 |
| **Closing balance, cash flow hedges** | **27,543** | **–122,105** |

Regarding cash flow hedges SEK 12,662 (–4,955) K is transferred to the Income statement.

At year-end, the share capital was SEK 149,526,711, divided into 272,507,708 shares with a par value of approximately SEK 0.55 and one vote per share. The Company held 3,249,870 ordinary shares in treasury at the reporting date. Shares held in treasury represent 1.2 per cent of the total number of shares in the Company.

# Parent Company cash flow statement

| AMOUNTS IN SEK THOUSANDS | Note | 2017 | 2016 |
|---|---|---|---|
| **Operating activities** | | | |
| Profit for the year | | –507,836 | 51,257 |
| Adjustments for non-cash items | | 1,897,033 | 305,109 |
| **Cash flow from operating activities before changes in working capital** | | **1,389,197** | **356,366** |
| | | | |
| **Cash flow from changes in working capital** | | | |
| Decrease (+)/Increase (–) in inventories | | –127,290 | –92,829 |
| Decrease (+)/Increase (–) in operating receivables | | –319,144 | –431,145 |
| Increase (+)/Decrease (–) in operating liabilities | | 406,024 | 537,676 |
| **Cash flow from operating activities** | | **1,348,787** | **370,068** |
| | | | |
| **Investing activities** | | | |
| Acquisition of subsidiaries | | –195 | — |
| Acquisition of intangible assets[1] | 17 | –91,922 | –118,657 |
| Acquisition of property, plant and equipment | 18 | –37,411 | –36,315 |
| Disposal of property, plant and equipment | | — | 4,202 |
| **Cash flow from investing activities** | | **–129,528** | **–150,770** |
| | | | |
| **Financing activities** | | | |
| Proceeds from borrowings | 27 | — | 496,914 |
| Repayment of loans[2] | 27 | –500,000 | –828,000 |
| Sale of shares | | — | 23,500 |
| **Cash flow from financing activities** | | **–500,000** | **–307,586** |
| | | | |
| **Change in cash and cash equivalents** | | **719,259** | **–88,288** |
| **Cash and cash equivalents at beginning of year** | | **662,110** | **750,398** |
| **Cash and cash equivalents at end of year** | | **1,381,369** | **662,110** |

1. The largest investment in the year concerns the right to take part in the rFIXFc-XTEN programme, amounting to SEK 56 M and LMS (education system) for SEK 7 M, see note 17.
2. Repayment of loans concerns the repayment of a loan of SEK 500 M from Handelsbanken and Danske Bank.

### Supplemental disclosures to the cash flow statement – Parent Company

| AMOUNTS IN SEK THOUSANDS | Note | 2017 | 2016 |
|---|---|---|---|
| **Interest and tax paid and received** | | | |
| Interest received | | 11,656 | 17,252 |
| Interest paid | | 22,831 | 30,822 |
| | | | |
| Tax paid | | — | — |
| | | | |
| **Adjustments for non-cash items** | | | |
| Depreciation, amortisation and impairment of assets | 7, 17, 18 | 322,750 | 269,323 |
| Revaluation of non-current debt | | — | 670 |
| Impairment of participations in subsidiaries | 19 | 1,000,000 | — |
| Deferred tax | 21 | –14,616 | –16,354 |
| Cost of share programmes[1] | | 39,598 | 35,477 |
| Excess depreciation | | 970,000 | 1,154,000 |
| Elocta and Alprolix[2] | | –437,690 | –1,150,850 |
| Other items | | 16,991 | 12,843 |
| | | **1,897,033** | **305,109** |

1. IFRS 2-expenses associated with the share programmes recognised in equity.
2. Refers to royalty revenues used to settle the liability to Bioverativ and interest expenses relating to the liability to Bioverativ.

# Notes

## Note 1

### General information

Swedish Orphan Biovitrum AB (publ), Corporate Registration Number 556038-9321, the Parent Company and its subsidiaries, collectively referred to as 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.

## Note 2

### Significant accounting policies and basis of preparation for the Parent Company and consolidated financial statements

**Summary of significant accounting policies for Groups**
The primary accounting policies applied in 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 under the historical cost convention, except in the case of certain financial assets and liabilities (including derivative instruments) which are measured at fair value through profit or loss.

**New and amended standards applied by the Group**
The accounting policies applied are consistent with those applied in the previous year.

**New standards, amendments and interpretations of existing standards not yet applied by the Group**
IFRS 15 Revenue from Contracts with Customers is effective on 1 January 2018 and replaces all previously issued revenue-related standards, such as IAS 18. The purpose of the new revenue standard is to provide a single, principles-based model for all revenue recognition, i.e., for all types of transactions and all sectors.

The standard works on the basis is that everything begins with a contract between two parties for the sale of a product or a service. The first step is to identify a customer contract, which generates an asset for the selling entity (right to receive the compensation promised under the contract) and a liability (obligation to transfer the promised goods or services). In accordance with the standard, the Company recognises revenue when the performance obligation is satisfied by transferring the promised goods or services to the customer. A fundamental difference from previous standards and interpretations is that IFRS 15 focuses on control rather than risks and benefits. The transfer of control of a product or service (and therefore the fulfilment of the performance obligation) is what triggers the revenue recognition rather than the transfer of risks and benefits.

Sobi's customer contracts stipulate rights and obligations, the right to receive payment and an obligation to deliver, and rights and obligations for customers, i.e. The right to receive delivery and an obligation to pay. The performance obligations associated with contracts between Sobi and its customers are short-term and consist mainly of distinct goods, own products, which are delivered for payment. This means that the customer contracts are such that, under normal circumstances, the obligations cease on delivery of goods to the customers and receipt of payment.

Sobi has conducted a thorough analysis of the effects that the introduction of IFRS 15 may have on the Group's financial statements, and the assessment is that it will not have any material impact on either earnings or the financial position. To reach this conclusion, agreements and transactions have been reviewed and tested against the standard's five-step model for revenue recognition.

Consequently, revenue recognition according to IFRS 15, which will be applied in its entirety, remains unchanged from the present standard. As a transition method, Sobi has chosen modified (prospective) retrospective application, which means that the Company applies IFRS 15 prospectively for contracts in place on the transition date. As revenue recognition remains unchanged on transition to the new standard, the choice of transition method is not of importance.

For further information concerning the Group's accounting policies for revenue, see "Revenue" further down in this note.

IFRS 9 Financial Instruments is effective for periods beginning on or after 1 January 2018 and replaces IAS 39 Financial Instruments: Recognition and Measurement. The standard contains rules for the classification and measurement of financial assets and liabilities, impairment of financial instruments and hedge accounting.

One of the changes relates to liabilities reported at fair value. The part of the change relating to fair value attributable to the own credit risk should be reported in other comprehensive income instead of in the result, unless this causes inconsistency in the accounting. Sobi has no liabilities valued at fair value and is therefore not affected by the change. Another change relates to hedge accounting and requires increased disclosure of risk management and the effect of hedge accounting. Sobi's hedge accounting will be made in accordance with IAS 39 with disclosures in accordance with IFRS 9. Finally, new principles have been introduced regarding impairment of financial assets, where the model is based on expected losses.

Sobi has analysed the effects that the introduction of IFRS 9 on the Group's financial statements, and the assessment is that it will not have any material impact on either earnings or the financial position. Sobi will apply the retrospective transition method, which means that the accumulated effect of the transition will be recognised as a change to retained earnings as at 1 January 2018. In accordance with IFRS 9, Sobi has chosen not to recalculate comparative figures.

IFRS 16 Leases is effective for periods beginning on or after 1 January 2019, and replaces IAS 17 Leases. The new standard introduces changed reporting requirements for lessees, with the present classification into operating leases and finance leases being replaced by a model in which assets and liabilities for all leases are recognised in the balance sheet. Under the standard, all leases, apart from short-term and low-value leases, are recognised as an asset with right of use and a corresponding liability in the lessee's balance sheet. Lease payments are recognised as depreciation, amortisation and interest expense. The financial reporting rules for lessors are unchanged. IFRS 16 will have some impact on Sobi's financial statement, particularly regarding property, plant and equipment and non-current liabilities, although the extent has not yet been determined. See note 10 for more information.

**BASIS OF CONSOLIDATION**
**General information**
The consolidated financial statements include the Parent Company and subsidiaries.

**Subsidiaries**
The consolidated financial statements have been prepared in accordance with the acquisition method. Accordingly, business combinations are seen as if the Group directly acquires the assets and assumes the liabilities of the entity acquired. The consolidated income statements and balance sheets of the Group include all entities in which the Company, directly or indirectly, has control. Control exists when the Company has power over the entity, is exposed, or has rights, to variable returns from its involvement with the entity and has the ability to use its power to affect its returns.

Subsidiaries are consolidated from the date on which the Group obtains control. They are deconsolidated from the date on which control ceases. The cost of acquisition comprises the sum of the acquisition-date fair values of the assets transferred, the equity instruments issued and the liabilities incurred by the acquirer to former owners of the acquiree.

Each contingent consideration is recognised at the acquisition-date fair value. 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 and

liabilities and contingent liabilities assumed in a business combination are measured at their acquisition-date fair value.

The difference between the cost of acquisition 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 at the acquisition date when control is obtained, and not at earlier stages of the acquisition. For step acquisitions, any previously held equity interests are remeasured at fair value and taken into account in the determination of goodwill, with any resultant gains or losses recognised in profit or loss. For each acquisition, the Group decides whether to measure the non-controlling interest in the acquiree at fair value or at the proportionate share of the net assets of the acquiree. Goodwill is not amortised, but is tested annually for impairment. If the net fair value of the acquiree's identifiable assets, liabilities and contingent liabilities exceeds the cost, the surplus (negative goodwill) is recognised immediately in profit or loss.

Intra-group transactions and balance-sheet items and unrealised gains or losses on transactions between Group companies are eliminated. Any losses are considered an indication of impairment of the asset transferred.

**Segment reporting**
Operating segments are presented using a management approach, which means that their presentation is the same as for internal reporting. The basis for identifying reportable segments is the internal reporting provided to and monitored by the chief operating decision maker. The Group has identified the CEO as the chief operating decision maker. Only one segment is used in internal reporting to the CEO. See also note 6.

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

*Transactions and balances*
Foreign currency transactions are translated into the functional currency using the exchange rates at the dates of the transactions. Exchange differences resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at closing rates are recognised in the statement of comprehensive income. Operating items are recognised in operating profit, while other items are recognised as finance income or expense.

*Translation of foreign subsidiaries*
The assets and liabilities of foreign subsidiaries are established in the functional currency of each subsidiary, meaning the primary economic environment in which the company operates. For Sobi's foreign subsidiaries, all assets, provisions and other liabilities are translated at the closing rate into the Group's presentation currency (SEK), with any resulting exchange differences recognised in other comprehensive income. All items in the income statement are translated using the average exchange rate for the year.

Goodwill and fair value adjustments arising on the acquisition of a foreign operation are treated as assets and liabilities of the foreign operation and translated at the closing rate.

**Revenue**
Revenue comprises the fair value of the sale of goods and services, net of value added tax, rebates and returns, after elimination of intra-group sales. Revenue is recognised as follows:

*Operating revenue*
Revenue from the sale of pharmaceuticals is recognised when Sobi has fulfilled its performance obligations, which means that control has passed to the customer. This occurs when the customer assumes responsibility for the goods and has an unconditional payment obligation, and when the risks and benefits associated with the goods have been transferred to the buyer. This normally occurs when the goods have been delivered from the Company's consignment stock to the end customer.

Contract manufacturing revenue (ReFacto) is recognised when the goods have been delivered to the customer, i.e. when the customer has obtained control of the goods.

Revenue also includes revenue from licensing agreements, such as out-licensing revenue, royalties from third parties and milestone payments. A milestone payment relates to partial payments received from partners triggered by the achievement of a specific part of the collaboration agreement, such as regulatory approval of a jointly developed product. Revenue of this type is recognised when the milestone has been achieved and the revenue is certain to materialise.

Due to various agreement formulations, licence revenue can be recognised in two ways. The revenue is either recognised directly when the licence revenue is received or allocated over its estimated duration.

Revenue from service assignments is recognised when the economic outcome of the work performed can be measured reliably and the economic benefits flow to the Group.

When the Group has undertaken to perform research and development assignments and receives payment for the services it provides, this is recognised as the work is performed. Revenue from research collaborations is recognised in the period in which the work is performed.

*Government grants*
Government grants are recognised when the company meets the conditions associated with the grant and it can be established with certainty that the grant will be received. Grants received are recognised as deferred income in the balance sheet and are recognised in profit or loss in the period in which expenses are recognised for the costs for which the grants compensate.

Sobi receives government grants mainly in the form of reduced employer's contributions for research for commercial purposes, which are utilised in full, and research grants from the EU. A minor proportion of Sobi's projects are financed through government grants.

*Other operating income/expenses*
Other operating income consists of revenue from activities outside the normal operations. The item includes currency effects on operating receivables and liabilities. Other operating expenses are expenses from activities outside the normal operations. The item includes currency effects on operating receivables and liabilities. Gains and losses on cash flow hedges accumulated in equity are reclassified to operating income/expenses in the periods in which the hedged item affects profit or loss. See also 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 reporting date. Non-current receivables and liabilities are essentially amounts expected to be settled later than one year from the reporting date.

**Intangible assets**
*Amortisation of intangible assets*
Amortisation of product rights and acquired R&D is charged to selling and administrative expenses. Amortisation of software is also charged to selling and administrative expenses. See also note 7.

*Goodwill*
Goodwill is the amount by which the cost of acquisition exceeds the fair value of the Group's share of the net identifiable assets of the acquired subsidiary/associate on the date of acquisition. Goodwill on acquisition of a subsidiary is recognised as an intangible asset. On acquisition of an associate, goodwill is included in the value of the holding in the associate. Goodwill is tested annually for impairment and is carried at cost less 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. The rights have a finite useful life and amortisation is applied to spread the cost over this period (5–20 years). Amortisation is on a straight-line basis over the useful life, reflecting the expected earnings of each product or marketing right. Amortisation is classified as selling expenses. See also note 4.

*Research & development expenditure*
Expenditure on development projects is recognised as an intangible asset if the Company can demonstrate that it is technically feasible to complete and profitably commercialise the results, and only if the cost of the project can be measured reliably. In practice, this means that the expenditure is not capitalised until such time as approval is granted by the US Food and Drug Administration (FDA) or the European Commission. Acquired research projects are capitalised with effect from the

## Note 2 contd.

acquisition date. Amortisation is applied in order to spread the cost of development projects over their estimated useful lives, and begins when the development project starts to generate revenue. Other research and development expenditure that does not meet the accounting requirements under IAS 38 is recognised as incurred.

*Software and IT projects in progress*
Acquired software licences are capitalised on the basis of the costs incurred when the software was acquired and placed in service. These costs are amortised over the estimated useful life of the software.

Costs associated with software development or maintenance are recognised as an expense as incurred. Costs directly associated with identifiable software products developed specifically for Sobi, which are controlled by the Company and are likely to generate economic benefits exceeding costs beyond one year, are recognised as intangible assets. Direct costs include the costs for employees working on software development and a reasonable proportion of overhead costs.

Expenditure to enhance the performance of software or extend its useful life (development expenditure) beyond the original plan is capitalised and added to the original cost of the software.

Regular amortisation for software reported under non-current assets is applied using the straight-line method over its useful life, up to a maximum of three years.

**Property, plant and equipment**
Items of property, plant and equipment are recognised as assets in the balance sheet when it is probable that future economic benefits associated with the asset will flow to the Company and the cost of the asset can be measured reliably.

All property, plant and equipment is stated at cost less depreciation. Cost includes expenditure that can be directly attributed to the acquisition of the asset. Subsequent costs are included in the asset's carrying amount or are recognised as a separate asset, depending on which is appropriate, only when it is probable that future economic benefits associated with the asset will flow to the Group and the cost of the asset can be measured reliably. All other forms of repair and maintenance are recognised as an expense in profit or loss as they occur.

*Depreciation of property, plant and equipment*
Regular depreciation of property, plant and equipment is based on their useful life. Depreciation is applied on a straight-line basis over the useful life of the asset, taking into account the residual value. The following depreciation periods are applied:

| | |
|---|---|
| *Plant and machinery* | |
| • Laboratory equipment and other investments | 3–7 years |
| • Other major investments, such as redevelopment of property | 5–20 years |
| *Equipment, tools and fixtures & fittings* | |
| • Servers and other major computer hardware items | 3–5 years |
| • Furniture, fixtures and fittings | 5–10 years |
| *Land and buildings* | |
| • Buildings | 20 years |
| • Land | Indeterminate useful life |

The assets' residual values and useful lives are tested on each reporting date and adjusted as necessary.

An asset's carrying amount is immediately written down to its recoverable amount if the asset's carrying amount exceeds its estimated recoverable amount.

The gain or loss arising from the disposal of property, plant and equipment is the difference between the selling price and the item's carrying amount less direct costs to sell. The profit/loss item is reported as other operating income or other operating expenses.

Leased assets are classified as finance leases or operating leases in the consolidated financial statements. Leased non-current assets where Sobi is responsible for the same risks and benefits as in the case of direct ownership are classified as finance leases. The asset is recognised as a non-current asset in the balance sheet. The corresponding obligation to make future lease payments is recognised under current or non-current liabilities. The leased assets are depreciated over their useful life, while lease payments are apportioned between the interest and the repayment of the liability. Leased assets for which the lessor substantially retains ownership are classified as operating leases and the lease payments are recognised as an expense on a straight-line basis over the term of the lease. See also note 10.

*Impairment of assets*
Goodwill, which has an indefinite useful life, and intangible assets not yet placed in service are not amortised but are tested for impairment, either annually or when there are indications of a decline in value for an asset. Product and marketing rights, which are amortised, are also tested annually for impairment as their carrying amount is significant for the Group. Other assets that are amortised are reviewed for impairment whenever events or changes in circumstances indicate that their carrying amounts may not be recoverable. An asset is impaired if its carrying amount exceeds its recoverable amount. Impairment is therefore the difference between the carrying amount and the recoverable amount, with the recoverable amount being defined as the greater of an asset's net realisable value and its value in use. To calculate the value in use, future cash flows that the asset is expected to generate are discounted at a rate corresponding to Sobi's weighted average cost of capital (WACC).

To test for impairment, goodwill is allocated to cash-generating units, i.e. the smallest identifiable group of assets generating cash inflows. Sobi has made the assessment that the Group's operations as a whole comprise one cash-generating unit. Goodwill impairment is not reversed. Impairment of assets other than goodwill is reversed if there has been any change in the conditions used to determine the recoverable amount. An impairment loss is reversed to the extent that the asset's value does not exceed the carrying amount that would have been determined, net of depreciation, had no impairment loss been recognised. 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 one enterprise and a financial liability or equity instrument in another enterprise. Financial instruments also include contract-based rights to receive cash, such as trade receivables. See also note 3.

The Group classifies its financial instruments in the following categories:
1. Loans and receivables
2. Financial instruments at fair value through profit or loss (including derivatives not classified as hedging instruments)
3. Other financial liabilities
4. Available-for-sale financial instruments (including derivatives classified as hedging instruments)

The classification is based on the purpose for which the instruments were acquired. Management makes a classification decision on initial recognition and reviews this decision at each reporting date.

Financial instruments are measured at their trade-date fair value plus transaction costs. This applies to all financial instruments not measured at fair value through profit or loss. 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 under assets in the balance sheet include cash and cash equivalents, trade receivables and endowment insurances. Financial liabilities include trade payables, equity instruments and loans.

*1. Loans and receivables*
Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are included in current assets, apart from items with maturities more than twelve months after the balance-sheet date, which are classified as non-current assets. The Group's loans and receivables consist of trade and other receivables, and cash and cash equivalents in the balance sheet.

Loans and receivables are measured at amortised cost less any impairment. As the expected maturities of trade receivables are short, the value is initially recognised at their nominal amount without discounting. Impairment of doubtful receivables, which are assessed on an individual basis, is recognised under operating expenses.

*2. Financial instruments at fair value through profit or loss (including derivatives not classified as hedging instruments)*
Financial assets measured at fair value through profit or loss are financial assets that do not constitute hedging instruments. A financial asset is classified in this category if it was acquired principally for the purpose of being sold in the short term. Assets in this category are classified as current assets if they are expected to be sold within twelve months; otherwise they are classified as non-current assets.

Derivatives are classified in this category if they have not been identified as hedges. Derivatives held for risk management in the financial operations are reported under net financial items and derivatives held to manage risks in the operating profit are recognized in other expenses / income.

Derivatives are recognised as assets or liabilities, depending on whether the fair value is positive or negative. If there are liabilities in this category, they are recognised in the same way as assets.

*3. Other financial liabilities*
This category comprises loans and trade payables. Liabilities in this category are measured at amortised cost using the effective interest method.

Borrowings are initially measured at fair value, net of 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 for twelve months or more after the reporting date.

*4. Available-for-sale financial instruments (including derivatives classified as hedging instruments)*
Available-for-sale financial assets are assets that have been identified as available for sale, or have not been classified in any other category. They are reported under non-current assets if management does not intend to dispose of them within twelve months of the reporting date.

A change in value in a financial asset in this category is recognised in other comprehensive income. When assets in this category are sold or impaired, the accumulated fair value adjustments are transferred from equity to the income statement and reported under gains and losses on financial instruments. This category includes financial instruments identified as hedges. These instruments are recognised as assets or liabilities depending on whether the fair value is positive or negative. Hedge accounting of financial instruments is described in the section below.

*Financial instruments and hedging measures*
The Group uses derivative instruments and loans to manage currency risks, and derivative instruments to manage interest-rate risks in the financing. All derivatives are assigned a market value and measured at fair value in the balance sheet, both initially and in any subsequent revaluation. The recognition method for the gain or loss arising on revaluation depends on whether the derivative is designated as a hedging instrument and, if so, on the nature of the hedged item. If a loan is designated as a hedging instrument for currency risk, the loan is measured at amortised cost in the balance sheet.

The entire fair value of a derivative that is a hedging instrument is classified as a non-current asset or liability if the hedged item has a term to maturity of more than twelve months, and is classified as a current asset or liability if the hedged item has a term to maturity of less than twelve months. Derivative instruments that do not constitute hedging instruments are always classified as current assets or current liabilities.

*Cash flow hedges*
The effective portion of changes in the fair value of a derivative instrument identified as a cash flow hedge is recognised in other comprehensive income. The gain or loss relating to the ineffective portion is recognised immediately in profit or loss. Gains or losses accumulated in equity are reclassified to profit or loss in the periods in which the hedged item affects profit or loss. If a hedging instrument expires, is sold or no longer qualifies for hedge accounting and there are cumulative gains or losses in equity, they remain in equity and are recognised when the hedged item is finally recognised in profit or loss. If a loan is designated as a hedging instrument for currency risk, the effective portion of the revaluation effect related to exchange rate changes is recognised in the same way as for derivatives, while the other components of the loan are recognised as a loan that is not included in a hedge.

*Current assets*
Receivables maturing within one year from the balance sheet date are classified as current assets.

*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 estimated selling price in the ordinary course of business less costs to sell. Obsolescence risk and established obsolescence are taken into account.

*Cash and cash equivalents*
Cash and cash equivalents for the Parent Company and the Group include the balances of cash pools and other bank accounts, and investments with a maturity of three months or less 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 of tax, as a deduction from the issue proceeds.

*Provisions*
Provisions are recognised when Sobi has a legal or constructive obligation as a result of a past event, and 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 at the best estimate of the expenditure 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 is obtained by reference to the pre-tax market rate 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, which means there are clear expectations that the plan will be implemented. Provisions for restructuring often include termination benefits, for both voluntary or involuntary termination. Termination benefits are recognised as described above, apart from where a service requirement is linked to the benefit, in which case the cost is distributed over the period of service. Restructuring provisions require estimates of the time and cost of planned future activities. The most significant estimates relate to the costs required for severance pay or other obligations in connection with termination of employment, as well as costs for termination of agreements and other associated costs. Such estimates are based on the current status of negotiations with the parties involved and/or their representatives. Salary relating to the period following termination of the duty to work is recognised as an expense when the decision is made and communicated.

Endowment insurance is recognised gross over the balance sheet as a financial asset and a provision. In previous years, these have been reported net.

Sobi has a provision for restoration reserve for the restoration of the rented property Paradiset 14 at the end of the contract period. The company reports the restoration reserve as a provision in the balance sheet.

Cash-based programs directed to employees are handled as a provision until the program expires.

*Taxes*
Taxes in the statement of comprehensive income consist of current tax and deferred tax. Current tax is income tax payable or recoverable in respect of the current year. Deferred tax is calculated using the liability method on temporary differences between the carrying amounts and tax bases of assets and liabilities, applying the tax rates and tax laws enacted or substantively enacted by the reporting date.

Deferred tax is not recognised for consolidated goodwill, nor for differences attributable to investments in subsidiaries, where the Parent Company is able to control the timing of a reversal of the temporary differences and such a reversal is unlikely in the foreseeable future. In the consolidated financial statements, untaxed reserves are divided into deferred tax liabilities and equity. Deferred tax assets for deductible temporary differences and loss carryforwards are only recognised to the extent that it is probable that they will be utilised. The carrying amounts of deferred tax assets are reduced when it is no longer probable that they can be utilised. Tax is reported under Tax on profit for the year, in the statement of comprehensive income apart from tax for items reported 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. The CEO and senior executives 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 on retirement is determined by the premiums paid and the return on the investments, less management expenses.

Pension costs relating to defined-contribution plans are charged to earnings as the benefits are earned. Pension obligations are calculated without discounting, as payments for these plans fall due within twelve months.

For defined-benefit plans, the pension is determined as a percentage of the pensionable final salary, taking into account the number of years of service and average final salary. The Group bears the risk associated with paying out the established benefits.

## Note 2 contd.

The defined-benefit liability recognised in the balance sheet is the net total of the estimated present value of the defined-benefit obligation less the fair value of the plan assets, which are recognised as a provision or a non-current financial receivable.

Pension costs and pension obligations under defined-benefit plans are calculated according to the applicable principles of IAS 19. The calculation is performed annually by independent actuaries.

The Company's obligations have been measured as the present value of expected future payments. The discount rate used for the obligations in Sweden corresponds to the market yield on mortgage bonds with a term consistent with the term of the pension obligations. The main actuarial assumptions are described in note 29.

Actuarial gains and losses may arise in determining the present value of the obligation and fair value of plan assets. These arise either when the actual outcome 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 finance cost. Other expense items in pension costs are charged to operating profit.

The accounting policy for defined benefit pension plans described above applies only to the consolidated accounts.

The retirement benefit and family pension obligation for employees in Sweden is covered by insurance with Alecta. According to Statement UFR3 issued by the Swedish Financial Accounting Standards Council's Emerging Issues Task Force, this is a multi-employer defined-benefit plan. For the 2005–2017 financial years, the Company did not have access to sufficient information to enable it to report this plan as a defined-benefit plan. Consequently, the ITP pension plan insured through Alecta is reported as a defined-contribution plan. Payroll tax is calculated on deductible pension premiums.

For some leading executives, the pension plan has been supplemented with commitments on direct pensions. In these cases, the Parent Company has, over time, signed endowment insurances which are pledged to the employee as security for the contract. The endowment insurances, subscribed by the Parent Company, are classified in the balance sheet as financial assets, since they are long-term holdings, and are reported at fair value. The pension commitment to the employee is included under provisions for pensions.

For the endowment insurance, a reserve for special payroll tax has also been reported. Premiums paid to capital insurances are not deductible. The payment to the beneficiary, on the other hand, 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, also taking into account conditions that are market-related. For the 2017 Share Programme, which includes the CEO, senior executives and managers, there is a revenue component, in which the fair value of the allotted shares may fluctuate depending on the assumptions on target fulfilment. The total amounts to be expensed are based on the fair value of the shares allotted.

The total amount is recognised as a personnel cost in the income statement, distributed over the vesting period, and corresponding adjustments are made in equity. At the end of every quarter, the Group reviews its assessments of the number of shares 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 covering all employees in the US, which do not constitute share-based remuneration. Three of them are for all US employees and one is for a number of executives in Sweden. As remuneration under these programmes is contingent on continuing employment with the Company, the costs are recognised continuously over the vesting period. A liability is calculated at each reporting date, taking into account the market value, new assessments of target outcomes and the amount earned. The net amount of these effects is recognised as a personnel cost in the consolidated income statement.

Costs for social security contributions are remeasured at each reporting date until settlement occurs and is allocated in accordance with the same principles as the cost for shares.

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

*Termination benefits*
A provision for costs in connection with termination of personnel is recognised only if the company is demonstrably obligated to terminate employment before the normal period of service has ended or when benefits are provided as an incentive to encourage voluntary termination, e.g. early retirement packages. In cases where the Company terminates employment, a detailed plan is prepared which, as a minimum, contains information on the workplace, positions and approximate number of individuals involved, remuneration due to each employee category or position and the schedule for the plan's implementation.

**Contingent liabilities**
A contingent liability is recognised when a possible obligation arises from past events whose existence will be confirmed only by the occurrence or non- occurrence of one or more uncertain future events, or when there is an obligation which is not recognised as a liability or provision because it is not probable that an outflow of resources will be required to settle the obligation.

**Parent Company's Accounting Policies**
The annual report for Swedish Orphan Biovitrum AB (publ), the Parent Company, has been prepared in accordance with 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*
In the calculation of defined-benefit pension plans, the Parent Company complies with the Swedish Pension Obligations Vesting Act, which is a prerequisite for tax deductibility. The most significant differences from the rules in IAS 19 relate to determination of the discount rate, calculation of the defined-benefit obligation, which is based on current salary levels without assumptions about future salary increases, and recognition of actuarial gains and losses in other comprehensive income as they arise. See note 29 for more information.

*Leased assets*
All 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*
Investments in subsidiaries are recognised in accordance with the cost model. The value of subsidiaries is measured 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 the initial assessment needs to be revised in subsequent periods, the cost is adjusted.

*Group contributions*
Sobi applies the alternative rule, which means that all Group contributions received/provided are reported as appropriations.

**Basis of preparation**
The Parent Company's functional currency is the Swedish krona (SEK), which is also the presentation currency for the Parent Company and the Group. The financial statements are therefore presented in SEK.

All amounts are stated in SEK thousands unless otherwise indicated. Assets and liabilities are measured at historical cost, apart from certain financial assets and liabilities which are measured at fair value.

To prepare the financial reports 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, and other information disclosed. These estimates and assumptions are based on historical experience and are regularly reviewed.

Estimates made by management when applying IFRS which have a material effect on the financial statements and assumptions have not resulted in material adjustments to the following year's financial statements. The accounting policies described above are used consistently in the preparation of the financial statements which are published and based on IFRS.

The previous year's amounts in tables and notes have been adjusted due to changes in current and deferred taxes relating to prior years but identified during the current year.

The amounts and figures in brackets are comparative figures for 2016. See also note 4.

# Note 3

## Financial risk management

**Financial risks and risk management**

In the course of its operations, Sobi is exposed to various types of risks that may affect its earnings and financial position. The risks can be divided into operational risks and financial risks. Financial risks are risks of 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 considered most significant for Sobi, and the management of these risks. Operational risk is also described in a separate section of the Directors' report.

Financial risk is centrally managed by Sobi's treasury department, which is also responsible for providing solutions for liquidity management and supporting the organisation in treasury-related matters.

The treasury policy, which is adopted by the Board, establishes the division of responsibility and control of financial matters between the Board, the CEO, the CFO, the central finance department and other Group companies. The Board has appointed an Audit Committee which has tasks that include monitoring the structure and content of the treasury policy and, if necessary, suggest changes to the Board. The main objective of the treasury policy is to maintain a low level of financial risk and to manage risk in a prudent way.

**Financial risk factors**

*Currency risk – Commercial transaction risk*

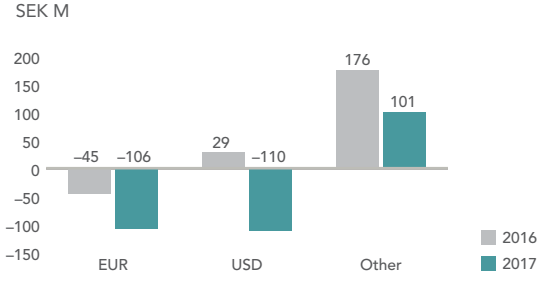
Commercial transaction risk is the risk of changes in exchange rates having a negative effect on operating profit during the period until a transaction is settled. As the Group's subsidiaries generally have most of their commercial flows in local currencies, this risk is limited, except in the Parent Company, which has significant commercial flows in foreign currencies, notably EUR and USD.

This risk is managed by limiting the net exposure, i.e. the net of all positive and negative exposures, in each currency and by entering into contracts in financial instruments such as forward contracts.

However, part of the transaction risk, associated with highly probable USD inflows, primarily from Elocta and Alprolix, is managed by using hedge accounting in the form of cash flow hedges. This means that the FX-effects from revaluing the liabilities for Elocta and Alprolix to Bioverativ are recognised in other comprehensive income and accumulated gains or losses on these revaluations are reclassified to profit or loss when the mentioned inflows affect profit or loss. See notes 17 and 27 for further information about these liabilities.

The currencies with the largest net exposures are shown in the graph below. The amounts in the graph correspond to the net amounts revalued in operating profit. At 31 December 2017, the exposure was linear and amounted to SEK –114 M (159). An instantaneous and permanent change of +/– 10 per cent in all rates against SEK would have an impact of SEK –11 M (16) on operating profit before tax.

**Commercial transaction exposure**

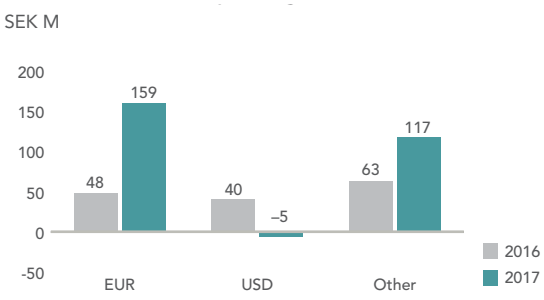



*Currency risk – Financial transaction risk*

Financial transaction risk refers to the risk of changes in exchange rates having a negative impact on net financial items. Loans and investments of subsidiaries are managed by the Group's treasury department and are generally denominated in the local currencies of the subsidiaries. In this way, financial transaction risk is centralised to the Parent Company.

This risk is managed by matching all transactions in their respective currencies, including assets, liabilities and other items revalued in net financial items, and by limiting any net exposure of a sufficiently large amount, compared with a fixed measure, by entering into financial contracts, such as forward contracts. The currencies with the largest net exposures are shown in the graph below. The amounts in the graph correspond to the net amounts (including derivatives) revalued in net financial items. At 31 December 2017, the exposure was linear and amounted to SEK 271 M (151). An instantaneous and permanent change of +/– 10 per cent in all rates against SEK would have an impact of +/– SEK 27 M (15) on financial profit before tax. Derivatives outstanding on the reporting date are shown in the table below.

**Financial transaction exposure**



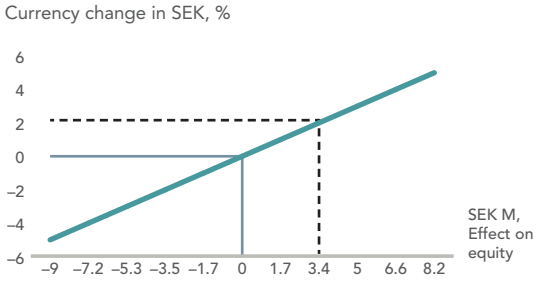

*Outstanding derivatives (nominal amounts in millions, local currency)*

| | 2017 | 2016 |
|---|---|---|
| USD | –30 | –21 |
| EUR | –29 | –23 |
| CAD | –5 | — |
| GBP | –1 | –1 |
| CZK | — | –24 |

*Currency risk – Translation risk*

Translation risk is the risk of fluctuations in exchange rates having a negative impact on equity when the balance sheets and income statements of foreign subsidiaries are translated into SEK. This risk is considered low and therefore not managed. The translation risk graph shows the Company's sensitivity to this risk. The graph shows that the translation effect on the Group's equity would be positive if SEK weakened, and vice versa. If, for example, SEK depreciated by 2 per cent against all currencies, the translation effect on consolidated equity would be SEK 3.4 M (1.8).

**Translation risk**




*Interest-rate risk*

Interest-rate risk is the risk of Sobi being adversely affected by changes in interest rates, with changes in general interest rates having a negative effect on earnings and changes in market values having a negative effect on fixed-rate instruments. Changes in market values are considered acceptable as Sobi's general principle is to minimise its volatility in earnings.

## Note 3 contd.

Sobi's financing sources primarily consist of equity, cash flow from operating activities and borrowings. Interest-bearing borrowings expose the Group to interest-rate risk. Sobi's long-term interest-bearing financing consists of an unused revolving credit facility of SEK 1,000 M with Svenska Handelsbanken AB (publ) and Danske Bank A/S, Danmark, Sverige filial. This was a three-year facility but an option to extend it by one year was exercised during the year and the new maturity date is 27 June 2020. During the year, the credit facility agreement was also restructured from the previous utilised credit facility of SEK 500 M and revolving term loan facility of SEK 500 M to a revolving credit facility of SEK 1,000 M, was utilised at the reporting date. There were no interest-rate derivatives outstanding on the reporting date. The liability to Bioverativ is non-interest bearing by agreement, but is discounted in the financial statements and the effect of the discounting is therefore recognised as an interest expense.

Sensitivity of earnings to interest-rate changes is measured by assuming a permanent interest-rate change of 1 percentage point. At 31 December 2017, such a change would have an annual impact of SEK 0 M (3) on net financial items. At 31 December 2017, Sobi's interest-bearing liabilities amounted to SEK 7 M (504).

*Credit risk*

Credit risk refers to the risk of loss if a counterparty fails to meet its obligations. Credit risk can be divided into credit risk in trade receivables and financial credit risk.

Sobi's credit risk is primarily related to trade receivables. These amounted to SEK 1,129 M (769) at the reporting date, SEK 290 M (272) of which were past due. See note 23 for information about overdue trade receivables. Sobi's customers are primarily hospitals and government agencies, which means that Sobi's customers to a large extent are funded by governments. If it is Sobi's assess that a receivable will not be paid, provisions must be made. At 31 December 2017, such provisions amounted to SEK 35 M (49). There are normally nor guarantees 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 are obtained from a market-recognised rating agency.

Sobi has established principles that limit of financial credit risk. Limit the financial credit risk further, financial transactions are primarily with banks with a high official credit rating.

*Liquidity risk*

Liquidity risk is the risk of Sobi being unable to obtain financing at acceptable terms or to honor its payment obligations, due to factors beyond Sobi's control. Management of liquidity risk is described in the treasury policy. Both short- and long-term forecasts of the Group's liquidity are regularly compiled to ensure the availability of sufficient funds to meet the needs of operating activities. Investment of any surplus liquidity shall be in liquid instruments with low credit risk and a high level of liquidity. Investments shall only be made 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. With high liquidity means that the investments can be readily converted into cash. According to the policy, there must also be a liquidity reserve, the size of which is based on a proportion of annual sales. The liquidity reserve comprises bank balances, short-term investments and the unutilised part of committed credit facilities. At 31 December 2017, the Company had unutilised committed credit facilities totalling SEK 1,135 M (635).

The long-term financing consists of a revolving credit facility of SEK 1,000 M with Handelsbanken and Danske Bank, with a maturity date of 27 June 2020. The credit agreement contains customary financial covenants regarding limitations in the Group's ratio of net debt to earnings ratio before interest rates, tax, depreciation and amortisation (EBITDA), the equity/assets ratio and interest coverage ratio. The credit agreement also contains covenants with regard to a change of control.

The following table shows the contractual undiscounted cash flows from the Group's financial liabilities, divided according to the time to contractual maturity as at the reporting date.

*Maturity analysis*

| 31 DECEMBER 2017 | Less than 1 year | 1-2 years | 2-5 years | More than 5 years |
|---|---|---|---|---|
| Derivatives | 2,624 | — | — | — |
| Trade payables | 358,449 | — | — | — |
| Other liabilities[1] | 1,624 | 3,700 | 1,707,761 | — |
| **Total** | **362,967** | **3,700** | **1,707,761** | — |

| 31 DECEMBER 2016 | Less than 1 year | 1-2 years | 2-5 years | More than 5 years |
|---|---|---|---|---|
| Borrowings | 7,351 | 7,531 | 502,920 | — |
| Trade payables | 280,173 | — | — | — |
| Other liabilities[1] | 1,800 | 3,502 | 2,426,195 | 0 |
| **Total** | **289,323** | **10,853** | **2,929,115** | **0** |

1. Other liabilities are mainly related to the liability to Bioverativ. The liability to Bioverativ is recorded at nominal amount on the contractual expiration date. Repayment of the liability to Bioverativ in USD is mainly via royalty revenue in USD. See note 17.

*Capital risk*

The goal of Sobi's capital structure is to generate high returns for shareholders and 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 needs by changing the dividends to shareholders, repaying capital to the shareholders, issuing new shares or selling assets to reduce debt.

The Group's capital structure is assessed on the basis of the equity/assets ratio. The Company's target is an equity/assets ratio of at least 40 per cent. At 31 December 2017, the equity/assets ratio was as follows:

| | 2017 | 2016 |
|---|---|---|
| Equity | 6,700,524 | 5,364,966 |
| Total assets | 10,902,907 | 9,974,139 |
| Equity/assets ratio, % | 61.5 | 53.8 |

*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:** Unobservable inputs used for measurement of the asset or liability.

| 31 DECEMBER 2017 | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| *Financial assets at fair value through profit or loss* | | | | |
| Derivatives held for trading | — | 2,471 | — | 2,471 |
| **Total assets** | **—** | **2,471** | **—** | **2,471** |

| 31 DECEMBER 2016 | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| *Financial assets at fair value through profit or loss* | | | | |
| Derivatives held for trading | — | 3,901 | — | 3,901 |
| **Total assets** | **—** | **3,901** | **—** | **3,901** |

All derivatives are measured at fair value based on market data in accordance with IFRS. At 31 December 2017, the carrying amount of derivatives in the balance sheet was SEK 2 M (4). See also note 26.

# Note 4

## Significant accounting estimates, assumptions and judgements

The Group makes estimates and assumptions about the future,and judgements for accounting purposes. Significant accounting estimates, assumptions and judgements that involve considerable risk of material adjustments to the carrying amounts of assets and liabilities during the next financial year are described below.

### ACCOUNTING JUDGEMENTS

**Revenue**

The Group assesses the likelihood of future economic benefits flowing to the Group on the basis of a number of factors, including customers' payment history and credit rating. If a receivable is considered doubtful by the Group, a provision is recognised until it is possible to determine whether the Group will receive payment or not. According to the Group's procedures for advances, advance payments are recognised as other current liabilities until they are earned. When recognising revenue, each agreement is interpreted individually and the Company makes an assessment of the remaining commitment.

Revenue is recognised when control of goods is transferred to the buyer. Revenue is calculated as invoiced gross revenue less actual and estimated rebates to public and private customers, adjustments for deliveries where control has not yet passed to the buyer, royalty costs to partners and payments to wholesalers and distributors. As the actual and final conditions concerning rebates on sales in the current period are not always known on the reporting date, some of the deductions from gross revenue are based on estimates. See also note 2 on revenue recognition of license fees and milestone payments.

**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 expenditure**

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. A write-down has been made to one of the clinical programmes in an early phase of SEK 12 M.

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, product rights 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. Sobi's goodwill amounted to SEK 1,554 M (1,554) on 31 December 2017. The impairment testing did not indicate any impairment.

*Acquired development projects*

The Group makes periodic impairment assessments of acquired development projects in accordance with the policy described in note 2. Impairment assessments require certain estimates to be made. These assumptions are specified in note 17.

*Product and marketing rights*

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

As the carrying amounts of these product and marketing rights are highly significant for the Group, they are tested annually for impairment. The Company has determined that most of the amortisation is attributable to selling 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. Other assumptions included in impairment testing of product rights are presented in note 17.

**Taxes**

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. The amounts are measured using the tax rates and tax laws enacted or substantively enacted by the reporting date. Under current Swedish tax legislation, loss carryforwards continue indefinitely. There are no loss carryforwards in the Group at the moment.

**Assumptions for the calculation of pension benefits**

The actuarial calculation of pension obligations 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 can 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. Obsolescence assessments are regularly updated based on historical obsolescence. 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 inventories are measured continuously with respect to the shelf life limitations of pharmaceuticals.

# Note 5

## Distribution of operating revenue

| GROUP | 2017 | 2016 |
|---|---|---|
| **Operating revenue by major revenue category** | | |
| Product sales | 4,746,175 | 2,990,343 |
| Manufacturing and contract development | 559,295 | 568,684 |
| Royalty revenue | 1,202,660 | 1,598,887 |
| Out-licensing and milestone revenue[5] | — | 13,783 |
| Service fee | 2,701 | 32,643 |
| **Total** | **6,510,831** | **5,204,340** |

| GROUP | 2017 | 2016 |
|---|---|---|
| **Revenue by geographic market[1]** | | |
| Europe[2] | 3,784,036 | 2,221,801 |
| MENAR[3] | 271,806 | 301,513 |
| North America | 1,168,279 | 1,002,050 |
| Rest of world | 84,050 | 66,306 |
| **Total** | **5,308,171** | **3,591,670** |
| Royalty revenue[4] | 1,202,660 | 1,598,887 |
| Out-licensing and milestone revenue[5] | — | 13,783 |
| **Total** | **6,510,831** | **5,204,340** |

Revenues for the Parent Company, Swedish Orphan Biovitrum AB (publ), amounted to SEK 5,756 M (4,594) with sales to Group companies accounting for SEK 2,732 M (1,472) of the amount.

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| **Operating revenue by major revenue category** | | |
| Product sales | 3,991,714 | 2,379,943 |
| Manufacturing and contract development | 559,295 | 568,684 |
| Royalty revenue[4] | 1,202,660 | 1,598,887 |
| Out-licensing and milestone revenue[5] | — | 13,783 |
| Service fee | 2,701 | 32,643 |
| **Total** | **5,756,370** | **4,593,940** |

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| **Revenue by geographic market[1]** | | |
| Europe[2] | 3,453,619 | 1,882,846 |
| MENAR[3] | 157,498 | 200,862 |
| North America | 857,941 | 830,642 |
| Rest of world | 84,652 | 66,920 |
| **Total** | **4,553,710** | **2,981,270** |
| Royalty revenue[4] | 1,202,660 | 1,598,887 |
| Out-licensing and milestone revenue[5] | — | 13,783 |
| **Total** | **5,756,370** | **4,593,940** |

1. The geographic distribution is based on where end-customers are located.
2. Sales in Sweden amounted to SEK 165 M (128).
3. Middle East, North Africa and Russia.
4. Royalty revenue includes royalties from our Haemophilia products which are not attributable to a specific region as shown above; royalties from Bioverativ's sales of Eloctate and Alprolix were SEK 1,168 M (803), One-time credits from Bioverativ relating to the approval of Elocta and Alprolix amounted to SEK 708 M in 2016. Royalty revenue from Pfizer's sales of ReFacto was SEK 34 M (88).
5. Milestone payment of SEK 14 M was received in 2016 in conjunctions with the European Commission's approval of Alprolix.

**Revenue by product category (Group)**

| SEK K | 2017 | 2016 |
|---|---|---|
| Elocta | 1,557,476 | 267,198 |
| Alprolix | 362,798 | 60,416 |
| Royalty revenue | 1,168,207 | 1,525,085 |
| **Haemophilia** | **3,088,481** | **1,852,699** |
| Orfadin | 861,866 | 769,992 |
| Kineret | 1,141,938 | 1,001,302 |
| Xiapex | 164,146 | 152,720 |
| Other | 660,652 | 771,347 |
| **Specialty Care** | **2,828,602** | **2,695,362** |
| Manufacturing revenue | 559,295 | 568,684 |
| Royalty revenue | 34,453 | 87,595 |
| **ReFacto** | **593,748** | **656,279** |
| **Total revenue** | **6,510,831** | **5,204,340** |

# Note 6

## Segment reporting

The Group reports one operating segment, sales of pharmaceuticals. The basis for identifying reportable segments is the internal reporting provided to and monitored by the chief operating decision maker. The Group has identified the CEO as the chief operating decision maker. Sobi reports revenue by geographic areas. See note 5 for more information on the distribution by major revenue category and geographic area.

Sobi's largest customers in 2017 were Bioverativ, with sales of SEK 691 M (1,176), and Pfizer, with sales of SEK 594 M (656), corresponding to 11 and 9 per cent respectively of the Company's total revenue for 2017. In 2017 and 2016, Sobi did not have any other customer for which revenue exceeded 10 per cent of the Company's total revenue. Most of the non-current assets are in Sweden.

# Note 7

## Depreciation, amortisation and write-down of assets

| GROUP | 2017 | 2016 |
|---|---|---|
| **Depreciation/amortisation according to plan by type of asset** | | |
| Capitalised software expenditure | –15,492 | –14,458 |
| Licences and patents | –38,766 | –39,200 |
| Product and marketing rights | –386,594 | –356,479 |
| Land and buildings | | –56 |
| Plant and machinery | –15,001 | –10,241 |
| Equipment, tools and fixtures & fittings | –15,599 | –17,571 |
| Other non-current assets | –2,525 | –2,705 |
| **Total** | **–473,977** | **–440,710** |
| **Depreciation/amortisation according to plan by function** | | |
| Cost of goods and services sold | –14,412 | –13,995 |
| Selling and administrative expenses | –453,538 | –422,848 |
| Development expenditure | –6,027 | –3,867 |
| **Total** | **–473,977** | **–440,710** |
| | | |
| **Write-down by type of asset**[1] | | |
| Licences and patents | –12,000 | — |
| **Total** | **–12,000** | — |
| **Write-down by function**[1] | | |
| Selling and administrative expenses | –12,000 | — |
| **Total** | **–12,000** | — |

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| **Depreciation/amortisation according to plan by type of asset** | | |
| Capitalised software expenditure | –15,321 | –14,458 |
| Licences and patents | –6,669 | –5,193 |
| Product and marketing rights | –262,213 | –224,747 |
| Land and buildings | — | –56 |
| Plant and machinery | –14,652 | –10,241 |
| Equipment, tools and fixtures & fittings | –11,371 | –14,108 |
| Other non-current assets | –524 | –520 |
| **Total** | **–310,750** | **–269,323** |
| **Depreciation/amortisation according to plan by function** | | |
| Cost of goods and services sold | –14,355 | –13,938 |
| Selling and administrative expenses | –290,553 | –251,733 |
| Development expenditure | –5,842 | –3,652 |
| **Total** | **–310,750** | **–269,323** |
| | | |
| **Write-down by type of asset**[1] | | |
| Licences and patents | –12,000 | — |
| **Total** | **–12,000** | — |
| **Write-down by function**[1] | | |
| Selling and administrative expenses | –12,000 | — |
| **Total** | **–12,000** | — |

1. See note 17 for more information.

# Note 8

## Other operating income

| GROUP | 2017 | 2016 |
|---|---|---|
| Sale of property | — | 4,166 |
| Exchange gains[1] | — | 30,807 |
| Other | 471 | 1,697 |
| **Total** | **471** | **36,670** |

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| Sale of property | — | 4,166 |
| Exchange gains[1] | — | 24,256 |
| Other | 120 | 1,500 |
| **Total** | **120** | **29,922** |

1. Exchange rate effects are reported net and represent a loss in 2017, see note 9.

# Note 9

## Other operating expenses

| GROUP | 2017 | 2016 |
|---|---|---|
| Exchange losses on operating receivables/liabilities[1] | –52,541 | — |
| Other | –207 | –225 |
| **Total** | **–52,748** | **–225** |

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| Exchange losses on operating receivables/liabilities[1] | –39,824 | — |
| **Total** | **–39,824** | — |

1. Exchange rate effects are reported net and represent a loss in 2017, last year were represented as a gain, see note 8.

# Note 10

## Operating lease payments

Contractual future rental payments for premises with non-cancellable contracts, due for payment as follows:

| | Group | | Parent Company | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Within one year | 69,395 | 68,476 | 59,144 | 58,119 |
| 1–5 years | 251,080 | 263,663 | 224,121 | 222,225 |
| Later than five years | 64,492 | 103,450 | 64,492 | 103,450 |
| **Total** | **384,967** | **435,589** | **347,757** | **383,794** |
| Leasings costs for the year | 72,530 | 62,942 | 58,120 | 52,980 |

Other future minimum lease payments under non-cancellable leases are due for payment as follows:

| | Group | | Parent Company | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Within one year | 6,082 | 8,215 | 318 | 324 |
| 1–5 years | 8,898 | 8,742 | 477 | — |
| **Total** | **14,980** | **16,957** | **795** | **324** |
| Leasing costs for the year | 11,565 | 10,552 | 323 | 279 |

Note 10 contd.

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 bases its position mainly 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.

# Note 11

## Employees, personnel costs and remuneration of the Board and senior executives

### Number of employees[1]

| GROUP | 2017 | % Female | % Male | 2016 | % Female | % Male |
|---|---|---|---|---|---|---|
| Sweden | 451 | 64 | 36 | 433 | 63 | 37 |
| Denmark | 14 | 59 | 41 | 16 | 64 | 36 |
| Finland/Baltics | 9 | 57 | 43 | 13 | 54 | 46 |
| Norway | 7 | 71 | 29 | 7 | 71 | 29 |
| UK | 51 | 47 | 53 | 47 | 44 | 56 |
| France | 38 | 63 | 37 | 36 | 71 | 29 |
| Germany | 35 | 66 | 34 | 33 | 58 | 42 |
| Italy | 36 | 47 | 53 | 30 | 50 | 50 |
| Greece[2] | 2 | 100 | 0 | – | – | – |
| Spain | 29 | 52 | 48 | 25 | 48 | 52 |
| Belgium | 16 | 38 | 62 | 15 | 45 | 55 |
| Russia | 6 | 83 | 17 | 6 | 67 | 33 |
| Switzerland | 9 | 42 | 58 | 5 | 26 | 74 |
| Austria | 4 | 71 | 29 | 6 | 87 | 13 |
| Central and Eastern Europe | 16 | 50 | 50 | 18 | 51 | 49 |
| US | 48 | 54 | 46 | 47 | 48 | 52 |
| Canada | 6 | 33 | 67 | 4 | 44 | 56 |
| United Arab Emirates | 23 | 17 | 83 | 19 | 17 | 83 |
| **Total** | **800** | **59** | **41** | **760** | **58** | **42** |

1. At 31 December 2017, the number of full-time employees was 800, while the number of persons employed on the same date was 850.
2. The Greece company was established 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 reporting date.

| GROUP | 2017 | 2016 |
|---|---|---|
| **Board of Directors** | | |
| Male | 4 | 5 |
| Female | 2 | 3 |
| **Total** | **6** | **8** |
| **CEO and senior executives** | | |
| Male | 7 | 9 |
| Female | 2 | 3 |
| **Total** | **9** | **12** |

GENDER DISTRIBUTION OF EMPLOYEES

59% ♀ ♂ 41%

### Salaries, other benefits and social security contributions

| GROUP AND PARENT COMPANY | 2017 Salaries and remunerations | 2017 Social security costs | 2016 Salaries and remunerations | 2016 Social security costs |
|---|---|---|---|---|
| Parent Company | 427,440 | 243,525 | 366,986 | 198,808 |
| *(of which pension costs)* | | *(78,864)* | | *(65,047)* |
| Subsidiaries | 500,024 | 91,861 | 426,043 | 79,102 |
| *(of which pension costs)* | | *(24,050)* | | *(25,100)* |
| Group total | 927,464 | 335,386 | 793,029 | 277,910 |
| *(of which pension costs)* | | *(102,914)* | | *(90,147)* |

### Salaries and other benefits by Board and CEO, and other employees

| | 2017 Board and CEO | 2017 Other employees | 2016 Board and CEO | 2016 Other employees |
|---|---|---|---|---|
| **Parent Company** | | | | |
| Salaries and other benefits | 16,862[1] | 410,867 | 6,565[1] | 360,421 |
| *(of which bonus)* | *(4,065)*[1] | *(52,312)* | *(772)*[1] | *(44,711)* |
| **Subsidiaries** | | | | |
| Salaries and other benefits | 14,732[1] | 485,292 | 10,090[1] | 415,953 |
| *(of which bonus)* | *(1,841)*[1] | *(84,261)* | *(3,090)*[1] | *(70,340)* |
| **Group total** | **31,305** | **896,159** | **16,655** | **776,374** |
| *(of which bonus)* | *(5,906)* | *(136,573)* | *(3,862)* | *(115,051)* |

1. 2017 includes both former CEO Geoffrey McDonaugh 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 2017

The 2017 AGM adopted the following guidelines for remuneration of senior executives.

The AGM adopted the Board's recommendation regarding guidelines for remuneration of the Company's senior executives for the period until the 2018 AGM, as set out below. In this context, senior executives refers to the CEO of Swedish Orphan Biovitrum AB and the managers reporting to the CEO, who are also included in company management, and any Board members who have signed employment or consulting contracts.

### Guidelines for remuneration of senior executives

*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 senior executives is based 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 senior executives.

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 contd.

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

| | Basic salary/fees | Bonus | Pension cost | Other benefits | Share programs | Total |
|---|---|---|---|---|---|---|
| 2017 | | | | | | |
| **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, CEO from 22 May 2017 | 5,126 | 3,585 | 1,497 | 171 | 2,772 | 13,151 |
| Other senior executives (8 persons)[6] | 7,765 | 3,953 | 1,069 | 901 | 3,777 | 17,465 |
| **Former CEO and other senior executives** | | | | | | |
| Geoffrey McDonough, CEO until 21 May 2017 | 15,141[8] | 2,321 | 144 | 780 | 5,785[7] | 24,171 |
| Former other senior executives (7 persons)[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 fee excluding social security costs. The gross payment to the Chairman's company was SEK 1,744 K, which includes 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 K, which includes compensation for social security costs.
4. Board member Jeffrey Jonas left the Board in connection with the AGM in May 2017.
5. Board member Theresa Heggie left the Board as of 7 April 2017.
6. In 2017, Sobi established a new management structure: an Executive Committee to replace the former Executive Leadership Team in its 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 fulfillment 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.

| | Basic salary/fees | Bonus | Pension cost | Other benefits | Share programs | Total |
|---|---|---|---|---|---|---|
| 2016 | | | | | | |
| **Chairman of the Board** | | | | | | |
| Håkan Björklund[2, 3] | 847 | | | | | 847 |
| Bo Jesper Hansen[2, 4] | 812 | | | | | 812 |
| **Other Board members[6]** | | | | | | |
| Helena Saxon | 477 | | | | | 477 |
| Hans GCP Schikan | 505 | | | | | 505 |
| Adine Grate Axén[5, 6] | 178 | | | | | 178 |
| Lennart Johansson | 484 | | | | | 484 |
| Hans Wigzell[5] | 158 | | | | | 158 |
| Matthew Gantz | 457 | | | | | 457 |
| Annette Clancy[7] | 653 | | | | | 653 |
| Jeffrey Jonas[5] | 330 | | | | | 330 |
| Theresa Heggie[5] | 297 | | | | | 297 |
| **CEO** | | | | | | |
| Geoffrey McDonough | 5,837 | 3,862 | 272 | 1,755 | 6,769[8] | 18,495 |
| Other senior executives[1] | 20,819 | 8,204 | 6,054 | 983 | 5,393[8] | 41,453 |
| **Total** | **31,854** | **12,066** | **6,326** | **2,738** | **12,162** | **65,146** |

1. Other senior executives refers to Sobi´s Leadership Team, comprising eleven individuals in addition to the CEO, at December 2016. The table shows the Company's costs (excluding social security costs). For more information about Board fees, see the Corporate Governance Report.
2. At the 2016 AGM, Håkan Björklund was elected to the Board, while former Chairman Bo Jesper Hansen left the Board.
3. The fee comprises the Board fee excluding social security costs. The gross payment to the Chairman's company was SEK 1,113 K, which includes compensation for social security costs.
4. Bo Jesper Hansen's employment and his monthly salary were not linked to his position as Chairman of the Board.
5. At the 2016 AGM, Jeffrey Jonas and Theresa Heggie were elected to the Board to replace the outgoing members Adine Grate Axén and Hans Wigzell.
6. The fee comprises the Board fee excluding social security costs. The gross payment to the Board member's company was SEK 234 K, which includes compensation for social security costs.
7. The fee comprises the Board fee and an additional fee of SEK 200 K for extraordinary services carried out in 2015, in accordance with the decision of the 2016 AGM, excluding social security costs. The gross payment to the Board member's company was SEK 658 K, which includes compensation for social security contributions.
8. See also allotment and fulfillment of long-term incentive programmes for the 2013 share programmes.

## Note 11 contd.

*Fixed Base Pay*
The fixed base pay of senior executives 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, departmental[1] 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 CEO and 50 per cent of the fixed annual salary for the other senior executives (pension compensation for the CEO may be included in the annual gross salary and therefore also be included as a basis for calculating Short-Term Incentives).

*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 the opportunity 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[2]. 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 arrangements are made for senior executive recruitment or retention purposes and are 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.

*Deviation from the guidelines*
The Board may decide to deviate from the above guidelines if it considers that there are special reasons for doing so in a particular case – for example, if the Board considers that a deviation is necessary or appropriate in order to recruit the most competent individual as new CEO.

*Deviations from the 2016 guidelines*
When Sobi's 2016 long-term incentive programme (LTI 2016) was introduced, the majority of employees, including senior executives, were legally prohibited from participating in the programme as they were in possession of inside information at that time. In the context of the 2016 AGM's adoption of the proposal for LTI 2016, intended for senior executives and other employees, and as the Board considers long-term incentive programmes to be a key part of a competitive overall remuneration package aimed at attracting and retaining senior executives and senior managers who are crucial to the Company's long-term success, the Board decided to deviate from the guidelines in order to enable employees who were legally prevented from participating in LTI 2016 to participate in a long-term cash-based incentive programme (LCI) instead. The deviation was made in accordance with the guidelines for remuneration of senior executives adopted by the 2016 AGM. Like LTI 2016, the LCI is a three-year programme with certain performance conditions that must be achieved in order for any remuneration to be paid to senior executives. For senior executives, the performance conditions are related to profitability and revenue growth. On an individual basis, the Company's maximum costs for the LCI may not exceed the maximum costs that could otherwise have arisen under LTI 2016.

In addition, when CEO Geoffrey McDonough left the Company in July 2017, the Company entered into an agreement with him that deviates from the remuneration guidelines for senior executives approved by the 2016 AGM. The deviation is that the fixed salary during the notice period together with the severance pay will total an amount equivalent to approximately 27 monthly fixed salaries, i.e. more than the maximum two years that is stipulated in the guidelines. Given that it was in both the Company's and the shareholders' interest to keep the CEO for as long as possible while the Company was recruiting a successor and that Geoffrey McDonough intended to remain in service during the entire notice period up until 1 July 2017, the Board of Directors resolved to deviate from the remuneration guidelines for senior executives approved by the Annual General Meeting 2016 in this individual case.

**Senior executives' employment conditions and remuneration**
Sobi aims to offer market terms that enable the company to recruit and retain competent personnel (for the complete guidelines, see the Director´s report. Remuneration to Directors elected by the AGM is paid in accordance with the decision of the AGM of 2017. 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.

A new management structure was established as of 1 November, 2017. The new management team consists of eight senior executives in addition to the CEO.

*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 2017 was capped at 75 per cent of the annual gross salary. The former CEO qualified for short-term variable remuneration for the first half of 2017 until his employment with the Company ceased. 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 50 per cent of the fixed salary and is based on targets at Group and division level, 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 reserved a premium of SEK 1,497 M for 2017. The retirement age is 65 years.

The former CEO had a defined contribution pension agreement, in which Sobi for 2017 paid a premium of SEK 144 K (272). Gross salary, excluding severance pay, including retirement provision in 2017 amounted to SEK 3,503 M (6,109).

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. The pensionable salary is limited to 50 income base amounts.

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.

1. Department-specific targets are not relevant for the CEO.
2. A defined-contribution pension plan determines the contribution level to be paid to the pension plan for each individual.

**Incentive programmes**
Sobi has five active share programmes as at the reporting date. To participate in the share programmes, employees must be permanently employed. All programmes run for three years. The company also has three cash-based programmes for employees in the US. The 2015 programme has a three-year vesting period, while the other programmes have a four-year vesting period.

**Long-term incentive programmes**
The 2014–2017 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 2014–2017 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 Management Programme, 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 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.

*2014 Share Programme (paid 2017)*
The 2014A and 2014B share programmes expired in 2017. For 2014A, the Board decided that the following performance conditions and other vesting terms were fully met when the 2014A Share Programme was redeemed on 9 May 2017. In the management programme for senior executives and managers, 249,209 shares with a market value of SEK 34.5 M were allotted. In the employee programme, 95,076 shares with a market value of SEK 13.2 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.

During the roll-out of the 2014A share programme, a number of employees became insiders and were therefore not able to participate in the programme. To compensate for any loss, the Board decided that the performance outcome in the 2014B share programme for these individuals would be calculated on the volume-weighted share price ten days before the 2014A share programme roll-out.

For 2014B, the Board decided that other vesting terms were met and performance conditions were met by up to 45.121 per cent (89.919 per cent for insiders) when the 2014B share programme was redeemed on 17 November 2017. In the management programme for senior executives and managers, 128,010 shares with a market value of SEK 14.5 M were allotted, of which the former CEO's proportion comprised 52,296 shares with a market value of SEK 5.9 M. In the employee programme, 5,859 shares with a market value of SEK 665 thousand 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.

*2014 Cash-based Programme (paid 2018)*
The 2014 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 2017 and the above target relating to the share price performance was 50 per cent fulfilled, the result relating to sales was achieved in full.

*2015 Share Programme*
The 2015 AGM approved a long-term share programme covering the former CEO, a programme for 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: The former CEO is allotted performance shares (no matching shares), contingent on the achievement of a certain share price performance. Allotment of performance shares in the CEO programme is contingent on the share price, adjusted for any dividends, exceeding the threshold value of 20 per cent. If the share price increases between 20 and 100 per cent, a proportional number of performance shares is allotted. The maximum possible allotment of performance shares is 400,000.

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 possible allotment of shares in the Management and Employee Programme is 398,004 performance shares and 111,288 matching shares.

*2015 Cash-based Programme*
The 2015 AGM approved a long-term cash-based programme for all employees in the US. The performance target is a 15–75 per cent increase in the share price from the volume-weighted share price ten days prior to the 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.

*2015 Share Programme*

| | No. of performance shares | No. of matching shares | Value in SEK |
|---|---|---|---|
| Other senior executives in the Group (4). | 32,650 | 2,697 | 1,724,411 |
| Former CEO and other senior executives in the Group (5). | 452,794 | 3,771 | 17,359,645 |
| **Total** | **485,444** | **6,468** | **19,084,056** |

*2016 Share Programme*
The 2016 AGM approved a long-term share programme covering the 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.

## Note 11 contd.

The maximum allocation possible in the Management and Employee Programme is 203,091 performance shares and 103,097 matching shares.

When Sobi's 2016 Share Programme was introduced, a number of employees, including the 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 ensure Sobi is able 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, see the 2016 annual report.

*2016 Cash-based Programme*
The formulation of the Cash Programme covering all employees in the US and Canada was adjusted in 2016. 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 measures.

The first performance measure (50 per cent) is an annual increase in the share price of at least 10 per cent over a four-year period. The second performance measure (50 per cent) is for North America's annual revenue to be at least 95 per cent of budget over a four-year period.

*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 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, programme participants will receive straight-line allotment of performance shares. For 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 2017 annual revenue target is fully achieved. The maximum possible allotment of shares is 912,539. 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 47,138.

*2017 Cash-based Programme*
The 2017 AGM adopted a long-term cash-based programme for all employees in the US and Canada, with one senior executive participating 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 measures.

The first performance measure (50 per cent) is an annual increase in the share price of at least 10 per cent over a four-year period. The second performance measure (50 per cent) is for North America's annual revenue to be at least 95 per cent of budget over a four-year period.

*2017 Share Programme*

| | No. of performance shares | No. of matching shares | Value in SEK |
|---|---|---|---|
| CEO and other senior executives in the Group (6). | 230,777 | — | 7,608,718 |
| Former other senior executives in the Group (5). | 75,485 | — | 2,488,740 |
| **Total** | **306,262** | **—** | **10,097,458** |

**Expensing of the 2015–2017 Share programmes is calculated using the following parameters:**

| | Start date | End date | No. of matching shares | No. of performance shares | Vesting period (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 2017 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 2015 Share Programme | 19 Aug 2015 | 19 Aug 2018 | 111,288 | 398,004 | 36 | 116.40 | 43.20 | n/a | 12 | 509,292 | 6,944 |
| 2015 share Programme CEO | 24 Sep 2015 | 24 Sep 2018 | n/a | 400,000 | 36 | n/a | 36.60 | n/a | — | 400,000 | — |
| 2016 Share Programme | 28 Oct 2016 | 28 Oct 2019 | 103,097 | 203,091 | 36 | 94.05 | 33.34 | n/a | 5 | 306,188 | 4,342 |
| Share Programme 2017:1 All employees | 9 May 2017 | 9 May 2020 | 47,138 | n/a | 36 | 136.85 | n/a | n/a | 5 | 47,138 | 210 |
| Share Programme 2017:2 Management | 9 May 2017 | 9 May 2020 | n/a | 912,539 | 36 | n/a | 54.95 | 136.85 | 5 | 912,539 | 12,193 |

1. Fair value of performance shares linked to share price development, see section 2017 Share Programme above.
2. Fair value of performance share associated with income, see section 2017 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. The valuation model also includes the corresponding historical volatility for the share prices of peer companies over the same period, and the correlation between all share prices.

# Note 12

## Remuneration of auditors

| GROUP | 2017 | 2016 |
|---|---|---|
| **EY** | | |
| Auditing assignments[1] | –4,782 | –4,164 |
| Other auditing assignments | –681 | –1,412 |
| Tax advisory services | –81 | –1,299 |
| Other services | –332 | –285 |
| **Total EY** | **–5,851** | **–7,160** |

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| **EY** | | |
| Auditing assignments[1] | –1,921 | –2,026 |
| Other auditing assignments | –593 | –1,308 |
| Tax advisory services | –81 | –1,287 |
| Other services | –332 | — |
| **Total EY** | **–2,927** | **–4,621** |

1. Audit assignments comprise the statutory audit, required in order to submit an audit report, and auditing consultancy.

# Note 13

## Expenses by nature

| GROUP | 2017 | 2016 |
|---|---|---|
| Raw materials and consumables | –1,509,077 | –1,228,611 |
| Other external costs | –1,499,690 | –1,265,018 |
| Costs for remuneration of employees | –1,363,445 | –1,173,332 |
| Depreciation, amortisation and write-down[1] | –485,977 | –440,710 |
| Other operating expenses | –145,226 | –81,746 |
| **Total** | **–5,003,415** | **–4,189,417** |

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| Raw materials and consumables | –1,516,485 | –1,144,774 |
| Other external costs | –1,565,730 | –1,387,869 |
| Costs for remuneration of employees | –711,675 | –615,657 |
| Depreciation, amortisation and write-down[1] | –322,750 | –269,323 |
| Other operating expenses | –133,824 | –81,631 |
| **Total** | **–4,250,464** | **–3,499,254** |

1. Depreciations in 2017 includes an impairment of one of the clinical programmes at an early stage of SEK 12 M.

The above costs correspond to: Cost of goods and services sold, selling and administrative expenses, research and development expenditure, depreciation, amortisation, write-down and other operating expenses in the income statement classified by function.

# Note 14

## Finance income

| GROUP | 2017 | 2016 |
|---|---|---|
| Other interest income | 1,219 | 1,427 |
| Exchange gains[1] | — | 6,498 |
| **Total** | **1,219** | **7,925** |

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| Interest income, Group companies | 11,258 | 16,329 |
| Other interest income | 398 | 923 |
| Exchange gains[1] | — | 4,631 |
| **Total** | **11,656** | **21,883** |

1. Exchange rate effects are reported net and consisted of a loss in 2017. See note 15.

# Note 15

## Finance costs

| GROUP | 2017 | 2016 |
|---|---|---|
| Interest expense, borrowing[1] | –13,886 | –27,722 |
| Interest expense, other[2] | –50,085 | –50,824 |
| Exchange loss[3] | –3,389 | — |
| Administrative expense | –1,277 | –2,319 |
| Other | –524 | –12,194 |
| **Total** | **–69,161** | **–93,060** |

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| Interest expense, Group companies | –8,945 | –3,100 |
| Interest expense, borrowing[1] | –13,886 | –27,722 |
| Interest expense, other[2] | –50,085 | –50,824 |
| Exchange loss[3] | –1,588 | — |
| Administrative expense | –1,277 | –2,319 |
| Other | –518 | –10,854 |
| **Total** | **–76,299** | **–94,819** |

1. The lower interest expense in 2017 is attributable to refinancing during 2016, where the existing bond of the time was replaced by a bank loan at a significantly lower interest rate.
2. Refers to interest costs for loans from Bioverativ.
3. Exchange rate effects are reported net and consisted of a loss in 2017, and a gain in the previous year, as reported in note 14. The figures include realised and unrealised currency effects of SEK 8 M (–17) from derivatives.

# Note 16

## Income tax

| GROUP | 2017 | 2016 |
|---|---|---|
| **Current tax expense (–)/tax income (+)** | | |
| Tax expense/tax income for the period | –209,067 | –79,993 |
| Adjustment of tax attributable to prior years | –61 | –2,161 |
| **Total current tax for the Group** | **–209,128** | **–82,154** |
| *Deferred tax arising from:* | | |
| Change in excess depreciation | –213,400 | –111,684 |
| Residual value depreciation | — | 40,702 |
| Change of depreciation method | 19,729 | –39,458 |
| Internal profit in inventories | –4,331 | 43,327 |
| Acquired product rights | 38,148 | 38,148 |
| Other intangible assets | –3,720 | –144,367 |
| Provision for pensions | 8,299 | 636 |
| Loss carryforwards | –15,447 | 15,110 |
| Other | –3,961 | –6,604 |
| **Total deferred tax for the Group** | **–174,683** | **–164,190** |
| **Total tax for the Group** | **–383,811** | **–246,344** |

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| **Current tax expense (–)/tax income (+)** | | |
| Tax expense/tax income for the period | –146,855 | –49,724 |
| Adjustment of tax attributable to prior years | 64 | –10 |
| **Total current tax for the Parent Company** | **–146,791** | **–49,734** |
| *Deferred tax arising from:* | | |
| Residual value depreciation | — | 40,702 |
| Change of depreciation method | 19,729 | –39,458 |
| Provision for pensions | 9,094 | — |
| Loss carryforwards | –15,447 | 15,110 |
| Other | 1,240 | — |
| **Total deferred tax for the Parent Company** | **14,616** | **16,354** |
| **Total tax for the Parent Company** | **–132,175** | **–33,380** |

## Reconciliation of effective tax

| GROUP | 2017 | 2016 |
|---|---|---|
| **Profit before tax** | **1,532,423** | **1,047,979** |
| Tax according to Parent Company's applicable tax rate | –337,133 | –230,555 |
| Effect of foreign tax rates | –10,254 | 7,699 |
| Effect of adjusted tax rate in the US[1] | –30,311 | — |
| Change of depreciation method | — | –33,495 |
| Provision for pensions | 6,608 | — |
| Non-deductible expenses | –19,318 | –8,761 |
| Non-taxable income | 2,241 | 3,648 |
| Deductible expenses, not recognised in the income statement | 1,710 | 7,274 |
| Taxable income, not recognised in the income statement | –19 | –1,571 |
| Adjustment of tax attributable to prior years | –61 | –2,161 |
| Deferred tax on tax losses not previously recognised | — | 15,050 |
| Other | 2,726 | –3,472 |
| **Recognised effective tax** | **–383,811** | **–246,344** |

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| **Profit before tax** | **–375,662** | **84,637** |
| Tax according to Parent Company's applicable tax rate | 82,646 | –18,620 |
| Write-down of shares in subsidiary | –220,000 | — |
| Change of depreciation method | — | –33,494 |
| Provision for pensions | 6,608 | — |
| Non-deductible expenses | –1,897 | –2,026 |
| Non-taxable income | 1 | 17 |
| Deductible expenses, not recognised in the income statement | 468 | 7,274 |
| Taxable income, not recognised in the income statement | — | –1,571 |
| Adjustment of tax attributable to prior years | — | –10 |
| Deferred tax on tax losses not previously recognised | — | 15,050 |
| **Recognised effective tax** | **–132,175** | **–33,380** |

1. The tax rate for our US subsidiary has been reduced from 34 to 21 per cent as of 1 January 2018.

The applicable tax rate for the Parent Company is 22 (22) per cent. Deferred tax related to 2016 has been adjusted during the year, for more information see note 21.

# Note 17

## Intangible assets and impairment testing

| GROUP | Goodwill | Licences & patents | Product & marketing rights | Advance payments | Capitalised expenditure on software | IT software in progress | Total |
|---|---|---|---|---|---|---|---|
| **1 January – 31 December 2016** | | | | | | | |
| Opening accumulated cost | 1,554,158 | 546,233 | 5,276,018 | 82,400 | 104,787 | 29,460 | 7,593,056 |
| Initiation of construction in progress | — | — | — | — | 30,584 | –30,584 | — |
| Acquisitions[1] | — | 15,067 | 1,382,384 | — | — | 31,196 | 1,428,647 |
| Reclassification | — | 11,797 | 79,988 | –82,400 | –8,945 | — | 440 |
| Exchange differences | — | — | 25 | — | — | — | 25 |
| **Closing cost** | **1,554,158** | **573,097** | **6,738,415** | **—** | **126,426** | **30,072** | **9,022,168** |
| Opening accumulated amortisation and impairment | — | –308,241 | –1,429,172 | — | –68,608 | — | –1,806,021 |
| Amortisation | — | –39,200 | –356,479 | — | –14,458 | — | –410,137 |
| Reclassification | — | –1,592 | — | — | 1,592 | — | — |
| **Closing accumulated amortisation and impairment** | **—** | **–349,033** | **–1,785,651** | **—** | **–81,474** | **—** | **–2,216,158** |
| **Closing carrying amount** | **1,554,158** | **224,064** | **4,952,764** | **—** | **44,952** | **30,072** | **6,806,010** |
| **1 January – 31 December 2017** | | | | | | | |
| Opening accumulated cost | 1,554,158 | 573,097 | 6,738,415 | — | 126,426 | 30,072 | 9,022,168 |
| Acquisitions[2] | — | — | 59,017 | — | 12,414 | 20,491 | 91,922 |
| Write-downs/scrapping[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. Acquisitions in 2016 relate to Alprolix opt-in (SEK 1,348 M), Kineret milestone (SEK 72 M) and other (SEK 8 M), divided among all intangible items.
2. Acquisitions in 2017 relate to the right to take part in the rFIXFc-XTEN programme for SEK 56 M, LMS (training programme) for SEK 7 M as well as other smaller investments totalling SEK 29 M divided between the various intangible items.
3. Refers to write-down/scrapping of one of the early-stage clinical programs.

Note 17 contd.

| PARENT COMPANY | Licences & patents | Product & marketing rights | Advance payments | Capitalised expenditure on software | IT software in progress | Total |
|---|---|---|---|---|---|---|
| **1 January – 31 December 2016** | | | | | | |
| Opening accumulated cost | 49,921 | 2,991,318 | 82,400 | 97,878 | 29,376 | 3,250,893 |
| Initiation of construction in progress | — | — | — | 30,584 | –30,584 | — |
| Acquisitions[1] | 15,067 | 1,721,037 | — | — | 31,196 | 1,767,300 |
| Reclassification | 11,797 | 79,998 | –82,400 | –8,945 | — | 440 |
| **Closing cost** | **76,785** | **4,792,343** | **—** | **119,517** | **29,988** | **5,018,633** |
| Opening accumulated amortisation and impairment | –11,663 | –435,811 | — | –64,762 | — | –512,236 |
| Amortisation | –5,193 | –224,747 | — | –14,458 | — | –244,398 |
| Reclassified accumulated amortisation | –1,592 | — | — | 1,592 | — | — |
| **Closing accumulated amortisation and impairment** | **–18,448** | **–660,558** | **—** | **–77,628** | **—** | **–756,634** |
| **Closing carrying amount** | **58,337** | **4,131,785** | **—** | **41,889** | **29,988** | **4,261,999** |
| **1 January – 31 December 2017** | | | | | | |
| Opening accumulated cost | 76,785 | 4,792,343 | — | 119,517 | 29,988 | 5,018,633 |
| Acquisitions[2] | — | 59,017 | — | 12,414 | 20,491 | 91,922 |
| Write-downs/scrapping[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. Acquisitions in 2016 relate to Alprolix opt-in (SEK 1,348 M), Kineret milestone (SEK 72 M) and other (SEK 8 M), divided between the various intangible items.
2. Acquisitions in 2017 relate to the right to take part in the rFIXFc-XTEN programme for SEK 56 M, LMS (training programme) for SEK 7 M as well as other smaller investments totalling SEK 29 M divided between the various intangible items. 3. Refers to write-down/scrapping of one of the early-stage clinical programs.
3. Refers to a impairment of one of the clinical programmes at an early stage.

**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 five-year period. The financial plans have been drawn up based on past performance, experiences and expectations in the market. The plans include assumptions about the current product development and future product launches. The financial plans also include assumptions concerning the development of prices, sales and expenses. Cash flows beyond five to ten-year periods have been extrapolated using an estimated growth rate of 2 per cent. Sobi's goodwill amounted to SEK 1,554 M (1,554) on 31 December 2017. There is no indication of goodwill impairment at Group level.

The following table shows the growth rate and pre-tax and post-tax discount rate used:

| PARAMETER, % | 2017 | 2016 |
|---|---|---|
| Growth rate beyond the initial five-year period | 2 | 2 |
| Pre-tax discount rate | 11.9 | 11.8 |
| Post-tax discount rate | 9.2 | 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:* 6.3 (6.1) per cent.
- *Beta coefficient:* Sobi's beta coefficient is calculated at 1.31 (1.30).
- *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 goodwill impairment testing: discount rate, margin, sales volume and perpetual 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 tabel.

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 concern forecasts of future sales, costs attributable to each product, product life and discount rate. In cases where the contract or patent for product and marketing rights exceed five years, the term of contract or patent is used as the remaining life. The impairment testing of product and marketing rights has not indicated any impairment.

**Impairment in 2017**

Sobi valued one of the early stage programmes during 2017 and it was deemed necessary to write down the value of the assets by SEK 12 M. The impairment has affected intangible assets.

## CONTRACTUAL COMMITMENTS ON ACQUISITIONS OF INTANGIBLE ASSETS

Sobi has undertaken to pay 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 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. Bioverativ will continue to collaborate with Sobi in our joint development programmes.

Under the agreement between Sobi and Bioverativ regarding the development and commercialisation of Elocta and Alprolix, Bioverativ 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 Bioverativ in place for the XTEN-programmes BIVV001 and BIVV002.

Under Sobi's 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). Bioverativ has commercialisation rights for North America (Bioverativ's North American territory) and for the rest of the world excluding Sobi's territory (Bioverativ's direct territory and Bioverativ's distribution territory). Sobi and Bioverativ receive a royalty on each other's sales of Elocta/Eloctate 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 making a deposit of USD 10 M per programme – for Elocta in 2014 and for Alprolix in 2015.

#### Liability arising from pipeline programmes

On taking over commercialisation and the regulatory process, Sobi became liable to reimburse Bioverativ 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.

#### Liability settlement

Sobi's reimbursement to Bioverativ for each pipeline 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 Bioverativ 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 Bioverativ'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 Bioverativ's first commercial sales for each programme, Bioverativ is entitled to request that Sobi pay the remaining amount within 90 days from the sixth anniversary of the date of Bioverativs first commercial sales.

#### Elocta

The total liability for development and commercialisation of Elocta is USD 211 M. On 24 November 2015, Sobi and Bioverativ 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 Bioverativ 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 2017, the remaining liability was SEK 835 M (USD 101), corresponding to the discounted value of the nominal liability, which amounted to USD 104 M.

#### Alprolix

The total liability for development and commercialisation of Alprolix is USD 185 M. On 13 May 2016, Sobi and Bioverativ 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 Bioverativ 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 2017, the remaining liability was SEK 811 M (USD 99), corresponding to the discounted value of the nominal liability, which amounted to USD 103 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 (rFVIIIFc-VWF-XTEN) in the agreement with Bioverativ. Under the agreement between Sobi and Bioverativ, 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 Bioverativ. Under the agreement between Sobi and Bioverativ, 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 Bioverativ based on net sales in Sobi's territory | Royalty on sales | 12 | Base rate plus 5% | 17 |
| Bioverativ to Sobi based on net sales in North America | Royalty on sales | 12 | Base rate minus 5% | 7 |
| Bioverativ to Sobi based on net sales in Bioverativ's territory outside North America | Royalty on sales | 17 | Base rate minus 5% | 12 |
| Bioverativ to Sobi based on net profit[1] from Bioverativ's distribution territory[2] | Royalty on net profit | 50 | Base rate minus 15% | 35 |

1. Net profit refers to Bioverativ's revenue before tax from distributors (third-party), less expenses incurred by Bioverativ for supporting these sales.
2. Bioverativ's distribution territory refers to the territory in which sales are conducted through a third party.
3. Base rate has an impact on the results. Repayment of the liability corresponds to the difference between the base rate and the adjusted royalty.
4. Actual payments that have an impact on cash flow.

# Note 18

## Property, plant and equipment

| GROUP | Land & buildings | Plant & machinery | Equipment, tools, fixtures & fittings | Other non-current assets | Construction In progress | Total |
|---|---|---|---|---|---|---|
| **1 January – 31 December 2016** | | | | | | |
| Opening accumulated cost | 6,728 | 409,544 | 216,517 | 15,439 | 10,902 | 659,130 |
| Acquisitions | — | 27,274 | 9,742 | 4,474 | 3,868 | 45,808 |
| Reclassification | — | –440 | –317 | — | — | –757 |
| Disposals | –6,728 | –1,819 | –1,010 | –4,552 | — | –14,109 |
| Exchange differences | — | — | 789 | — | — | 789 |
| **Closing cost** | **—** | **435,449** | **225,281** | **15,361** | **14,770** | **690,861** |
| Opening accumulated depreciation and impairment | –2,801 | –368,720 | –170,765 | –4,168 | — | –546,454 |
| Depreciation | –56 | –10,241 | –17,571 | –2,705 | — | –30,573 |
| Disposals | 2,857 | 1,488 | 772 | 2,437 | — | 7,554 |
| Exchange differences | — | — | –365 | — | — | –365 |
| **Closing accumulated depreciation and impairment** | **—** | **–377,473** | **–187,929** | **–4,436** | **—** | **–569,838** |
| **Closing carrying amount** | **—** | **57,536** | **37,792** | **10,925** | **14,770** | **121,023** |
| **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 |
| Disposals | — | –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 |
| Depreciation | — | –15,001 | –15,599 | –2,525 | — | –33,125 |
| Reclassifications | — | — | –542 | — | — | –542 |
| Disposals | — | 922 | 1,713 | 1,721 | — | 4,356 |
| Exchange differences | — | –13 | –67 | — | — | –80 |
| **Closing accumulated depreciation and impairment** | **—** | **–391,565** | **–202,424** | **–5,240** | **—** | **–599,229** |
| **Closing carrying amount** | **—** | **71,634** | **31,510** | **9,997** | **21,041** | **134,182** |

Note 18 contd.

| PARENT COMPANY | Land & buildings | Plant & machinery | Equipment, tools, fixtures & fittings | Other non-current assets | Construction in progress | Total |
|---|---|---|---|---|---|---|
| **1 January – 31 December 2016** | | | | | | |
| Opening accumulated cost | 6,728 | 404,721 | 194,740 | 5,210 | 10,902 | 622,301 |
| Acquisitions | — | 27,724 | 4,723 | — | 3,868 | 36,315 |
| Reclassification | — | –440 | — | — | — | –440 |
| Disposals | –6,728 | –1,819 | — | — | — | –8,547 |
| **Closing cost** | **—** | **430,186** | **199,463** | **5,210** | **14,770** | **649,629** |
| Opening accumulated depreciation and impairment | –2,801 | –362,897 | –159,114 | –1,040 | — | –525,852 |
| Depreciation | –56 | –10,241 | –14,108 | –520 | — | –24,925 |
| Disposals | 2,857 | 1,488 | — | — | — | 4,345 |
| **Closing accumulated depreciation and impairment** | **—** | **–371,650** | **–173,222** | **–1,560** | **—** | **–546,432** |
| **Closing carrying amount** | **—** | **58,536** | **26,241** | **3,650** | **14,770** | **103,197** |
| **1 January – 31 December 2017** | | | | | | |
| Opening accumulated cost | — | 430,186 | 199,463 | 5,210 | 14,770 | 649,629 |
| Acquisitions | — | 28,557 | 2,583 | — | 6,271 | 37,411 |
| Disposals | — | –922 | — | — | — | –922 |
| **Closing cost** | **—** | **457,821** | **202,046** | **5,210** | **21,041** | **686,118** |
| Opening accumulated depreciation and impairment | — | –371,650 | –173,222 | –1,560 | — | –546,432 |
| Depreciation | — | –14,652 | –11,371 | –524 | — | –26,547 |
| Disposals | — | 922 | — | — | — | 922 |
| **Closing accumulated depreciation and impairment** | **—** | **–385,380** | **–184,593** | **–2,084** | **—** | **–572,057** |
| **Closing carrying amount** | **—** | **72,441** | **17,453** | **3,126** | **21,041** | **114,061** |

# Note 19

## Investments in subsidiaries

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| **Accumulated cost** | | |
| At beginning of year | 4,059,573 | 4,059,573 |
| Investment[1] | 195 | — |
| **Total** | **4,059,768** | **4,059,573** |
| **Accumulated impairment** | | |
| At beginning of year | –177,435 | –177,435 |
| Impairment for the year[2] | –1,000,000 | — |
| **Total** | **–1,177,435** | **–177,435** |
| **Carrying amount at end of period** | **2,882,333** | **3,882,138** |

1. The investment for the year concerns a newly formed subsidiary in Greece.
2. The Parent Company has written down the value of the shares in the subsidiary Swedish Orphan Biovitrum International AB by SEK 1,000 M. The impairment is the result of a revision of the underlying forecast cash flow from certain products owned by Swedish Orphan Biovitrum International AB, which has had a negative impact on the value of the Parent Company's shares. The impairment does not affect the consolidated profit or financial position, as the surplus value in the form of assets in the Group is written off annually according to plan.

Note 19 contd.

### Specification of Parent Company and Group holdings of shares in subsidiaries

| SUBSIDIARY/REG. NO./DOMICILE | Number of participations | Participations, %[1] | Carrying amount |
|---|---|---|---|
| Swedish Orphan Biovitrum International AB (publ), 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, Åbo, 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, US | 1,000 | 100 | 7 |
| Swedish Orphan Biovitrum s.r.o., 28171276, Prague, Czech Republic[2] | 1 | 1 | 8 |
| BVBA Swedish Orphan Biovitrum, 0536.217.087, Brussels, Belgium | 100 | 100 | 162 |
| Swedish Orphan Biovitrum AG, 284.917.678, Lucerne, Switzerland | 100 | 100 | 723 |
| Swedish Orphan Biovitrum GmbH, 416986, Vienna, Austria | 100 | 100 | 313 |
| Swedish Orphan Biovitrum (SOBI) Canada, Inc. 949375-1, Oakville, Canada | 10,000 | 100 | 69 |
| Sobi Single Member I.K.E, 142300401000, Athens, Greece | 20,000 | 100 | 195 |
| **Total** | | | **2,882,333** |

1. 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 (publ).

# Note 20

## Financial assets

| GROUP | 2017 | 2016 |
|---|---|---|
| **Accumulated cost** | | |
| At beginning of year | 1,956 | 1,791 |
| Divestment of Akinion | — | –20 |
| Endowment insurance[1] | 32,391 | — |
| Financial receivables | 1,356 | 158 |
| Returned deposit | –619 | –67 |
| Other | 71 | 95 |
| **Accumulated cost** | **35,155** | **1,956** |
| **Carrying amount at end of period** | **35,155** | **1,956** |

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| **Accumulated cost** | | |
| At beginning of year | 1 | 21 |
| Divestment of Akinion | — | –20 |
| Endowment insurance[1] | 32,391 | — |
| **Accumulated cost** | **32,392** | **1** |
| **Carrying amount at end of period** | **32,392** | **1** |

1. Sobi has elected to report the endowment insurance gross over the balance sheet. In previous years, the endowment insurance has been reported net. In connection with the amendment, an adjustment of provisions for special payroll tax was also made.

# Note 21

## Deferred tax assets and liabilities

**Recognised deferred tax assets and liabilities**

| GROUP 2017 | Deferred tax asset | Deferred tax liability | Net |
|---|---|---|---|
| Excess depreciation | — | –467,280 | –467,280 |
| Change of depreciation method | — | –19,729 | –19,729 |
| Internal profit in inventories | 115,929 | — | 115,929 |
| Acquired product rights | — | –251,906 | –251,906 |
| Other intangible assets | 68,613 | — | 68,613 |
| Provision for pensions | 11,390 | — | 11,390 |
| Restoration reserve | — | –689 | –689 |
| Derivatives | — | –544 | –544 |
| Doubtful debts | 1,671 | — | 1,671 |
| Other | 6,242 | — | 6,242 |
| **Total** | **203,845** | **–740,149** | **–536,303** |
| Offsetting | –72,416 | 72,416 | — |
| **Tax assets/tax liabilities, net** | **131,429** | **–667,733** | **–536,303** |

Note 21 contd.

| GROUP 2016 | Deferred tax asset | Deferred tax liability | Net |
|---|---|---|---|
| Excess depreciation | — | –253,880 | –253,880 |
| Change of depreciation method | — | –39,458 | –39,458 |
| Internal profit in inventories | 120,260 | — | 120,260 |
| Acquired product rights | — | –290,054 | –290,054 |
| Other intangible assets | 72,333 | — | 72,333 |
| Provision for pensions | 2,805 | — | 2,805 |
| Restoration reserve | — | –803 | –803 |
| Loss carryforwards | 15,368 | — | 15,368 |
| Other | 11,768 | — | 11,768 |
| **Total** | **222,534** | **–584,195** | **–361,661** |
| Offsetting | –88,637 | 88,637 | — |
| **Tax assets/ltax iabilities, net** | **133,897** | **–495,558** | **–361,661** |

The Parent Company's total deferred tax liabilities/tax assets amount to SEK –10 M (–25), and consist of deferred tax liability related to the change of depreciation method of SEK –20 M (–40), deferred tax asset related to provision for pensions of SEK 9 M (0), deferred tax asset related to doubtful debts of SEK 2 M (0), deferred tax liability related to restoration reserve of SEK –1 M (–1) and deferred tax liability related to exchange rate derivatives of SEK –1 M (0). The Parent Company's total loss carryforwards of SEK 70 M are utilised this year and thereby offset against the Parent Company's taxable profits. The value of deferred tax after the end of the year is calculated using a tax rate of 22 (22) per cent.

**ADJUSTMENT OF DEFERRED TAX**

Deferred tax has been adjusted during the year related to changes in depreciation method, i.e. amount to return to taxation due to the return to accounting depreciation from the residual depreciation initiated in Q2 of 2016, and cash flow hedging, where deferred tax has previously been reported, although the effect cannot be considered temporary and thus should only have affected current tax. The adjustments have been reported against capitalised earnings and have affected deferred tax in both the Group and the Parent Company, but have not had any effect on paid taxes. The closing balance for 2016 has in total been adjusted with an amount of SEK 11 M, distributed as below, of which SEK –7 M has been adjusted against the 2016 result and SEK 18 M against the 2015 result.

**Net closing balance and change versus previously reported**

| | Previously reported amount | Adjusted amount | Adjustment |
|---|---|---|---|
| Excess depreciation | –253,880 | –253,880 | — |
| Change of depreciation method | –69,475 | –39,458 | 30,017 |
| Internal profit in inventories | 120,260 | 120,260 | — |
| Acquired product rights | –290,054 | –290,054 | — |
| Other intangible assets | 72,333 | 72,333 | — |
| Provision for pensions | 2,805 | 2,805 | — |
| Restoration reserve | –803 | –803 | — |
| Cash flow hedging | 34,439 | — | –34,439 |
| Loss carryforwards | 258 | 15,368 | 15,110 |
| Other | 11,768 | 11,768 | — |
| **Total** | **–372,349** | **–361,661** | **10,688** |

## Changes in deferred tax on temporary differences and loss carryforwards

| GROUP 2017 | Amount at beginning of year | Recognised in income statement | Recognised in OCI | Amount at end of year |
|---|---|---|---|---|
| Excess depreciation | –253,880 | –213,400 | — | –467,280 |
| Change of depreciation method | –39,458 | 19,729 | — | –19,729 |
| Internal profit in inventories | 120,260 | –4,331 | — | 115,929 |
| Acquired product rights | –290,054 | 38,148 | — | –251,906 |
| Other intangible assets | 72,333 | –3,720 | — | 68,613 |
| Provision for pensions | 2,805 | 8,299 | 286 | 11,390 |
| Restoration reserve | –803 | 115 | — | –689 |
| Derivatives | — | –544 | — | –544 |
| Doubtful debts | — | 1,671 | — | 1,671 |
| Loss carryforwards | 15,368 | –15,447 | 79 | — |
| Other | 11,768 | –5,202 | –326 | 6,242 |
| **Total** | **–361,661** | **–174,683** | **39** | **–536,303** |

| GROUP 2016 | Amount at beginning of year | Recognised in income statement | Recognised in OCI | Amount at end of year |
|---|---|---|---|---|
| Excess depreciation | –142,196 | –111,684 | — | –253,880 |
| Residual value depreciation | –40,702 | 40,702 | — | — |
| Change of depreciation method | — | –39,458 | — | –39,458 |
| Internal profit in inventories | 76,933 | 43,327 | — | 120,260 |
| Acquired product rights | –328,202 | 38,148 | — | –290,054 |
| Other intangible assets | 216,700 | –144,367 | — | 72,333 |
| Provision for pensions | 2,500 | 636 | –331 | 2,805 |
| Restoration reserve | –803 | — | — | –803 |
| Loss carryforwards | 258 | 15,110 | — | 15,368 |
| Other | 18,047 | –6,604 | 325 | 11,768 |
| **Total** | **–197,465** | **–164,190** | **–6** | **–361,661** |

Note 21 contd.

### Adjustment in Group statements

| GROUP | Previously reported amount 2016 | Adjusted amount 2016 |
|---|---|---|
| **Balance sheet** | | |
| Equity | 5,354 | 5,365 |
| Deferred tax asset | 506 | 496 |
| **Total equity and liabilities** | **9,974** | **9,974** |
| **Income statement** | | |
| Tax on profit for the year | –239 | –246 |
| Profit for the year | 809 | 802 |
| **Effect on Income statement from adjustment of deferred tax** | | **–7** |

# Note 22

## Inventories

| GROUP | 2017 | 2016 |
|---|---|---|
| Raw materials and consumables | 20,905 | 25,557 |
| Products in progress | 536,603 | 433,244 |
| Finished goods and merchandise | 495,760 | 411,245 |
| **Total** | **1,053,268** | **870,046** |

The cost of inventories recognised as an expense is included in cost of goods sold and amounted to SEK 1,516,822 K (1,145,708). 2017 includeds a positive one-time adjustment of stock of SEK 59 M in connection with the delayed release of the pharmaceutical substance for Kineret manufactured in 2016.

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| Raw materials and consumables | 20,905 | 25,557 |
| Products in progress | 536,603 | 433,244 |
| Finished goods and merchandise | 336,166 | 307,584 |
| **Total** | **893,674** | **766,384** |

The cost of inventories recognised as an expense is included in cost of goods sold and amounted to SEK 1,516,485 thousand (1,144,773). 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.

# Note 23

## Trade and other receivables

| GROUP | 2017 | 2016 |
|---|---|---|
| Trade receivables | 1,164,054 | 818,043 |
| Minus: Provision for doubtful debts | –35,038 | –49,279 |
| **Trade receivables, net** | **1,129,016** | **768,765** |
| Tax receivables | 25,232 | 35,011 |
| Other receivables | 38,732 | 40,532 |
| **Total other receivables** | **63,964** | **75,543** |
| **Total trade and other receivables** | **1,192,980** | **844,307** |

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| Trade receivables | 413,296 | 293,048 |
| Minus: Provision for doubtful debts | –7,594 | –12,799 |
| **Trade receivables, net** | **405,702** | **280,249** |
| Tax receivables | 22,261 | 27,203 |
| Other receivables | 30,831 | 27,329 |
| **Total other receivables** | **53,092** | **54,532** |
| **Total trade and other receivables** | **458,794** | **334,781** |

Profit for the year was adversely affected by established customer losses of SEK 5,271 K, of which SEK 4,167 K is attributable to the Parent Company.

At 31 December 2017, the Group's past due trade receivables amounted to SEK 291 M (272), SEK 35 M (49) of which were considered doubtful debts.

A new reporting standard IFRS 9 Financial Instruments comes into force on 1 January 2018 and includes rules for classification and valuation of financial assets and liabilities and impairment of financial Instruments. Sobi has analysed the effects of the introduction of IFRS 9 on the Group's financial statements, and the assessment is that it will not have any material impact on either earnings or the financial position. See also note 2.

Changes in the provision for doubtful debts are as follows:

## Doubtful debts

| GROUP | 2017 | 2016 |
|---|---|---|
| At beginning of year | –49,279 | –25,280 |
| Provision for doubtful debts | –10,566 | –25,219 |
| Reversed provisions | 24,807 | 1,220 |
| **At end of year** | **–35,038** | **–49,279** |

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| At beginning of year | –12,799 | –13,171 |
| Provision for doubtful debts | –2,296 | –849 |
| Reversed provisions | 7,501 | 1,220 |
| **At end of year** | **–7,594** | **–12,799** |

Note 23 contd.

### Past due trade receivables

| GROUP | 2017 | 2016 |
|---|---|---|
| Not past due | 838,737 | 497,161 |
| Past due 1–30 days | 183,050 | 150,588 |
| Past due 31–90 days | 68,366 | 70,830 |
| Past due 91–120 days | 11,954 | 21,981 |
| Past due > 121 days | 27,273 | 28,204 |
| **Total** | **1,129,016** | **768,765** |

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| Not past due | 335,870 | 212,234 |
| Past due 1–30 days | 62,111 | 28,906 |
| Past due 31–90 days | 5,754 | 38,383 |
| Past due 91–120 days | — | 128 |
| Past due > 121 days | 1,967 | 598 |
| **Total** | **405,702** | **280,249** |

### Recognised amount per currency for trade and other receivables

| GROUP | 2017 | 2016 |
|---|---|---|
| AUD | 10,459 | 12,720 |
| CHF | 20,333 | 8,414 |
| CZK | 2,088 | 5,033 |
| DKK | 24,786 | 95,962 |
| EUR | 661,603 | 310,339 |
| GBP | 101,106 | 58,223 |
| NOK | 35,945 | 16,246 |
| PLN | 5,129 | 5,942 |
| RON | 10,248 | 13,405 |
| SEK | 167,292 | 152,400 |
| USD | 150,155 | 161,123 |
| Other currencies | 3,834 | 4,500 |
| **Total** | **1,192,980** | **844,307** |

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| AUD | 10,459 | 12,720 |
| CHF | 20,333 | 8,414 |
| CZK | 1,799 | 1,640 |
| DKK | 24,619 | 16,425 |
| EUR | 172,013 | 84,446 |
| GBP | — | 887 |
| NOK | 35,404 | 15,745 |
| PLN | 5,129 | 5,942 |
| RON | 10,248 | 13,405 |
| SEK | 167,292 | 152,400 |
| USD | 9,631 | 20,555 |
| Other currencies | 1,865 | 2,202 |
| **Total** | **458,794** | **334,781** |

# Note 24

### Prepayments and accrued income

| GROUP | 2017 | 2016 |
|---|---|---|
| Accrued royalty revenue | 327,390 | 285,858 |
| Prepaid lease payments | 176 | 88 |
| Prepaid rents | 16,174 | 17,412 |
| Prepaid insurance expenses | 14,469 | 12,233 |
| Accrued interest income | 2,884 | 144 |
| Prepaid IT licences | 11,229 | 15,567 |
| Prepaid charges to supervisory authorities | 16,975 | 10,066 |
| Other accrued income | 179 | — |
| Other prepayments | 42,850 | 69,741 |
| **Total** | **432,326** | **411,109** |

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| Accrued royalty revenue | 327,390 | 285,858 |
| Prepaid rents | 15,012 | 15,134 |
| Prepaid insurance expenses | 13,343 | 10,360 |
| Accrued interest income | 2,884 | — |
| Prepaid IT licences | 11,229 | 15,567 |
| Prepaid charges to supervisory authorities | 16,975 | 10,066 |
| Other prepayments | 31,361 | 62,688 |
| **Total** | **418,194** | **399,373** |

# Note 25

### Cash and cash equivalents

| | 2017 | | 2016 | |
|---|---|---|---|---|
| GROUP | Fair value | Carrying amount | Fair value | Carrying amount |
| Cash and cash equivalents | 1,478,496 | 1,478,496 | 785,790 | 785,790 |
| **Total** | **1,478,496** | **1,478,496** | **785,790** | **785,790** |

| | 2017 | | 2016 | |
|---|---|---|---|---|
| PARENT COMPANY | Fair value | Carrying amount | Fair value | Carrying amount |
| Cash and cash equivalents | 1,381,369 | 1,381,369 | 662,110 | 662,110 |
| **Total** | **1,381,369** | **1,381,369** | **662,110** | **662,110** |

Cash equivalents refer to the retention of funds in bank accounts.

# Note 26

## Financial assets and liabilities per category (Group)

| | Loans and receivables | Assets at fair value through profit or loss | Available-for-sale assets | Total |
|---|---|---|---|---|
| **31 December 2017** | | | | |
| **Assets in the balance sheet** | | | | |
| Trade receivables | 1,129,016 | — | — | 1,129,016 |
| Endowment insurance | — | 32,391 | — | 32,291 |
| Derivatives | — | 5,095 | — | 5,095 |
| Cash and cash equivalents | 1,478,496 | — | — | 1,478,496 |
| **Total** | **2,607,512** | **37,476** | — | **2,644,998** |
| **31 December 2016** | | | | |
| **Assets in the balance sheet** | | | | |
| Trade receivables | 768,765 | — | — | 768,765 |
| Derivatives | — | 3,901 | — | 3,901 |
| Cash and cash equivalents | 785,790 | — | — | 785,790 |
| **Total** | **1,554,555** | **3,901** | — | **1,558,456** |

| | Liabilities at fair value through profit or loss | Other financial liabilities | Available-for-sale liabilities | Total |
|---|---|---|---|---|
| **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** | **2,624** | **2,011,845** | — | **2,014,469** |
| **31 December 2016** | | | | |
| Liabilities in the balance sheet | | | | |
| Borrowing | — | 496,914 | — | 496,914 |
| Finance leases | — | 7,102 | — | 7,102 |
| Trade payables | — | 280,173 | — | 280,173 |
| Other liabilities | — | 2,305,613 | — | 2,305,613 |
| **Total** | **—** | **3,089,802** | **—** | **3,089,802** |

See note 2 for further information about what is included in the different categories. Advance payments are not included in trade and other receivables, as the analysis is only required for financial instruments. Accrued social security costs etc. are excluded from this table for the same reason.

## Reconciliation of liabilities arising from financing activities

| | Borrowing | Finance leases |
|---|---|---|
| **2016** | **496,914** | **7,102** |
| Cash flow | –500,000 | — |
| Dissolution of prepaid borrowing costs | 3,086 | — |
| Other | — | –434 |
| **2017** | **—** | **6,668** |

# Note 27

## Other liabilities, non-current

| GROUP | 2017 | 2016 |
|---|---|---|
| Liability to Bioverativ | 1,066,833 | 1,808,916 |
| Liabilities to credit institutions | — | 496,914 |
| Financial leasing | 5,044 | 5,302 |
| **Total** | **1,071,877** | **2,311,132** |

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| Liability to Bioverativ | 1,066,833 | 1,808,916 |
| Liabilities to credit institutions | — | 496,914 |
| **Total** | **1,066,833** | **2,305,830** |

Following EU approval of Elocta and Alprolix, Sobi acquired the right to market the products in certain markets. The cost of marketing rights corresponds to 50 per cent of Bioverativ'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, the discounted amounts after repayment are reflected in the balance sheet (USD 101 M for Elocta and USD 99 M for Alprolix). The right to market the products in certain markets, reported under intangible assets, is initially recognised at the same amount as the liabilities. The costs of acquisition correspond to the discounted liability, and the difference compared with the 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. The effect of the remeasured liabilities is reflected in other comprehensive income. If full payment has not been made within six years of the first commercial sales for each product, Bioverativ is entitled to request that Sobi pay the remaining amount within 90 days of the sixth anniversary of Bioverativ´s first commercial sales.

During the year the bank loan of SEK 500 M from Svenska Handelsbanken AB (publ) and Danske Bank was repaid. Also see note 26.

# Note 28

## Other liabilities, current

| GROUP | 2017 | 2016 |
|---|---|---|
| Liability to Bioverativ | 579,895 | 496,697 |
| Goods received, not invoiced | 14,678 | 58,367 |
| Other | 67,539 | 97,756 |
| **Total** | **662,112** | **652,820** |

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| Liability to Bioverativ | 579,895 | 496,697 |
| Goods received, not invoiced | 14,678 | 58,367 |
| Other | 12,535 | 42,117 |
| **Total** | **607,108** | **597,181** |

The liability to Bioverativ refers to the current portion of the liability described in note 27.

# Note 29

## Post-employment benefits

Group employees have various forms of pension benefits, either defined-contribution or defined-benefit plans. In Sweden, compensation after the end of employment is primarily through defined-contribution plans.

Pension obligations are calculated annually on the reporting date, based on actuarial principles. Sobi has a defined-benefit pension plan for the subsidiary in Norway and for two individuals 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 reported under Selling, Administrative Expenses and Research and Development expenditure.

**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 obligations concern life-long benefits for employees covered by the plan, which means that longer life expectancy assumptions will result in higher pension liabilities. This is most significant in the Swedish plan, where increases in inflation result in greater sensitivity to changes in life expectancy assumptions.

*Inflation risk:* Some of the plan's pension obligations are linked to inflation. Higher inflation leads to higher liabilities (although, in most cases, an inflation ceiling has been set to protect the plan against exceptional increases in inflation). Most of the plan assets are either unaffected by inflation (fixed-rate bonds), or weakly correlated with inflation (equities), which means that an increase in inflation will also increase the deficit.

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

**Pension benefits**

For white-collar employees in Sweden, the ITP 2 plan's defined-benefit pension obligations for retirement and family pensions are insured through Alecta. According to the Financial Reporting Board's statement *UFR 10 Accounting for ITP 2 Plans Financed by Insurance with Alecta,* this is a multi-employer defined-benefit plan. The Company did not have access to sufficient information for the 2017 financial year 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. Expected contributions in the next reporting period for ITP 2 pension plans insured through Alecta are SEK 25 M (21). 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 insurance obligations calculated by reference 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 2017, Alecta's surplus in the form of the collective funding ratio was 154 (149) per cent.

Some current and previous office-holders are not covered by the governing principle, 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 senior office-holder.

The Norwegian pension plan is covered by the Norwegian Pensions Act (Foretagspensjonsloven) 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.

## Note 29 contd.

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

| 1 January – 31 December 2017 | Present value of obligations | Fair value of plan assets | Total |
|---|---|---|---|
| **At beginning of year** | **–40,639** | **26,679** | **–10,960** |
| Current service cost | –1,859 | — | –1,859 |
| Interest expense | –983 | — | –983 |
| Revaluations: | | | |
| Return on plan assets, excl. amounts in interest expense | — | 732 | 732 |
| Changed financial assumptions | –1,251 | 20 | –1,231 |
| Experience 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** |

| 1 January – 31 December 2016 | Present value of obligations | Fair value of plan assets | Total |
|---|---|---|---|
| **At beginning of year** | **–37,874** | **28,300** | **–9,576** |
| Current service cost | –1,866 | — | –1,866 |
| Interest expense | –1,094 | — | –1,094 |
| Revaluations: | | | |
| Return on plan assets, excl. amounts in interest expense | 2,177 | –135 | 2,041 |
| Changed financial assumptions | –2,350 | –36 | –2,386 |
| Experience assumptions | –1,400 | 1,791 | 391 |
| Contributions: | | | |
| Employer | 3,328 | –712 | 2,616 |
| Settlements | — | –277 | –277 |
| Exchange differences | –1,599 | 749 | –810 |
| **At end of year** | **–40,639** | **29,679** | **–10,960** |

**Net obligation per country**

| | 2017 | 2016 |
|---|---|---|
| Sweden | –744 | –3,088 |
| Norway | –7,895 | –7,872 |
| **Total** | **–8,639** | **–10,960** |

**Actuarial assumptions on the reporting date**

| SWEDISH PENSION PLAN | 2017 | 2016 |
|---|---|---|
| Discount rate, % | 2.5 | 2.8 |
| 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 | 2017 | 2016 |
|---|---|---|
| Discount rate, % | 2.3 | 2.1 |
| 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. At the reporting date, Norway had seven active employees and Sweden had no active employees and two retired employees. The retirement age is set at 65 years.

**Distribution by asset class**

| | 2017 | Quoted, % | 2016 | Quoted, % |
|---|---|---|---|---|
| Equity funds[1] | 10,878 | 100 | 8,601 | 100 |
| Interest-bearing securities | 18,070 | 100 | 17,281 | 100 |
| Property | 1,016 | — | 527 | — |
| Other funds | 2,669 | — | 3,243 | — |
| Other | 142 | — | 27 | — |
| **Total** | **32,775** | | **29,679** | |

1. The pension and assets are managed by Procordias Pensionsstiftelse. Some of their equity funds (e.g. the AMF Aktiefond Sweden) have holdings of Sobi shares.

**Sensitivity analysis**

| | 2017 | 2016 |
|---|---|---|
| Pension obligation under current assumptions | 41,413 | 40,639 |
| Discount rate –0.5% | 45,870 | 45,018 |
| Discount rate +0.5% | 37,482 | 36,767 |
| Inflation +0.5% | 45,699 | 43,558 |
| Inflation –0.5% | 39,489 | 37,839 |
| Life expectancy after retirement –1 year | 38,867 | 38,257 |
| Life expectancy after retirement +1 year | 43,335 | 42,403 |

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 2018 financial year, contributions to plans for post-employment benefits are expected to be SEK 1,362 K (1,336). The weighted average maturity of the obligation is estimated at 29.8 years.

# Note 30

## Provisions

| | Group | | Parent Company | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Provisions at beginning of year | 44,389 | 41,966 | 33,060 | 32,390 |
| Endowment insurance | 32,391 | — | 32,391 | — |
| Cash-based incentives programme | 16,817 | — | 16,817 | — |
| Commitment lease | 2,725 | — | — | — |
| Restoration Reserve | 171 | 1,039 | 175 | 670 |
| Changes in pension obligations | –2,321 | 1,384 | — | — |
| Other | 3,783 | — | — | — |
| **Provisions at end of year** | **97,955** | **44,389** | **82,443** | **33,060** |

1. Sobi has chosen to account for the endowment insurance on a gross basic; in previous years, endowment insurance has been accounted for on a net basis. In conjunction with this change, an adjustment has been made for a special salary tax. On the reporting date, endowment insurance reached SEK 32 M.
2. The long-term cash-based incentive programme reached SEK 17 M on 31 December 2017. See note 11.
3. Sobi has returned the rented property Paradiset 14 to acceptable condition with consideration of the operations the Company has run there in accordance with the Rental Agreement (IAS38). The Company has recorded a provision of SEK 33 M in the accounts as of 31 December 2017.

| | Group | | Parent Company | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Non-current | 94,172 | 44,389 | 82,443 | 33,060 |
| Current | 3,783 | — | — | — |
| **Total provisions** | **97,955** | **44,389** | **82,443** | **33,060** |

# Note 31

## Accruals and deferred income

| GROUP | 2017 | 2016 |
|---|---|---|
| Provision for holiday pay and bonuses, incl. social security contributions | 239,469 | 239,037 |
| Accrued social security contributions | 89,205 | 48,334 |
| Accrued royalty expenses | 112,849 | 26,614 |
| Accrued manufacturing costs | 46,014 | 41,143 |
| Accrued R&D expenditure | 64,960 | 45,782 |
| Accrued interest expenses | 175 | 253 |
| Accrued consulting and travel expenses | 23,351 | 14,738 |
| Accrued discounts | 145,446 | 176,435 |
| Pharmaceutical taxes | 141,894 | 12,198 |
| Accrued expenses for audit and Annual Report | 4,700 | 3,762 |
| Accrued expenses sold goods | 10,426 | — |
| Other accruals | 240,189 | 201,004 |
| **Total** | **1,118,678** | **809,300** |

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| Provision for holiday pay and bonuses, incl. social security contributions | 146,223 | 134,958 |
| Accrued social security contributions | 51,856 | 34,676 |
| Accrued royalty expenses | 112,849 | 26,189 |
| Accrued manufacturing costs | 46,014 | 27,731 |
| Accrued R&D expenditure | 64,960 | 45,782 |
| Accrued interest expenses | 175 | 253 |
| Pharmaceutical taxes | 45,150 | 1,390 |
| Accrued consulting and travel expenses | 7,295 | 4,893 |
| Accrued expenses for audit and Annual Report | 2,756 | 2,149 |
| Other accruals | 205,552 | 180,904 |
| **Total** | **682,830** | **458,926** |

# Note 32

## Pledged assets and contingent liabilities

| GROUP | 2017 | 2016 |
|---|---|---|
| **Collaterals** | | |
| Endowment insurance | 32,391 | — |
| Other pledged assets | 686 | 2,298 |
| **Total** | **33,077** | **2,298** |

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| **Collaterals** | | |
| Endowment insurance | 32,391 | — |
| Other pledged assets | 43 | 43 |
| **Total** | **32,434** | **43** |

| PARENT COMPANY | 2017 | 2016 |
|---|---|---|
| **Contingent liabilities** | | |
| Guarantee commitment | 36,835 | 19,915 |
| **Total** | **36,835** | **19,915** |

Guarantees for 2017 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 has received a claim from a distributor in connection with the termination of the agreement for losses/damage they believe they have incurred. Sobi has made an initial assessment that the claim is groundless for their claims, and is expected to submit its response to the court on 10 April 2018.

# Note 33

## The share

At year-end, the share capital was SEK 149,527, divided into 272,507,708 shares with a par value of approximately SEK 0.55. Previously issued Class C shares were converted to ordinary shares in 2017, which means that all issued shares are now ordinary shares. Ordinary shares carry one vote per share, and Class C shares 1/10 vote per share. The Company held 3,249,870 ordinary shares in treasury at the reporting date. Shares held in treasury represent 1.2 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.

| | 2017 | 2016 |
|---|---|---|
| Earnings attributable to Parent Company shareholders | 1,148,612 | 801,635 |
| Weighted average number of ordinary shares outstanding (thousands) | 269,020 | 268,362 |
| Earnings per share before dilution (SEK per share) | 4.27 | 2.99 |
| Earnings per share after dilution (SEK per share) | 4.25 | 2.98 |

# Note 34

## 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.

# Note 35

## Proposed appropriation of profit

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

| SEK | |
|---|---|
| Share premium reserve | 4,231,346,499 |
| Retained earnings | 763,083,789 |
| Profit for the year | –507,835,892 |
| **Total** | **4,486,594,396** |

The Board proposes that no dividend be paid for the 2017 financial year.

The Board proposes that the available funds of SEK 4,486,594,396 be carried forward.

# Note 36

## Events after the reporting date, up to 27 March 2018

- The FDA approved an application for a clinical trial and granted Fast Track status for the product candidate SOBI003 for the treatment of MPS IIIA.
- Elocta was reimbursed in Poland and Slovakia.
- Sobi signed a two-year agreement with the Health Services Executive in Ireland to provide Elocta and Alprolix to all patients who had previously been treated with factor replacement therapy.
- Kineret (anakinra) has received a positive opinion from CHMP for the treatment of Still's disease.
- Henrik Stenqvist was appointed as new Chief Financial Officer.
- Sobi launched Ravicti in Europe and advances the care for Urea Cycle Disorders.
- New market data was received from the pharmaceutical industry association in France after the end of the financial year which indicates that the provision made by Sobi's French subsidiary for pharmaceutical tax may be too high. One component in the calculation of pharmaceutical tax is based on the development of the French market. Preliminary prognoses from an independent organisation in France are submitted to the industry body during the financial year, and provide a foundation for pharmaceutical tax provisions. In February 2018, the industry body reported that the growth figure on which the received forecasts were based could be too high. A final figure for pharmaceutical tax will be received during the second quarter of 2018, at which point the provision in the annual report will be adjusted, if required, and reported.

See Directors´ Report for more information.

The Board and CEO confirm that the consolidated annual 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 performance and position. The Parent Company's annual financial statements have been prepared in accordance with generally accepted accounting principles in Sweden and provide a true and fair view of the Company's financial performance and position.

The Directors' Report for the Group and the Parent Company provides a fair overview of the development of the Group and the Parent Company's operations, financial position and performance and describes material risks and uncertainties faced by the Parent Company and the companies in the Group.

The income statements and balance sheets will be presented for adoption at the Annual General Meeting on 9 May 2018.

**Stockholm, 27 March 2018**

**Håkan Björklund**
Chairman

**Annette Clancy**
Board Member

**Matthew Gantz**
Board Member

**Lennart Johansson**
Board Member

**Helena Saxon**
Board Member

**Hans GCP Schikan**
Board Member

**Pia Axelsson**
Employee representative

**Bo-Gunnar Rosenbrand**
Employee representative

**Guido Oelkers**
CEO

**Our audit report was submitted on 10 April 2018**
**Ernst & Young AB**

**Björn Ohlsson**
Authorised Public Accountant

# Sobi's Corporate Governance

**Swedish Orphan Biovitrum AB (publ) "Sobi" is a Swedish public limited liability company with its registered office in Stockholm, Sweden. Sobi is listed on Nasdaq Stockholm. In addition to the rules under laws or other regulations, Sobi applies the Swedish Corporate Governance Code without any derogations. This report covering the 2017 financial year is part of Sobi's Directors' Report and has been reviewed by the Company's auditors.**

## 1. Annual General Meeting

Sobi's highest decision-making body is the Annual General Meeting (AGM) at which all shareholders have the right to elect Board members and the Chairman of the Board. The AGM must be held within six months of the end of the fiscal year in order to decide on adoption of the income statement and balance sheet and appropriation of profits. The AGM also elects the Company's auditor.

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 motivates 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.

### 2017 AGM

The AGM was held on 4 May 2017 in Stockholm. The Meeting was attended by 169 (208) shareholders, in person or by proxy, representing 65.2 (60.0) per cent of the total votes. Lawyer Eva Hägg was elected to chair the Meeting.

The full minutes and information from the 2017 AGM are available at www.sobi.com.

### 2018 AGM

The AGM will be held on Wednesday, 9 May 2018 at Näringslivets Hus in Stockholm. More information about the AGM can be found on page 134.

### Shareholders, share capital, the share and voting rights

Sobi had a total of 22,938 (32,397) shareholders at the end of the year. Investor AB was the largest shareholder, with 39.5 (39.6) per cent of the share capital and 39.5 (39.8) per cent of the votes. The 15 largest shareholders accounted for 73.2 (68.3) per cent of the share capital and 73.2 (68.2) per cent of the votes. No shareholders other than Investor AB has a direct or indirect shareholding that represents one-tenth or more of the voting rights 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 directors or on amendments to the Articles.

### Conversion of shares

The Annual General Meeting on 4 May 2017 authorised the Board to issue C shares and repurchase the issued C shares for the purpose of hedging long-term incentive programmes. The Meeting also adopted the Board's proposal concerning the transfer of shares. On 31 December 2017, Sobi held 3,249,870 ordinary shares. All previously issued C-shares were converted into ordinary shares during 2017. For more detailed information about the total number of shares in the Company, the number of shares by category and the number of votes carried by the shares, see 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 2017. In the short-term, the Company intends to use profits to finance the continuing development and expansion of its operations.

**Important internal regulations**

- Articles of Association
- Charter of the Board
- CEO Instructions
- Policy documents
- Charters of the Board Committée

**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 has the sole task of 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, three of whom represent the Company's three largest shareholders on the final banking day of August, based on shareholder list from Euroclear Sweden AB. As stipulated in the same resolution, the fourth person shall be the Chairman of the Board. 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 2018 AGM, the Nomination Committee has the following composition: Petra Hedengran, Investor AB, Chairman of the Nomination Committee, Lennart Francke, Swedbank Robur Fonder AB, Thomas Ehlin, Fjärde AP-fonden and Håkan Björklund, Chairman of the Board of Swedish Orphan Biovitrum AB (publ). Prior to the 2018 AGM, the Nomination Committee has held three meetings, with contact by telephone between meetings, and has also met and interviewed a number of potential Board candidates. 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, remuneration of Board and Committee members, the appointment of auditors and their fees, and the Chairman of the AGM.

**Nomination Committee for 2018 AGM**

| Name/Represented | Share of votes 2017-12-31, % | Share of votes 2017-08-31, % |
|---|---|---|
| Petra Hedengran (Chairman of Nomination Committee) | | |
| Investor AB | 39.5 | 39.5 |
| Lennart Francke | | |
| Swedbank Robur Fonder AB | 5.5 | 5.0 |
| Tomas Ehlin | | |
| Fjärde AP-fonden | 4.3 | 3.8 |
| Håkan Björklund | | |
| Chairman of the Board of Swedish Orphan Biovitrum AB (publ) | 0.0 | 0.0 |
| **Total** | **49.3** | **48.3** |

## 3. Board/Chairman of the Board

Sobi is a pharmaceutical company with a focus on marketing, developing and producing pharmaceutical products to treatment of 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 and adopts annual and interim reports, and proposes dividend, if any, 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 nominating Board members to the AGM. 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 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 2017 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 2017 AGM resolved in accordance with the Nomination Committee's revised proposal, to the effect that from the 2017 AGM the Board has consisted of six members elected by the AGM (all re-elected at the 2017 AGM) and two employee representatives appointed by the trade union organisations (plus two deputies for the employee representatives). One third of the members elected by the AGM are women.

More detailed information about the Board is presented on pages 116–117.

**Resolutions 2017 AGM**
The following resolutions were adopted by the 2017 AGM:

- Re-election of six Board members.
- Re-election of Chairman of the Board Håkan Björklund.
- Re-election of EY as auditors.
- Adoption of remuneration of the Board and auditors.
- Adoption of proposed guidelines for remuneration of senior executives.
- Discharge from liability for the Board and CEO for the 2016 financial year.

**Chairman of the Board**
In addition to leading the Board 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.

**Independence**
The Company fulfills 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. The Board has scheduled a total of nine meetings for 2018.

**The Board's work in 2017**
The Board held a total of 16 meetings in 2017, 10 of which were scheduled and 6 were extra meetings. Sobi's CEO and President attends Board meetings, as does Sobi's General Counsel, who has served as secretary at the meetings. Other Sobi employees have attended in a reporting capacity. The number of extra Board meetings was motivated by discussions concerning strategic projects and extensions to product and distribution agreements. The agenda items are shown in the illustration below.

**Board fees**
The AGM on 4 May 2017 adopted total Board fees of SEK 3,995 K for the period until the next AGM, distributed as follows: SEK 1,275 K to the Chairman and SEK 425 K to be paid to each of the AGM-elected members. Fees for Audit Committee work were adopted as follows: SEK 125 K to the Chairman SEK 75 K to each of the other members. Fees for Compensation & Benefits Committee work were adopted as follows: SEK 80 K to the Chairman SEK 40 K to each of the other members. Fees for Scientific Committee work were adopted as follows: SEK 80 K to the Chairman SEK 40 K to each of the other members. Board fees paid in 2017 totalled SEK 4,212 K, including fees 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.

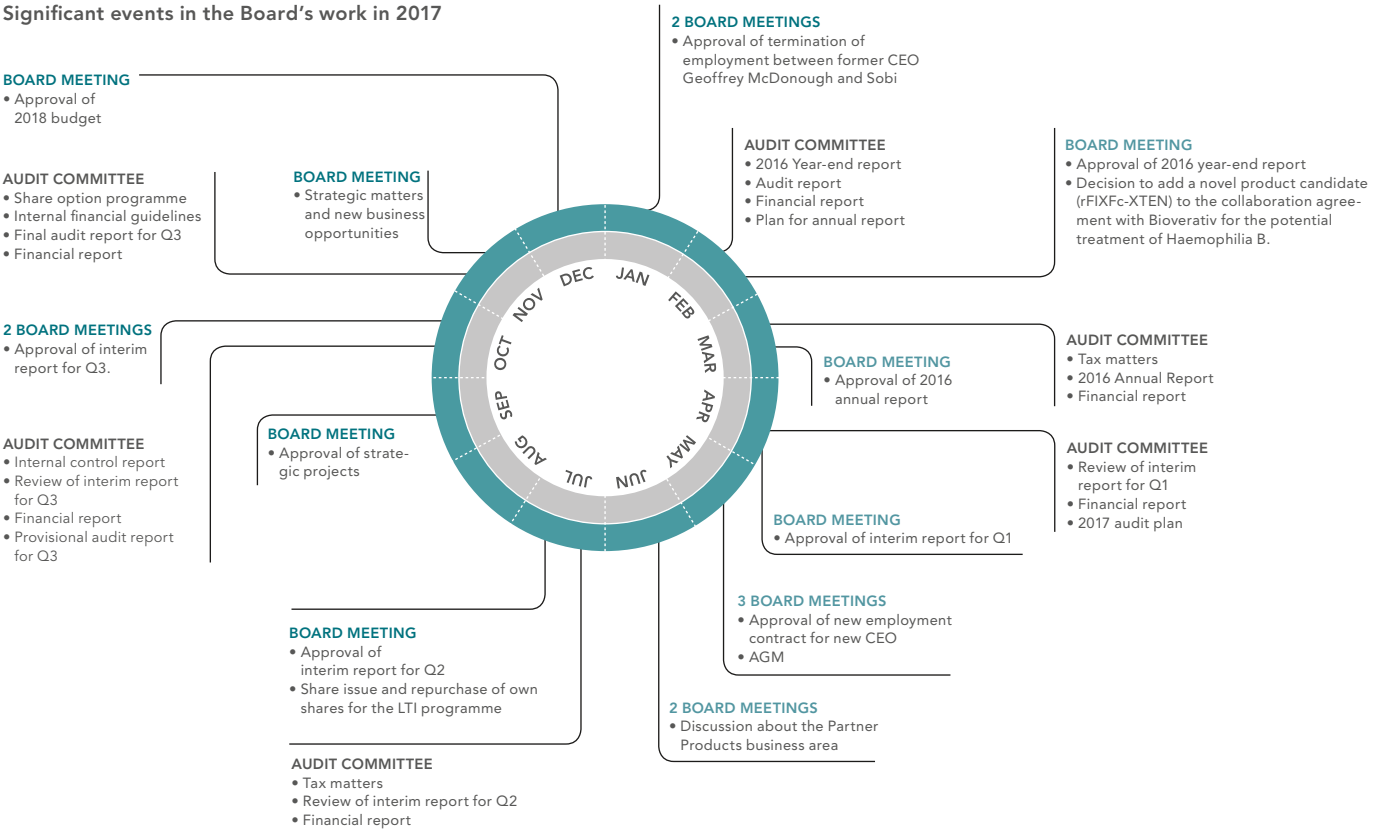
More information about the remuneration of Board members can be found in note 11 and in the table on page 111.

## 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

**Significant events in the Board's work in 2017**



Sobi's CFO attends in a reporting capacity and serves as secretary to the Committee, but is not a member. Sobi´s CEO has taken part in 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 attendance and remuneration of Board members at the Committee meetings are shown 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 two members, both of whom are independent of management:

- Håkan Björklund (Chairman)
- Helena Saxon

Former member Theresa Heggie resigned from the Board, and therefore from the Compensation & Benefits Committee, on 31 March 2017.

Sobi's acting Head of Human Resources attends in a reporting capacity and serves as secretary to the Committee, but is not a member. The Compensation & Benefits Committee held seven meetings 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 guidelines on remuneration of the CEO and senior executives will be presented at the AGM in May 2018 for adoption by shareholders. The Board members' attendance at the Committee meetings is shown in the table below.

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 two members, both of whom are independent of management:

- Annette Clancy (Chairman)
- Hans GCP Schikan.

Annette Clancy has been Chairman of the Scientific Committee since May 2017, when former Chairman Jeffrey Jonas resigned from the Board.

Sobi's CEO and the Head of Research and Development/Chief Medical Officer have taken part in the meetings, but they are not formal members. The Head of RD/CMO serves as Secretary to the Committee but is not a member.

The Committee held five meetings in 2017. These meetings dealt with the development of the company's research and development pipeline, reviews of individual projects, feedback from expert networks, goals for 2018, budget and opportunities for external research and development programme sourcing. The Committee reports regularly to the Board about its work.

## 7. CEO/Executive Committee

Up to the end of October 2017, Group Management consisted of twelve members, including the CEO.

On 1 November 2017, a new management group, the Executive Committee, was formed, consisting of CEO and eight managers of the most important functions and regions. The new Executive Committee has a broad composition of individuals with extensive experience in R&D, the production and sale of drugs and Sobi's markets. The Executive Committee members also have the required expertise in economics, finance and law. The Executive Committee held a meeting every month in 2017. More detailed information about the Executive Committee is presented on 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 control model according to which Sobi works and is governed.

At Board meetings, the CEO and, if required, the CFO, General Counsel and other senior executives present matters to be dealt with by the Board.

**Remuneration of senior executives**

To attract and retain qualified and motivated employees, Sobi has long-term incentive

| | | Remuneration (SEK thousands) | | | | | | Attendance [1] | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Independence | Fees | Audit Committee | Compensation & Benefits Committee | Scientific Committee | Other | Total | Board | Audit Committee | Compensation & Benefits Committee | Scientific Committee |
| Håkan Björklund [6] | • | 1,250 | – | 77 | – | – | 1,327 | 16 | – | 7 | – |
| Lennart Johansson | [2] | 405 | 117 | – | – | – | 522 | 16 | 6 | – | – |
| Helena Saxon | [2] | 405 | 70 | 38 | – | – | 513 | 15 | 6 | 7 | – |
| Hans GCP Schikan | • | 405 | 70 | – | 38 | 50 | 553 | 14 | 6 | – | 5 |
| Matthew Gantz | • | 405 | – | – | – | 116 | 502 | 15 | – | – | – |
| Annette Clancy [6] | • | 405 | – | – | 65 | 40 | 510 | 15 | – | – | 5 |
| Theresa Heggie [3] | • | 91 | – | 9 | – | 10 | 110 | 3 | – | 2 | – |
| Jeffrey Jonas [3] | • | 122 | – | – | 23 | – | 145 | 1 | – | – | 2 |
| Pia Axelsson [5] | [4] | – | – | – | – | – | – | 15 | – | – | – |
| Bo-Gunnar Rosenbrand | [4] | – | – | – | – | – | – | 16 | – | – | – |
| Catarina Larsson [5] | [4] | – | – | – | – | – | – | 3 | – | – | – |

1. The table figures show the totals for attendances/meetings. The Board held a total of 16 meetings in 2017, ten of which were scheduled and six extra meetings. The Audit Committee held six meetings in 2017. The Compensation & Benefits Committee held seven meetings and the Scientific Committee held five meetings.
2. Board member not considered independent of major shareholders.
3. Theresa Heggie and Jeffrey Jonas left the Board in April and May 2017 respectively.
4. Employee representative.
5. At the 2017 AGM Pia Axelsson was appointed as new employee representative on the Board to replace outgoing Catarina Larsson.
6. The fee in the table does not include social security contributions. The total including social security contributions for Håkan Björklund was SEK 1,744 K and for Annette Clancy SEK 670 K.

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 variable salary component for senior executives, apart from the CEO, may not exceed 10–50 per cent of the annual salary.

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 2018 AGM and has been Sobi's auditor since the AGM 2014. The external auditors discuss the external audit plan and risk management with the Audit Committee. The auditors perform a review of the Q3 interim report and an audit of the annual accounts and consolidated financial statements. The auditors also express an opinion on whether this Corporate Governance Report has been prepared in accordance with the Annual Accounts Act, and whether certain disclosures herein are consistent with the annual accounts and consolidated financial statements. The auditors report 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 auditors present detailed findings from their reviews to the Audit Committee three times a year, and to the full Board once a year.

For more information about remuneration of the Company's auditors, see note 12.

**Björn Ohlsson**
Authorised Public Accountant

## 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.

A new position was created in 2017, and a person was hired with the task of strengthening internal control within the Group. The position reports to the CFO and prepares an annual internal control plan, which is approved and followed up by the CFO.

### COSO Framework

Sobi's internal control environment follows the established COSO 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

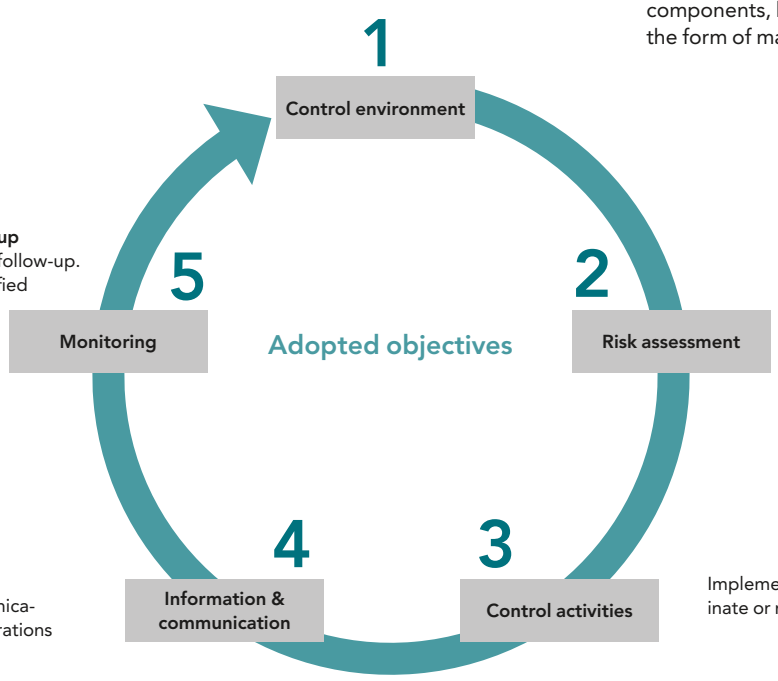
The illustration below shows how the five components of the COSO model work together to improve the operations' ability to achieve defined targets.

### 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.

**Corporate culture**
Tone at the top is important, i.e. management's behaviour.

**Governing documents**
Overall framework and policies are in place and implemented




**Evaluation, monitoring and follow-up**
1. Implement a process for ongoing follow-up.
2. Evaluation and reporting of identified derogations

1. Identify and analyse risks that may impede target achievement
2. Identify what risks that have a material effect on operations
3. Decide on measures and persons responsible

**Internal**
Clearly functioning two-way communication between management and operations

**External**
Correct information to external stakeholders within the prescribed time.

Implement control activities that reduce, eliminate or monitor significant identified risks.

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 & Ethics.
- Organisational structure and descriptions of positions.
- Administrative procedures, guidelines and instructions such as powers, authorisation instructions, risk management policy, purchasing and investment policy, security 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.

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.

Risk management during 2017 focused on following up work carried out by the units involving process-based evaluation and reporting on the internal management and control. Risk management reports are submitted quarterly to the Executive Committee, Risk Committee, Audit Committee and the Board.

**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 monitoring of forecasts and budgets, earnings and balance-sheet analyses, reconciliation, trend analysis and market intelligence. The result of this work is reported to the relevant business area managers, and to management and the Board.

**4. Information and communication**

Sobi has internal information and communication channels aimed at ensuring efficient 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 and social media guidelines, 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 are aimed at to providing the market with relevant, reliable and correct information about Sobi's development and financial position. Sobi has a communication policy, which 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 auditors report their observations and their assessment of internal control to the Audit Committee.

*2017 activities to strengthen internal control*

- Appointment of a person responsible for strengthening internal control within the Group.
- Local visits by internal control function to the subsidiaries in Denmark, France, Italy, and the UK.
- Commencement of the new purchasing system roll-out to the subsidiaries.
- Preparation of policies for the Group.
- Process analyses conducted within the financial function.

*Activities in focus for 2018 to further strengthen internal control*

- Implementation of new budget system.
- Continued roll-out of the new purchasing system at the subsidiaries.
- Production and implementation of a financial manual for the Group.
- Continued work to conduct process analyses within the financial function.

*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*

The Company has not breached any rules of the stock exchange on which its shares are traded, or acted contrary to 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 556038-9021

**Engagement and responsibility**
It is the Board of Directors who is responsible for the corporate governance statement for the year 2017 on pages 108–113 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, 10 April 2018
Ernst & Young AB

Björn Ohlsson
Authorized Public Accountant


SciLifeLab
sobi
Pioneer in Rare Diseases

# The board

### 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

### HÅKAN BJÖRKLUND

Born 1956.

Chairman. Board member since 2016.

Ph.D. from Karolinska Institutet in Stockholm.

Other appointments: Industry Executive at Avista Capital Partners, chairman of the board for Bonesupport AB.

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

### 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: 6,631

### BO-GUNNAR ROSENBRAND

Born 1963.

Board member since 2006. Representative of the council for negotiation and cooperation. Deputy board member 2001–2005.

Employee Representative.

Laboratory engineer.

Shares: 9,148 (including shareholdings of related physicals)

## HANS GCP SCHIKAN

Born 1958.

Board member since 2011.

Pharm D, Utrecht University.

Other appointments: Chairman of the Board of Directors of Asceneuron, Switzerland, Interna, The Netherlands and Complix, Belgium. Member of the Board of Directors of Hansa Medical and Wilson Therapeutics, 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, Board member of Top Institute Pharma, Chairman of Dutch Association of the Innovative Pharmaceutical Industry, Nefarma. Various senior management positions within previous Organon and Genzyme.

Shares: 4,000

## 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

## 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, 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

# Executive committee


TORBJÖRN HALLBERG


MATS-OLOF WALLIN


GUIDO OELKERS


PHILIP WOOD

## 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: Board member of Sartorius AG.

Previous positions: CEO, BSN Medical. Board member Meda. President & CEO, Gambro AB. Executive roles in Nycomed, Invida Holding and DKSH Group. Various country management positions in Aventis.

No shares: 0

## MATS-OLOF WALLIN

Chief Financial Officer

Born 1951

Employed since 2013

BSc from Uppsala University, Sweden.

Previous positions: CFO, Biotage AB. Over 30 years of experience from life science industry in diffent leadership roles at Pharmacia and Ortivus.

Shares: 104,011

## TORBJÖRN HALLBERG

General Counsel and Head of Legal Affairs

Born 1969

Employed since 2018

Master of Laws from University of Lund, Sweden.

Previous positions: Vice President, General Counsel, Emerging Markets, Takeda Pharmaceuticals. Senior Director and Senior Corporate Counsel, Takeda Pharmaceuticals. Corporate Councel, Nycomed Pharma. Corporate Councel, Ferring Pharmaceuticals. Senior Associate/ Lawer, Advokatfirman Lindahl.

Shares: 0

## PHILIP WOOD

Head of Haemophilia

Born 1968

Employed since 2012

BSc Joint Honours degree in Geology and Physical Geography, Charted Institute of Marketing certification, UK.

Previous positions: Head of European Strategic Asset team, Haemophilia, and Business Unit Head Haemophilia, UK, Pfizer.

Shares: 29,292


NORBERT OPPITZ


RAMI LEVIN


MILAN ZDRAVKOVIC


HEGE HELLSTRÖM


ARMIN REININGER

## 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: 0

## HEGE HELLSTRÖM

Head of EMENAR

Born 1965

Employed since 2013

BSc in Bioengineering, Oslo, Norway.

Previous positions: Global Head Cardiovascular, Sanofi, Vice President Renal Europe and Head of Regional Liaisons, Sanofi. Vice President Renal and Endocrine Europe, Genzyme. General Manager Benelux, Genzyme. 13 years in Baxter in different leadership roles.

Shares: 51,191

## 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: Vice President of Marketing US, Managing Director Scandinavia, Global Marketing Head, Business Unit Manager, Merck. Product Manager, Schering AG.

Shares: 0

## ARMIN REININGER

Head of Medical and Scientific Affairs

Born 1957

Employed since 2017

MD, PhD, Ludwig-Maximilians-University Munich, Germany; certified specialist in Transfusion Medicine.

Previous positions: Head of Medical Affairs EMEA 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

## 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: DIA Advisory Council Europe, Middle East and Africa. Board member and co-founder 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: 0

# Auditor's report

**TO THE GENERAL MEETING OF THE SHAREHOLDERS OF SWEDISH ORPHAN BIOVITRUM AB (PUBL), CORPORATE IDENTITY NUMBER 556038-9321**

## Report on the annual accounts and consolidated accounts

### Opinions

We have audited the annual accounts and consolidated accounts of Swedish Orphan Biovitrum AB (publ) for the year 2017. The annual accounts and consolidated accounts of the company are included on pages 56–107 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 2017 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 2017 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 marketing rights, goodwill and shares in subsidiaries

| Description | How our audit addressed this key audit matter |
|---|---|
| At December 31, 2017 the majority (55% or 6,179 MSEK) of the Group's total assets were related to product rights, marketing rights and goodwill. A substantial part (26% or 2,882 MSEK) of the Parent Company's assets consisted of shares in subsidiaries (hereinafter referred to as 'the assets' together with product rights, marketing rights and goodwill). The Company tests the assets for impairment annually or when events or change in conditions indicate that the carrying amount of the assets may fall below the recoverable amount. Testing impairment of the assets involves several significant estimates and assessments. This includes estimating the value in use by identifying cash-generating units, estimating expected future cash flows including the growth rate and calculating weighted average capital cost ("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 directors' business plans and forecasts.<br>We focused on this area as the reported value of the assets is 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 were not limited to the following audit procedures:<br>• obtained an understanding of the Company's process for identifying indicators of impairment<br>• evaluation of methods used by management when performing the impairment test including the sensitivity analysis and<br>• 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.<br><br>We have assessed if the disclosed information is suited for the purpose. For further information, refer to the Group's accounting principles in note 2, significant estimates and assumptions in note 4, as well as information on product rights and market rights, goodwill and participations in subsidiaries in notes 17 and 19. |

**Accounting of liabilities to Bioverativ**

| Description | How our audit addressed this key audit matter |
|---|---|
| SOBI and Bioverativ collaborates regarding the development and commercialisation of the hemophilia products Elocta and Alprolix. The collaboration is regulated by agreement and defines the rights and obligations under the collaboration. As at December 31, 2017 the nominal value of liabilities for development costs amounted to USD 207 M.<br>The repayment of the liabilities for development costs is made by adjusted royalty rates and is based on each party's sales until full repayment has been made. Refer to note 17 for specification. The carrying value of the liabilities to Bioverativ is a net present value of the future repayments based on a forecast of the repayment period and the discount calculation of future repayments. As the liabilities are nominated in USD the carrying value of the liabilities are also affected by a currency revaluation effect. The Company has assessed that since the royalty income from Bioverativ also is nominated in USD an effective hedge relationship with the liabilities exists. The currency revaluation effect of the liabilities is therefore recorded in the other comprehensive income.<br>Due to the significant amount that the liabilities represents in relation to the Company's financial position and the complex agreement and accounting assessments required we consider the accounting of liabilities to Bioverativ to be key audit matter in our audit. | We have reviewed the agreement with Bioverativ and assessed the reasonableness of management's forecast of the repayment period based on our knowledge of the Company's business and past accuracy in developing forecasts. We have evaluated the reasonability in the used discount rate and performed a recalculation of the net present value.<br>We have evaluated the Company's own assessment of the effectiveness in the hedging relationship and audited the currency revaluation of the liabilities and the effects of the hedge accounting in other comprehensive income.<br>Refer to note 2 and 17 in the annual report for a detailed description of the agreement with Bioverativ and the reported liabilities. We have assessed if the disclosed information is suited for the purpose. |

**Other Information than the annual accounts and consolidated accounts**
This document also contains other information than the annual accounts and consolidated accounts and is found on pages 1–11, 14–35, 48–55, 115–119 and 134–135. 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 Directors of Swedish Orphan Biovitrum AB (publ) for the year 2017 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 Directors 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 Directors**
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 Directors 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 Directors in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional scepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

Ernst & Young AB, Box 7850, 103 99 Stockholm was appointed auditor of Swedish Orphan Biovitrum AB (publ) by the general meeting of the shareholders on May 4, 2017 and has been the company's auditor since May 8, 2014.

Stockholm, 10 April, 2018
Ernst & Young AB

Björn Ohlsson
Authorized Public Accountant

# Sustainability Management

Sobi's material sustainability issues, based on an analysis of value creation and critical issues in relation to Sobi and its stakeholders, have been identified as improving global access to treatments of rare diseases, strategic research and development as well as quality and supply chain management. Sobi has also determined to act with compliance and ethics in relation to the regulatory and legal environment, when developing our people and by only engaging in ethical practices and collaborations. In relation to Sobi's responsibility, important sustainability issues are identified as reducing the company's environmental impact, safeguarding patient and customer integrity, ensuring responsible tax payments, ruling out anti-corruption and anti-competitive practices.

**Stakeholders and materiality analysis**
Sobi's stakeholders are groups and individuals whose interests, directly or indirectly, have influence on or are influenced by the company's actions. Sobi's management and the Board of Directors have the overall responsibility for weighing up these interests, while ensuring the continuity of the company. Following this approach, Sobi aims to create long-term value for and to earn trust of all its stakeholders. To ensure regular dialogue, Sobi engages with a broad range of internal as well as external stakeholders through several different channels. As part of a comprehensive materiality analysis in 2016, web-surveys and targeted interviews were used for internal and external stakeholders to raise relevant issues.

## IMPORTANT EXTERNAL STAKEHOLDERS

Important external stakeholders that we are listening to:

- Patient organisations
- Families and carers
- Regulators
- Pharmaceutical companies
- Governments and Government agencies
- Regulatory authorities
- Health care systems
- Budget holders and insurers
- Academic researchers
- Centres of expertise
- Specialist physicians and nurses
- Investors and analysists
- Shareholders

**Stakeholder's engaging with Sobi discuss the following sustainability areas:**

| Internal stakeholders | External stakeholders |
|---|---|
| Access to healthcare and medicine | Access to healthcare and medicine |
| Product safety and quality | Sustainable supply chain |
| Ethics, safety, transparency in clinical trials | Ethics, safety, transparency in clinical trials |
| Engagement with patient organisations | Regulatory and legal environment |
| Anti-corruption | Responsible marketing and sales activities |
| Responsible marketing and sales activities | Product safety and quality |
| Research and development | Pharmaceuticals in the environment |
| Sustainable supply chain | Engagement with patient organisations |
| Diversity and equal opportunity | Anti-corruption |
| Employee recruitment, development, retention | Research and development |

During 2017, the materiality analysis has been further developed and adapted to be in line with the revised corporate strategy aiming to create a more sustainable business growth, both short and long term. Important aspects to consider have been Sobi's value creation model as well as the new requirements on sustainability reporting found in the Annual Accounts Act. In the end of the year Sobi's Executive Committee approved the updated materiality analysis.

## Sobi's material sustainability issues

| Value creation | Material issues |
|---|---|
| **Value** | • Improving global access to treatments for rare diseases<br>• Quality and supply chain management<br>• Strategic research and development |
| **Compliance and ethics** | • Regulatory and legal environment<br>• Developing our people<br>• Ethical practices and collaborations |
| **Responsibility** | • Environmental impact<br>• Patient and customer integrity<br>• Responsible tax<br>• Anti-corruption<br>• Anti-competitive practices |

A detailed description on how Sobi is performing in relation to its material sustainability issues is found in the section Sustainability, page 36–47.

**Sustainability governance, management and organisation**
Sobi's Board of Directors holds the overall responsibility for Sobi's sustainability performance, while the CEO and the executive management team approve Sobi's sustainability programme and ensure compliance of 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 Communication is responsible for communication and operationalisation of the programme in close collaboration with the business units. The approved sustainability programme and goals are broken down into specific targets and activities to ensure that sustainability targets are well-integrated with Sobi's overall objectives and business plans. The annual reporting of the sustainability performance is presented in Sobi's Annual- and Sustainability Report.

| Policies guiding Sobi's sustainability performance |
|---|
| Annual Limits on Compensation for Healthcare professionals |
| Anti-Corruption Policy |
| Charitable Contributions and Sponsorships Policy |
| Code of Conduct and Ethics |
| Communications Policy |
| Compensation for Healthcare Professionals Policy |
| Consultants and Speakers Policy |
| Educational Grants Policy |
| Environment Health and Safety Management |
| Fair Competition Policy |
| Global Policy Risk Management |
| Information Security Policy |
| Insider Policy |
| Interactions with Patient Organisations Policy |
| IT Security Policy |
| Patient Access Bridging Programmes 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 |
| Sobi Inc Policy on Compliance Enforcement Discipline |
| Sobi Inc Policy on Reporting Investigating and Responding to Compliance Issues |
| Travel Policy |

## Sustainability objectives, targets and programme

Sobi's overall objective from a sustainability perspective is tied to the overall vision: to contribute to the societies in which Sobi operates by improving access to treatment of 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.

Sustainability is a vital part of Sobi's vision and overall corporate strategy. A sustainable business entails a commitment to responsibility for patients and employees, reduced environmental impact from operations and treatment, as well as long-term sustainable profitability so that we can continue to reinvest in developing new therapies for rare diseases and serve our communities for many years to come.

During the year Sobi has developed a comprehensive sustainability program. The sustainability programme is based on Sobi's material sustainability issues and will be further developed in terms of activities, targets, key performance indicators and implementation during the current year. The sustainability programme will make it possible for Sobi to follow progress towards the overall sustainability objectives and vision.

| Material issues | Overall sustainability objectives |
|---|---|
| • Improving global access to treatments for rare diseases | • Ensure that Sobi's products are made available to patients through local healthcare budgets |
| • Strategic research and development | • Invest in R&D to build a self-sustaining pipeline |
| • Quality and supply chain management | • Our products are to improve the lives of rare disease patients and their families |

| Material issues | Sustainability targets |
|---|---|
| • Regulatory and legal environment | • Allways be compliant with laws and regulations |
| • Developing our people | • Engaged and skilled people who are offered a safe and developing workplace |
| • Ethical practices and collaborations | • Allways be compliant with Code of Conduct and Ethics |
| • Environmental impact | • Reduce Sobi's environmental impact |
| • Patient and customer integrity | • Always secure patients integrity |
| • Responsible tax | • Tax to be paid where revenue is generated |
| • Anti-corruption<br>• Anti-competitive practices | • Always be compliant with laws, regulations Code of Conduct and Ethics |

## Sustainability risks

Sustainability risks and the assessment of their impact are an integral element of Sobi's risk management process. The sustainability risk table identifies material risks in relation to our identified sustainability strategies. For those areas that coincide with operational risks, see pages 64–65.

| Risk | Description of risk | Management and comments |
|---|---|---|
| Global access to drugs for rare diseases | The market is increasingly affected by cost-consciousness 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.<br>A decline in revenue 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 the 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 paying regulators in the event of approval. |
| | The use of medications may be affected 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.<br>The degree of market acceptance for each of the Company's products therefore depends 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 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. |
| | Sobi donates drugs to patients with rare diseases in cases where humanitarian aid has been considered necessary. These donations require the existence of a long-term plan describing how drugs can be guaranteed aside from the donation. | In developing countries and growth markets, Sobi works in consultation with regulators and international patient organisations in order to meet humanitarian needs. At the same time, Sobi works with key stakeholders to build and lay the foundations for a shift from donations to a sustainable reimbursement system that is owned by governments and/or healthcare systems.<br>In cases where healthcare systems do not yet include Sobi's treatments, Sobi works in consultation with regulators to identify possible ways of making sure that patients are given access to drugs through programmes that provide a bridging arrangement until access through subsidy has been achieved. |
| Quality and Supply Chain Management | Biologics Manufacturing and Quality in Operational risks, see pages 64–65. | |
| Strategic Research and Development | Drug Development in Operational risks, see pages 64–65. | |
| | Sobi develops new drugs for serious diseases for which there is no treatment. Drugs under development must be tested on patients in the first instance and cannot be tested on healthy volunteers. | Looking after the safety of those people taking part in our studies is extremely important and is based on precise, scientifically based evaluations of our clinical expertise in collaboration with supervisory authorities, independent ethical committees and stakeholders. Sobi applies the Declaration of Helsinki's ethical principles for medical research involving human subjects, and all clinical studies that we sponsor are conducted and reported in accordance with current laws, regulations and ordinances as well as the international standard for Good Clinical Practice (GCP). |
| | Patients who are being treated with Sobi's drugs often have chronic, life-threatening diseases and are expected to be treated with Sobi's drugs for a long time. The safety of the products is extremely important. One of our most important tasks is to secure patient safety throughout the whole life cycle of products. | Sobi has a comprehensive safety system for our drugs and we are constantly monitoring the risk-benefit profile of our products. We provide annual training for all our employees in order to make sure that all safety information for our products is reported. Our goal is to provide correct, updated information to legislators, healthcare personnel and patients by collecting and analysing safety data from all available sources. |

| Risk | Description of risk | Management and comments |
|---|---|---|
| Regulatory and legal environment | Sobi operates in a strictly regulated environment and we must comply with laws and regulations governing not only production, but also research and marketing. Any change in legislation and regulations can have a direct impact on Sobi by limiting access to the market, manufacturing opportunities or development strategies. | Sobi monitors all laws and regulations carefully in order to make sure that the company's work complies with current legislation. 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.<br>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. |
| Developing our employees | Sobi operates in a competitive market, where our employees form the basis of the company's ability to develop special drugs to meet our patients' needs. If we are unable to attract employees who can contribute to this work through their various competencies and experiences, we risk becoming less efficient and not being able to produce the right drugs at the right price. | Sobi works with a learning organisation and involves employees in high-performance teams in order to achieve and deliver in a competitive market. |
| Anti-corruption, anti-competition and ethical approach, as well as collaborations | The risk of corruption is greatest in activities in which Sobi interacts with the healthcare sector. | To mitigate corruption risks, Sobi has for several years had a Health Care Compliance ("HCC") programme 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 programme includes processes and controls that aim to mitigate the risks of, for example, corruption. |
| Environmental impact | Sobi's business activities involve business trips that give rise to greenhouse gas emissions. The consumption of energy, water, products and services as well as the handling of chemicals in the manufacturing facility also 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 has been agreed with the regulators for the manufacturing facility. Risk assessments of the business are performed annually and in connection with changes, and action plans are drawn up as required. |
| Patient and customer integrity | Sobi processes personal data in the course of its business. 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. | A programme is in place for the purpose of ensuring compliance with emerging legislation regarding the processing of personal data. |
| Reponsible tax management | Sobi carries out decentralised business activities in various different countries. Changing local rules and interpretations may thus lead to incorrect tax treatment in the local companies. All local companies are required to monitor that correct taxes are paid in their respective country. | Sobi's tax policy clearly states that tax must be paid in the countries where revenue is generated in accordance with determined transfer pricing methods. |

## Sustainability performance 2017

Sobi is committed to report relevant data on economic, social and environmental performance, focusing on material issues and to communicate their progress. 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 Thousands) | 2017 |
|---|---|
| Revenues | 6,512,521 |
| **Economic Value Distributed** | |
| Operating costs | –3,632,615 |
| Employee wages & benefits | –1,262,850 |
| Payments to providers of capital | –69,161 |
| Payments to government | –209,128 |
| Community investments[1] | –15,471 |
| **Direct economic value** | **1,323,295** |

Calculation is based on the consolidated statement of comprehensive income 2017.

1. Community investments is based on costs reported in May 2017 related to support to Patients Organisations during 2016. Costs for 2017 will be reported in our Transparency Report to be published in May 2018.

#### Indirect economic impact

Sobi and Bioverativ, a Sanofi company, have pledged to donate up to 1 billion IUs of coagulation factor to humanitarian aid between 2015–2025.

500 million IUs have been donated 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 Bioverativ's contribution to the programme.

| | 2017 | 2016 | 2015 |
|---|---|---|---|
| Total MIU's delivered | 262 | 146 | 19 |
| New patients treated | 15,072 | 12,311 | 2,347 |
| Acute bleeds treated | 40,557 | 33,876 | 4,984 |
| Total surgeries | 709 | 719 | 78 |
| Paediatric patients, % | 39 | 28 | 14 |

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

| ($CO_2$ tonnes) | 2017 | 2016 |
|---|---|---|
| Indirect emissions from energy (metric tonnes) | 221 | 222 |
| Emissions from travel (metric tonnes) | 983 | 1,112 |

Reported emissions reflects only operations in Sweden. Travelling emissions include emissions from business travel and company cars.

#### Waste

| Waste (metric tonnes) | 2017 | 2016 | 2015 | 2014 | 2013 |
|---|---|---|---|---|---|
| Recycled waste | 50 | 46 | 68 | 52 | 42 |
| Hazardous waste | 22 | 16 | 13 | 13 | 16 |
| Landfill | 0.1 | 0.0 | 1.6 | 0.1 | 1.1 |
| **Total waste** | **72** | **62** | **82** | **65** | **59** |

Waste reporting is based on Sobi's only production facility found in Solna, Stockholm.

Waste data does not include waste from marketing and sales offices.

## Social performance

### Employees per region 2017

| Region | New employee hires | Female | Male | Employees 2017 |
|---|---|---|---|---|
| Sweden | 67 | 41 | 26 | 451 |
| EMENAR (Europe, Middle East, North Africa, Russia) (excluding Sweden) | 67 | 41 | 26 | 295 |
| North America (USA & Canada) | 10 | 7 | 3 | 54 |
| **Total** | **144** | **89** | **55** | **800**[1] |

1. Per year-end 2017, the number of full-time equivalent employees was 800, while the number of persons employed at the same date was 850.

### New hires

| | Female | | | | Male | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Region | Under 30 years old | 30–50 years old | Above 50 years old | Female Total | Under 30 years old | 30-50 years old | Above 50 years old | Male Total | Total |
| Sweden | 8 | 21 | 12 | 41 | 9 | 14 | 3 | 26 | 67 |
| EMENAR (Europe, Middle East, North Africa, Russia) (excluding Sweden) | 4 | 29 | 8 | 41 | 2 | 20 | 6 | 28 | 67 |
| North America (USA & Canada) | 1 | 5 | 1 | 7 | | 2 | 1 | 3 | 10 |
| **Total** | **13** | **55** | **21** | **89** | **9** | **38** | **8** | **55** | **144** |

### Turnover 2017

| Employees | 2017 | 2016 |
|---|---|---|
| Number of employees[1] | 812 | 757 |
| Departures | 90 | 83 |
| Turnover | 11.1% | 11% |

1. Mean number of employees during the year, including only permanent contracts.

### Employees, contract type and type of employment 2017

| Employees | Male | Female | Totalt |
|---|---|---|---|
| Permanent contract | 337 | 497 | 834 |
| Temporary contract | 8 | 8 | 16 |

| Employees | Sweden | Other region | Totalt |
|---|---|---|---|
| Permanent contract | 473 | 361 | 834 |
| Temporary contract | 15 | 1 | 16 |

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.

# Global Reporting Initiative Index

Sobi´s Sustainability Report 2017 is defined in the GRI Index below. Its main components are found in the following sections of the Annual and Sustainability Report 2017:

- Business Model is found in the section Sobi's Value Creation, page 12–13
- Description of sustainability approach, activities and performance 2017 are found in the section on Sustainability, pages 36–47.
- Information on objectives and targets on Sustainability issues is reported in the non-financial notes, on pages 128–129.
- Information on the buildup of the Sustainability Report is found in the section Sustainability Management, on pages 123–132.

This sustainability report has been prepared in accordance with the GRI Standards: Core option. It also fulfills the requirements on sustainability reporting in the Annual Accounts Act. The 2016 sustainability report was published in April 2017.

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 124–125. All page references below refer to pages in Sobi's 2017 Annual- and Sustainability Report or at www.sobi.com. For questions regarding the Sustainability Report, please contact info@sobi.com.

| GRI Standard | Disclosure | Page reference | Comment |
|---|---|---|---|
| GRI 101: Foundation 2016 | | | Sobi complies with the reporting principles for defining reporting content and quality stipulated by GRI. |
| STANDARD DISCLOSURES | | | |
| **Organisational Profile** | | | |
| GRI 102: General Disclosures | 102-1 Name of the organisation | 76 | |
| | 102-2 Activities, brands, products, and services | 7, 10–13, 58 | |
| | 102-3 Location of headquarters | 76 | |
| | 102-4 Location of operations | 20, 23, 86, 98 | |
| | 102-5 Ownership and legal form | 76 | |
| | 102-6 Markets served | 20, 23, 98 | |
| | 102-7 Scale of the organisation | 6–7, 84 | |
| | 102-8 Information on employees and other workers | 86, 129 | |
| | 102-9 Supply chain | 12–13, 39 | |
| | 102-10 Significant changes to the organisation and its supply chain | | No material changes to the organisation and supply chain during the year. |
| | 102-11 Precautionary Principle or approach | 64–65, 126–127 | |
| | 102-12 External initiatives | 43, 45, 130 | Sobi complies with the European Federation of Pharmaceutical Industries and Associations (EFPIA) Disclosure Code in Europe and the Physician Payments Sunshine Act in the US. Sobi's clinical programmes and testing follow the ethical principles of the Declaration of Helsinki and EMA's policy on the publication of clinical trial data. |
| | 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-maker | 8–9, 55 | |
| **Ethics and Integrity** | | | |
| GRI 102: General Disclosures | 102-16 Values, principles, standards, and norms of behaviour | 36, 124 | |
| **Governance** | | | |
| | 102-18 Governance structure | 108–113, 124 | |

| GRI Standard | Disclosure | Page reference | Comment |
|---|---|---|---|
| **Stakeholder Engagement** | | | |
| GRI 102: General Disclosures | 102-40 List of stakeholder groups | 123 | |
| | 102-41 Collective bargaining agreements | 129 | |
| | 102-42 Identifying and selecting stakeholders | 37, 123 | |
| | 102-43 Approach to stakeholder engagement | 37, 123 | |
| | 102-44 Key topics and concerns raised | 37, 123 | |
| **Reporting Practice** | | | |
| GRI 102: General Disclosures | 102-45 Entities included in the consolidated financial statements | 98 | |
| | 102-46 Defining report content and topic boundaries | 124–125, 130, GRI 101 | |
| | 102-47 List of material topics | 37, 124 | |
| | 102-48 Restatements of information | 98 | |
| | 102-49 Changes in reporting | 123–124 | |
| | 102-50 Reporting period | 130 | |
| | 102-51 Date of most recent report | 130 | |
| | 102-52 Reporting cycle | 130 | |
| | 102-53 Contact point for questions regarding the report | 130 | |
| | 102-54 Claims of reporting in accordance with the GRI Standards | 130 | |
| | 102-55 GRI content index | 130–133 | |
| | 102-56 External assurance | | Sobi's Sustainability Report has not been subject to external assurance. |

MATERIAL TOPICS

| | | | |
|---|---|---|---|
| **Economic** | | | |
| **Economic Performance** | | | |
| GRI 103: Management Approach | 103-1/2/3 Management approach | 124 | |
| GRI 201: Economic Performance | 201-1 Direct economic value generated and distributed | 128 | |
| Indirect Economic Impacts | | | |
| GRI 103: Management Approach | 103-1/2/3 Management approach | 124 | |
| GRI 203: Indirect Economic Impacts | 203-2 Significant indirect economic impacts | 128 | |
| **Anti-corruption** | | | |
| GRI 103: Management Approach | 103-1/2/3 Management approach | 45, 47, 124 | |
| GRI 205: Anti-corruption | 205-1 Operations assessed for risks related to corruption | 47, 127 | |
| | 205-2 Communication and training about anti-corruption policies and procedures | 45 | |
| | 205-3 Confirmed incidents of corruption and actions taken | 45 | |
| **Anti-competitive Behaviour** | | | |
| GRI 103: Management Approach | 103-1/2/3 Management approach | 45, 47, 124 | |
| GRI 206: Anti-competitive Behaviour | 206-1 Legal actions for anti-competitive behaviour, anti-trust, and monopoly practices | 45 | |
| **Environmental** | | | |
| **Emissions** | | | |
| GRI 103: Management Approach | 103-1/2/3 Management approach | 124 | |
| GRI 305: Emissions | 305-2 Energy indirect (Scope 2) GHG emissions | 128 | |
| **Effluents and Waste** | | | |
| GRI 103: Management Approach | 103-1/2/3 Management approach | 124 | |
| GRI 306: Effluents and Waste | 306-2 Waste by type and disposal method | 128 | |

| GRI Standard | Disclosure | Page reference | Comment |
|---|---|---|---|
| **Social** | | | |
| **Employment** | | | |
| GRI 103: Management Approach | 103-1/2/3 Management approach | 41–42, 124 | |
| GRI 401: Employment | 401-1 New employee hires and employee turnover | 129 | |
| **Occupational Health and Safety** | | | |
| GRI 103: Management Approach | 103-1/2/3 Management approach | 42, 124 | |
| GRI 403: Occupational Health and Safety | 403-2 Types of injury and rates of injury, occupational diseases, lost days, and absenteeism, and number of work-related fatalities | 42 | |
| **Training and Education** | | | |
| GRI 103: Management Approach | 103-1/2/3 Management approach | 42 | |
| GRI 404: Training and Education | 404-1 Average hours of training per year per employee | 42 | |
| | 404-2 Programmes for upgrading employee skills and transition assistance programmes | 42 | |
| | 404-3 Percentage of employees receiving regular performance and career development reviews | 42 | |
| **Non-discrimination** | | | |
| GRI 103: Management Approach | 103-1/2/3 Management approach | 42, 124 | |
| GRI 406: Non-discrimination | 406-1 Incidents of discrimination and corrective actions taken | 42 | |
| **Local Communities** | | | |
| GRI 103: Management Approach | 103-1/2/3 Management approach | 124 | |
| GRI 413: Local Communities | 413-1 Operations with local community engagement, impact assessments, and development programmes | 19, 38 | |
| **Supplier Social Assessment** | | | |
| GRI 103: Management Approach | 103-1/2/3 Management approach | 46, 124 | |
| GRI 414: Supplier Social Assessment | 414-1 New suppliers that were screened using social criteria | 46 | |
| **Customer Health and Safety** | | | |
| GRI 103: Management Approach | 103-1/2/3 Management approach | 124 | |
| GRI 416: Customer Health and Safety | 416-1 Assessment of the health and safety impacts of product and service categories | 39, 44 | |
| **Marketing and Labeling** | | | |
| GRI 103: Management Approach | 103-1/2/3 Management approach | 124 | |
| GRI 417: Marketing and Labeling | 417-2 Incidents of non-compliance concerning product and service information and labeling | 39 | |
| | 417-3 Incidents of non-compliance concerning marketing communications | 41 | |
| **Customer Privacy** | | | |
| GRI 103: Management Approach | 103-1/2/3 Management approach | 44, 124 | |
| GRI 418: Customer Privacy | 418-1 Substantiated complaints concerning breaches of customer privacy and losses of customer data | 44 | |
| **Socioeconomic Compliance** | | | |
| GRI 103: Management Approach | 103-1/2/3 Management approach | 124 | |
| GRI 419: Socioeconomic Compliance | 419-1 Non-compliance with laws and regulations in the social and economic area | 45 | |

# Auditor's report on the statutory sustainability statement

To the general meeting of the shareholders of Swedish Orphan Biovitrum AB (publ), corporate identity number 556038-9321

**Engagement and responsibility**
It is the Board of Directors who is responsible for the statutory sustainability statement for the year 2017 on pages 12–13, 36–47 and 123–132 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.

10 April 2018, Stockholm
Ernst & Young AB

Björn Ohlsson
Authorised Public Accountant

# 2018 Annual General Meeting

**2018 Annual General Meeting**
Swedish Orphan Biovitrum AB (publ) will hold its Annual General Meeting on Wednesday, 9 May 2018, in Näringslivets Hus, Storgatan 19, Stockholm, Sweden.

**To participate**
Shareholders who wish to participate in the Meeting must be recorded in the share register maintained by Euroclear Sweden AB on Thursday, 3 May 2018. Shareholders must notify the company of their intention to participate no later than Thursday, 3 May 2018 in one of the following ways:
- Visiting Sobi's website: www.sobi.com
- By phone: +46 (0)8-697 31 91, Monday to Friday 9:00–16:00
- By mail: Swedish Orphan Biovitrum AB (publ), Annual General Meeting, SE-112 76 Stockholm, Sweden

The notification should include the shareholder's:
- Name
- Personal/corporate identity
- Address and telephone number (daytime)
- Number of shares held
- Where applicable, information about any representatives/advisors

**Nominee shares**
Shareholders who have registered their shares with a bank or another nominee must, to be entitled to participate in the Annual General Meeting, register their shares in their own name, so that the person concerned is recorded in the share register maintained by Euroclear Sweden AB on Thursday, 3 May 2018. 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 expiration shown on the power of attorney, but not later than five years. The registration certificate shall evidence 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 above 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 2018**

| | |
|---|---|
| January–March Interim Report | 26 April 2018 |
| Annual General Meeting | 9 May 2018 |
| January–June Interim Report | 18 July 2018 |
| January–September Interim Report | 31 October 2018 |

The Annual Report can be downloaded in PDF format from www.sobi.com, as well as previous annual reports, interim reports and press releases.

**Contact details**
Swedish Orphan Biovitrum AB (publ)
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# Definitions

**Earnings per share**
Profit/loss divided by the average number of shares.

**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.

**Profit/loss**
Profit/loss for the period.

## Alternative key figures

**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 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.

**EBIT**
Earnings before interest and tax (Operating income).

**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**
Total assets divided by equity.

**Gross margin**
Gross profit as a percentage of sales.

**Gross profit**
Operating revenues less cost of goods and services sold.

**Net 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 expenses as a percentage of average total assets.

**Weighted Capital Cost (WACC)**
Risk-free interest rate (1.0%) plus Beta (1.31) multiplied with a risk premium (6.28). 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

**Acute gout**
An autoinflammatory disease and an intensely painful and disabling inflammatory arthritis involving one or several joints. Gout is also a disease that is associated with multiple comorbidities, which may limit the use of some conventional treatment regimens.

**Alprolix**
Alprolix (eftrenonacog alfa) is a recombinant extended half-life clotting factor IX therapy approved for the treatment of haemophilia B in adults and children of all ages in the EU, Iceland, Liechtenstein, Norway, Kuwait, Switzerland and Saudi Arabia. It is also approved in the United States, Canada, Japan, Australia and other countries.

**anaGO**
A randomised, double-blind, multicentre study being conducted in North America studying two subcutaneous 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, administrated subcutaneously, in comparison to placebo for the treatment of Still's disease.

**A-SURE**
A multicentre, non-interventional study to evaluate the effectiveness of Elocta compared to conventional factor products in the prophylactic treatment of patients with haemophilia A.

**Bioverativ**
Bioverativ, a Sanofi company, spun out of Biogen's haemophilia business. Bioverativ collaborates with Sobi on our joint haemophilia programmes.

**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.

**Dupuytren's contracture**
Dupuytren's contracture is a condition caused by a thickening of the tissues under the skin of the palm where one or more fingers are bent forwards toward the palm and cannot be fully straightened.

**EC**
European Commission.

**EHL**
Extended half-life.

**Elocta**
Elocta (efmoroctocog alfa) is a recombinant extended half-life clotting factor VIII therapy approved for the treatment of haemophilia A in adults and children of all ages in the EU, Iceland, Liechtenstein, Norway, Kuwait, Switzerland and Saudi Arabia. It is also approved in the United States, Japan, Canada, Australia and other countries, where it is known as Eloctate.

**EMA**
European Medicines Agency.

**EMENAR**
A business region including Europe, Middle East, North Africa and Russia.

**FDA**
US Food and Drug Administration.

**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, irreversible joint damage and life-threatening haemorrhages.

**HT-1**
Hereditary tyrosinaemia type 1 (HT-1) is a rare genetic disorder that can cause liver failure, kidney dysfunction and neurological problems and can be fatal if left untreated.

**IFRIC**
International Financial Reporting Interpretations Committee.

**IL-1**
Interleukin-1 (IL-1) is a key mediator of inflammation and driver of autoinflammatory diseases.

**Intrapreneurship**
Intrapreneurship is about taking responsibility and driving development, change and innovation within one's company or organisation.

**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**
Kineret (anakinra) is a drug used to treat inflammatory diseases.

**MAH**
Marketing authorisation holder, the company in whose name the marketing authorisation has been granted and who is responsible for all aspects of the product.

**MPS IIIA**
Sanfilippo syndrome (MPS IIIA) is 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**
Orfadin (nitisinone) is a drug used to treat hereditary tyrosinaemia type 1 (HT-1).

**Peyronie's disease**
Peyronie's disease is a condition that involves the development of collagen plaque, or scar tissue, on the shaft of the penis. The scar tissue may harden and reduce flexibility causing bending or arching of the penis during erection.

**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.

**SOBI003**
A chemically modified variant of a recombinant human sulfamidase product candidate intended as an enzyme replacement therapy in lysosomal storage disease MPS IIIA, aimed to reduce heparan sulfate storage materials in affected cells.

**Still's disease**
Still's disease is an autoinflammatory disease that affects both children and adults, and is 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).

**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.

**Xiapex**
Xiapex (collagenase clostridium histolyticum), is a pharmacological treatment for Dupuytren's contracture and Peyronie's disease.

**XTEN**
XTEN is a technique used to extend the half-life of proteins.

**WFH**
World Federation of Hemophilia, an international not-for-profit organisation.



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